August 2015

Food Processing Sector Study

Contract HHSF-223-2011-10005B, Task Order 20

Final Report

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Executive Summary

The FDA Food Safety Modernization Act (FSMA or the Act) (Public Law 111-353), signed into law on January 4, 2011, entrusted FDA with new authority and legislative mandates designed to improve the safety of the food supply. The FSMA also required FDA to conduct a study of the food processing sector under FDA's jurisdiction to provide data needed for implementation of hazard analysis and risk-based preventive controls in food facilities. This report provides the results of the study regarding size and scope of the food processing industry, including the colocation of farms with food processing facilities, and the relative risks of foodborne illness from processed foods, including the attribution of foodborne illness to different activities involved in food production.

Key results of the portion of the study on the size and scope of the food industry were as follows:

- Based on current data, the food processing industry generates total annual revenue of approximately $211 billion across about 20,519 establishments, including pet food and animal feed processing facilities but excluding facilities not affected by the FSMA (meat, poultry, egg products, juice, and seafood processing)
- About 85% of establishments in the food processing industry have fewer than 100 employees.
- About 61% of total food industry sales are made by food processing establishments with fewer than 100 employees.
- Less than 2% of food processing establishments are colocated on farms according to Dun & Bradstreet data, and 8% of growers with produce sales said they were packing on the farm, according to Ag

Census data, although they may not have been packing produce. According to industry experts, estimates of colocated farms range from less than 1% to 55% across different commodities.

Key results of the portion of the study on foodborne illness risk are as follows:

- Fresh produce, dry (low-moisture) foods, and refrigerated foods ranked the highest in terms of contributing to human foodborne illness risk, while sugars and sweets, milled and pressed foods, and beverages ranked the lowest.
- Exposure to animal feed and pet food ranked low in contributing to human illness.
- There was no consistent pattern across food categories in terms of which sizes of establishments contributed most to foodborne illness risk.
- No foods can be said to have no reported or known hazards.
- Although more foodborne illness risk is attributed to food processing than to commingling, transporting, or storing, all of these other activities contribute to foodborne illness risk to some degree. Also, the relative importance of processing in contributing to foodborne illness risk compared with farm production activities, retail operations, and consumer food handling is unknown.
- The scale of processing activity is very important as a contributor to foodborne illness risk, while the duration of activity contributes to increased foodborne illness risk for only some activities and some foods.

1 Introduction

The purpose of this study was to address the requirements in the FSMA for data on the size and scope of and foodborne illness risk associated with the food processing industry.

The FDA Food Safety Modernization Act (FSMA or the Act) (Public Law 111-353), signed into law on January 4, 2011, entrusted FDA with new authority and legislative mandates designed to improve the safety of the food supply. For domestic food facilities, the law targets three main areas of regulation: prevention, inspection and compliance, and response. In terms of prevention, food facilities are required to document the implementation of a written preventive hazard control plan, the records of which have to be made accessible to FDA. In the area of inspection and compliance, the law directs FDA to set risk-based mandatory inspection frequencies for food facilities and establish an accreditation program for U.S. food testing laboratories. In terms of response, the law grants FDA the authority to issue mandatory recalls when facilities fail to voluntarily recall unsafe foods. The FSMA gives FDA more flexible standards for administratively detaining foods believed to be adulterated or misbranded. If food produced by a facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA is authorized to suspend the registration of the facility. FDA is also tasked with developing an enhanced food product traceability system and issuing rules on record-keeping requirements for facilities that produce high-risk foods.

The FSMA required FDA to conduct a study of the food processing sector under FDA's jurisdiction to provide data needed for implementation of hazard analysis and risk-based preventive controls in food facilities. Specifically, the Act requires the study to determine the

i. distribution of food production by type and size of operation, including monetary value of food sold;

ii. proportion of food produced by each type and size of operation;

iii. number and types of food facilities colocated on farms, including the number and proportion by commodity and by manufacturing or processing activity;

iv. incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known hazard exists; and

v. effect on foodborne illness risk associated with commingling, processing, transporting, and storing food and raw agricultural commodities, including differences in risk based on the scale and duration of such activities.

Under contract with FDA, a study was conducted to address the requirements stated above.[1] In addition to FDA, contributions were also made by U.S. Department of Agriculture's (USDA), Economic Research Service, American Farm Bureau, and Agricultural Marketing Service (AMS). Section 1 of the study provides an introduction that describes general study definitions and organization. Section 2 of this report addresses parts (i), (ii), and (iii) using commercially available data and other sources, and Section 3 addresses parts (iv) and (v) using an expert elicitation approach with references to the available literature.

1.1 GENERAL STUDY DEFINITIONS

In conducting the study, all references to food were assumed to include animal feed and pet food in addition to food intended for human consumption. For food intended for human consumption, we excluded meat, poultry, and egg products because they are under the jurisdiction of USDA, Food Safety and Inspection Service (FSIS). In addition, some foods under FDA's jurisdiction were excluded because they are already being produced under requirements for risk-based systems; these include seafood and juice, which are required to be produced under Hazard Analysis Critical Control Points programs, and low-acid canned foods (microbiological hazards only) because they are required to be produced under the low-acid canned foods regulation. The definition of "food processor"

[1] This report updates a previous report completed in 2011 (Muth et al.) by using more recent industry data on food processing establishments, expanding the sources of data used for estimating colocation of food processing establishments with farm operations, and considering other possible data sources on foodborne illness attribution.

is an establishment that engages in making food from one or more ingredients or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. (Examples of manufacturing or processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, distilling, acidification, fermentation, labeling, or packaging.)

The definition of "farm" according to FDA's *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes establishments that, in addition to these activities,

(1) pack or hold raw agricultural commodities;

(2) pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (3)(ii)(A) of this definition; and

(3) manufacture/process food, provided that:

  (i) all food used in such activities is consumed on that farm or another farm under the same management; or

  (ii) any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

    (A) drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins) and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(B) artificially ripening raw agricultural commodities (such as by treating produce with ethylene gas) and packaging and labeling the artificially ripened raw agricultural commodities, without additional manufacturing/processing; and

(C) packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is modified atmosphere packaging).

A farm is also an operation devoted only to the harvesting (such as hulling or shelling), packing, and/or holding raw agricultural commodities, provided that the farm(s), as described earlier, that grows or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the operation owns, or jointly owns, a majority interest in the operation.

Although many farms conduct different types of postharvest activities, only some types of activities would be considered food processing. Table 1-1 lists examples of activities that cause a food to remain a raw agricultural commodity or to become a processed food.

Table 1-1. Activities Determining Whether a Raw Agricultural Commodity Becomes a Processed Food

Remains a Raw Agricultural Commodity	Becomes a Processed Food
• Application of pesticides (including by washing, waxing, fumigation, or packing) • Coloring • Drying for the purpose of storage or transportation • Hydro-cooling • Otherwise treating fruits in their unpeeled natural form • Packing • Refrigeration • Removal of leaves, stems, and husks • Shelling of nuts • Washing • Waxing • Isolating or separating the commodity from foreign objects or other parts of the plant	• Canning • Chopping • Cooking • Cutting • Drying that creates a distinct commodity • Freezing • Grinding • Homogenization • Irradiation • Milling • Pasteurization • Peeling • Slicing

In defining the types of food processing operations, we relied primarily on the codes in data from Dun & Bradstreet (D&B), a commercial data source. The D&B data available to FDA are based on the 6-digit North American Industry Classification System (NAICS) codes, and up to six separate NAICS codes are provided for each facility in the database. To avoid double-counting establishments in the analysis, we assigned the type of operation based on the first of its food-related NAICS codes. For example, if the primary NAICS code was for an activity other than food processing and the secondary NAICS code was for food processing, we assigned the type based on the secondary NAICS code.

We defined food processing establishment size using the following definitions:

- fewer than 20 employees
- 20 to 99 employees
- 100 to 499 employees
- 500 or more employees

Other possible definitions of size that may be relevant to food safety include the square footage of the plant or food production volume. However, there is no currently available reliable data source for using these alternative definitions.

For farm operations, we defined operation size using Census Bureau data as follows:

- less than $25,000 in produce sales
- $25,000 to less than $500,000 in produce sales
- $500,000 to less than $5 million in produce sales
- $5 million or more in produce sales

1.2 ORGANIZATION OF THE REPORT

The remainder of this report is organized as follows. Section 2 presents data on the distribution of food production facilities by type and size of operation, the share of revenue produced by each type and size of food production facility, and colocation of farms and food processing facilities. Section 3 describes the existing literature and sources of data examined on foodborne

illness attribution and presents the results of an expert elicitation that ranked foods by foodborne illness risk and attributed foodborne illness to different activities involved in food production.

Supplementary materials are included in the appendices. Appendix A provides the detailed industry codes used to categorize colocated establishments using D&B data in Section 2 of the report. Appendix B includes a discussion of colocation of food processing with farms for selected commodities in selected states. Appendix C provides the materials used for the expert elicitation.

2 Food Processing by Type and Size of Operation

We used D&B Inc.'s proprietary database to calculate the size and scope of the food processing industry affected by the FSMA.

As part of the FSMA, FDA was directed to determine the distribution of food production facilities by type and size of operation, the monetary share of food produced by each type and size of operation, and the number of facilities colocated on farms and proportion of food produced by these facilities. This information will help inform FDA rulemaking on food safety requirements for domestic food facilities. In this section, we use multiple sources of data to provide such information, including D&B Inc.'s Dun's Market Identifiers (DMI) file, 2012 Census of Agriculture data, Agricultural Resource Management Survey data, commodity specialists and commodity commissions data, research and promotion boards data, community-supported agriculture data, and on-farm packaging facility data. We describe each of these sources of data and how they were used in more detail in Section 2.1.

2.1 DATA SOURCES AND METHODS

We examined several existing data sources particularly for investigating other methods of determining the extent of colocated facilities. We describe the following data sources and methods in this section:

- D&B's DMI data on the food processing industry
- Census data
- Agricultural Resource Management Survey (ARMS) data
- commodity specialists and commodity commissions
- research and promotion boards and marketing order boards

- community-supported agriculture (CSA)
- on-farm packaging facilities

2.1.1 D&B's DMI Data on the Food Processing Industry

First, FDA created a list of establishments from their FDA Facility Registration Database. Development of the Facility Registration Database is one of the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This Act directs FDA to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies that include requiring food facilities to register with FDA. In 2011, FSMA additionally required that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA.

FDA provided this list to D&B to which D&B matched the DMI file. The DMI is an establishment-level business directory file containing basic company information such as business name, physical address, legal status, organizational status (i.e., single location, headquarters, or branch location), sales and employment numbers, the NAICS code for the establishment's primary line of business, and up to five additional NAICS codes. Each business establishment is identified by a unique Data Universal Numbering System (DUNS) number, which is not recycled to index another establishment if the current establishment closes. The DMI file is updated monthly by D&B staff through visiting companies' Web sites; contacting business owners and managers by phone from D&B's call centers; and collecting information from all federal bankruptcy filing locations; all U.S. secretaries of state; public utilities; the U.S. Postal Service; over 2,500 state filing locations; and daily newspapers, publications, and electronic news services.

After receiving the final data, RTI extracted all establishments from the DMI file where food processing, animal feed processing, pet food processing, and food additive production NAICS codes matched with at least one of the NAICS codes on the list of NAICS codes within the scope of the food processing sector study in Appendix A. Each establishment may have up to six NAICS codes to reflect the types of products produced; all six NAICS codes were used to identify whether an establishment should be classified as a food processing

establishment and whether it has farming operations. RTI then used this data for tabulation and analysis.

Despite D&B's extensive data collection effort to obtain complete data, a number of establishments in the DMI file have zero employee count and missing sales data. Although some of the missing employment data might be attributed to single owner-operator establishments, it is unlikely to be the main cause because the DMI file purportedly includes owners/managers and partners in their employment totals (Neumark, Zhang, & Wall, 2005, p. 9). Therefore, the missing employment counts may be better treated as a general missing data problem rather than a problem specific to the smallest establishment size category.

We classified each industry at the NAICS level into four size categories: fewer than 20 employees, 20 to 99 employees, 100 to 499 employees, and 500 or more employees. There are 42 industry NAICS codes used in this study. To avoid double-counting in the data summaries, each establishment was assigned to only one NAICS code based on the importance of the assigned NAICS code in the establishment's business. Because an establishment can have up to six NAICS codes, we assumed they appear in the DMI file in descending order of importance for the establishment. Using this assumption, for reporting purposes, an establishment was assigned to the NAICS code that first matches with its list of up to six NAICS codes.

To impute missing employee counts in the DMI file, within each NAICS code we proportionally assigned establishments with missing employee counts to the four size categories such that the final size distribution matches the size distribution of establishments that reported employee counts. At the end of this imputation, every establishment was assigned to a size category. This is the same method used in FDA's previous calculations.

For many situations in the DMI file, sales data are only available for the company's headquarters, not the branch establishments. To impute missing sales data for establishments that can be linked to headquarters with reported sales, we first divided the number of food processing establishments of the company by its total number of establishments. This ratio was then multiplied by company total

sales to get an estimate of the company's total food sales. We then divided the estimated company-wide total food sales by total employment of the company at its food processing establishments. Next, this estimate of food sales per employee was multiplied by the employee count of each establishment to impute the establishment-specific sales data. For those establishments whose size categories were imputed, we assumed the following employee counts to derive the sales-per-employee estimate:

- for the fewer than 20 employees category: 19 employees
- for the 20 to 99 employees category: 50 employees
- for the 100 to 499 employees category: 300 employees
- for the 500 or more employees category: 500 employees

After the above imputations were completed, sales data were still missing for establishments that did not have headquarters or have missing headquarters sales data. Therefore, we calculated average sales by size of operation and company type (i.e., single location or a company location) using sales data from reporting establishments and those imputed from headquarters sales. These averages were then used to replace the remaining missing sales.

2.2.2 Census Data

The Census of Agriculture (Ag Census) is the leading source of facts and figures about American agriculture. Conducted every 5 years, the Ag Census provides a detailed picture of U.S. farms and ranches and the people who operate them. It is the only source of uniform, comprehensive agricultural data for every state and county in the United States. The 2012 Ag Census, which is the most recent, collected information concerning all areas of farming and ranching operations, including production expenses, market value of products, and operator characteristics.

We examined two aspects of the data: using the summary data to extrapolate proportions of farms that conduct food processing activities and determining whether the survey questions could be used to estimate the number of farms conducting food processing activities. We calculated the number

of colocated farms by applying the portion of farms that conduct food processing activities obtained from experts to the Ag Census farm counts. The most applicable portion of the survey asked questions about whether a farm also did packing on the property, by state and by size.

2.1.3 ARMS Data

The ARMS is USDA's primary source of information on the financial condition, production practices, and resource use of America's farm businesses. The ARMS is a nationally representative survey administered using several phases targeting about 5,000 fields and 30,000 farms each year. The field-level phase collects information on production practices and costs (e.g., fertilizer, pesticide, labor, tillage, seed) for target commodities. The farm-level phase collects financial information for farm businesses and a variety of financial and demographic information (e.g., age, education, occupation, off-farm income) for farm operators and their households. As part of the ARMS, certain commodities are oversampled during different years to gather more in-depth information on these crops.

We investigated whether the ARMS asks questions regarding processing on the farm. The most relevant question we found in these surveys was "At any time during [year], did this operation produce and sell value-added crops, livestock, or products such as beef jerky, fruit jams, jelly, preserves, floral arrangements, cider, wine, etc.?" The commodities for which this question was asked were the following (the most recent year the survey was conducted is in parentheses):

- apples (2007)
- soybeans (2012)

The responses to this question can be used to estimate the proportions of these farm types that conduct further processing. We received estimates of these proportions from the ARMS survey through the USDA Economic Research Service (ERS).

2.1.4 Commodity Specialists and Commodity Commissions

Commodity specialists are individuals with in-depth knowledge of a specific agricultural commodity at trade associations, government agencies, and universities. Commodity commissions are developed to conduct advertising, promotion,

education, trade oversight, and market development for a specific commodity. They are usually governed and funded entirely by growers in the industry.

With help from Linda Calvin of ERS, RTI contacted specialists within these organizations for a variety of commodities to obtain additional estimates of the proportion of farms that conduct processing on site. RTI contacted individuals from California Citrus Mutual, California Fresh Fruit Association, Florida Fruit and Vegetable Association, National Pecan Association, Georgia Pecan Growers Association, ERS, California Pistachio Orchards, Michigan State, University of Massachusetts, University of California, University of Florida, North Carolina State University, and the North Carolina Sweet Potato Commission. Linda Calvin contacted the Washington Apple Commission, the California Cantaloupe Advisory Board, and a member of the California tomato industry.

The specific question we asked the specialists was "Based on your knowledge of this commodity, what percentage of farms in the commodity group conducts some form of processing on their own farm?" Linda Calvin also asked questions regarding the number of members belonging to the commission, vertical integration of processes, and colocation. Although some specialists provided ballpark figures to RTI for the proportion of farms in their area that conducted some sort of processing on the farm, others were not able to provide estimates because of minimal data existing on this topic.

We applied the limited estimates we received to the Census farm counts to calculate the number of potential colocated facilities.[1]

2.1.5 Research and Promotion Boards

AMS reached out to the staff of research and promotion (R&P) boards and marketing order boards for various vegetables, fruits, and tree nuts to request information on colocated facilities for use in this study. According to AMS, R&P boards administer programs that facilitate the efficient, fair marketing of U.S. agricultural products, including food, fiber, and specialty crops. Marketing orders are initiated by industry to help provide

[1] Linda Calvin also prepared case studies of the industry structure for several commodities, including apples, cantaloupe, and tomatoes, that are provided in Appendix B.

stable markets for dairy products, fruits, vegetables, and specialty crops. According to AMS, marketing orders help maintain the quality of produce being marketed; standardize packages or containers; and authorize advertising, research, and market development. Each order is tailored to the individual industry's marketing needs. AMS has oversight authority over 22 R&P programs and 28 marketing orders.

For this project, AMS reached out to 8 R&P boards, 26 fruit and vegetable marketing orders, and the AMS Dairy Division, which manages 10 federal milk marketing orders. The R&P boards who were contacted cover mangos, honey, avocados, blueberries, mushrooms, peanuts, raspberries, and watermelons. The marketing order boards cover citrus (Florida and Texas), desert grapes (California), kiwifruit (California), avocados (Florida), apricots (Washington), sweet cherries (Washington), pears (Oregon/Washington), plums (California), tomatoes (Florida), onions (Idaho/Oregon, Georgia, Texas, and Washington/Oregon), almonds (California), walnuts (California), pistachios (California/Arizona/New Mexico), and hazelnuts (Oregon/Washington). Representatives were asked how many producers were in the production area, and based on their experience, how many colocated facilities operated in the marketing order production area. We applied these estimates to the Census farm counts to calculate the number of potential colocated facilities. The fruit and vegetable marketing orders included: oranges, grapefruit, tangerines, and tangelos (MO #905); oranges and grapefruit (MO #906); avocados (MO #915); cranberries (MO #929); tart cherries (MO #930); Vidalia onions (MO #955); onions (MO #959); tomatoes (MO #966); Washington apricots (MO #922); sweet cherries (MO #923); pears (MO #927); potatoes (MO #945); potatoes (MO #946); potatoes (MO #948); sweet onions (MO #956); onions (MO #958); hazelnuts (MO #982); kiwifruit (MO #920); grapes (MO #925); olives (MO #932); almonds (MO #981); pistachios (MO #983); walnuts (MO #984); dates (MO #987); raisins (MO #989); and dried prunes (MO #993).

2.1.6 CSA

CSA refers to a locally based economic model of agriculture and food distribution (USDA, n.d.). A CSA is a network or association of individuals who have pledged to support one or more local farms, with growers and consumers sharing the risks

and benefits of food production. CSA members pay at the onset of the growing season for a share of the anticipated harvest; once harvesting begins, they receive weekly shares of vegetables and fruit. Often, CSAs also include herbs, honey, eggs, dairy products, and meat, in addition to conventional produce offerings. While some CSAs include small community deliveries, other CSAs expand to large groups of individuals who can pick up their shares at a farmer's market-type setup.

Data collected in 2012 by USDA indicate that 12,617 farms in the United States reported marketing products through a CSA arrangement, a 0.5% increase over the 12,549 farms marketing through CSAs in 2007. However, estimates of food processing activities conducted by CSAs are not available.

2.1.7 On-Farm Packaging Facilities

Field preparation and packaging of produce is possible for only a limited number of crops and for particular markets. After harvest, most horticultural crops must be cleaned, sorted, sized, and usually packaged if they are to be sold in the fresh produce market. Produce that is not suitable to sell for eating because of cosmetic defects is removed and sold for juices or other uses. Usually these procedures take place in packing houses of different types. The packing house design and facilities needed depend very much on local infrastructure, types and quantities of produce, markets being served, and the funds available. The operations carried out in a packing house include some or all of the following:

- receipt, checking, and unloading
- packaging, including washing, waxing, fungicide treatment, grading, sizing, and packing
- dispatch, checking, and loading
- storage, fumigation, ripening, curing, and cooling

Because we do not have data on the percentage of packing houses that are owned by farmers, estimates of the number of farms with on-farm packing facilities (23,274 farms as of the 2012 Ag Census) can serve as a proxy. The case studies in Appendix B of the report also discuss packing houses with regard to the vertical integration of farms for the tomato, cantaloupe, and apple industries.

2.2 DISTRIBUTION OF TYPES AND SIZES OF FOOD PROCESSING OPERATIONS

Using the D&B data described above, Table 2-1 presents information on number of establishments, total sales, proportion of food sold, and average sales by industry and size of operation. Table 2-2 shows the number of food processing establishments under FDA jurisdiction by state and establishment size.

In total, the food processing, animal feed processing, pet food processing, and food additive industries included in the study generate a combined estimated annual sales of about $211 billion across a total establishment count of 20,519 based on D&B data.

The two largest NAICS codes in dollar sales are NAICS 312111 (Bottled and Canned Soft Drinks) and NAICS 311119 (Prepared Feed and Feed Ingredients for Animals and Fowls, Except Dogs and Cats), which account for 14.0% and 10.2% of total sales, respectively. They are followed by NAICS 311999 (Food Preparations, Not Classified Elsewhere) at 7.5% of total sales, NAICS 311511 (Fluid Milk) at 7.3% of total sales, and NAICS 311812 (Commercial Bakeries) at 5.9% of total sales. None of the remaining NAICS codes individually account for more than 5% of total sales. These results in product ranking are roughly consistent with a priori expectations based on other data sources. For example, scanner data indicate that carbonated beverages are the single largest product category in sales at supermarkets (Bronnenberg, Kruger, & Mela, 2008). The same supermarket scanner data source also suggests that, among the 30 product categories examined, fluid milk has the second highest dollar sales after carbonated soft drinks.

Within each 6-digit level NAICS code, the vast majority of the establishments (approximately 85%) belong to the two smallest employment size categories. The highest concentration of small establishments is found in NAICS 312113 (Manufactured Ice), where over 98% of the establishments have fewer than 100 employees. It is important to note that employment is just one of many ways to define the size of the establishment. For capital-intensive industries, another important dimension of establishment size is capital. However, employment is the only

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014

				Establishment Size				
Industry	NAICS	NAICS Description	Establishment Information	<20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
Food Processing	311211	Flour Milling	Number of Establishments	200	192	42	2	436
			Total Sales ($ millions)	1,750.0	5,360.0	1,080.0	23.3	8,213.3
			% of Total Food Industry Sales	0.8%	2.5%	0.5%	0.0%	3.9%
			Average Sales per Establishment ($ millions)	8.8	27.9	25.7	11.7	18.8
	311212	Rice Milling	Number of Establishments	52	35	15	1	103
			Total Sales ($ millions)	546.0	447.0	304.0	14.4	1,311.4
			% of Total Food Industry Sales	0.3%	0.2%	0.1%	0.0%	0.6%
			Average Sales per Establishment ($ millions)	10.5	12.8	20.3	14.4	12.7
	311213	Malt Manufacturing	Number of Establishments	15	15	2	0	32
			Total Sales ($ millions)	370.0	160.0	151.0	0.0	681.0
			% of Total Food Industry Sales	0.2%	0.1%	0.1%	0.0%	0.3%
			Average Sales per Establishment ($ millions)	24.7	10.7	75.5	0.0	21.3
	311221	Wet Corn Milling	Number of Establishments	42	35	22	3	102
			Total Sales ($ millions)	327.0	1,240.0	1,520.0	180.0	3,267.0
			% of Total Food Industry Sales	0.2%	0.6%	0.7%	0.1%	1.6%
			Average Sales per Establishment ($ millions)	7.8	35.4	69.1	60.0	32.0

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	311224	Soybean and Other Oilseed Processing	Number of Establishments	66	80	24	2	172
			Total Sales ($ millions)	674.0	4,770.0	1,420.0	218.0	7,082.0
			% of Total Food Industry Sales	0.3%	2.3%	0.7%	0.1%	3.4%
			Average Sales per Establishment ($ millions)	10.2	59.6	59.2	109.0	41.2
	311225	Fats and Oils Refining and Blending	Number of Establishments	168	75	24	0	267
			Total Sales ($ millions)	763.0	1,870.0	160.0	0.0	2,793.0
			% of Total Food Industry Sales	0.4%	0.9%	0.1%	0.0%	1.3%
			Average Sales per Establishment ($ millions)	4.5	24.9	6.7	0.0	10.5
	311230	Breakfast Cereal Manufacturing	Number of Establishments	59	37	61	12	169
			Total Sales ($ millions)	333.0	1,390.0	2,190.0	495.0	4,408.0
			% of Total Food Industry Sales	0.2%	0.7%	1.0%	0.2%	2.1%
			Average Sales per Establishment ($ millions)	5.6	37.6	35.9	41.3	26.1
	311313	Beet Sugar Manufacturing	Number of Establishments	11	10	16	3	40
			Total Sales ($ millions)	54.5	158.0	376.0	70.7	659.2
			% of Total Food Industry Sales	0.0%	0.1%	0.2%	0.0%	0.3%
			Average Sales per Establishment ($ millions)	5.0	15.8	23.5	23.6	16.5

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	311314	Cane Sugar Manufacturing	Number of Establishments	25	20	32	3	80
			Total Sales ($ millions)	119.0	352.0	761.0	53.9	1,285.9
			% of Total Food Industry Sales	0.1%	0.2%	0.4%	0.0%	0.6%
			Average Sales per Establishment ($ millions)	4.8	17.6	23.8	18.0	16.1
	311340	Nonchocolate Confectioneries	Number of Establishments	620	164	57	20	861
			Total Sales ($ millions)	1,200.0	1,390.0	1,200.0	568.0	4,358.0
			% of Total Food Industry Sales	0.6%	0.7%	0.6%	0.3%	2.1%
			Average Sales per Establishment ($ millions)	1.9	8.5	21.1	28.4	5.1
	311351	Chocolate and Confectionery Products from Cacao Beans	Number of Establishments	254	61	31	6	352
			Total Sales ($ millions)	517.0	458.0	728.0	105.0	1,808.0
			% of Total Food Industry Sales	0.2%	0.2%	0.3%	0.0%	0.9%
			Average Sales per Establishment ($ millions)	2.0	7.5	23.5	17.5	5.1
	311352	Confectionery Products from Purchased Chocolate	Number of Establishments	92	26	7	0	125
			Total Sales ($ millions)	52.0	112.0	119.0	0.0	283.0
			% of Total Food Industry Sales	0.0%	0.1%	0.1%	0.0%	0.1%
			Average Sales per Establishment ($ millions)	0.6	4.3	17.0	0.0	2.3

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	311411	Frozen Fruit, Fruit Juices, and Vegetables	Number of Establishments	102	80	84	19	285
			Total Sales ($ millions)	649.0	911.0	2,720.0	765.0	5,045.0
			% of Total Food Industry Sales	0.3%	0.4%	1.3%	0.4%	2.4%
			Average Sales per Establishment ($ millions)	6.4	11.4	32.4	40.3	17.7
	311412	Frozen Specialties, Not Elsewhere Classified	Number of Establishments	216	151	92	12	471
			Total Sales ($ millions)	965.0	954.0	2,280.0	381.0	4,580.0
			% of Total Food Industry Sales	0.5%	0.5%	1.1%	0.2%	2.2%
			Average Sales per Establishment ($ millions)	4.5	6.3	24.8	31.8	9.7
	311421	Fruit and Vegetable Canning	Number of Establishments	529	232	181	18	960
			Total Sales ($ millions)	1,440.0	2,980.0	4,370.0	792.0	9,582.0
			% of Total Food Industry Sales	0.7%	1.4%	2.1%	0.4%	4.5%
			Average Sales per Establishment ($ millions)	2.7	12.8	24.1	44.0	10.0
	311422	Canned Specialties	Number of Establishments	260	72	46	10	388
			Total Sales ($ millions)	372.0	624.0	1,060.0	226.0	2,282.0
			% of Total Food Industry Sales	0.2%	0.3%	0.5%	0.1%	1.1%
			Average Sales per Establishment ($ millions)	1.4	8.7	23.0	22.6	5.9

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	311423	Dried and Dehydrated Foods	Number of Establishments	147	89	26	5	267
			Total Sales ($ millions)	239.0	667.0	683.0	149.0	1,738.0
			% of Total Food Industry Sales	0.1%	0.3%	0.3%	0.1%	0.8%
			Average Sales per Establishment ($ millions)	1.6	7.5	26.3	29.8	6.5
	311511	Fluid Milk	Number of Establishments	148	163	202	12	525
			Total Sales ($ millions)	3,260.0	4,340.0	6,770.0	1,080.0	15,450.0
			% of Total Food Industry Sales	1.5%	2.1%	3.2%	0.5%	7.3%
			Average Sales per Establishment ($ millions)	22.0	26.6	33.5	90.0	29.4
	311512	Creamery Butter Manufacturing	Number of Establishments	20	17	6	0	43
			Total Sales ($ millions)	43.6	678.0	121.0	0.0	$ 842.6
			% of Total Food Industry Sales	0.0%	0.3%	0.1%	0.0%	0.4%
			Average Sales per Establishment ($ millions)	2.2	39.9	20.2	0.0	19.6
	311513	Natural, Processed and Imitation Cheeses	Number of Establishments	253	172	115	9	549
			Total Sales ($ millions)	1,370.0	3,380.0	4,180.0	291.0	9,221.0
			% of Total Food Industry Sales	0.7%	1.6%	2.0%	0.1%	4.4%
			Average Sales per Establishment ($ millions)	5.4	19.7	36.3	32.3	16.8

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	311514	Dry, Condensed, and Evaporated Dairy Products	Number of Establishments	245	144	44	5	438
			Total Sales ($ millions)	591.0	2,940.0	1,220.0	184.0	4,935.0
			% of Total Food Industry Sales	0.3%	1.4%	0.6%	0.1%	2.3%
			Average Sales per Establishment ($ millions)	2.4	20.4	27.7	36.8	11.3
	311520	Ice Cream and Frozen Desserts	Number of Establishments	399	115	37	4	555
			Total Sales ($ millions)	909.0	746.0	748.0	102.0	2,505.0
			% of Total Food Industry Sales	0.4%	0.4%	0.4%	0.0%	1.2%
			Average Sales per Establishment ($ millions)	2.3	6.5	20.2	25.5	4.5
	311811	Retail Bakeries	Number of Establishments	387	191	31	3	612
			Total Sales ($ millions)	413.0	503.0	442.0	58.8	1,416.8
			% of Total Food Industry Sales	0.2%	0.2%	0.2%	0.0%	0.7%
			Average Sales per Establishment ($ millions)	1.1	2.6	14.3	19.6	2.3
	311812	Commercial Bakeries	Number of Establishments	1,365	641	331	21	2,358
			Total Sales ($ millions)	3,430.0	4,040.0	4,420.0	504.0	12,394.0
			% of Total Food Industry Sales	1.6%	1.9%	2.1%	0.2%	5.9%
			Average Sales per Establishment ($ millions)	2.5	6.3	13.4	24.0	5.3

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	311813	Frozen bakery products, except bread	Number of Establishments	70	51	37	6	164
			Total Sales ($ millions)	258.0	357.0	756.0	180.0	1,551.0
			% of Total Food Industry Sales	0.1%	0.2%	0.4%	0.1%	0.7%
			Average Sales per Establishment ($ millions)	3.7	7.0	20.4	30.0	9.5
	311821	Cookies and Crackers	Number of Establishments	281	121	65	14	481
			Total Sales ($ millions)	1,540.0	1,850.0	1,840.0	455.0	5,685.0
			% of Total Food Industry Sales	0.7%	0.9%	0.9%	0.2%	2.7%
			Average Sales per Establishment ($ millions)	5.5	15.3	28.3	32.5	11.8
	311824	Dry Pasta, Dough and Flour Mixes Manufacturing from Purchased Flour	Number of Establishments	202	92	37	2	333
			Total Sales ($ millions)	262.0	826.0	802.0	34.9	1,924.9
			% of Total Food Industry Sales	0.1%	0.4%	0.4%	0.0%	0.9%
			Average Sales per Establishment ($ millions)	1.3	9.0	21.7	17.5	5.8
	311830	Tortilla Manufacturing	Number of Establishments	174	87	25	0	286
			Total Sales ($ millions)	129.0	368.0	549.0	0.0	1,046.0
			% of Total Food Industry Sales	0.1%	0.2%	0.3%	0.0%	0.5%
			Average Sales per Establishment ($ millions)	0.7	4.2	22.0	0.0	3.7

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	311911	Nuts: dried, dehydrated, salted or roasted	Number of Establishments	113	84	30	1	228
			Total Sales ($ millions)	775.0	2,920.0	1,300.0	61.7	5,056.7
			% of Total Food Industry Sales	0.4%	1.4%	0.6%	0.0%	2.4%
			Average Sales per Establishment ($ millions)	6.9	34.8	43.3	61.7	22.2
	311919	Potato Chips, Corn Chips, and Similar Snacks	Number of Establishments	235	123	97	20	475
			Total Sales ($ millions)	1,410.0	1,550.0	2,300.0	451.0	5,711.0
			% of Total Food Industry Sales	0.7%	0.7%	1.1%	0.2%	2.7%
			Average Sales per Establishment ($ millions)	6.0	12.6	23.7	22.6	12.0
	311920	Coffee and Tea	Number of Establishments	434	123	39	1	597
			Total Sales ($ millions)	901.0	938.0	849.0	1.7	2,689.7
			% of Total Food Industry Sales	0.4%	0.4%	0.4%	0.0%	1.3%
			Average Sales per Establishment ($ millions)	2.1	7.6	21.8	1.7	4.5
	311930	Flavored syrups, concentrates, fruit juices	Number of Establishments	142	79	36	1	258
			Total Sales ($ millions)	665.0	794.0	793.0	50.0	2,302.0
			% of Total Food Industry Sales	0.3%	0.4%	0.4%	0.0%	1.1%
			Average Sales per Establishment ($ millions)	4.7	10.1	22.0	50.0	8.9

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	311941	Pickles, sauces, seasonings, and salad dressings	Number of Establishments	232	82	41	2	357
			Total Sales ($ millions)	552.0	659.0	1,110.0	4.6	2,325.6
			% of Total Food Industry Sales	0.3%	0.3%	0.5%	0.0%	1.1%
			Average Sales per Establishment ($ millions)	2.4	8.0	27.1	2.3	6.5
	311942	Spice and Extracts	Number of Establishments	418	164	38	1	621
			Total Sales ($ millions)	521.0	1,740.0	1,390.0	1.6	3,652.6
			% of Total Food Industry Sales	0.2%	0.8%	0.7%	0.0%	1.7%
			Average Sales per Establishment ($ millions)	1.2	10.6	36.6	1.6	5.9
	311991	Ready-to-eat meals, salads, and sandwiches	Number of Establishments	87	76	25	4	192
			Total Sales ($ millions)	133.0	589.0	394.0	91.5	1,207.5
			% of Total Food Industry Sales	0.1%	0.3%	0.2%	0.0%	0.6%
			Average Sales per Establishment ($ millions)	1.5	7.8	15.8	22.9	6.3
	311999	Food Preparations, Not Elsewhere Classified	Number of Establishments	1,378	509	188	19	2,094
			Total Sales ($ millions)	4,020.0	5,310.0	5,450.0	984.0	15,764.0
			% of Total Food Industry Sales	1.9%	2.5%	2.6%	0.5%	7.5%
			Average Sales per Establishment ($ millions)	2.9	10.4	29.0	51.8	7.5

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
	312111	Bottled and Canned Soft Drinks	Number of Establishments	479	567	433	27	1,506
			Total Sales ($ millions)	4,140.0	11,500.0	12,900.0	907.0	29,447.0
			% of Total Food Industry Sales	2.0%	5.5%	6.1%	0.4%	14.0%
			Average Sales per Establishment ($ millions)	8.6	20.3	29.8	33.6	19.6
	312112	Natural and Carbonated Waters	Number of Establishments	148	59	20	0	227
			Total Sales ($ millions)	226.0	297.0	355.0	0.0	878.0
			% of Total Food Industry Sales	0.1%	0.1%	0.2%	0.0%	0.4%
			Average Sales per Establishment ($ millions)	1.5	5.0	17.8	0.0	3.9
	312113	Manufactured Ice	Number of Establishments	338	117	5	0	460
			Total Sales ($ millions)	330.0	398.0	36.5	0.0	764.5
			% of Total Food Industry Sales	0.2%	0.2%	0.0%	0.0%	0.4%
			Average Sales per Establishment ($ millions)	1.0	3.4	7.3	0.0	1.7
Pet Food	311111	Dog and Cat Food	Number of Establishments	146	79	47	5	277
			Total Sales ($ millions)	462.0	859.0	1,250.0	546.0	3,117.0
			% of Total Food Industry Sales	0.2%	0.4%	0.6%	0.3%	1.5%
			Average Sales per Establishment ($ millions)	3.2	10.9	26.6	109.2	11.3

(continued)

Table 2-1. Number of Establishments, Total Sales, Percentage of Total Food Industry Sales, and Average Sales per Establishment for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

Industry	NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
Animal Feed	311119	Prepared Feed and Feed Ingredients for Animals and Fowls, Except Dogs and Cats	Number of Establishments	1,168	550	51	4	1,773
			Total Sales ($ millions)	7,930.0	11,500.0	1,920.0	154.0	21,504.0
			% of Total Food Industry Sales	3.8%	5.5%	0.9%	0.1%	10.2%
			Average Sales per Establishment ($ millions)	6.8	20.9	37.6	38.5	12.1
Total			Number of Establishments	11,720	5,780	2,742	277	20,519
			Total Sales ($ millions)	44,641	82,925	73,018	10,184	210,768
			% of Total Food Industry Sales	21.18%	39.34%	34.64%	4.83%	100.00%
			Average Sales per Establishment ($ millions)	3.8	14.3	26.6	36.8	10.3

Table 2-2. Number of Establishments by State and Establishment Size for Food Processing Establishments Under FDA Jurisdiction, 2014

	Establishment Size				
State	**<20 Employees**	**20–99 Employees**	**100–499 Employees**	**500+ Employees**	**Total**
Alabama	125	49	32	4	210
Alaska	26	6	2	0	34
Arizona	158	83	28	2	271
Arkansas	111	55	32	4	202
California	1,513	766	341	31	2,651
Colorado	229	102	29	3	363
Connecticut	127	44	18	4	193
Delaware	28	12	4	1	45
District of Columbia	10	4	0	0	14
Florida	513	200	104	6	823
Georgia	226	140	87	14	467
Hawaii	121	46	14	0	181
Idaho	98	50	29	7	184
Illinois	506	283	154	25	968
Indiana	206	123	64	6	399
Iowa	190	129	63	3	385
Kansas	115	86	30	3	234
Kentucky	136	61	46	3	246
Louisiana	153	79	39	2	273
Maine	96	34	18	2	150
Maryland	136	87	40	1	264
Massachusetts	282	112	59	2	455
Michigan	331	193	86	6	616
Minnesota	272	172	99	12	555
Mississippi	65	29	15	0	109
Missouri	220	129	61	5	415
Montana	105	33	7	0	145
Nebraska	114	58	35	0	207
Nevada	72	26	9	0	107
New Hampshire	64	19	7	1	91
New Jersey	435	184	100	10	729
New Mexico	101	47	16	0	164
New York	755	304	120	12	1,191
North Carolina	274	131	63	8	476
North Dakota	60	37	11	0	108
Ohio	404	224	110	14	752
Oklahoma	130	48	29	3	210
Oregon	297	111	50	9	467
Pennsylvania	519	253	161	22	955
Puerto Rico	65	42	11	3	121
Rhode Island	55	20	5	0	80
South Carolina	87	54	27	1	169

(continued)

Table 2-2. Number of Establishments by State and Establishment Size for Food Processing Establishments Under FDA Jurisdiction, 2014 (continued)

State	Establishment Size				Total
	<20 Employees	20–99 Employees	100–499 Employees	500+ Employees	
South Dakota	55	26	7	1	89
Tennessee	160	94	60	9	323
Texas	740	333	143	16	1,232
Utah	141	67	32	1	241
Vermont	119	27	8	0	154
Virgin Islands	3	0	0	0	3
Virginia	205	84	45	5	339
Washington	335	158	66	8	567
West Virginia	60	26	8	0	94
Wisconsin	339	292	115	8	754
Wyoming	33	8	3	0	44
Total	11,720	5,780	2,742	277	20,519

Source: RTI calculations based on FDA facility registration matched with D&B data obtained October 16, 2014.

size variable available in the DMI file. In addition to the concentration of establishments in the two smallest size categories, on average, 61% of total sales occur at establishments with fewer than 99 employees.

The three states with the largest number of food processing establishments are California with 2,651 establishments, Texas with 1,232 establishments, and New York with 1,191 establishments.

2.3 COLOCATION OF FOOD PROCESSING ON FARMS

An overall summary of estimated colocated facilities is shown in Table 2-3. In the table, food manufacturing establishments refer to those establishments listed in the FDA Facility Registration Database, and farming operations refer to farms in the 2012 Census of Agriculture. We describe the derivation of these estimates below.

Table 2-3. Summary of Colocated Facility Estimates

	No. of Categories	Estimated No. of Establishments or Operations	Estimated No. of Colocated Operations	Estimated % Colocated Operations
Food Manufacturing Establishments:	41	20,519	358	1.7%
Categories with colocated facilities	34	19,485	358	1.8%
Categories without colocated facilities	7	1,034	0	0.0%
Farming Operations:	122	1,585,691	33,236	2.1%
Categories with colocated facilities	26	511,146	33,236	6.5%
Categories without colocated facilities	17	101,359	0	0.0%
Categories with unknown colocation status	79	973,186	n/a	n/a

2.3.1 Estimates of Colocated Facilities Based on D&B's DMI Data on the Food Processing Industry

Table 2-4 presents number of colocated establishments, total sales for colocated establishments, percentage of total sales of colocated establishments for each NAICS code, and percentage of establishments that are colocated, all by NAICS code and size of operation. Table 2-5 presents the number of food processing establishments colocated on farms by state and establishment size.

Overall, 1.7% of all food processing establishments included in this study are colocated with farms. In the food processing sector, NAICS 311314 (Cane Sugar Manufacturing) has the highest proportion of establishments colocated on farms at 7.5%. Only four other NAICS codes examined have more than 5% of their establishments colocated on farms: NAICS 311411 (Frozen Fruit, Fruit Juices, and Vegetables), NAICS 311423 (Dried and Dehydrated Foods), NAICS 311511 (Fluid Milk), and NAICS 311911 (Nuts: Dried, Dehydrated, Salted or Roasted). NAICS 311512 (Creamery Butter Manufacturing) has the highest percentage of total sales occurring at colocated establishments at 11.9%. Only one other industry examined draws more than 5% of its total sales from colocated establishments: NAICS 311314 (Cane Sugar Manufacturing) at 5.3%.

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
311211	Flour Milling	Number of Establishments	5	0	0	0	5
		Total Sales ($ millions)	1.2	0	0	0	1.2
		% of Total Sales for NAICS Code	0.1%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	2.5%	0.0%	0.0%	0.0%	1.1%
311212	Rice Milling	Number of Establishments	3	1	0	0	4
		Total Sales ($ millions)	1.4	8.6	0.0	0.0	10.0
		% of Total Sales for NAICS Code	0.3%	1.9%	0.0%	0.0%	0.8%
		% of Colocated Establishments for NAICS Code	5.8%	2.9%	0.0%	0.0%	3.9%
311213	Malt Manufacturing	Number of Establishments	0	0	0	0	0
		Total Sales ($ millions)	0.0	0.0	0.0	0.0	0.0
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
311221	Wet Corn Milling	Number of Establishments	1	0	0	0	1
		Total Sales ($ millions)	0.2	0.0	0.0	0.0	0.2
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	2.4%	0.0%	0.0%	0.0%	1.0%
311224	Soybean and Other Oilseed Processing	Number of Establishments	1	1	0	0	2
		Total Sales ($ millions)	1.1	1.7	0.0	0.0	2.8
		% of Total Sales for NAICS Code	0.2%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	1.5%	1.3%	0.0%	0.0%	1.2%

(continued)

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014 (continued)

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
311225	Fats and Oils Refining and Blending	Number of Establishments	3	0	0	0	3
		Total Sales ($ millions)	12.3	0.0	0.0	0.0	12.3
		% of Total Sales for NAICS Code	1.6%	0.0%	0.0%	0.0%	0.4%
		% of Colocated Establishments for NAICS Code	1.8%	0.0%	0.0%	0.0%	1.1%
311230	Breakfast Cereal Manufacturing	Number of Establishments	0	0	0	0	0
		Total Sales ($ millions)	0.0	0.0	0.0	0.0	0.0
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
311313	Beet Sugar Manufacturing	Number of Establishments	0	0	0	0	0
		Total Sales ($ millions)	0.0	0.0	0.0	0.0	0.0
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
311314	Cane Sugar Manufacturing	Number of Establishments	0	2	3	1	6
		Total Sales ($ millions)	0.0	7.3	53.7	7.3	68.3
		% of Total Sales for NAICS Code	0.0%	2.1%	7.1%	13.5%	5.3%
		% of Colocated Establishments for NAICS Code	0.0%	10.0%	9.4%	33.3%	7.5%
311340	Nonchocolate Confectioneries	Number of Establishments	6	1	0	0	7
		Total Sales ($ millions)	4.7	9.3	0.0	0.0	14.0
		% of Total Sales for NAICS Code	0.4%	0.7%	0.0%	0.0%	0.3%
		% of Colocated Establishments for NAICS Code	1.0%	0.6%	0.0%	0.0%	0.8%

(continued)

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014 (continued)

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
311351	Chocolate and Confectionery Products from Cacao Beans	Number of Establishments	0	0	0	0	0
		Total Sales ($ millions)	0.0	0.0	0.0	0.0	0.0
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
311352	Confectionery Products from Purchased Chocolate	Number of Establishments	1	0	0	0	1
		Total Sales ($ millions)	0.1	0.0	0.0	0.0	0.1
		% of Total Sales for NAICS Code	0.2%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	1.1%	0.0%	0.0%	0.0%	0.8%
311411	Frozen Fruit, Fruit Juices, and Vegetables	Number of Establishments	9	4	2	1	16
		Total Sales ($ millions)	6.3	60.8	45.7	69.7	182.5
		% of Total Sales for NAICS Code	1.0%	6.7%	1.7%	9.1%	3.6%
		% of Colocated Establishments for NAICS Code	8.8%	5.0%	2.4%	5.3%	5.6%
311412	Frozen Specialties, Not Elsewhere Classified	Number of Establishments	1	1	0	0	2
		Total Sales ($ millions)	0.9	1.0	0.0	0.0	1.9
		% of Total Sales for NAICS Code	0.1%	0.1%	0.0%	0.0%	0.0%
		% of Number of Establishments for NAICS Code	0.5%	0.7%	0.0%	0.0%	0.4%
311421	Fruit and Vegetable Canning	Number of Establishments	32	6	6	1	45
		Total Sales ($ millions)	96.7	40.6	93.5	22.0	252.9
		% of Total Sales for NAICS Code	6.7%	1.4%	2.1%	2.8%	2.6%
		% of Colocated Establishments for NAICS Code	6.0%	2.6%	3.3%	5.6%	4.7%

(continued)

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014 (continued)

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
311422	Canned Specialties	Number of Establishments	1	0	0	0	1
		Total Sales ($ millions)	0.1	0.0	0.0	0.0	0.1
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.4%	0.0%	0.0%	0.0%	0.3%
311423	Dried and Dehydrated Foods	Number of Establishments	9	5	3	0	17
		Total Sales ($ millions)	4.8	28.9	29.2	0.0	62.9
		% of Total Sales for NAICS Code	2.0%	4.3%	4.3%	0.0%	3.6%
		% of Colocated Establishments for NAICS Code	6.1%	5.6%	11.5%	0.0%	6.4%
311511	Fluid Milk	Number of Establishments	14	14	6	0	34
		Total Sales ($ millions)	45.3	218.3	87.8	0.0	351.4
		% of Total Sales for NAICS Code	1.4%	5.0%	1.3%	0.0%	2.3%
		% of Colocated Establishments for NAICS Code	9.5%	8.6%	3.0%	0.0%	6.5%
311512	Creamery Butter Manufacturing	Number of Establishments	0	1	0	0	1
		Total Sales ($ millions)	0.0	100.0	0.0	0.0	100.0
		% of Total Sales for NAICS Code	0.0%	14.7%	0.0%	0.0%	11.9%
		% of Colocated Establishments for NAICS Code	0.0%	5.9%	0.0%	0.0%	2.3%
311513	Natural, Processed and Imitation Cheeses	Number of Establishments	13	3	3	1	20
		Total Sales ($ millions)	3.3	44.9	136.5	45.9	230.6
		% of Total Sales for NAICS Code	0.2%	1.3%	3.3%	15.8%	2.5%
		% of Colocated Establishments for NAICS Code	5.1%	1.7%	2.6%	11.1%	3.6%

(continued)

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014 (continued)

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
311514	Dry, Condensed, and Evaporated Dairy Products	Number of Establishments	1	3	0	0	4
		Total Sales ($ millions)	7.3	115.5	0.0	0.0	122.7
		% of Total Sales for NAICS Code	1.2%	3.9%	0.0%	0.0%	2.5%
		% of Colocated Establishments for NAICS Code	0.4%	2.1%	0.0%	0.0%	0.9%
311520	Ice Cream and Frozen Desserts	Number of Establishments	5	2	1	0	8
		Total Sales ($ millions)	1.7	16.6	6.3	0.0	24.6
		% of Total Sales for NAICS Code	0.2%	2.2%	0.8%	0.0%	1.0%
		% of Colocated Establishments for NAICS Code	1.3%	1.7%	2.7%	0.0%	1.4%
311811	Retail Bakeries	Number of Establishments	9	6	1	0	16
		Total Sales ($ millions)	8.8	10.1	10.2	0.0	29.1
		% of Total Sales for NAICS Code	2.1%	2.0%	2.3%	0.0%	2.1%
		% of Colocated Establishments for NAICS Code	2.3%	3.1%	3.2%	0.0%	2.6%
311812	Commercial Bakeries	Number of Establishments	5	5	0	0	10
		Total Sales ($ millions)	1.5	12.9	0.0	0.0	14.4
		% of Total Sales for NAICS Code	0.0%	0.3%	0.0%	0.0%	0.1%
		% of Colocated Establishments for NAICS Code	0.4%	0.8%	0.0%	0.0%	0.4%
311813	Frozen bakery products, except bread	Number of Establishments	0	0	0	0	0
		Total Sales ($ millions)	0.0	0.0	0.0	0.0	0.0
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%

(continued)

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014 (continued)

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
311821	Cookies and Crackers	Number of Establishments	3	0	0	0	3
		Total Sales ($ millions)	2.1	0.0	0.0	0.0	2.1
		% of Total Sales for NAICS Code	0.1%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	1.1%	0.0%	0.0%	0.0%	0.6%
311824	Dry Pasta, Dough and Flour Mixes Manufacturing from Purchased Flour	Number of Establishments	2	1	0	0	3
		Total Sales ($ millions)	1.3	1.0	0.0	0.0	2.2
		% of Total Sales for NAICS Code	0.5%	0.1%	0.0%	0.0%	0.1%
		% of Colocated Establishments for NAICS Code	1.0%	1.1%	0.0%	0.0%	0.9%
311830	Tortilla Manufacturing	Number of Establishments	0	0	0	0	0
		Total Sales ($ millions)	0.0	0.0	0.0	0.0	0.0
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
311911	Nuts: dried, dehydrated, salted or roasted	Number of Establishments	7	4	1	0	12
		Total Sales ($ millions)	10.0	12.9	4.6	0.0	27.5
		% of Total Sales for NAICS Code	1.3%	0.4%	0.4%	0.0%	0.5%
		% of Colocated Establishments for NAICS Code	6.2%	4.8%	3.3%	0.0%	5.3%
311919	Potato Chips, Corn Chips, and Similar Snacks	Number of Establishments	2	0	0	0	2
		Total Sales ($ millions)	1.1	0.0	0.0	0.0	1.1
		% of Total Sales for NAICS Code	0.1%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.9%	0.0%	0.0%	0.0%	0.4%

(continued)

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014 (continued)

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
311920	Coffee and Tea	Number of Establishments	1	1	0	0	2
		Total Sales ($ millions)	0.1	8.1	0.0	0.0	8.2
		% of Total Sales for NAICS Code	0.0%	0.9%	0.0%	0.0%	0.3%
		% of Colocated Establishments for NAICS Code	0.2%	0.8%	0.0%	0.0%	0.3%
311930	Flavored syrups, concentrates, fruit juices	Number of Establishments	1	0	0	0	1
		Total Sales ($ millions)	0.1	0.0	0.0	0.0	0.1
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.7%	0.0%	0.0%	0.0%	0.4%
311941	Pickles, sauces, seasonings, and salad dressings	Number of Establishments	1	4	0	0	5
		Total Sales ($ millions)	0.3	15.1	0.0	0.0	15.4
		% of Total Sales for NAICS Code	0.1%	2.3%	0.0%	0.0%	0.7%
		% of Colocated Establishments for NAICS Code	0.4%	4.9%	0.0%	0.0%	1.4%
311942	Spice and Extracts	Number of Establishments	2	2	0	0	4
		Total Sales ($ millions)	1.0	7.7	0.0	0.0	8.7
		% of Total Sales for NAICS Code	0.2%	0.4%	0.0%	0.0%	0.2%
		% of Colocated Establishments for NAICS Code	0.5%	1.2%	0.0%	0.0%	0.6%
311991	Ready-to-eat meals, salads, and sandwiches	Number of Establishments	0	0	0	1	1
		Total Sales ($ millions)	0.0	0.0	0.0	34.9	34.9
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	38.1%	2.9%
		% of Colocated Establishments for NAICS Code	0.0%	0.0%	0.0%	25.0%	0.5%

(continued)

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014 (continued)

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
311999	Food Preparations, Not Elsewhere Classified	Number of Establishments	69	17	10	1	97
		Total Sales ($ millions)	68.4	45.8	173.2	14.1	301.5
		% of Total Sales for NAICS Code	1.7%	0.9%	3.2%	1.4%	1.9%
		% of Colocated Establishments for NAICS Code	5.0%	3.3%	5.3%	5.3%	4.6%
312111	Bottled and Canned Soft Drinks	Number of Establishments	3	2	0	0	5
		Total Sales ($ millions)	13.0	1.3	0.0	0.0	14.4
		% of Total Sales for NAICS Code	0.3%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.6%	0.4%	0.0%	0.0%	0.3%
312112	Natural and Carbonated Waters	Number of Establishments	2	0	0	0	2
		Total Sales ($ millions)	0.2	0.0	0.0	0.0	0.2
		% of Total Sales for NAICS Code	0.1%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	1.4%	0.0%	0.0%	0.0%	0.9%
312113	Manufactured Ice	Number of Establishments	1	0	0	0	1
		Total Sales ($ millions)	1.3	0.0	0.0	0.0	1.3
		% of Total Sales for NAICS Code	0.4%	0.0%	0.0%	0.0%	0.2%
		% of Colocated Establishments for NAICS Code	0.3%	0.0%	0.0%	0.0%	0.2%
Pet Food							
311111	Dog and Cat Food	Number of Establishments	0	0	0	0	0
		Total Sales ($ millions)	0.0	0.0	0.0	0.0	0.0
		% of Total Sales for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%
		% of Colocated Establishments for NAICS Code	0.0%	0.0%	0.0%	0.0%	0.0%

(continued)

Table 2-4. Number of Establishments and Total Sales by NAICS Code for Food Processing Establishments Colocated on Farms, 2014 (continued)

NAICS	NAICS Description	Establishment Information	Establishment Size <20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
Animal Feed							
311119	Prepared Feed and Feed Ingredients for Animals and Fowls, Except Dogs and Cats	Number of Establishments	16	1	0	0	17
		Total Sales ($ millions)	54.2	1.7	0.0	0.0	55.9
		% of Total Sales for NAICS Code	0.7%	0.0%	0.0%	0.0%	0.3%
		% of Colocated Establishments for NAICS Code	1.4%	0.2%	0.0%	0.0%	1.0%
Total		Number of Colocated Establishments	229	87	36	6	358
		Total Sales of Colocated Establishments ($ millions)	350.8	770.0	640.7	193.9	1955.4
		% of Total Sales for Food Processing	0.8%	0.9%	0.9%	1.9%	0.9%
		% of Colocated Establishments for Food Processing	2.0%	1.5%	1.3%	2.2%	1.7%

Source: RTI calculations based on FDA facility registration matched with D&B data obtained October 16, 2014.
Note: This table does not include NAICS 311611 (Animal Slaughtering-except poultry), 311612 (Meat Processed from Carcasses), 311613 (Rendering and Meat Byproduct Processing), and 311615 (Poultry Processing),

California has the most colocated establishments of any state at 50 farms, and Michigan (28 establishments) and Wisconsin (24 establishments) are the only other two states over 20. Most colocated establishments are small operations with fewer than 20 employees (see Table 2-5).

Table 2-5. Number of Food Processing Establishments Colocated on Farms by State and Establishment Size, 2014

	Establishment Size				
State	<20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
Alabama	2	1	1	0	4
Alaska	1	0	0	0	1
Arizona	2	1	0	0	3
Arkansas	2	0	0	0	2
California	33	8	7	2	50
Colorado	6	2	1	0	9
Connecticut	2	2	0	0	4
Delaware	0	0	0	0	0
Florida	7	5	3	1	16
Georgia	3	2	0	0	5
Hawaii	2	1	0	0	3
Idaho	0	1	1	1	3
Illinois	4	5	3	1	13
Indiana	3	0	0	0	3
Iowa	4	2	0	0	6
Kansas	0	1	0	0	1
Kentucky	2	0	0	0	2
Louisiana	1	0	1	0	2
Maine	2	2	0	0	4
Maryland	1	2	0	0	3
Massachusetts	11	2	1	0	14
Michigan	20	6	2	0	28
Minnesota	4	3	0	0	7
Mississippi	0	0	1	0	1
Missouri	3	0	0	0	3
Montana	4	0	0	0	4
Nebraska	2	0	0	0	2
Nevada	0	0	0	0	0
New Hampshire	2	1	0	0	3
New Jersey	3	2	0	0	5
New Mexico	2	3	0	0	5
New York	16	3	1	0	20
North Carolina	3	0	0	1	4
North Dakota	2	1	0	0	3
Ohio	9	4	2	0	15
Oklahoma	4	0	2	0	6

(continued)

Table 2-5. Number of Food Processing Establishments Colocated on Farms by State, 2014 (continued)

State	Establishment Size				
	<20 Employees	20–99 Employees	100–499 Employees	500+ Employees	Total
Oregon	10	3	2	0	15
Pennsylvania	4	6	2	0	12
Rhode Island	1	1	0	0	2
South Carolina	2	1	0	0	3
South Dakota	2	0	0	0	2
Tennessee	3	0	0	0	3
Texas	4	1	2	0	7
Utah	2	0	0	0	2
Vermont	8	2	0	0	10
Virginia	3	2	0	0	5
Washington	9	5	1	0	15
West Virginia	3	0	0	0	3
Wisconsin	15	6	3	0	24
Wyoming	1	0	0	0	1
Total	229	87	36	6	358

Source: RTI calculations based on FDA facility registration matched with D&B data obtained October 16, 2014.

2.3.2 Estimates of Colocated Facilities Derived from Ag Census Data

The 2012 Ag Census provides information on a broad variety of farm activities that can be used to estimate or infer colocation of farms with food processing operations. The summary data on farms are presented in Table 2-6, which shows the number of farms in the United States for 121 commodities.

The 2012 Ag Census asked growers several questions that can be used to infer possible food processing activities on farms. However, responses to these questions do not provide definitive estimates of colocated facilities. Table 2-7 summarizes the results of these questions, which are described below, presenting data on the number of growers with produce sales (not just produce production) where produce includes vegetables, potatoes, melons, fruit, tree nuts, and berries and excludes greenhouse produce and mushrooms.

Table 2-6. Number of Farms in the United States by Commodity According to the 2012 Ag Census

Commodity	Total Farms
Almonds	7,052
Apples	25,129
Apricots	2,305
Artichokes (excluding Jerusalem)	167
Asparagus	2,691
Avocados	7,495
Bananas	1,169
Barley	18,667
Beans	23,198
Beets	3,719
Blackberries and dewberries	7,291
Blueberries	13,432
Boysenberries	375
Broccoli	3,636
Brussels sprouts	658
Buckwheat	352
Cabbage	4,916
Camelina	22
Canola	3,995
Cantaloupes and muskmelons	9,684
Carrots	4,468
Cauliflower	1,330
Celery	488
Cherries	10,715
Chestnuts	919
Chicory	48
Coffee	1,577
Collards	1,407
Corn	374,162
Cranberries	1,040
Cucumbers and pickles	14,183
Currants	528
Daikon	207
Dates	213
Dry edible beans	7,051
Dry edible peas	2,628
Eggplant	3,473
Emmer and spelt	1,012
Escarole and endive	109
Figs	989
Flaxseed	1,480
Garlic	3,408
Ginseng	140
Grapefruit	2,144
Grapes	27,878
Guavas	399
Hazelnuts (filberts)	1,458
Herbs, fresh cut	2,255
Honey	22,827
Honeydew melons	534
Horseradish	124
Kale	2,500
Kiwi	345
Kumquats	102
Lemons	3,007
Lentils	1,093
Lettuce, all	5,757
Limes	583
Loganberries	135
Macadamia nuts	995
Mangoes	933
Mustard greens	1,095
Mustard seed	178
Nectarines	1,275
Oat	35,038
Okra	2,487
Olives	2,092
Onions	8,021
Oranges, all	9,437
Other berries	1,286
Other citrus fruit	873
Other noncitrus fruit	3,096
Other nuts	1,126
Other vegetables	8,057
Papayas	401
Parsley	482
Passion fruit	153

(continued)

Table 2-6. Number of Farms in the United States by Commodity According to the 2012 Ag Census (continued)

Commodity	Total Farms
Peaches	13,916
Peanuts	6,561
Pears	10,246
Peas	9,341
Pecans	19,253
Peppers	19,519
Persimmons	1,389
Pima cotton	439
Pistachios	1,496
Plumcots, pluots and other plum-apricot hybrids	223
Plums and prunes	5,888
Pomegranates	1,056
Popcorn	1,040
Potatoes	21,079
Proso millet	762
Pumpkins	15,840
Radishes	1,228
Rapeseed	32
Raspberries	8,052
Rhubarb	697
Rice	5,591
Rye	4,775
Safflower	525
Sorghum	20,037
Soybeans	302,963
Spinach	1,594
Squash, all	14,090
Strawberries	10,388
Sugarbeets	3,996
Sugarcane	1,127
Sunflower seed, all	4,953
Sweet potatoes	2,202
Tangelos	507
Tangerines	1,395
Temples	37
Tomatoes in the open	32,383
Triticale	598
Turnip greens	719
Turnips	1,107
Walnuts, English	6,656
Watercress	100
Watermelon	12,996
Wheat	303,026
Wild rice	72

Source: U.S. Department of Agriculture. (2012). *Census of agriculture*. Vol. 1, Ch. 1, Tables 38, 39, and 40. Retrieved from http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_1_US/

Table 2-7. Farm Activities Associated with Growers Who Had Produce Sales in 2012 Based on the 2012 Ag Census

	Growers with Produce Sales in 2012, by Sales Category				
	Less than $25,000	$25,000 to Less than $500,000	$500,000 to Less than $5 Million	$5 Million and Up	All
Number of growers	100,875	46,279	9,939	1,539	158,632
Number of acres in produce	422,946	1,942,133	3,413,147	3,525,252	9,303,478
	Growers with Specific Activities as a Percentage of Total Produce Growers and Acres				
Growers packing on the farm					
% of growers	6.4	11.0	12.6	14.9	8.2
% of acres	7.1	9.8	12.2	14.3	12.3
Growers with value-added activities					
% of growers	10.5	9.5	4.9	3.1	9.8
% of acres	8.8	7.0	3.1	2.6	4.0
Growers with produce marketed directly to retail outlets					
% of growers	14.3	16.2	11.0	11.6	14.6
% of acres	12.5	11.6	8.8	11.3	10.5
Growers with CSA					
% of growers	4.9	4.6	1.5	0.8	4.6
% of acres	2.9	2.1	0.7	0.4	1.0
Growers with direct sales to consumers					
% of growers	44.0	26.3	9.9	5.3	36.3
% of acres	32.9	16.9	7.6	4.3	9.5

Source: ERS calculations conducted using 2012 Ag Census data.

First, the 2012 Ag Census asked if growers were packing on the farm: "At any time during 2012, did this operation have an on-farm packing facility for distributing vegetables, potatoes, fruit, nuts, berries or other crops." Overall 8% of growers with produce sales said they were packing on the farm, although

they may not have been packing produce.[1] The share of growers with on-farm packing increases as sales size increases but is only 15% for the largest size category. Growers in the United States are often very specialized, and not every growing operation has its own packing operation because they can be very capital intensive; thus, one packing operation may pack for many growers.

Because we do not have data on the percentage of packing houses that are owned by farmers, estimates of the number of farms with on-farm packing facilities (23,274 farms as of the 2012 Ag Census) can serve as a proxy in Table 2-8.

The Ag Census also asked, "At any time during 2012, did this operation produce and sell value added crops, livestock, or products such as beef jerky, fruit jams, jelly, preserves, floral arrangements, cider, wine, etc.?" Growers that conduct value-added activities do not necessarily conduct value-added activities associated with produce. In some cases, their value-added activities are associated with another commodity. The share of growers with these valued-added activities declines with size, ranging from 11% for the smallest size class to 3% for the largest size class. While small growers may have value-added activities, many large firms are very specialized. For example, a large grower may have a packing facility that does value-added activities and other growers send their produce to the facility for these activities. However, note that a large value-added operation such as a bagged salad packaging plant may not have any growing operations at all and would not show up in this Census data.

To determine which operations have direct sales to retail outlets, the Ag Census asked the question "At any time during 2012, did this operation market products directly to retail outlets (including restaurants, grocery stores, schools, hospitals, or other businesses) that in turn sell directly to consumers?" Note that this does not mean the sales are all produce sales. Overall, 15% of growers market directly to retail outlets. Small growers may be selling directly to local

[1] All numbers about percentage of growers with different farm activities are the number of growers with that activity divided by the number of growers in that sales size category. Therefore, the percentages do not add across rows or down columns.

Table 2-8. Number of Farms with On-Farm Packing Facilities According to the 2012 Ag Census

State	Number of Farms
Alabama	196
Alaska	48
Arizona	180
Arkansas	135
California	1,920
Colorado	407
Connecticut	243
Delaware	37
Florida	628
Georgia	283
Hawaii	568
Idaho	274
Illinois	338
Indiana	549
Iowa	519
Kansas	107
Kentucky	847
Louisiana	228
Maine	456
Maryland	199
Massachusetts	396
Michigan	813
Minnesota	434
Mississippi	202
Missouri	406
Montana	271
Nebraska	100
Nevada	39
New Hampshire	202
New Jersey	298
New Mexico	284
New York	1,065
North Carolina	931
North Dakota	47
Ohio	953
Oklahoma	582
Oregon	761
Pennsylvania	1,124
Rhode Island	60
South Carolina	192
South Dakota	33
Tennessee	669
Texas	1,949
Utah	198
Vermont	389
Virginia	704
Washington	756
West Virginia	226
Wisconsin	946
Wyoming	82
United States	23,274

Source: U.S. Department of Agriculture. (2012). *Census of agriculture*. Vol. 1, Ch. 2, Table 43. Retrieved from http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_2_US_State_Level/st99_2_043_043.pdf

restaurants or retail outlets. Larger growers often sell directly to retail, foodservice operations, and wholesalers on a national or even international scale. Slightly lower percentages of direct sales for larger growers may reflect specialization where one large grower/packer/marketer firm may sell for a group of growers.

The Ag Census asked, "At any time during 2012, did this operation market products through a Community Supported Agriculture (CSA) arrangement?" Again, these sales are not necessarily produce. The number of growers with CSAs declines steeply with size. CSAs are generally time- and labor-intensive activities that involve preparing family size loads of farm products and perhaps arranging for delivery. Larger growers selling larger volumes of produce are less likely to be involved in CSAs.

Data collected in 2012 by USDA indicates that 12,617 farms in the United States reported marketing products through a CSA arrangement, a 0.5% increase over the 12,549 farms marketing through CSAs in 2007. Table 2-9 shows the number of farms by state that marketed products through CSAs in 2012. However, estimates of food processing activities conducted by CSAs are not available.

Finally, the Ag Census also asked about direct sales to individual consumers: "During 2012, did you produce, raise or grow any crops, livestock, poultry, or agricultural products that were sold directly to individual consumers for human consumption? Include sales from roadside stands, farmers markets, pick your own, door to door, etc., and Community Supported Agriculture (CSA). Exclude craft items, processed products such as cheese, butter, jellies, sausages, and hams, wine, and cider." Growers with direct sales to consumers also decline sharply with sales size class, ranging from 44% for the smallest size to 5% for the largest size. Again, the time-consuming nature of direct sales to individual consumers makes it unlikely that very large growers with large quantities to market will engage in direct sales.

The produce industry is characterized by a large number of small growers with small acreage and sales and a small number of very large growers with large acreage and sales. Growers with less than $25,000 in produce sales in 2012 accounted for

Table 2-9. Number of Farms Marketing Products through CSAs According to the 2012 Ag Census

State	Number of Farms	State	Number of Farms
Alabama	184	New Hampshire	173
Alaska	42	New Jersey	88
Arizona	112	New Mexico	196
Arkansas	115	New York	578
California	1,015	North Carolina	579
Colorado	234	North Dakota	49
Connecticut	218	Ohio	374
Delaware	22	Oklahoma	164
Florida	277	Oregon	391
Georgia	261	Pennsylvania	551
Hawaii	138	Rhode Island	50
Idaho	152	South Carolina	152
Illinois	262	South Dakota	70
Indiana	230	Tennessee	266
Iowa	260	Texas	590
Kansas	144	Utah	141
Kentucky	361	Vermont	332
Louisiana	97	Virginia	386
Maine	406	Washington	388
Maryland	119	West Virginia	104
Massachusetts	431	Wisconsin	392
Michigan	410	Wyoming	45
Minnesota	305	United States	12,617
Mississippi	137		
Missouri	291		
Montana	124		
Nebraska	144		
Nevada	67		

Source: U.S. Department of Agriculture. (2012). *Census of agriculture*. Vol. 1, Ch. 2, Tables 43. Retrieved from http://www.agcensus.usda.gov/Publications/2012/Full_Report/Volume_1,_Chapter_2_US_State_Level/st99_2_043_043.pdf

64% of growers but only 5% of produce acreage. Growers with $500,000 or more in sales (the two largest categories in the table) accounted for 7% of growers but 75% of produce acreage. However, even within the larger size categories, there is increasing concentration. Growers with sales of $500,000 to less than $5 million accounted for 6% of the growers and 37% of the produce acres, while the top 1% of growers, those with

$5 million or more in sales, accounted for 38% of the produce acres.

2.3.3 Estimates of Colocated Facilities Derived from Industry Interviews

AMS received estimates of colocated facilities from the staff of two types of boards over which AMS has oversight authority—research and promotion (R&P) boards and marketing order boards. The R&P boards contacted were for the following commodities: raspberries, blueberries, honey, mangoes, peanuts, watermelons, avocados, and mushrooms. For mangoes, peanuts, watermelons, and avocados the R&P boards reported no colocated facilities. In addition, AMS received estimates of colocated facilities from marketing order board employees covering the following commodities: Vidalia onions, tart cherries, hazelnuts, almonds, dates, and dried prunes. Board staff for the following commodities reported no evidence of colocation: oranges, grapefruit, tangerines, tangelos, cranberries, onions, tomatoes, apricots, cherries, pears, hazelnuts, kiwifruit, grapes, olives, pistachios, walnuts, and raisins. Many of those products are grown only for the fresh market. Table 2-10 provides a summary of the number of colocated facilities in production areas of federal marketing orders by commodity and marketing order number. The table also includes the number of producers (growers) in the marketing order production area, the committee name, and whether or not the commodity is grown for the fresh market.

Table 2-10. Number of Colocated Farms in Production Areas of Federal Marketing Orders

Commodity and Marketing Order Number	Production Area	No. of Producers (Growers)	Committee Name	No. of Colocated Facilities (CLFs)
Southeastern U.S., Texas, and Multistate				
Oranges, grapefruit, tangerines, and tangelos (MO #905)	Florida	8,000	Citrus Administrative Committee	No CLFs. Grown for fresh market.
Oranges and grapefruit (MO #906)	Lower Rio Grande Valley, Texas	170	Texas Valley Citrus Committee	No information on which to base estimate of CLFs. Grown for fresh market.
Avocados (MO #915)	South Florida	300	Avocado Administrative Committee	No information on which to base estimate of CLFs. Grown for fresh market.

(continued)

Table 2-10. Number of Colocated Farms in Production Areas of Federal Marketing Orders (continued)

Commodity and Marketing Order Number	Production Area	No. of Producers (Growers)	Committee Name	No. of Colocated Facilities (CLFs)
Cranberries (MO #929)	10 states: MA, RI, CT, NJ,WI, MI, MN, OR, WA, NY – (Long Island)	1,200	Cranberry Marketing Committee	All 50 handlers are processors; none are colocated
Tart cherries (MO# 930)	7 states: MI, NY, PA, OR, UT, WA, WI	600	Cherry Administrative Board	**One CLF** (freezing)
Vidalia onions (MO# 955)	Georgia	80	Susan Waters Vidalia Onion Committee	**Two CLFs** (combinations of freezing, canning, cooking, chopping, cutting, peeling, grinding, slicing)
Onions (MO #959)	Texas	60	South Texas Onion Committee	No information on which to base estimate of CLFs. Grown for fresh market.
Tomatoes (MO# 966)	Florida	100	Florida Tomato Committee	No information on which to base estimate of CLFs. Grown for fresh market.
Northwestern U.S. and Colorado				
Washington Apricots (MO #922)	Designated Counties in Washington	94	Washington Apricot Marketing Committee	No CLFs
Sweet cherries (MO #923)	Designated Counties in Washington	1,500	Washington Cherry Marketing Committee	No CLFs
Pears (MO #927)	Oregon and Washington	1,500	Fresh Pear Committee and Processed Pear Committee	No CLFs
Potatoes (MO #945)	Designated counties in Idaho, and Malheur County, OR	450	Idaho-Eastern Oregon Potato Committee	No information on which to base estimate of CLFs. Grown for fresh market.
Potatoes (MO #946)	Washington	250	Washington Potato Committee	No CLFs. Grown for fresh market.

(continued)

Table 2-10. Number of Colocated Farms in Production Areas of Federal Marketing Orders (continued)

Commodity and Marketing Order Number	Production Area	No. of Producers (Growers)	Committee Name	No. of Colocated Facilities (CLFs)
Potatoes (MO #948)	Colorado	180	Colorado Potato Committee, Area 2; Colorado Potato, Committee, Area 3	No CLFs. Grown for fresh market.
Sweet Onions (MO #956)	Walla Walla Valley of SE Washington and NE Oregon	21	Walla Walla Sweet Onion Marketing Committee	No CLFs. Grown for fresh market.
Onions (MO #958)	Designated Counties in Idaho, and Malheur County, OR	250	Idaho-Eastern Oregon Onion Committee	No CLFs. Grown for fresh market.
Hazelnuts (MO # 982)	Oregon and Washington	650	Hazelnut Marketing Board	**11 CLFs** is rough approximation
California and Southwestern U.S.				
Kiwifruit (MO # 920)	California	175	Kiwifruit Administrative Committee	No information on which to base estimate of CLFs. Grown for fresh market; some may be used for juice.
Grapes (MO # 925)	Southeastern California	41	California Desert Grape Administrative Committee	No information on which to base estimate of CLFs. Grown for fresh market.
Olives (MO # 932)	California	1,000	California Olive Committee	Not aware of any CLFs. MO covers black ripe olives for canning; only two olive canners in California.
Almonds (MO # 981)	California	6,400	Almond Board of CA	**24** CLFs [**12 -** Chopping/ Cutting/ Slicing] **[12 - Peeling** (Blanching); **Pasteurizing** (Roasting, Steam, PPO, Other)]
Pistachios (MO # 983)	California, Arizona and New Mexico	1,040	Administrative Committee for Pistachios	Number of CLFs not known; believe there are some, but represent very small portion of industry volume.

(continued)

Table 2-10. Number of Colocated Farms in Production Areas of Federal Marketing Orders (continued)

Commodity and Marketing Order Number	Production Area	No. of Producers (Growers)	Committee Name	No. of Colocated Facilities (CLFs)
Walnuts (MO # 984)	California	4,100	Walnut Marketing Board	No information on which to base estimate of CLFs.
Dates (MO #987)	Riverside County, California	70	California Date Administrative Committee	**Approximately 12 CLFs** in Riverside County. No info on dates grown outside of county.
Raisins (MO #989)	California	3,000	Raisin Administrative Committee	No information on which to base estimate of CLFs.
Dried Prunes (MO #993)	California	800	Prune Marketing Committee	**Approximately 25 CLFs**

Note: Table populated by Don Hinman with AMS in response to FDA data request on colocated facilities in production areas of federal marketing orders. Federal marketing orders are under the oversight authority of the Marketing Order Administrative Division (MOAD), Fruit and Vegetable Program (FVP), Agricultural Marketing Service (AMS), USDA.

Table 2-11 provides a summary of estimates of colocated facilities based on discussions with R&P boards, marketing order boards, commodity specialists, and commodity commissions. Most individuals we contacted prefaced their estimates by stating that their estimates only applied to the proportion of the commodity produced in their state and, therefore, the estimates should be considered rough approximations. Several experts were not able to provide estimates of the proportion of their commodity that is processed on the farm. For the R&P, trade associations, extension specialists, ERS specialists, and ARMS data, we applied the estimated percentages for the relevant commodities to Ag Census farm counts shown in Table 2-11. For the marketing order boards, the estimated percentages are calculated based on the data received by AMS from the staff of the marketing order boards. Below are some examples of how the colocation estimates were derived from the R&P boards.

- Of the 27 processors who pay assessments to the National Processed Raspberry Council, 15 are colocated establishments with freezing being the most common processing activity.

Table 2-11. Number of Colocated Farms in the U.S. by Commodity

Commodity	Estimated No. of Colocated Farms	Percentage of Farms	Source
Almonds	24	<1%	Marketing order board
Apples[a]	2,513	12%	ARMS data
Beans	1,114	<5%	Trade association
Blackberries and dewberries	729	<10%	Extension
Blueberries, tame[b]	3,358	26%	R&P board
California Cantaloupes and muskmelons	164	<2%	ERS
Celery	122	<25%	Trade association
Cherries, tart	1	<1%	Marketing order board
Cranberries[e]	10	<1%	Extension
Dairy	100	uncertain	Marketing order board
Dates	12	6%	Marketing order board
Escarole and endive	27	<25%	Trade association
Grapefruit[c, e]	107	<5%	Extension
Hazelnuts (filberts)[d, e]	146	10–15%	ERS
Honey	10,888	48%	R&P board
Lemons	150	<5%	Extension
Lettuce, all	1,900	<33%	Trade association
Limes	29	<5%	Extension
Mushrooms	46	45%	R&P board
Oranges, all[e]	472	<5%	Extension
Pecans	5,776	<30%	ERS
Prunes, dried	25	<5%	Marketing order board
Radishes	405	<33%	Trade association
Raspberries	4,429	55%	R&P board
Soybeans		1.6%	ARMS data
Strawberries	519	<5%	Trade association
Sweet potatoes	22	<1%	Trade association
Tangelos[e]	25	<5%	Extension
Tangerines[e]	70	<5%	Extension
Temples	2	<5%	Extension
California tomatoes (fresh-market tomatoes, field grown)[e]	211	<1%	ERS
Vidalia onions	2	<1%	Marketing order board

[a] In addition to the ARMS data estimate, an agricultural extension specialist estimated 10–15% of apple farms are colocated, which is consistent with the ARMS estimate. In contrast, ERS estimated that 2 of 57 grower/packer apple farms are colocated, but this estimate was focused on Washington state apple producers.

[b] The percentage of colocated facilities for blueberries was estimated at <10% by an agricultural extension specialist.

[c] The percentage of colocated facilities for grapefruit was also verified by a trade association.

[d] The percentage of colocated facilities for hazelnuts in marketing order boards is approximately 2%.

[e] Marketing order board staff could provide no evidence of colocation for this commodity.

- The National Highbush Blueberry Council does not keep data on colocated facilities but provided AMS with a list of 284 suppliers. AMS sorted the list to identify U.S. firms that were both growers and processors. They identified 75 firms that have growing and processing facilities within the same firm; however, they were not

able to specifically count colocated establishments because some vertically integrated firms have multiple facilities and growing and processing facilities at separate locations. Therefore, 75 is an upper bound estimate and the actual number of colocated facilities may only be a small proportion of the 75.

- The National Honey Board collects assessments from 44 U.S. processors (packers and importers with 250,000 pounds or more of annual sales). Of the 44 packers, 21 are packers/producers that operate colocated facilities.
- For *agaricus* mushrooms (the dominant variety), there are an estimated 103 growers, of which 66 are in Pennsylvania, the dominant producing state. Of the 103 growers, 46 also conduct on-site processing. The primary food processing that the colocated facilities do is slicing. Other processing on a limited scale includes washing, freezing, blanching, and, in only one case, canning. U.S. specialty mushroom producers (other than *agaricus*) sell entirely to the fresh market (i.e., no processing).

Furthermore, AMS estimated the number of dairy processing colocated facilities in 2015 at approximately 100, with approximately 65 of those CLFs having sales under 150,000 pounds of milk annually.[4] It should be noted that California is a major milk producing area not currently covered by a federal milk marketing order; therefore, their production is not included in this estimate.

[4] In terms of valuing the 150,000 pounds of milk, AMS used average price per pound paid to dairy farmers (not at the dairy processing level), making the estimate understate the value at the processor level. The average price per pound of milk for 2014 is 24 cents a pound. For the first 5 months of 2015, the price per pound of milk received by dairy farmers is approximately 17 cents. At 24 cents per pound, the value of 150,000 pounds of milk at the farm level is $36,000. At 17 cents per pound, the value of 150,000 pounds of milk at the farm level is $25,500.

Based on our industry discussions, we were unable to find evidence that any of the following types of farms conduct on-farm processing:

- apricots
- artichokes
- avocados
- cabbage
- cherries
- collards
- dry edible peas
- eggplant
- grapes
- honeydew melons
- kale
- kiwifruit
- lentils
- mangoes
- mustard greens
- olives
- onions
- other citrus fruits
- peanuts
- pears
- peppers
- pistachios
- potatoes
- raisins
- squash
- walnuts
- watermelon

2.3.4 Estimates Derived from ARMS Data

According to the ARMS, in 2007, 11.8% of apple operations indicated that they conducted value-added activities. The value-added products are not necessarily using apples, although they probably do in most cases according to ERS. These operations are relatively small, accounting for only 6.4% of harvested acres of apples. Most operations (70%) also had direct sales to consumers via pick-your-own or farm stands.

In 2012, 1.6% of soybean operations indicated that they conducted value-added activities on the ARMS. According to ERS, the value-added products are not necessarily using soybeans and likely are not in most cases. These are small operations, accounting for only 1.3% of total acres of soybeans.

2.4 ANALYSIS LIMITATIONS

In any empirical investigation, accommodations need to be made to address limited data availability and data imperfections. We describe the limitations regarding this section of the report below.

First, besides the obvious problem with missing employee counts and sales, D&B's DMI file has other limitations as well. Although the DMI file is perhaps by far the most comprehensive establishment-level business directory file, previous research using the DMI file has documented several issues with the data. For example, in a study of the local food environment in Salt Lake County, Utah, Kowaleski-Jones et al. (2009) compared the D&B data with ReferenceUSA (another proprietary business directory data) and administrative data from local government agencies. The authors found that one-third of the records in any one data set were not represented in the other two data sets. Although the quality of the DMI file is likely to have improved over time, thanks to advances in information technology, and discrepancies between the DMI file and other data sets do not necessarily suggest one is superior in quality, these findings provide important caveats about interpreting results and drawing conclusions based on the DMI file.

Second, the imputation of missing employment and sales may result in some loss of precision. Using headquarters sales to impute establishment-level sales may overestimate or underestimate sales at some establishments if their primary lines of business are not the same as their sister establishments. In addition, allocating headquarters sales to individual establishments in proportion to employee counts largely ignores the fact that there may be economies of scale in food processing. However, the extent to which economies of scale apply to each of the NAICS codes is difficult to determine.

Third, by assigning each establishment to one and only one NAICS code, its entire sales is used to proxy for the value of food sold under this one NAICS. If establishments engage in multiple revenue-generating activities that fall under different NAICS codes, the sales data would not be very accurate estimates of the value of food for any single NAICS code. It is hoped that, by assigning each establishment to its most important line of business, this imputation practice would generate roughly unbiased sales estimates for each industry in aggregate. However, the degree of accuracy is likely to vary across industries.

In addition, limitations exist when working with the Census and ARMS data on farms. First, Census may miss many of the smaller farms that are more likely to conduct processing

activities on the farm, according to the D&B data in Table 2-6. Second, no reliable source of data exists on how many of these are likely to process on the farm. The information gathered from the commodity experts that will be applied to the Census numbers is mostly anecdotal evidence based on expert opinion with limited data to substantiate estimates. Third, the ARMS data are available only for select commodities and the results are based on one survey question regarding value-added production.

3 Foodborne Illness Attribution in Food Processing

We used an expert elicitation approach to obtain estimates of foodborne illness risk associated with hazards that are unintentionally introduced at various stages of processing.

Potential foodborne hazards are unintentionally introduced at various stages of production from the farm through consumption at home or away-from-home locations. To address the FSMA requirements, we focused on foodborne illness associated with hazards that are introduced unintentionally at various stages of processing, including transportation between the stages. The specific data requested under the FSMA—the incidence of foodborne illness originating from each size and type of operation and the effect on foodborne illness risk associated with commingling, processing, and transportation—are not available in existing reporting systems or publications. Thus, we relied on an expert elicitation approach to obtain relevant estimates.

In this section, we begin with a discussion of the existing foodborne illness attribution data from the literature and identify the limitations of these data for addressing the study requirements. We then describe other potential sources of data that we examined to determine if available data could be used to develop the required foodborne illness attribution estimates. Next, we describe the methodology we used for conducting the expert elicitation to obtain the needed estimates; present the results of the expert elicitation, including the quantitative estimates provided by the experts and comments they provided during the exercise; and describe the limitations of the approach. Materials used for the expert elicitation are provided in Appendix C.

3.1 PUBLISHED FOODBORNE ILLNESS ATTRIBUTION DATA

To identify sources of attribution data requested under the FSMA—the incidence of foodborne illness originating from each size and type of operation and the effect on foodborne illness risk associated with commingling, processing, and transportation—we began with a literature search. The literature includes studies that quantify the incidence of foodborne illness without attributing it to specific foods and those that attribute foodborne illness cases to specific foods. Although the studies that quantify foodborne illness serve a valuable purpose, the needs of the FSMA require determining the sources of illnesses (i.e., food types under FDA jurisdiction and stage of processing). Relevant studies identified in the literature are summarized in Table 3-1, though none meet the specific needs of the FSMA.

In the United States, the primary source of data that links foodborne illness to specific foods is the Centers for Disease Control and Prevention's (CDC's) outbreak surveillance data. Although the number of illnesses reported is substantial, these data represent only a fraction of the total number of cases of foodborne illness because of underreporting and underdiagnosis. Thus, modeling approaches are applied to estimate the total number of cases of foodborne illness using surveillance data in two ways: (1) beginning with surveillance data and scaling up to the number of illnesses and (2) beginning with the U.S. population and scaling down to the estimated number of illnesses (Scallan et al., 2011). For those illnesses that are reported directly in CDC's outbreak surveillance data, many outbreaks have unknown etiology or unknown food vehicle, or both. In addition, CDC's outbreak surveillance data only consider outbreaks (defined as two or more persons with reported illness linked to a specific pathogen), though many single cases of foodborne illness are reported (CDC, 2010). Further, CDC has difficulty tracking foodborne illness that results from pathogens in minor ingredients, such as spices, that are used in a wide variety of foods.

Table 3-1. Foodborne Illness Quantification and Attribution Literature

Citation	Objective	Method	Food Categories	Major Findings
Studies that quantify cases of foodborne illness				
Centers for Disease Control and Prevention. (2009). *FoodNet 2007 surveillance report*. Atlanta, GA: U.S. Department of Health and Human Services.	Determine the burden of foodborne disease in the U.S.	Active surveillance	N/A	Of the 18,039 lab-confirmed infections in 2007, 38% were due to *Salmonella* and 33% due to *Campylobacter*. Five percent were outbreak related.
Cole, D., Griffin, P. M., Fullerton, K. E., Ayers, T., Smith, K., Ingram, L. A., Kissler B., & Hoekstra, R. M. (2014). Attributing sporadic and outbreak-associated infections to sources: blending epidemiological data. *Epidemiology and Infection*, *142*, 295–302.	Calculate the annual number of STEC O157 infections attributable to foodborne illness.	Multivariable models from two case-control studies	N/A	65% of infections in 1996 and 34% of STEC O157 infections in 1999 were attributed.
Newbold, B., Watson, S., Mackay, K., & Issacs, S. (2013). Exploring the relationship between food access and foodborne illness by using spatial analysis. *Journal of Food Protection, 76*(9), 1615–1620.	Examine associations between food deserts and the spatial distribution of gastrointestinal illnesses.	Spatial analysis using Canadian public health data	N/A	Statistical analysis shows no statistical relationship between location, access to food outlets, and rates of gastrointestinal illness.
Scallan, E., Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., Jones, J., & Griffin, P. M. (2011b). Foodborne illness acquired in the United States—Major pathogens. *Emerging Infectious Diseases, 17*(1), 7–15.	Estimate the overall number of annual foodborne illness in the U.S. from major pathogens.	Modeling approaches based on surveillance data	N/A	Foodborne illness from 31 known agents cause 9.4 million illnesses, 5,961 hospitalizations, and 1,351 deaths annually.
Scallan, E., Griffin, P. M., Angulo, F. J., Tauxe, R. V., & Hoekstra, R. M. (2011a). Foodborne illness acquired in the United States—Unspecified agents. *Emerging Infectious Diseases, 17*(1), 16–22.	Estimate the overall number of annual foodborne illnesses in the U.S. from unknown pathogens.	Modeling approaches based on the U.S. population	N/A	An estimated 38.4 million foodborne illnesses are caused by unspecified agents annually.

(continued)

Table 3-1. Foodborne Illness Quantification and Attribution Literature (continued)

Citation	Objective	Method	Food Categories	Major Findings
Studies that attribute cases of foodborne illness				
Batz, M. B., Hoffmann, S., & Morris, J. G., Jr. (2011). *Ranking the risks: The 10 pathogen-food combinations with the greatest burden on public health*. Gainesville, FL: University of Florida, Emerging Pathogens Institute.	Compare the risks posed by different pathogen food combinations in the U.S. (at point of consumption).	Expert elicitation applied to CDC data	• Beef • Deli/other meats • Pork • Poultry • Game • Eggs • Dairy products • Seafood • Produce • Beverages • Baked goods • Complex foods (nonmeat multi-ingredient dishes)	Consumption of FDA-regulated foods is estimated to cause about half of all foodborne disease. Among FDA-regulated foods, complex foods was ranked second; produce was ranked fourth; dairy was seventh; and eggs, baked goods, and beverages completed the list as tenth, eleventh, and twelfth, respectively.
Center for Science in the Public Interest. (2009). *Outbreak alert! Analyzing foodborne outbreaks 1998 to 2007*. Washington, DC: Center for Science in the Public Interest.	To attribute foodborne illness outbreaks in the U.S. to specific foods.	CDC data analysis	• Beef • Luncheon/other meats • Pork • Poultry • Game • Eggs • Dairy • Seafood • Produce • Beverages • Breads & bakery • Multi-ingredient (with meat) • Multi-ingredient (without meat)	Multi-ingredient dishes (without meat) caused the highest number of outbreaks, followed by seafood, produce, and meat dishes (poultry, beef, multi-ingredient foods with meat, and pork). Dairy and breads were ranked eighth and ninth, while eggs and beverages were ranked eleventh and twelfth.

(continued)

Table 3-1. Foodborne Illness Quantification and Attribution Literature (continued)

Citation	Objective	Method	Food Categories	Major Findings
Centers for Disease Control and Prevention. (2010). Surveillance for foodborne disease outbreaks—United States, 2007. *Morbidity and Mortality Weekly Report, 59*(31), 973–979. Retrieved from http://www.cdc.gov/outbreaknet/surveillance_data.html	Summarize epidemiologic data for outbreaks occurring during 2007.	Tabulation of epidemiologic data reported to CDC	• Beef • Pork • Poultry • Game • Eggs • Dairy • Finfish • Shellfish • Grains—Beans • Produce • Multicommodity • Unknown commodity	A food vehicle was identified in 43% of reported outbreaks. Commodities most commonly implicated in outbreaks were finfish, poultry, and beef, while commodities with the highest number of foodborne illnesses were poultry, beef, and leafy vegetables. The pathogen-commodity pair responsible for the most illnesses was norovirus in leafy vegetables.
Davidson, V. J., Ravel, A., Nguyen, T. N., Fazil, A., & Ruzante, J. M. (2011). Food-specific attribution of selected gastrointestinal illnesses: Estimates from a Canadian expert elicitation study. *Foodborne Pathogens and Disease*, *8*(9), 983–995.	Estimate food-specific attribution for nine enteric illnesses in Canada.	Expert elicitation	• Beef • Luncheon meats • Pork • Poultry • Game • Eggs • Dairy • Seafood • Produce • Breads and bakery • Beverages • Other	More than 50% of foodborne illnesses were attributed to poultry, beef, luncheon meat, seafood, and pork. *E. coli* O157:H7 in produce and *Listeria monocytogenes* in dairy were also significant contributors to foodborne illness.

(continued)

Table 3-1. Foodborne Illness Quantification and Attribution Literature (continued)

Citation	Objective	Method	Food Categories	Major Findings
Greig, J. D., & Ravel, A. (2009). Analysis of foodborne outbreak data reported internationally for source attribution. *International Journal of Food Microbiology, 130*(2), 77–87.	Explore the usefulness of foodborne outbreak data obtained from published international reports.	Analysis of data from CDC, EU Food Safety Authority, and other published sources	• Beef • Pork • Chicken • Turkey • Other poultry • Other meats • Eggs • Dairy products • Seafood • Produce • Nuts • Cereals • Bakery items • Multi-ingredient foods • Home canned goods • Beverages • Other foods	The highest reported food categories implicated in foodborne illness outbreaks were multi-ingredient foods, eggs, produce, and beef.
Havelaar, A. H., Galindo, A. V., Kurowicka, D., & Cooke, R. M. (2008). Attribution of foodborne pathogens using structured expert elicitation. *Foodborne Pathogens and Disease, 5*(5), 649–659.	Estimate the fraction of human illness in the Netherlands by five major pathways, including food, and by 11 groups of food.	Expert elicitation	• Beef and lamb • Pork • Chicken and other poultry • Eggs • Dairy products • Fish and shellfish • Fruit and vegetables • Breads, grains, pastas, and bakery products • Beverages • Other foods including composite foods	Food was the most dominant pathway of enterically transmitted illness. The authors did not rank food categories in terms of illness but provided a ranking of pathogens for each food category. For example, *Listeria monocytogenes* was the most common pathogen associated with dairy outbreaks.

(continued)

Table 3-1. Foodborne Illness Quantification and Attribution Literature (continued)

Citation	Objective	Method	Food Categories	Major Findings
Hoffmann, S., Fischbeck, P., Krupnick, A., & McWilliams, M. (2007). Using expert elicitation to link foodborne illnesses in the United States to foods. *Journal of Food Protection, 70*(5), 1220–1229.	Attribute foodborne illness outbreaks in the U.S. to specific foods.	Expert elicitation	• Beef • Luncheon/other meats • Pork • Poultry • Game • Eggs • Seafood • Produce • Breads and bakery • Beverages • Other	Produce and poultry were estimated to have the highest impact on the number of foodborne illness cases, hospitalizations, and deaths due to foodborne illness.
Jessup, A., Sertkaya, A., & Morgan, K. (2013). Attributing foodborne illness using consumption data and expert elicitation. Working Paper. Methods for Research Synthesis: A Cross-Disciplinary Workshop.	Examine likelihood of illness associated with foods as they sit on the store shelf.	Expert elicitation applied to Nielsen data and data from select food trade associations	• Meat (raw) • Milk and cream (unpasteurized)	Experts subdivided the original 96 food subcategories into 353 relevant food subcategories to express differing levels of likelihood of contamination for *Salmonella*; results suggest that, according to these experts, the majority of foodborne illness cases for most pathogens are introduced to the product after the product leaves the store shelf.

(continued)

Table 3-1. Foodborne Illness Quantification and Attribution Literature (continued)

Citation	Objective	Method	Food Categories	Major Findings
Painter, J. A., Hoekstra, R. M., Ayers, T., Tauxe, R. V., Braden, C. R., Angulo, F. J., & Griffin, P. M. (2013). Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998–2008. *Emerging Infectious Diseases, 19*(3), 407–415.	Estimate annual U.S. foodborne illnesses, hospitalizations, and deaths.	Modeling approaches based on CDC outbreak data	• Fish • Crustaceans • Mollusks • Dairy • Eggs • Beef • Game • Pork • Poultry • Grains—Beans • Oils—Sugars • Fruits—Nuts • Fungi • Leafy vegetables • Root vegetables • Sprouts • Vine-Stalk vegetables	Attributed 46% of illnesses to produce and found that more deaths were attributed to poultry than to any other commodity.
Sertkaya, A., Berlind, A., Lange, R., & Zink, D. L. (2006). Top ten food safety problems in the United States food processing industry. *Food Protection Trends, 26*(5), 310–315.	Identify the main problems that pose microbiological, chemical, and physical safety hazards to food at the processor level.	Expert elicitation	• Baked goods • Dairy • Frozen • Refrigerated • Shelf stable	Refrigerated foods and dairy foods pose the highest risk, while baked goods and shelf-stable products pose the lowest risk.
Williams, M. S., Ebel, E. D., Golden, N. J., & Schlosser, W. D. (2014). Temporal patterns in the occurrence of *Salmonella* in raw meat and poultry products and their relationship to human illnesses in the United States. *Food Control, 35*, 267–273.	Estimate the seasonal change in the proportion of test-positive samples for raw meat and poultry products.	Modeling approaches based on FSIS data	• Beef • Pork • Chicken • Turkey	Results generally support a seasonal increase of *Salmonella* during the summer months. A comparison of the pathogen's seasonal pattern in meat and poultry with human cases reveals that the seasonal increase in human cases precedes the seasonal increase in meat and poultry by between 1 and 3 months.

Researchers who analyze the relationship between foodborne illness and consumer exposure to specific foods have used two primary methods—analysis of foodborne illness outbreak data and expert elicitation. Pires et al. (2009) evaluated the various methods of foodborne illness attribution and concluded that the usefulness of each approach depends on data availability, pathogen, and the public health questions being addressed.

Regardless of method used in food attribution, one of the primary tasks required is to categorize foods. Food categorization tends to be driven by both the purpose of the study and data availability. As shown in Table 3-1, many different categorizations of foods have been used for attribution of foodborne illness. For example, foods can be categorized by species (beef versus pork), type of processing (raw versus ready to eat), origin (domestic versus imported), storage method (refrigerated versus frozen), moisture level (dry foods versus beverages), and so on (Batz et al., 2011). Several researchers (Batz et al., 2011; Greig & Ravel, 2009; Pires et al., 2009) have suggested that harmonizing food categories would be beneficial for foodborne illness attribution efforts. The food categorization schemes in the literature combine foods regulated by USDA and FDA and, thus, are not directly useful for addressing the requirements of the FSMA.

Some of the studies reviewed in Table 3-1 look at attribution for food–pathogen pairs, while some look only at foods or pathogens separately. For instance, Davidson et al. (2011) estimated food-specific attribution for nine enteric illnesses in Canada, and Painter et al. (2013) estimated the annual U.S. foodborne illnesses, hospitalizations, and deaths of food-pathogen pairs. However, Cole et al. (2014) examined the annual number of STEC O157 infections attributable to foodborne illness. All of the literature considered foods at a relatively high level of aggregation and considered foods at the point of consumption without considering at what point the contamination is introduced. Only two articles (Center for Science in the Public Interest [CSPI], 2009; CDC, 2010) included both microbiological and chemical hazards in their analysis; the remainder only considered microbiological hazards.

In addition to attribution of foodborne illness to type of foods, the FSMA also requires data on foodborne illness risk associated with commingling, processing, storage, and transportation.

Only one study, Sertkaya et al. (2006), analyzed food safety problems at the processing-sector level, but this study did not consider commingling, transportation, or storage. The remaining studies identified through the literature search did not consider foodborne illness risk at the sector level. CDC (2010) surveillance data report the location where the food was consumed (e.g., banquet facility, church, nursing home) but do not report at which point in the farm-to-fork continuum the food might have become contaminated.

3.2 DATA SOURCES EXAMINED FOR FOODBORNE ILLNESS ATTRIBUTION RELEVANT TO THE STUDY

We examined numerous data sources to determine the feasibility of attributing foodborne illness. In Table 3-2, we provide a summary of the data sources we examined from state agencies, CSPI, CDC, and FDA.

First, we obtained and examined state-level data from the California, Florida, and Michigan Departments of Health. Data from Florida and Michigan were limited in that trace-backs only went to the retail level. California's data were more detailed with regard to trace-back information including the suspect vehicle and causative agent. The Minnesota Department of Health provided their 2010 Minnesota Gastroenteritis Summary; however, the information only provided a narrative description about individual outbreaks. CSPI produced a publication with state profiles of outbreaks, but the data are provided in a summary format only.

We also examined the National Outbreak Reporting System (NORS) maintained by CDC. This system contains voluntary outbreak data reported to CDC by states. Information is collected on mode of transmission, investigation methods, geographic location, dates of exposure, number of primary cases (lab confirmed, probable, estimated), primary case outcomes (died, hospitalized, emergency room, visited doctor), incubation period, symptoms, duration of illness, trace-back (source name, source type, location), recall, and etiology, isolates/strains, food information). However, because the data are reported voluntarily, a majority of the fields are left blank in any given report and the data are not linked to information about facility.

Table 3-2. Additional Foodborne Illness Attribution Data Sources Examined

Data Source	Organization	Data Description	Time Frame of Data	Relation to Study Needs
California state data	CA Dept of Health	Outbreak and pathogen findings; includes suspect vehicle, causative agent, CDC outbreak designation, type of facility, number of states, cases CA, cases U.S.	2001–2013	Detailed but can only be used as an example
Florida state data	FL Dept of Health	Outbreak data; includes outbreak vehicle, region, number of cases, site, pathogen status, pathogen name, contamination factor, level of preparation	2012–2013	Most trace-backs only go to retail level
Michigan state data	MI Dept of Health	Outbreak data; includes establishment type, number ill, food suspected, confirmed etiology, CDC risk factor, preparation process/location	2010–2014	Most trace-backs only go to retail level
MN gastroenteritis summary	MN Dept of Health	Outbreak narratives for each individual outbreak; summary tables for confirmed foodborne outbreaks, confirmed waterborne outbreaks, and outbreaks with other/unknown routes of transmission; maps of outbreaks by category and county	2010	Not detailed enough for the study
All Over the Map	CSPI	State profiles of outbreaks (reported outbreaks, solved outbreaks, solved outbreaks only affecting the particular state, pathogens implicated, outbreak size)	1998–2007	Not detailed; only summary information
National Outbreak Reporting System (NORS)	CDC	Voluntary outbreak data reported to CDC; includes mode of transmission, investigation methods, geographic location, dates of exposure, number of primary cases (lab confirmed, probable, estimated), primary case outcomes (died, hospitalized, emergency room, visited doctor), incubation period, symptoms, duration of illness, trace-back (source name, source type, location), recall, etiology, isolates/strains, food information)		Trace-back data are not comprehensive

(continued)

Table 3-2. Additional Foodborne Illness Data Sources Examined (continued)

Data Source	Organization	Data Description	Time Frame of Data	Aid the Study Needs
CORE	FDA	Tracks outbreaks and illness associated with FDA-regulated human foods and cosmetic products as well as animal foods and feeds (subset of outbreaks tracked by CDC); summaries of reported number of illnesses, hospitalizations, deaths, and outbreaks by product and year associated with FDA-regulated products; data set includes year, vehicle, vehicle category, vehicle type, contaminated ingredient, whether confirmed, state, genus and species, source, number of cases, hospitalizations, deaths	1996–2011	No trace-back data to facility
Filth samples	FDA	Domestic and import sample analyses by product, year, city; also includes lab conclusions and finding remarks	2013	No trace-back data to facility and not linked to outbreaks
Microbiological samples	FDA	Domestic and import sample analyses by product, year, city; also includes lab conclusions and finding remarks	2013	No trace-back data to facility and not linked to outbreaks
Sensory decomposition	FDA	Mostly fish products; domestic and import sample analyses by product, year, city; also includes lab conclusions and finding remarks	2013	No trace-back data to facility and not linked to outbreaks
Analytical decomposition	FDA	All fish products; domestic and import sample analyses by product, year, city; also includes lab conclusions and finding remarks	2013	No trace-back data to facility and not linked to outbreaks
Mycotoxin data	FDA	Food products (e.g., peanuts, rice cereal, fruit juices, spaghetti, wheat flour); domestic and import sample analyses by product, year, city; also includes lab conclusions and finding remarks	2013	No trace-back data to facility and not linked to outbreaks
LACF data	FDA	Low-acid canned food products; domestic and import sample analyses by product, year, city; also includes lab conclusions and finding remarks	2013	No trace-back data to facility and not linked to outbreaks

(continued)

Table 3-2. Additional Foodborne Illness Data Sources Examined (continued)

Data Source	Organization	Data Description	Time Frame of Data	Aid the Study Needs
RFR	FDA	Location of the reportable food (name and type of organization), date, reason why the food is reportable, how the food was heard about, determination of which products/lots were impacted, whether contaminated product has been removed from commerce, corrective actions taken to prevent future occurrences, root cause, whether a human adverse event has been reported, supplier information, distribution information	2013	No trace-back data to facility and not linked to outbreaks

Furthermore, we also conducted meetings between RTI, FDA's Center for Food Safety and Applied Nutrition Division of Risk Assessment, and FDA's epidemiology teams to brainstorm additional potential data sources and methods for addressing the questions on foodborne illness attribution posed in FSMA. For the initial brainstorming session on September 23, 2014, RTI prepared a set of materials for the meeting, including a brief description of the project objectives; the definition of processing, ; the 2011 Food Processing Sector final report; a summary of foodborne illness literature; the FDA-risk contract summary; and samples of the California, Florida, and Michigan data. The discussion began with the types of foods where foodborne illness originates, the distribution of primary Reportable Food Registry (RFR) entries by commodity, and FDA's FACTS data. The group reached the conclusion that connecting commodities to pathogen testing is fairly easy, but connecting incidence to facility size or types of processing activities is difficult. However, larger establishments likely have better data and trace-back than smaller establishments and therefore are more likely to be associated with outbreaks. It is also likely that products that go through a packing house are commingled.

Modeling techniques in the literature that extrapolate from CDC outbreak data were discussed, in addition to the work the Interagency Food Safety Analytics Collaboration is conducting

in this area. It was decided that a better data source needed to be found before discussing modeling techniques in detail. The group also discussed processing practices that lower risk such as instituting a kill step, reducing the number of steps in getting food to the consumer, and shortening the chain of transportation.

Follow-up meetings were also conducted to discuss the following FDA data sources in more detail:

- RFR data: The testing reported in the RFR is done voluntarily by manufacturers and there is not necessarily a link between positive findings and foodborne illness because the results indicate hazards and not foodborne illness outbreaks.
- FACTS/contract testing data: FACTS/contract testing data also do not have a direct link to foodborne illness. These data are sample analyses (filth samples, microbiological samples, sensory decomposition, analytical decomposition, mycotoxin data, and low-acid canned foods samples). FACTS data often do not have the size of the facility recorded, and contract testing is done in labs that do intensified testing on a specific commodity at the retail level.
- Coordinate Outbreak Response and Evaluation Network (CORE) data: The CORE data are related to outbreaks and patterns of contamination; however, the data cannot be traced back to the source.

We examined samples of all these data sets, but none identified sources of attribution requested under the FSMA—the incidence of foodborne illness originating from each size and type of operation and the effect on foodborne illness risk associated with commingling, processing, and transportation. Therefore, the data were not used in the analyses presented in this report.

3.3 EXPERT PANEL METHODOLOGY

Several different processes can be used for conducting expert elicitations depending on the type and format of information to be obtained, the types and number of experts needed to participate, whether the elicitation is conducted remotely or in person, how the information is combined across experts, and the number of rounds conducted. For this expert elicitation, time constraints required that we conduct the panel in one round and in 1 day because of the short lead time for

scheduling and conducting the study. We conducted the panel in person to allow for discussion among the experts to ensure that they were responding using common definitions and assumptions; to allow us to adjust the definitions, assumptions, and worksheets as needed based on the discussion; and to ensure that all of the questions were answered completely and correctly.

In conducting the expert elicitation, we conveyed to the experts the general philosophy for using expert elicitation as a data collection method. We have found in previous expert elicitation projects that some experts may be concerned that their responses are opinions rather than actual data. Therefore, we instructed the experts to use whatever knowledge they have based on related data but that we understood the specific data needed are not available from published sources; thus, we were relying on their expert opinions as the next-best option for obtaining these data. In general, most experts also seem to be more comfortable with the expert elicitation concept if they are informed that the data they provide will be combined with that of other experts and that the data will be used as starting-point values for additional refinement as new information becomes available.

3.3.1 Expert Elicitation Materials

Prior to the expert elicitation, RTI developed the materials needed for recruiting experts, providing background information for the experts, and obtaining the specific estimates needed for the study. These materials included the following:

- **Project description and interest form**—background document used to introduce potential experts to the project and obtain an expression of interest in participating and the experts' areas of expertise.
- **Expert elicitation worksheets**—tables to be completed by the experts to provide responses to expert elicitation questions (also includes a statement of purpose, key definitions and assumptions, and instructions for completing the worksheet).
- **Food product fact sheets**—for each food product of interest for the expert elicitation, data on the foods included, the nature of the food product, type of packaging, number of foodborne outbreaks

(calculated using CDC outbreak data), estimated consumption (daily grams per capita, calculated using National Health and Nutrition Examination Survey [NHANES] dietary recall data); imports as a percentage of consumption, and number of production plants by employment size (calculated using D&B data).

- **Related literature**—copies of relevant articles and reports (as described in Section 3.1 above).

We provide copies of the project description and interest form, expert elicitation worksheets, and food product fact sheets in Appendix C.

The product categories used for the expert elicitation were selected at a broad level to facilitate rankings on several different dimensions under a short timeline. The categories and their descriptions are listed in Table 3-3. Note that the canned foods category excludes microbiological hazards because these are already addressed through the low acid canned foods regulation. Furthermore, seafood and juice are excluded from these categories because establishments that produce these products are exempted from the FSMA because they already are required to be operating under a HACCP plan. Additionally, shell eggs and infant formula are excluded because these are being addressed separately from the other products under the FSMA, and products under the FSIS's jurisdiction (meat, poultry, and egg products) are also excluded.

For consistency with other FDA analyses, processing establishment size categories were defined based on number of employees as follows:

- fewer than 20 employees
- 20 to 99 employees
- 100 to 499 employees
- 500 or more employees

RTI developed the worksheets in consultation with FDA based on the information needs addressed in the FSMA as follows:

- the incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known hazard exists

Table 3-3. Product Categories Included in the Expert Elicitation

Product Category	Description
Beverages	Includes soft drinks; coffee; flavored beverages (e.g., lemonade and juice drinks); flavoring extracts and syrups; soy, rice, coconut, and almond milk or water but *excludes* juices, milk, bottled plain water, and alcoholic beverages
Canned foods (for hazards other than microbiological)	Includes canned and pickled (acidified and fermented) fruits and vegetables, soups, sauces, dressings, jams, and jellies
Dairy products	Includes milk, butter, cheese, ice cream, yogurt, and other dairy products, including dry, condensed, and evaporated forms but *excludes* raw milk beverages
Low-moisture (dry) foods	Includes cereals, dry mixes, breads, bakery products, chips and crackers, noodles, dried fruits, tea, nuts and nut products, dry vegetable protein products, and chocolate and cocoa powder
Food additives	Includes flavorings, preservatives, colorings, synthetic sweeteners, thickeners, texturizers, yeast, fat replacers, added vitamins and minerals, spices, and herbs
Fresh produce	Includes minimally processed fresh fruits and vegetables but *excludes* unprocessed fresh produce
Frozen foods	Includes frozen fruits, vegetables, and bakery products; prepared frozen foods such as frozen dinners and pizza; and ice
Milled and pressed foods	Includes flours, grains, rice, meal products, and plant (e.g., vegetable, nut, and seed) oils
Refrigerated foods[a]	Includes refrigerated prepared foods such as salsa, guacamole, fresh pasta, dips, refrigerated pizza, and refrigerated puddings but *excludes* products with components under FSIS inspection
Sugars and sweets	Includes cane and beet sugar, confections, candy, chewing gum, and syrups (e.g., maple and corn syrup)
Animal feed and pet food	Includes feed for poultry, livestock, horses, and aquaculture and cat, dog, fish, bird, and other types of pet food, including pet treats

[a]The refrigerated foods category was added by the experts on the day of the expert elicitation meeting because they believed hazards associated with refrigerated foods differ from the other food product categories.

- the effect on foodborne illness risk associated with commingling, processing, transporting, and storing food and raw agricultural commodities, including differences in risk based on scale and duration of such activities

For each information need, we formulated the specific wording of the question and the format for the experts' responses. The format of the responses included numerical estimates such as percentages and rankings and check boxes for scales of values from strongly disagree to strongly agree. To allow for the maximum utility of the responses, we designed all questions to provide numerical or categorical responses that could be

summarized and combined across experts. In other words, we avoided open-ended questions with written responses. However, we did ask experts to provide comments regarding their responses if they believed that additional explanation was needed to understand their responses.

After developing the initial worksheets, we conducted a pretest of the elicitation by teleconference with two experts who were unavailable to participate in the in-person meeting. With the pretest participants, we reviewed the definitions, assumptions, and worksheets as we would for the actual elicitation. This allowed us to determine whether the information was presented clearly and whether the response fields were logical and complete. Based on their feedback, we revised the materials prior to the date of the in-person meeting.

In addition to the worksheet and background materials, we also prepared a PowerPoint presentation to use as a moderator's guide for conducting the meeting. The presentation covered the purpose of the panel, the definitions and assumptions the experts were to use when answering the worksheets, and the food product fact sheets.

3.3.2 Key Assumptions and Definitions for the FSMA Expert Elicitation

Because of the importance of ensuring that the experts provided responses from a common frame of reference, we provided key assumptions and definitions as background. The definitions are based on the text of the FSMA, the Institute of Medicine report *A Risk-Characterization Framework for Decision-Making for the FDA,* and RTI's interpretation of the study needs as stated in the FSMA. In some cases, the definitions are further refined based on discussion with experts in the field. The definitions are as follows:

- **Commingling**—(1) Combining same product (and form) harvested on different days or from different growing areas or (2) combining same product (and form) from containers with different container codes or different production lots.
- **Processing**—Making food from one or more ingredients or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. (Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating,

rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, distilling, acidification, fermentation, labeling, and packaging.) Processing includes cleaning and sanitation in the processing establishment.

- **Storage**—Holding food ingredients and finished food products at all stages, including warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. Storage includes cleaning and sanitation of the storage facility.
- **Transporting**—Movement of food ingredients and finished food products and loading, unloading, and storage incidental to the movement of food ingredients or finished food products. It includes all stages of shipping from the farm to initial processing, to ingredient manufacturing, to final product manufacturing, to a distribution center or warehouse, and to a retail establishment (grocery store, restaurant, or institution). Transporting includes cleaning and sanitation of the transportation vehicle.
- **Mortality**—Number of deaths in a year attributable to a product.
- **Morbidity**—Number of people who suffer adverse health effects (illnesses or injuries) in a year that are at least serious enough to affect quality of life and are attributable to a product.
- **Number of foodborne illness cases**—Total cases, including reported and unreported, of mortality and morbidity attributable to a product.
- **Foodborne illness severity**—Total reduction in quality of life, accounting for number of reported and unreported cases, severity of illness, and duration of illness, attributable to a product.
- **Duration of activity**—Length of time from when food ingredients or finished food products begin an activity to when those products end the activity. For example, in processing, the duration of activity is the length of time from when the ingredients for a food product are added to when the final product is packaged. In transportation, the duration of activity is the length of time that the food ingredient or finished food product is loaded on a truck until it is unloaded at its destination.

- **Scale of activity**—Relative volume of product handled during an activity. For example, it might refer to operating capacity of a processing establishment, storage warehouse, or truck used for hauling.

In considering their responses, the experts were asked to use the following assumptions:

- **Consider average recent year**—Base your estimates on your knowledge of foodborne illness cases, outbreaks, and recalls for an average year over the past decade (approximately 2001 to 2011).
- **Include all sources of unintentional contamination**—Provide responses based on illnesses associated with any biological, chemical, radiological, or physical agent that is reasonably likely to cause illness or injury in the absence of its control. This also includes allergens such as milk, egg, wheat, fish, crustacean shellfish, soybeans, peanuts, and tree nuts.
- **Exclude intentional contamination**—Provide responses based only on unintentional contamination of food; in other words, exclude bioterrorism or other intentional contamination events.
- **Aggregate all stages after the farm and before retail**—Provide responses based on aggregate foodborne illnesses associated with all stages of processing and preparation of food ingredients and finished food products after leaving the farm through warehousing or distribution centers. That is, exclude foodborne illnesses associated with farm-level production, food retailing, restaurants/foodservice, and home preparation. Assume that the product leaves the farm with whatever level of contamination is typical and that the product is handled at retail or by consumers using whatever practices are typical.
- **Aggregate all populations**—Provide responses based on aggregate foodborne illnesses for all populations, including adults, children, elderly, and other vulnerable populations.
- **Aggregate domestic production and imports**—Provide responses based on aggregate product volume for domestic and imported product, assuming the typical distribution of sources of the food in the marketplace.

3.3.3 Participants on the Expert Elicitation Panel

We developed an initial list of 34 potential experts to serve on the expert elicitation panel based on our literature review by talking with stakeholders and foodborne illness attribution experts and obtaining recommendations from the Institute of Food Technologists and other food safety researchers. After further review of the experts' credentials and areas of expertise, we selected 15 experts to contact for recruitment. We contacted each of them by phone and followed up by sending them the project description and interest form by e-mail. As a result of our recruitment efforts, we identified 9 experts with relevant expertise who were available to attend the in-person expert panel meeting and 2 experts with relevant expertise who were not available to attend the in-person meeting but could serve as protesters. The final set of 9 experts who served on the panel is as follows:[5]

- Dr. Robert Brackett, Illinois Institute of Technology, Institute for Food Safety and Health
- Dr. Mike Doyle, University of Georgia, Center for Food Safety
- Dr. Joe Eifert, Virginia Polytechnic Institute and State University, Department for Food Safety and Technology
- Dr. Paul Hall, AIV Microbiology & Food Safety Consultants, LLC
- Dr. Linda Harris, University of California at Davis, Department of Food Safety and Technology
- Dr. Kevin Keener, Purdue University, Department of Food Sciences
- Dr. Jeffrey Kornacki, Kornacki Microbiology Solutions
- Dr. John Rushing, North Carolina State University, Department of Food, Bioprocessing, and Nutrition Sciences (retired)
- Dr. Donald Schaffner, Rutgers University, Department of Food Science

Additional details on the experts' expertise in specific food products and specific hazards is provided in Table 3-4.

[5] The experts received an honorarium and travel reimbursement for their participation.

Table 3-4. Pretest and Expert Panel Members, Affiliations, and Major Areas of Expertise

Name	Affiliation	Expertise—Hazards	Expertise—Foods
Pretest Panel Participants			
Gale Prince	Sage Food Safety Consultants	Microbiological, chemical, and physical hazards, and counterfeit foods	Dairy, meats, produce, bakery, refrigerated foods, frozen foods, beverages, canned foods
William Sperber	Retired from Cargill, Inc.	*Salmonella*, *Listeria*, *Staphylococcus, C. botulinum, C. perfringens, B. cereus*, Shiga-like toxin-producing *E. coli* (STEC)	Flours and bakery, ice cream, refrigerated and frozen foods, canned foods, meat and poultry, nuts/peanut butter
Expert Panel Participants			
Robert Brackett	Illinois Institute of Technology	*Listeria, Clostridium, Salmonella*, mycotoxins	Fresh fruits and vegetables, fermented dairy products, processed cheese
Michael Doyle	University of Georgia, Griffin campus	Enterohemorrhagic *Escherichia coli* (EHEC), *Salmonella, Campylobacter, Listeria, Clostridium, Shigella*	Produce, dairy, spices, seafood, poultry, eggs
Joseph Eifert	Virginia Polytechnic Institute and State University	*Campylobacter, Listeria, Salmonella*, mycotoxins, *Clostridium*	Poultry, eggs, seafood, produce, milk
Paul Hall	AIV Microbiology & Food Safety Consultants, LLC	*Salmonella, Listeria, Clostridium, Bacillus* and related spp., *Staphylococcus aureaus*	Processed meats, nuts and nut products, cereals, dairy products, ready-to-eat (RTE) meals
Linda Harris	University of California at Davis	*Salmonella, E. coli* O157:H7, *Listeria, Shigella*	Produce (leafy greens and others), tree nuts
Kevin Keener	Purdue University	*Salmonella*, *Listeria, Campylobacter, E. coli* O157:H7	Poultry, pork, beef, eggs
Jeffrey Kornacki	Kornacki Microbiology Solutions, Inc.	*Salmonella, Listeria, Chronobacter* spp. (enterobacter sakazakii), *Enterohemorrhagic E. coli, Staphylococcus aureas, B. cereus*	Dry-based powders (milk, cheese, whey), nonsterile dry infant formula, breakfast and infant cereals, spices, RTE meat products, cheese products (wide variety from low to high moisture), fluid milk products
John Rushing	North Carolina State University (retired)	Vegetative pathogens, psychotropic pathogens, physical hazards	Dairy, low-acid canned foods, refrigerated and frozen foods, dehydrated foods
Donald Schaffner	Rutgers University	*Salmonella, Clostridium perfringens, Listeria, E. coli* O157:H7, norovirus	Nuts, sprouts, tomatoes, leafy greens, dairy

All of the experts have general industry knowledge conducive to responding to the questions for the expert elicitation. However, it should be noted that the experts provided responses to the elicitation questions based on their own experience and knowledge of the food industry and foodborne hazards. Differences in their estimates reflect differences in various industry segments (e.g., dairy versus milled foods), geographic differences, and experience with different establishment sizes. Thus, the combined estimates can be thought of as generally representative of industry practices in the United States as a whole.

During the in-person meeting, the experts were asked to self-score their levels of experience or knowledge across each of the food categories and establishment sizes using a scale from 1 (none or minimal) to 3 (extensive). The food categories with average scores below 2.0 were milled and pressed products, sugars and sweets, pet food, and animal feed; the other eight food categories had average scores ranging from 2.0 (food additives) to 2.7 (fresh produce and canned foods). The establishment size categories all had average scores above 2.0 with the "fewer than 20 employees" category having an average score of 2.1 and the "100 to 499 employees" category having an average score of 2.7.

3.3.4 Expert Elicitation Process

We conducted the expert elicitation meeting on July 18, 2011, in RTI's offices in Washington, DC. We began with the introductory presentation to discuss and, if necessary, revise the definitions, assumptions, and food category descriptions to be used for the expert elicitation. Following the discussion, we reviewed each worksheet with the experts and requested that they do the following:

- complete each of the questions in the worksheet to the best of their ability based on their knowledge and experience of the food industry and
- complete the worksheet independently without conferring with other members of the expert panel.

During the discussions, the experts suggested several modifications to the definitions and assumptions and three major modifications to the worksheets. The first major modification was to include refrigerated foods as an additional product category because these foods were not captured in the

other categories. The second major modification was to break out the effects of duration of activity on foodborne illness by product category (previously the worksheet combined all product categories). Finally, the third major modification was to rank the risk of human illness due to exposure to animal feed and pet food relative to the entire list of human food categories instead of individually comparing the risk for animal feed and pet food relative to each human food category.

After the experts completed the worksheet, we reviewed the responses to ensure that the responses were complete; the experts were asked to complete those responses prior to leaving the meeting. In the week following the meeting, we contacted a few of the experts to obtain additional clarification on their responses. We then entered the individual responses into an Excel spreadsheet and calculated minimum, maximum, mean, and median responses for each response. We also recorded any explanatory comments included on the worksheets and prepared written summaries of the discussions conducted during the in-person meeting. This qualitative information is provided in the discussion of the results below.

3.4 EXPERT PANEL RESULTS

We present summaries of the expert panel results for each of the questions addressed in the spreadsheet grouped into the following areas:

- food category and establishment size foodborne illness risk rankings
- whether foodborne hazards are reported or known to exist
- attribution of foodborne illness to food production activities
- magnitude of effects of scale and duration of food production activities on foodborne illness

For each worksheet question, we present the minimum, maximum, mean, and median of the set of nine responses.

3.4.1 Results of Food Category and Establishment Size Foodborne Illness Risk Rankings

The results of ranking food categories and establishment sizes by foodborne illness are presented as follows:

- Table 3-5 presents rankings of human and animal food categories by their contributions to the total number of annual cases of human foodborne illness.
- Table 3-6 presents rankings of human and animal food categories by their contributions to the severity of human foodborne illness.
- Table 3-7 presents rankings of establishment sizes within human food categories by their contributions to the total number of annual cases of human foodborne illness.

Table 3-5. Rankings of Food Categories by Their Contributions to the Annual Number of Foodborne Illness Cases[a]

Category	Minimum	Maximum	Mean	Median	Combined Rank by Means
Human Foods					
Beverages	2	10	7.2	8	8
Canned foods	2	10	6.8	7	7
Dairy products	2	8	4.3	4	4
Dry (low-moisture) foods	2	6	3.3	3	2
Food additives	3	10	6.6	7	6
Fresh produce	1	2	1.1	1	1
Frozen foods	4	9	6.2	5	5
Milled and pressed products	3	10	7.3	8	9
Refrigerated foods	1	6	3.6	4	3
Sugars and sweets	7	10	8.6	8	12
Animal Foods[b]					
Animal feed	4	10.5	8.2	9.5	11
Pet food	6	10.5	8.0	7.5	10

[a]Lower numbers indicate more contribution to the number of human cases of foodborne illness, while higher numbers indicate less contribution.

[b]Rankings were provided relative to the human food categories.

Table 3-6. Rankings of Food Categories by Their Contributions to the Severity of Foodborne Illness Cases[a]

Category	Minimum	Maximum	Mean	Median	Combined Rank by Means
Human Foods					
Beverages	4	10	8.0	8	9
Canned foods	1	10	6.0	6	5
Dairy products	2	8	4.3	4	4
Dry (low-moisture) foods	2	6	3.6	4	2
Food additives	3	10	7.6	8	8
Fresh produce	1	2	1.1	1	1
Frozen foods	4	8	6.1	6	6 (tie)
Milled and pressed products	3	9	6.1	6	6 (tie)
Refrigerated foods	2	6	3.7	3	3
Sugars and sweets	3	10	8.6	9	10
Animal Foods[b]					
Animal feed	2	10.5	6.6	7	7 (tie)
Pet food	2	10.5	6.6	7	7 (tie)

[a]Lower numbers indicate more contribution to the number of human cases of foodborne illness, while higher numbers indicate less contribution.

[b]Rankings were provided relative to the human food categories.

Table 3-7. Rankings of Establishment Size Categories for Each Food Category by Their Contributions to the Annual Number of Foodborne Illness Cases[a]

Category	Size	Minimum	Maximum	Mean	Median
Beverages	Fewer than 20 employees	1	4	2.3	1
	20–99 employees	2	3	2.6	3
	100–499 employees	1	4	2.6	3
	500 or more employees	1	4	2.6	2
Canned foods	Fewer than 20 employees	1	4	2.3	1
	20–99 employees	2	3	2.6	3
	100–499 employees	1	3	2.3	2
	500 or more employees	1	4	2.8	4
Dairy products	Fewer than 20 employees	1	4	2.3	1
	20–99 employees	2	3	2.6	3
	100–499 employees	1	4	2.4	3
	500 or more employees	1	4	2.7	2

(continued)

Table 3-7. Rankings of Establishment Size Categories for Each Food Category by Their Contributions to the Annual Number of Foodborne Illness Cases[a]

Category	Size	Minimum	Maximum	Mean	Median
Dry (low-moisture) foods	Fewer than 20 employees	1	4	3.3	4
	20–99 employees	2	3	2.8	3
	100–499 employees	1	3	2.0	2
	500 or more employees	1	4	1.9	1
Food additives	Fewer than 20 employees	1	4	2.8	4
	20–99 employees	1	3	2.3	2
	100–499 employees	1	3	2.4	3
	500 or more employees	1	4	2.4	2
Fresh produce	Fewer than 20 employees	1	4	3.1	4
	20–99 employees	2	3	2.7	3
	100–499 employees	1	4	2.2	2
	500 or more employees	1	4	2.0	1
Frozen foods	Fewer than 20 employees	1	4	2.3	1
	20–99 employees	2	4	2.7	3
	100–499 employees	1	4	2.4	3
	500 or more employees	1	4	2.6	2
Milled and pressed products	Fewer than 20 employees	1	4	3.3	4
	20–99 employees	2	3	2.8	3
	100–499 employees	1	3	1.9	2
	500 or more employees	1	4	2.0	1
Refrigerated foods	Fewer than 20 employees	1	4	2.6	2
	20–99 employees	1	3	2.4	3
	100–499 employees	1	4	2.4	3
	500 or more employees	1	4	2.6	2
Sugars and sweets	Fewer than 20 employees	1	4	2.7	4
	20–99 employees	2	3	2.6	3
	100–499 employees	1	3	2.2	2
	500 or more employees	1	4	2.6	2

[a]Lower numbers indicate more contribution to the number of human cases of foodborne illness, while higher numbers indicate less contribution.

In these tables, lower numerical values mean greater risk of foodborne illness in terms of number of cases or, on a per-serving basis, severity of illness.[6] The experts were asked to consider both reported and unreported cases of foodborne illness when assigning their rankings and to aggregate over all populations consuming the food.[7] In response to a clarifying question, we instructed the experts to include acute and chronic illness in considering foodborne illness risk and to include mortality in addition to morbidity.

As shown in Tables 3-5 and 3-6, the experts ranked animal feed and pet food relative to the human food categories as a separate exercise. That is, they first ranked all of the human food categories. Then, as we began the discussion regarding risk to humans from handling animal feed and pet food, they believed it was easiest to indicate their rankings within the set of rankings for human food categories rather than indicate their responses in a different manner. To provide a sense of the combined rankings across the experts, we indicate in the last column the reranking of human and animal food categories by the mean of the experts' rankings.

Based on these tables, the results indicate the following:

- Fresh produce, dry (low-moisture) foods, and refrigerated foods ranked highest in terms of contributing to human foodborne illness risk regardless of whether the food categories were ranked by annual number of cases or severity of foodborne illness.[8]
- Within the human food categories, sugars and sweets, milled and pressed foods, and beverages ranked the lowest in terms of contributing to human foodborne illness risk based on annual numbers of cases of foodborne illness, but food additives replaced milled and pressed foods in the bottom three based on severity of foodborne illness risk.

[6] One expert said that one way to think of severity is to answer the question, "If someone gets sick, how sick does that person get?" In this way, severity could be considered independent of the frequency of consumption.

[7] One expert noted that by aggregating all populations, we are in a sense weighting them equally when assigning the rankings.

[8] One expert stated that a lot of foodborne illness is likely due to dry foods, but these cases are not attributable to dry foods because they are used in a lot of other foods. However, the rankings bore out a high ranking for dry foods.

- Exposure to animal feed and pet food ranked low in contributing to human illness regardless of whether they were ranked based on annual cases or severity of illness, but their rankings were higher for annual cases than for severity of illness, suggesting that when people become ill from animal feed and pet food, the illness is relatively more severe.
- There was no consistent pattern across food categories in terms of which sizes of establishments contributed most to the number of cases of human foodborne illness. For some food categories, the smallest size category (fewer than 20 employees) or largest size category (500 or more employees) ranked highest, while in others, they ranked the lowest. In all cases, the middle two size categories did not rank highest or lowest. However, given the range of responses for the rankings by size category and the small variation in the mean rankings, differences in rankings by size category should be interpreted with caution.

When considering the rankings by size, the experts said they factored in likely noncompliance with food safety practices by size and the implication for the amount of exposure to food products based on volume of production. They tend to believe that smaller establishments have higher levels of noncompliance with food safety practices because they do not have established procedures or appropriate training in place, and larger establishments have more resources available for food safety. However, they also had a general concern that defining establishment size based on number of employees may not be the best approach because many companies are working to reduce the number of employees in their plants by using more automation. Other options for defining establishment size are based on volume of production or square footage of the plant.

As part of the discussion on these rankings, the experts suggested that food safety risk factors could be divided into intrinsic and extrinsic factors; thus, the rankings could have been done separately based on these. Examples of these factors are as follows:

- Intrinsic factors—pH, water activity, contamination load, and fattiness
- Extrinsic factors—whether there is a lethality step, possibility of postlethality recontamination, facility

with poor hygiene design, older facilities, and whether the product is cooked

According to some of the experts, many plants do not have the expertise to deal with some of the intrinsic factors affecting food safety.

3.4.2 Results Related to Whether Hazards Are Reported or Known to Exist

The results related to whether the experts believe that some human or animal foods may not be associated with reported or known hazards are presented in Tables 3-8 and 3-9. We asked the experts to provide their responses on a 5-point scale ranging from 1 for strongly disagree (meaning hazards have been reported or are known to exist) to 5 for strongly agree (meaning hazards have not been reported and are not known to exist). For human foods, the experts provided their responses based on human illness, and, for animal foods, they provided their responses separately based on human and

Table 3-8. Level of Agreement with the Statement that No Reported or Known Hazard Exists: Human Foods[a]

Category	Minimum	Maximum	Mean	Median
Beverages	1	2	1.4	1
Canned foods	1	2	1.2	1
Dairy products	1	1	1.0	1
Dry (low-moisture) foods	1	2	1.1	1
Food additives	1	4	1.8	1
Fresh produce	1	1	1.0	1
Frozen foods	1	2	1.1	1
Milled and pressed products	1	2	1.2	1
Refrigerated foods	1	1	1.0	1
Sugars and sweets	1	3	1.9	2

[a]Values range from 1 for strongly disagree to 5 for strongly agree that no hazard exists.

Table 3-9. Level of Agreement with the Statement that No Reported or Known Hazard Exists: Animal Foods[a]

	Minimum	Maximum	Mean	Median
Human illness from animal feed	1	2	1.3	1
Human illness from pet food	1	1	1.0	1
Animal illness from animal feed	1	2	1.2	1
Animal illness from pet food	1	2	1.2	1

[a]Values range from 1 for strongly disagree to 5 for strongly agree that no hazard exists.

animal illness. Although not explicitly stated in the FSMA, the intent of this question is likely to determine whether some human or animal foods could be exempted from establishing preventive controls.

Based on these results, it is clear that the experts believe that all human and animal food categories have reported or known hazards. The median response was 1 for all human food categories with the exception of sugars and sweets, for which the median response was 2. The median response was 1 for both animal food categories regardless of whether the hazards considered related to human illness or animal illness. These results are consistent with Greig and Ravel (2009), who state that almost all foods can serve as the vehicle for a foodborne illness outbreak.

In discussing the foodborne illness hazards associated with animal feed and pet food, the experts listed the following potential hazards:

- *Salmonella* (which they believe occurs frequently)
- chemicals such as melamine (introduced intentionally for economic adulteration) and mycotoxin (introduced unintentionally)
- pesticides
- heavy metals
- bovine spongiform encephalopathy materials
- parasites such as *Trichonella*

The experts also noted that animals could become infected from food or feed and not become ill themselves yet transmit infections to humans.

3.4.3 Results Related to Attribution of Foodborne Illness to Food Production Activities

To provide a sense of the risks associated with commingling, processing, transporting, and storing human foods and animal foods, we asked the experts to estimate the percentage of annual foodborne illness cases associated with each of these activities by food category. It is important to keep in mind that the estimates provided by the experts are for the food processing sector only. That is, these estimates do not show the percentage of foodborne illness cases associated with activities that occur on the farm, at a retail establishment, or in a consumer's home. The experts commented in particular that processing is just a small part of the entire farm-to-fork continuum. Furthermore, outbreaks usually occur because of a series of events occurring at the farm, during processing, and during food preparation.

Table 3-10 provides the results for human foods, and Table 3-11 provides the results for animal foods. Because the direct median estimates do not sum to 100% in all cases, we also show rescaled median estimates that sum to 100%. Based on Table 3-10, the results for human foods indicate the following:

- The highest estimated percentage of annual foodborne illness cases in the food processing sector is associated with the processing activity itself rather than commingling, transporting, or storing. The estimated average percentages of cases attributed to processing ranged from 49% for refrigerated foods to 85% for canned foods.
- The highest estimated percentages of annual foodborne illness cases associated with commingling were for food additives (mean of 36%), milled and pressed foods (mean of 29%), and sugars and sweets (mean of 27%), while the lowest percentages were for canned foods (mean of 6%), beverages (mean of 8%), and dairy products (mean of 8%).
- The highest estimated percentages of annual foodborne illness cases associated with transporting were for fresh produce (mean of 19%), beverages (mean of 16%), and dairy products (mean of 14%), while the lowest percentages were for canned foods (mean of 3%), food additives (mean of 3%), and sugars and sweets (mean of 5%).

Table 3-10. Estimated Percentages of the Annual Number of Cases of Foodborne Illness Likely Attributable to Each Activity by Human Food Category

Category	Activity	Minimum	Maximum	Mean	Median[a]
Beverages	Commingling	0%	25%	8%	5% (5%)
	Processing	10%	100%	66%	80% (80%)
	Transporting	0%	40%	16%	10% (10%)
	Storing	0%	40%	11%	5% (5%)
Canned foods	Commingling	0%	25%	6%	5% (5%)
	Processing	50%	100%	85%	90% (91%)
	Transporting	0%	10%	3%	1% (1%)
	Storing	0%	20%	6%	3% (3%)
Dairy products	Commingling	0%	30%	8%	10% (10%)
	Processing	40%	90%	64%	60% (60%)
	Transporting	2%	25%	14%	10% (10%)
	Storing	0%	25%	14%	20% (20%)
Dry (low-moisture) foods	Commingling	0%	60%	15%	10% (10%)
	Processing	20%	100%	74%	90% (88%)
	Transporting	0%	20%	6%	1% (1%)
	Storing	0%	20%	7%	1% (1%)
Food additives	Commingling	0%	97%	36%	15% (15%)
	Processing	1%	90%	56%	80% (81%)
	Transporting	0%	10%	3%	1% (1%)
	Storing	0%	20%	5%	3% (3%)
Fresh produce	Commingling	0%	50%	14%	10% (10%)
	Processing	10%	85%	51%	50% (50%)
	Transporting	5%	40%	19%	20% (20%)
	Storing	0%	40%	16%	20% (20%)
Frozen foods	Commingling	0%	80%	13%	5% (5%)
	Processing	20%	97%	72%	80% (84%)
	Transporting	0%	25%	6%	5% (5%)
	Storing	0%	30%	9%	5% (5%)

(continued)

Table 3-10. Estimated Percentages of the Annual Number of Cases of Foodborne Illness Likely Attributable to Each Activity by Human Food Category (continued)

Category	Activity	Minimum	Maximum	Mean	Median[a]
Milled and pressed products	Commingling	5%	97%	29%	20% (20%)
	Processing	1%	90%	53%	60% (60%)
	Transporting	0%	30%	6%	5% (5%)
	Storing	0%	20%	11%	15% (15%)
Refrigerated foods	Commingling	0%	25%	10%	10% (11%)
	Processing	10%	90%	49%	50% (56%)
	Transporting	0%	50%	19%	10% (11%)
	Storing	0%	50%	22%	20% (22%)
Sugars and sweets	Commingling	0%	97%	27%	10% (9%)
	Processing	1%	100%	60%	90% (85%)
	Transporting	0%	25%	5%	1% (1%)
	Storing	0%	25%	8%	5% (5%)

[a]Median values rescaled to add to 100% are shown in parentheses.

Table 3-11. Estimated Percentages of the Annual Number of Cases of Foodborne Illness Likely Attributable to Each Activity by Animal Food Category

Category	Activity	Minimum	Maximum	Mean	Median[a]
Animal feed	Commingling	5%	49%	23%	20% (24%)
	Processing	30%	85%	54%	50% (59%)
	Transporting	0%	40%	8%	5% (6%)
	Storing	0%	40%	15%	10% (12%)
Pet food	Commingling	0%	49%	17%	10% (11%)
	Processing	40%	95%	72%	80% (84%)
	Transporting	0%	10%	3%	0% (0%)
	Storing	0%	40%	9%	5% (5%)

[a]Median values rescaled to add to 100% are shown in parentheses.

- The highest estimated percentages of annual foodborne illness cases associated with storing were for refrigerated foods (mean of 22%), fresh produce (mean of 16%), and dairy products (mean of 14%), while the lowest percentages were for food additives (mean of 5%), canned foods (mean of 6%), and dry (low-moisture) foods (mean of 7%).

In reflecting on the processing activities in particular, the experts noted that many foodborne illness problems are associated with establishments not following basic good manufacturing practices during production. Specifically, problems are often due to basic sanitation issues. Furthermore, persistent strains can be a problem on some equipment because the design of the equipment does not permit thorough cleaning and can even become more contaminated during cleaning (e.g., equipment intended for production of dry products can become more contaminated with wet cleaning). The experts also noted that for some high-risk foods, contamination of the product often occurs after the main processing step in the production process.

Based on Table 3-11, the results for animal foods indicate the following:

- As with human foods, the highest estimated percentage of annual foodborne illness cases in the food processing sector are associated with the processing activity itself rather than commingling, transporting, or storing. The estimated average percentages of cases attributed to processing are 54% for animal feed and 72% for pet food.
- Commingling is associated with more annual foodborne illness cases (mean of 23% for animal feed and 17% for pet food) than storage (mean of 15% and 9%, respectively) and transporting (mean of 8% and 3%, respectively).

3.4.4 Results Related to the Effects of Scale and Duration of Activities on Foodborne Illness

In the final set of questions, we asked the experts to consider scale and duration of activity in the processing sector in contributing to the annual foodborne illness cases. These questions focused only on human food categories.

In discussing the meaning of "scale of activity," we asked the experts to consider whether a larger scale of activity means more than a proportionate increase in foodborne illness. One way to think about this question is "If the scale is increased 100-fold, will the number of foodborne illness cases increase by more than 100 times?" The experts were asked to provide their responses on a 5-point scale ranging from 1 for not at all important to 5 for extremely important. In responding to this

question, the experts felt they could provide a response that aggregated across all food categories.

The results for the scale-of-activity question are provided in Table 3-12. For the most part, there was no general consensus across the experts because they indicated the full range of responses from 1 to 5, and the mean and median of the responses were a value of 3 for "important." However, the level of agreement was somewhat higher for the importance of scale of activity for processing (mean value of 4 and median value of 5). This means that the experts believe that a larger scale of activity for processing is very or extremely important in contributing to foodborne illness risk.

Table 3-12. Importance of the Scale of Activity in Contributing to the Number of Cases of Foodborne Illness, All Food Categories Combined[a]

Activity	Minimum	Maximum	Mean	Median
Commingling	2	5	3.6	4
Processing	1	5	4.0	5
Transporting	1	5	3.3	3
Storing	1	5	3.1	3

[a]Values range from 1 for not at all important to 5 for extremely important.

In discussing the meaning of "duration of activity," we asked the experts to consider the amount of time that elapses from when an ingredient or product enters an activity to when it exits an activity. As with the scale-of-activity question, the experts were asked to provide their responses on a 5-point scale ranging from 1 for not at all important to 5 for extremely important. In this case, the experts thought that it would be best to provide responses individually for each product category rather than aggregated across all human foods because duration varies substantially across products. Therefore, during the in-person meeting, we expanded the worksheet tables to allow the experts to provide separate responses for each food category.

The results for the duration-of-activity question are provided in Table 3-13. Mean scores were generally highest across commingling, processing, transporting, and storing for dairy products, fresh produce, and refrigerated foods and generally lowest for sugars and sweets, frozen foods, and canned foods.

Table 3-13. Importance of the Duration of Activity in Contributing to the Number of Cases of Foodborne Illness, All Food Categories Combined and by Food Category[a]

Category	Activity	Minimum	Maximum	Mean	Median
All foods	Commingling	2	4	2.7	2
	Processing	1	5	3.6	4
	Transporting	2	5	3.7	4
	Storing	2	5	3.8	4
Beverages	Commingling	1	4	2.8	3
	Processing	2	5	3.4	3
	Transporting	1	5	3.3	4
	Storing	1	5	3.3	4
Canned foods	Commingling	1	4	2.1	2
	Processing	1	5	3.6	4
	Transporting	1	4	2.0	2
	Storing	2	4	2.6	2
Dairy products	Commingling	2	5	3.4	3
	Processing	3	5	4.2	4
	Transporting	2	5	3.9	4
	Storing	3	5	4.2	4
Dry (low-moisture) foods	Commingling	3	4	3.8	4
	Processing	2	5	3.4	4
	Transporting	1	4	2.2	2
	Storing	2	5	2.8	2
Food additives	Commingling	2	5	3.9	4
	Processing	2	5	3.6	4
	Transporting	1	4	1.9	2
	Storing	1	4	2.3	2
Fresh produce	Commingling	2	5	3.4	3
	Processing	3	5	3.9	4
	Transporting	3	5	4.0	4
	Storing	3	5	4.4	5

(continued)

Table 3-13. Importance of the Duration of Activity in Contributing to the Number of Cases of Foodborne Illness, All Food Categories Combined and by Food Category[a] (continued)

Category	Activity	Minimum	Maximum	Mean	Median
Frozen foods	Commingling	1	3	2.3	2
	Processing	1	4	3.3	4
	Transporting	1	5	3.1	3
	Storing	1	5	3.2	3
Milled and pressed products	Commingling	2	4	3.2	3
	Processing	2	4	3.2	4
	Transporting	1	4	2.4	2
	Storing	1	5	2.8	3
Refrigerated foods	Commingling	2	5	3.3	3
	Processing	2	5	3.9	4
	Transporting	3	5	4.4	5
	Storing	3	5	4.6	5
Sugars and sweets	Commingling	2	4	2.9	3
	Processing	2	4	2.9	3
	Transporting	1	4	2.0	2
	Storing	1	5	2.2	2

[a]Values range from 1 for not at all important to 5 for extremely important.

Mean scores were highest for the following food categories for each activity:

- Duration of commingling—highest mean scores for food additives (3.9), dry (low-moisture) foods (3.8), and fresh produce and dairy products (3.4). During the discussions, the experts said that a longer duration of commingling means that pathogens in a product have more opportunity to be transferred to other products.
- Duration of processing—highest mean scores for dairy products (4.2), fresh produce (3.9), and refrigerated foods (3.9).
- Duration of transporting—highest mean scores for refrigerated foods (4.4), fresh produce (4.0), and dairy products (3.9).

- Duration of storing—highest mean scores for refrigerated foods (4.6), fresh produce (4.4), and dairy products (4.2).

Thus, duration of activity was most important for the refrigerated foods, fresh produce, and dairy products categories, with the exception of commingling, in which additives and dry (low-moisture) foods also had high scores. These results are consistent with a comment by one of the experts that most of the effect of duration is on microbiological growth rather than other possible contaminants.

3.5 QUALIFICATIONS AND LIMITATIONS OF THE APPROACH

As mentioned above, expert elicitation is an approach used in cases where data are unavailable; thus, the judgment of experts knowledgeable about a field is the next best option. Therefore, the approach has inherent limitations because data are not available through surveillance systems, surveys, or other systematic data collection efforts. In addition to these inherent limitations, the experts expressed other qualifications or limitations that may be relevant in considering the results presented above:

- Although the experts gave some consideration to allergens, they were mostly thinking about biological contamination because most of the data on contamination relates to microbiological contamination.
- We did not have an allergist or toxicologist on the panel; thus, chemical contaminants were considered less.
- Viruses did not generally factor into rankings because they occur mostly postprocessing.
- In the food categories used, the experts felt that we may have generalized too much. In some categories, there are specific high-risk foods such as raw milk cheeses in the dairy category and chocolate in dry products.
- In ranking risks, we could have asked the experts to rank risks separately for biological, chemical, and physical hazards rather than combining them.

Thus, if additional expert elicitations are conducted, it may be useful to address these concerns in the design of the panel and materials.

Finally, another issue raised during the meeting relates to foodborne illness attribution in the available reporting systems. Specifically, although an outbreak might be referred to as a specific food outbreak (e.g., “spinach” or “peanut butter” outbreak), the outbreak could be due to activities that occur at the farm, processing establishment, or retail establishment. In many cases, the outbreak might not have anything to do with the product itself but be related to the irrigation water used at the farm or handling practices in a restaurant. The implication is that the data that individuals have in mind in providing responses to expert elicitation questions may be based on data that attribute more foodborne illness risk to specific products than is warranted.

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Appendix A: Farm NAICS Codes Used to Determine Colocation

As described in Section 2, this appendix contains the table of NAICS codes for farming activities for determining the colocation of processing establishments and farms.

Table A-1. Farm NAICS Codes Used to Identify Establishments Colocated on Farms

NAICS Code	NAICS Description
111110	Soybean Farming
111120	Oilseed (except Soybean) Farming
111130	Dry Pea and Bean Farming
111140	Wheat Farming
111150	Corn Farming
111160	Rice Farming
111199	All Other Grain Farming
111211	Potato Farming
111219	Other Vegetable (except Potato) and Melon Farming
111310	Orange Groves
111320	Citrus (except Orange) Groves
111331	Apple Orchards
111332	Grape Vineyards
111333	Strawberry Farming
111334	Berry (except Strawberry) Farming

(continued)

Table A-1. Farm NAICS Codes Used to Identify Establishments Colocated on Farms (continued)

NAICS Code	NAICS Description
111335	Tree Nut Farming
111336	Fruit and Tree Nut Combination Farming
111339	Other Noncitrus Fruit Farming
111411	Mushroom Production
111419	Other Food Crops Grown Under Cover
111920	Cotton Farming
111930	Sugarcane Farming
111940	Hay Farming
111991	Sugar Beet Farming
111992	Peanut Farming
111998	All Other Miscellaneous Crop Farming
112120	Dairy Cattle and Milk Production
112410	Sheep Farming
112420	Goat Farming
112910	Apiculture

Appendix B: Case Studies of Colocated Facilities

Collecting data is the main challenge in examining colocated facilities. Very little is known about smaller growers marketing to the direct-to-consumer market. Although more is known about the larger producers who may belong to producer organizations that sometimes publish lists of producers or marketers, data in this area are also scarce. These case studies examine three commodity groups to estimate the numbers of colocated operations. These three commodities are California fresh-market tomatoes, California fresh-market cantaloupe, and Washington apples.[9] Information for California fresh-market cantaloupe and Washington apples comes from industry publications that do not focus on smaller producers selling mostly to the direct-to-consumer market. Information on the California tomato industry comes from a member of the industry familiar with larger producers. Smaller producers who rely on direct-to-consumer sales may be very different from these larger growers.

For each commodity, the strategy was to identify firms that market the product (because those data are more available) and then work backward to determine if the firm was also a

[9] These commodities should not necessarily be considered representative of the entire produce industry. These three commodities were relatively easy to investigate. The California fresh-market tomato industry is relatively small in terms of marketers, and the structure of the industry could be identified with several phone calls. The California fresh-market cantaloupe industry has a marketing order that requires food safety practices; all participating marketers are listed on the organization's Web page, and the structure could be identified with some Web research and a phone call to a prominent shipper. The Washington Apple Commission lists all marketers (sales agencies), packers, and packer/marketers; again one phone call provided enough information to sketch out the structure.

grower. The trends toward increasing concentration in marketing and vertical integration are very strong in each of these commodities. Without any data on growers by name, the risk exists of missing some growers who do not market but could be colocated. In the case of California tomatoes and California cantaloupe, industry leaders asserted that there were very few, if any, growers in these two industries who only packed that would be missed with this top-down strategy focusing on marketers. The Washington Apple Commission web page also provided data on packers, which was crucial because the role of grower/packers, not just grower/packer/marketers, is quite important in that industry. All numbers, however, should only be considered approximations.

Terminology can also differ between industries. A shipper in the California cantaloupe industry might typically be thought of as someone selling the product into commerce. In the Washington apple industry, a shipper refers to the person who organizes the transportation for the sales agency (marketer). In these case studies, marketers refer to firms that are selling into commerce and shippers are people concerned with transportation.

B.1 STRUCTURE OF THE CALIFORNIA FIELD TOMATO INDUSTRY

In 2012, 2,759 farms in California grew field tomatoes for the fresh market (as opposed to greenhouse tomatoes for the fresh market or field tomatoes grown for canning (a separate industry)) with a total of 39,196 acres. Many of these farms are small—on a national level, only 1.2% of farms growing field tomatoes for the fresh market have 25 acres or more, but these account for 79% of total production.

The typical operations for field tomatoes include growing and harvesting; cooling, packing, storing, and ripening (for mature green tomatoes and roma tomatoes); shipping; and

marketing.[10] Packing and ripening are complicated and expensive processes involving washing, sorting for color, sorting for size, ripening for some tomatoes, and putting tomatoes into containers. Some firms also operate repacking operations close to destination markets but never at the farm itself. There are no independent packing operations in California (packers without a grower base), but there are independent repacking operations.

Starting from the vertically integrated operations that market, there are approximately 17 large to medium-sized vertically integrated grower/packer/shipper/marketer operations in California for fresh-market field tomatoes (not counting small operations for direct-to-consumer sales).[11] One other firm is partially integrated with growing/packing/shipping, but another firm does its marketing.

Most, if not all, of the vertically integrated field-tomato firms pack and market for others in addition to their own tomatoes. For these firms tomatoes are packed in packinghouses (i.e., no field packing). Locations of the packing operations are not known, although one vertically integrated firm thought that off the farm was the most common location.[12] So there may be very few colocated operations.

The only processing operation that is common in the fresh-market field tomato industry is fresh-cut processing. No

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[10] Mature green tomatoes and romas, two of the most important types of tomatoes in California, are picked while green but still sufficiently ripe to continue ripening after harvesting. Ripening facilities treat the tomatoes with ethylene gas to finish ripening. The mature green tomatoes are then shipped to a repacker near the destination market. In the meantime, the tomatoes are turning red, but the exact coloration depends on the degree of maturing at picking. The repackers open the boxes, re-sort, and repack to get a more homogenous color for each box. Tomatoes can be held in storage before ripening depending on market conditions. It is a large and capital-intensive process. Other types of tomatoes (cherry and grape) are picked at their full color and do not need to be ripened.

[11] Several of these firms have growing/packing/shipping/marketing operations in other states too, as well as operations in Mexico.

[12] Three of four greenhouse operations in California are integrated grower/packer/shipper/marketer operations. One other firm is a grower/packer/shipper but relies on another firm to market. Greenhouse operations do not need ripening facilities. Three of the four have their roots in Canadian operations (the parent company). Even greenhouses have become more diversified and are packing and selling for others, sometimes both greenhouse and field tomatoes. Greenhouse tomatoes typically grow and pack in one facility.

vertically integrated firms do fresh-cut on their California operations. In the past, repack operations near major cities might have sliced tomatoes for local buyers, but this practice is declining. Now most tomatoes for fresh-cut go to specialist fresh-cut firms. A fresh-cut operation would be outside the scope of most California growers/shippers. However, one firm that operates in California owns a fresh-cut operation in another state.

Conclusion: Most of the 18 firms discussed in this section are unlikely to be colocated since most post-harvest operations are thought to be off the farm.

B.2 STRUCTURE OF THE CALIFORNIA CANTALOUPE INDUSTRY

California is the dominant producer of cantaloupe in the United States and had 70% of commercial production in 2013. In 2012, 1,182 farms grew cantaloupe for the fresh market in California, accounting for 37,058 acres. Many of these are small growers who may rely on direct-to-consumer sales.

The California cantaloupe industry involves four activities: growing; harvesting and packing (in the field or in a packinghouse); cooling, storing, and shipping; and marketing. Working backward from a list of marketers, in late 2014, 21 marketers put cantaloupe in commerce; of those, 20 were vertically integrated through all four activities.[13] These 20 operations have the potential to fall under both the Produce Rule and the Preventive Controls Rule depending on where their post-harvest operations are located. Nine of the 20 firms marketed only their own production; the other 11 firms marketed for themselves and other cantaloupe growers.[14]

Working from the grower end, some growers, representing less than an estimated 10% of the California production, are not completely vertically integrated but may do just one or two of the other activities. These growers might also fall under both

[13] Information from the California Cantaloupe Advisory Board (http://www.californiacantaloupes.com/food-safety/members). There were actually 22 handler members listed in the 2014–15 season, but one had gone out of business by early 2015.

[14] Cantaloupe is different from tomatoes and apples in this respect, perhaps because of the relatively low-cost field packing compared with the capital-intensive packinghouse operations for other crops.

rules depending on the location of their post-harvest operations.

A firm that markets only its own production *may* have packing, cooling, and storing facilities on its own farm or next door to its farm. These firms do not need to be centrally located to accommodate other growers. They would, however, still need good roads (something not always found on farms) to accommodate shipping. Packing facilities are not an important component of the California cantaloupe industry. All but one of the 20 vertically integrated firms did field packing; the other one packs in a packinghouse. Producers outside of California and Arizona more commonly pack in a packinghouse.

Some cantaloupe produced for the fresh market goes to processing. Although several shippers have experimented over the years with doing fresh-cut processing as part of their integrated operation, none do fresh-cut processing now. Marketers now sell to specialized processors who may sell the cantaloupe as fresh-cut, frozen, brined in sugar for fruit salad, or other processed forms.

Conclusion: There are 20 farms that both grow and have post-harvest activities but the number of collocated operations is not known. Since about half of these firms only use their own production in post-harvest activities, it is possible that they are more likely to be colocated than the others. Those who do post-harvest activities for other growers too might have more incentive to be located off the farm in a convenient location for suppliers.

B.3 STRUCTURE OF THE WASHINGTON APPLE INDUSTRY

In 2012, 2,839 apple growers in Washington State accounted for 174,152 acres (bearing and nonbearing acres). Typical activities in the apple industry are: growing and harvesting; packing, cooling, storing, and shipping (just transportation); and sales or marketing.

Apples are handpicked and sent immediately to packers. Packers pack, cool, store, and ship apples. At most, 36 firms pack but do not market apples, and all of them are vertically

integrated grower/packers.[15] Six of these firms are grower-owned packing cooperatives. Almost all packing operations pack fruit for more than one grower; however, there are two possible exceptions. One of these exceptions is a very large producer whose orchards are in an isolated area and this firm only packs its own apples. In addition, packing operations are typically not located on the grower's farm with the exception of the two farms who may only pack for themselves.

Marketers (sales agencies) are also concentrated with only 24 firms. Sales agencies do the marketing for packers/shippers who then ship the apples to the appropriate market. All but three of these sales agencies are owned or co-owned by integrated grower/packer/shipper/sales firms (including one integrated grower/packer/shipper/sales agency cooperative).

The focus of the Washington apple industry is on the fresh market. Processing is generally only for apples that are not the right quality or size for the fresh market or are not valuable enough to pay for packing. Processed apple products include juice, sauce, fresh-cut slices, cut apples for food ingredients, dried apples, and purees. TreeTop is the big processor cooperative owned by growers and produces a wide range of processed apple products. There is only one other vertically integrated grower/packer/shipper/sales agency with a processing operation that produces frozen apples and fresh-cut sliced apples.

Smaller apple orchards may operate quite differently. For example, hard cider producers in western Washington can be integrated grower/processors.

Conclusion: Of the 57 integrated operations with a growing base (36 that are just grower/packers/shippers and another 21 that are grower/packer/shipper/marketers) only two appear to have colocated facilities.

[15] Information on Washington state apple packer and sales agencies came from the Washington State Apple Commission (http://www.bestapples.com/international/international_exporters.aspx). There is more vertical integration than is obvious from looking at the list of firms. Many growers and their sales agencies have different names and appear to be under separate ownership at first glance.

Appendix C: Materials Used for the Foodborne Illness Expert Panel

The materials included in this appendix were used to conduct the expert elicitation on July 18, 2011, in Washington, DC. During the meeting, we revised these documents based on input from the experts who attended; the versions provided are revised versions of the following:

- introductory presentation with definitions and assumptions
- worksheets completed by the experts
- food product factsheets

In the food product factsheets, the refrigerated foods category was not included because it was added during the in-person meeting upon the suggestion of the experts. We developed a slide in the introductory presentation to briefly define the product category, but because of time constraints we were not able to create a fact sheet for refrigerated foods during the meeting.


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Washington, DC
July 18, 2011
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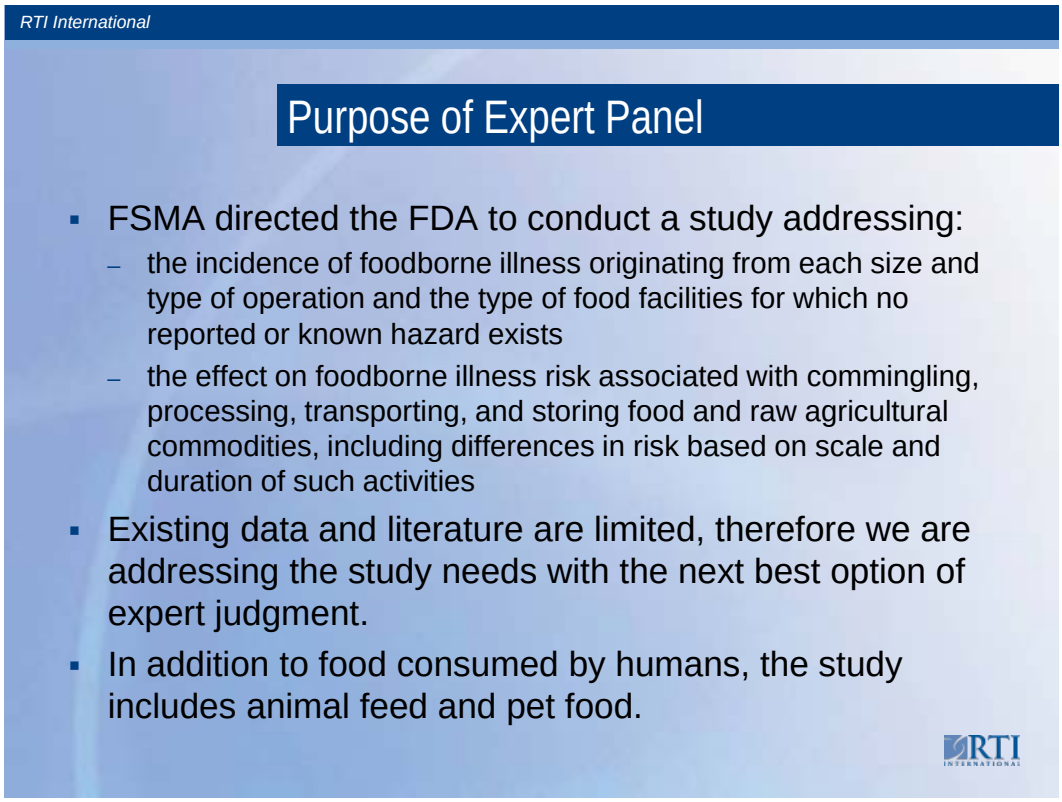
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Purpose of Expert Panel
FSMA directed the FDA to conduct a study addressing:
the incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known hazard exists
the effect on foodborne illness risk associated with commingling, processing, transporting, and storing food and raw agricultural commodities, including differences in risk based on scale and duration of such activities
Existing data and literature are limited, therefore we are addressing the study needs with the next best option of expert judgment.
In addition to food consumed by humans, the study includes animal feed and pet food.
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Food Products Addressed

- Beverages
- Canned & Preserved Foods
- Dairy Foods
- Dry Foods
- Food Additives
- Fresh Produce
- Frozen Foods
- Milled Products
- Sugars & Sweets
- Animal Feed & Pet Food

What's Excluded?

- Products under FSIS jurisdiction—meat, poultry, & egg products
- Juice (already under HACCP)
- Seafood (already under HACCP)
- Shell eggs (will be addressed separately)
- Infant formula (will be addressed separately)

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Definitions: Commingling

- (1) combining same product (and form) harvested on different days or from different growing areas—most common definition
- (2) combining same product (and form) from containers with different container codes or different production lots; includes rework

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Definitions: Processing

- Making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients.
  - Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, distilling, acidification, fermentation, labeling, or packaging.
  - Includes cleaning and sanitation in the processing establishment.

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Definitions: Storage

- Holding of food ingredients and finished food products at all stages, including warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
  - Includes cleaning and sanitation in the storage establishment.

RTI International

Definitions: Transporting

- Movement of food ingredients and finished food products and loading, unloading, or storage incidental to the movement of food ingredients and finished food products
  - It includes all stages of shipping from the farm to initial processing, to ingredient manufacturing, to final product manufacturing, to a distribution center or warehouse, and to a retail establishment (grocery store, restaurant, or institution).
  - Includes cleaning and sanitation of the vehicle.

RTI International

Definitions: Mortality and Morbidity

- **Mortality**—number of deaths in a year attributable to a product.
- **Morbidity**—number of people who suffer adverse health effects (illnesses or injuries) in a year that are at least serious enough to affect quality of life attributable to a product.

Developed based on IOM report "A Risk-Characterization Framework for Decision-Making for the FDA"

RTI International

Definitions: Foodborne Illness

- **Number of Foodborne Illness Cases**—total cases, including reported and unreported, of mortality and morbidity attributable to a product.
- **Foodborne Illness Severity**—total reduction in quality of life, accounting for number of reported and unreported cases, severity of illness, and duration of illness, attributable to a product.
  - Do we need to define a common metric for severity?

RTI International

Definitions: Duration of Activity

- Length of time from when food ingredients or finished food products begin an operation to when those products exit the activity.
  - Examples:
    - In processing, the duration of the activity is the length of time from when the ingredients for a food product are added to the process when the final product is packaged.
    - In transportation, the duration of activity is the length of time from when the food ingredient or finished food product is loaded on a truck until it is unloaded at its destination.

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Definitions: Scale of Activity

- Relative volume of product handled during an activity.
  - For example, it might refer to operating capacity of a processing establishment, storage warehouse, or a truck used for hauling.

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Assumptions: Average Year

- **Consider average recent year**—Base your estimates on your knowledge of foodborne illness cases, outbreaks, and recalls for an average year over the past decade (approximately 2001-2011).

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Assumptions: Sources of Contamination

- **Include all sources of unintentional contamination**—Provide responses based on illnesses associated with any biological, chemical, radiological, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
  - This also includes allergens such as milk, egg, wheat, fish, crustacean shellfish, soybeans, peanuts, and tree nuts.
- **Exclude intentional contamination**—Provide responses based only on unintentional contamination of food
  - In other words, we are excluding bioterrorism or other intentional contamination events.

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Assumptions: Stages

- **Aggregate all stages after the farm and before retail**—Provide responses based on aggregate foodborne illnesses associated with all stages of processing and preparation of the product after leaving the farm through warehousing or distribution centers
  - That is, exclude foodborne illnesses associated with farm-level production, food retailing, restaurants/foodservice, and home preparation.
  - Assume that the product leaves the farm with whatever level of contamination is typical and that the product is handled at retail or by consumers using whatever practices are typical.

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Assumptions: All Populations

- **Aggregate all populations**—Provide responses based on aggregate foodborne illnesses for all populations, including adults, children, elderly, and other vulnerable populations.

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Assumptions: Domestic & Imports

- **Aggregate domestic production and imports**—Provide responses based on aggregate product volume for domestic and imported product, assuming the typical distribution of sources of the food in the marketplace.

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Food Category—Beverages

- Includes soft drinks, coffee, and flavored beverages including flavoring extracts and syrups
- Includes soy, rice, coconut, almond etc. milk/water/beverages
- Excludes juices and milk
- Excludes alcoholic beverages

- Most are liquid products, either fully or partially constituted
- Water is a primary ingredient but is not included as a beverage in this category (unless has added ingredients)
- Most products are shelf stable

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Food Category—Canned

- Includes canned and pickled (acidified and fermented) fruits and vegetables, soups, sauces, dressings, jams, and jellies

Note: Biological hazards associated with low acid canned foods (covered under 21 CFR part 113) are excluded from FSMA but all other hazards are relevant.

- Fruits, vegetables, and liquid products (sauces and dressings) that are processed and packaged in airtight containers
- Typically combined with ingredients such as high fructose corn syrup, fats and oils, and herbs and spices
- Typically thermally processed and shelf stable

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Food Category—Dairy

- Milk, butter, cheese, ice cream, yogurt, and other dairy products; including dry, condensed, and evaporated dairy products
- Excludes raw milk beverages

- Primary ingredient is pasteurized or non-pasteurized milk (e.g., cow, sheep, and goat)
- Most must be refrigerated or frozen and do not require cooking
- May be aged or fresh
- May be liquid, semi-solid, or solid
- May have added non-dairy ingredients

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Food Category—Low Moisture (Dry) Foods

- Cereals, dry mixes, breads, bakery products, chips and crackers, noodles, dried fruits, tea
- Includes nuts and nut products, including nut butters
- Includes dry vegetable protein products
- Includes chocolate and cocoa powder

- Made with major ingredients such as milled wheat and corn or nuts
- Most are solids and are shelf stable because they are dry
- Some (e.g., bread, chips, and crackers) can be consumed directly while others are cooked alone (e.g., noodles) or mixed with additional ingredients (e.g., dry mixes)

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Food Category—Food Additives

- Examples include flavorings, preservatives, colorings, synthetic sweeteners, thickeners and texturizers, yeast, fat replacers, and added vitamins and minerals; spices and herbs

- Can be natural or artificial
- Can be liquid or dry products
- Direct food additives are those added to food for a specific functional purpose in that food

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Food Category—Fresh Produce

- Minimally processed fruits and vegetables

- All are perishable
- Can be consumed raw or cooked
- Fresh produce may be washed and is cut, peeled, or otherwise minimally processed before it is packed

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Food Category—Frozen Foods

- Frozen fruits, vegetables, and bakery products; prepared foods such as frozen dinners and pizza; and ice
- Must be stored frozen to avoid spoilage and pathogen growth
- Some frozen products are intended to be heated for quality or food safety, while others such as frozen fruits and bakery products can be consumed without further preparation

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Food Category—Refrigerated Foods

- Refrigerated prepared foods such as salsa, guacamole, fresh pasta, dips, refrigerated pizza, puddings
- Excludes components under FSIS inspection
- Must be refrigerated to avoid spoilage and pathogen growth
- Some refrigerated products are intended to be heated for quality or food safety, while others such can be consumed without further preparation

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Food Category—Milled and Pressed Foods

- Flours, grains, rice, meal products, and plant (e.g., vegetable, nut, seed) oils
- Specific examples: olive oil, sunflower oil, etc.

- Includes crops that are milled into flour and oil and used as ingredients in processed food products and in recipes prepared by consumers
- Generally shelf stable
- When used as ingredients by food processors, milled foods are shipped in bulk

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Food Category—Sugars & Sweets

- Cane and beet sugar, confections, candy, and chewing gum
- Includes syrups such as maple, corn, etc.

- Natural sugar or artificial sweeteners are a primary ingredient of products in this category
- Mostly solid products but some are liquid
- Most products are shelf stable

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Animal Feed & Pet Food

- Animal feed includes food for poultry, livestock, and aquaculture.
- Pet food includes cat, dog, fish, bird, reptiles (companion animals) and other types of pet food and includes pet treats.
- Products may be low or intermediate moisture, dry, canned, or bulk unpackaged
- Ingredients might include roughage, forage, grains, milling byproducts, animal protein and byproducts, added vitamins, minerals, fats/oils, and other nutritional and energy sources
- Drugs might be added to some animal feeds

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Next Steps

- Complete tables rating your knowledge and experience with each food category and establishment size
- Discuss assumptions, definitions, and issues for each worksheet table to be completed
  - Note that your qualitative comments are useful for understanding the context of the panelists responses
- Complete each table following the discussion

Reminder: You will be listed as a participant in the expert panel, but your individual responses will be combined with the others in the report.

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Added Note

- Excluded—address separately: Indirect food additives are those that become part of food in trace amounts due to its packaging, storage, or other handling

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Table C-1. Beverages

	Assumptions and Data
Foods Included	Soft drinks, coffee, and flavored beverages including flavoring extracts and syrups; excludes juices, milk, and alcoholic beverages
Nature of Products	Beverages are liquid products, either fully or partially constituted. While water is a primary ingredient in beverages, water is not included as a beverage in this category. Most products are shelf stable.
Types of Packaging	Plastic bottles, glass bottles, aluminum cans, aseptic cartons
Estimated Imports	*Not available*
Reported Outbreaks, 2000–2008[a]	Number of outbreaks: 112 Number of individuals affected by outbreaks: 3,388
Estimated Consumption[b]	Daily grams per capita: 681 ± 348 (95% C.I.)
Production Plants[c]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	2,613	$12
20–99 employees	656	$28
100–499 employees	309	$778
500+ employees	37	$35,927

Notes

[a]Estimated using CDC site http://wwwn.cdc.gov/foodborneoutbreaks

[b]Estimated using NHANES dietary recall data.

[c]Estimated using Dun & Bradstreet data.

Table C-2. Canned Foods

	Assumptions and Data
Foods Included	Canned and pickled fruits and vegetables, soups, sauces, dressings, and jams and jellies, and other prepared foods including peanut butter
Nature of Products	Canned and preserved foods are fruits, vegetables, and liquid products such as sauces and dressings that are processed and packaged in airtight containers to prevent spoilage. They are typically combined with ingredients such as high fructose corn syrup, fats and oils, and herbs and spices. Canned and preserved foods are typically processed using some type of thermal treatment and are shelf stable.
Types of Packaging	Steel cans, glass jars with steel lids, plastic bottles with plastic lids
Estimated Imports[a]	Canned fruit (2009): 31% of consumption Canned vegetables (2009): 13% of consumption
Reported Outbreaks, 2000–2008[b]	Number of outbreaks: 288 Number of individuals affected by outbreaks: 6,930
Estimated Consumption[c]	Daily grams per capita: 51 ± 25 (95% C.I.)
Production Plants[d]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	1,316	$6
20–99 employees	507	$14
100–499 employees	281	$1,378
500+ employees	61	$11,721

Notes

[a]Estimated from USDA/ERS Fruit and Tree Nut Yearbook and Vegetables and Melons Yearbook.

[b]Estimated using CDC site http://wwwn.cdc.gov/foodborneoutbreaks

[c]Estimated using NHANES dietary recall data.

[d]Estimated using Dun & Bradstreet data.

Table C-3. Dairy Products

	Assumptions and Data
Foods Included	Milk, butter, cheese, ice cream, yogurt, and other dairy products; also includes dry, condensed, and evaporated dairy products. Excludes raw milk beverages.
Nature of Products	The primary ingredient in all dairy products is milk (from cows, sheep, or goats). Most dairy products must be refrigerated or frozen, and do not require cooking. Dairy products can be aged or fresh; liquid, semi-solid, or solid; produced from pasteurized or non-pasteurized milk; and may have added non-dairy ingredients or cultures, flavorings, and inhibitors.
Types of Packaging	Plastic jugs and bottles, glass bottles, aseptic cartons, tubs, plastic sheets, molded plastic
Estimated Imports[a]	2% of consumption (2008)
Reported Outbreaks, 2000–2008[b]	Number of outbreaks: 294 Number of individuals affected by outbreaks: 8,489
Estimated Consumption[c]	Daily grams per capita: 218 ± 8 (95% C.I.)
Production Plants[d]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	2,871	$3
20–99 employees	726	$26
100–499 employees	399	$1,420
500+ employees	30	$9,989

Notes

[a]Estimated from USDA/ERS Livestock, Dairy, and Poultry Outlook.

[b]Estimated using CDC site http://wwwn.cdc.gov/foodborneoutbreaks

[c]Estimated using NHANES dietary recall data.

[d]Estimated using Dun & Bradstreet data.

Table C-4. Dry (Low Moisture) Foods

	Assumptions and Data
Foods Included	Cereals, dry mixes, breads, bakery products, chips and crackers, dried fruit, salted and roasted nuts, noodles, tea and chocolate. Includes nuts and nut products, including nut butters, and dry vegetable protein products.
Nature of Products	Dried products are made with major ingredients such as milled wheat and corn. Dry foods are mostly solids and are shelf stable. Some dried products (e.g., bread, chips, and crackers) can be consumed directly from the package, while some (e.g., noodles) are typically cooked before consumption and still others (e.g., dry mixes) require additional ingredients such as water, milk, and/or eggs before cooking.
Types of Packaging	Outer paperboard carton with inner liner made of high-density polyethylene (HDPE) film and various types of single and multiple layer plastic bags
Estimated Imports	*Not available*
Reported Outbreaks, 2000–2008[a]	Number of outbreaks: 423 Number of individuals affected by outbreaks: 11,913
Estimated Consumption[b]	Daily grams per capita: 143 ± 27 (95% C.I.) (Consumption estimate includes water weight for cooked foods but excludes prepared flour used as ingredient in recipes.)
Production Plants[c]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	5,115	$2
20–99 employees	1,586	$8
100–499 employees	931	$316
500+ employees	88	$18,259

Notes

[a]Estimated using CDC site http://wwwn.cdc.gov/foodborneoutbreaks

[b]Estimated using NHANES dietary recall data.

[c]Estimated using Dun & Bradstreet data.

Table C-5. Food Additives

	Assumptions and Data
Foods Included	Examples include herbs and spices, flavorings, preservatives, colorings, synthetic sweeteners, thickeners and texturizers, yeast, fat replacers, and added vitamins and minerals. Also includes minor ingredients.
Nature of Products	Additives can be natural or artificial and can be liquid or dry products. Direct food additives are those added to food for a specific functional purpose in that food.
Types of Packaging	Food additives are typically packaged in bulk for use by food processors, but some food additives are packaged for use by consumers in a wide variety of packaging (e.g., baking soda, yeast, and flavorings).
Estimated Imports	*Not available*
Reported Outbreaks, 2000–2008	Number of outbreaks: *Not available* Number of individuals affected by outbreaks: *Not available*
Estimated Consumption	Daily grams per capita: *Not available*
Production Plants[a]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	1,606	$32
20–99 employees	459	$260
100–499 employees	166	$722
500+ employees	22	$3,050

Note: Number of plants is likely overestimated because food additives cannot be identified separately in the industry code for "Industrial Organic Chemicals, Not Elsewhere Classified."

Notes

[a]Estimated using Dun & Bradstreet data.

Table C-6. Fresh Produce

	Assumptions and Data
Foods Included	Minimally processed fruits and vegetables
Nature of Products	Fresh produce is perishable and, with the exception of nuts, not generally shelf stable. It can be consumed raw or cooked. Fresh produce may be washed and is minimally processed before it is packed (for example, cut, peeled, diced).
Types of Packaging	Plastic bags, cardboard boxes, plastic clam shells
Estimated Imports[a]	Fresh fruit (2009): 47% of consumption Fresh vegetables (2009): 23% of consumption Tree nuts (2009): 41% of consumption
Reported Outbreaks, 2000–2008[b]	Number of outbreaks: 1,244 Number of individuals affected by outbreaks: 44,788
Estimated Consumption[c]	Daily grams per capita: 151 ± 141 (95% C.I.)
Production Plants[d]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	874	$1
20–99 employees	187	$7
100–499 employees	77	$209
500+ employees	9	*Not available*

Note: Number of plants is substantially underestimated using Dun & Bradstreet data. The reliability of the average annual sales estimates is unknown.

Notes

[a]Estimated from USDA/ERS Fruit and Tree Nut Yearbook and Vegetables and Melons Yearbook.

[b]Estimated using CDC site http://wwwn.cdc.gov/foodborneoutbreaks

[c]Estimated using NHANES dietary recall data.

[d]Estimated using Dun & Bradstreet data.

Table C-7. Frozen Foods

	Assumptions and Data
Foods Included	Frozen fruits, vegetables, and bakery products; prepared foods such as frozen dinners and pizza; and ice
Nature of Products	Must be stored frozen to avoid spoilage and pathogen growth. Some frozen products are intended to be heated for quality or food safety purposes, while others such as frozen fruits and bakery products can be consumed without further preparation.
Types of Packaging	Plastic bags and overwraps, paperboard cartons
Estimated Imports[a]	Frozen fruit (2008): 32% of consumption Frozen vegetables (2000–2008): 27% of consumption (Import estimates are not available for the other foods.)
Reported Outbreaks, 2000–2008[b]	Number of outbreaks: 64 Number of individuals affected by outbreaks: 2,199
Estimated Consumption[c]	Daily grams per capita: 26 ± 17 (95% C.I.) (Consumption estimate excludes ice.)
Production Plants[d]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	1,419	$4
20–99 employees	503	$8
100–499 employees	210	$1,177
500+ employees	45	$8,506

Notes

[a]Estimated from USDA/ERS Fruit and Tree Nut Yearbook and USDA/ERS Vegetables and Melons: Trade.

[b]Estimated using CDC site http://wwwn.cdc.gov/foodborneoutbreaks

[c]Estimated using NHANES dietary recall data.

[d]Estimated using Dun & Bradstreet data.

Table C-8. Milled & Pressed Foods

	Assumptions and Data
Foods Included	Flours, grains, rice, meal products, and plant (e.g., vegetable, nut, seed) oils, including olive and sunflower oil. Excludes wild rice.
Nature of Products	Crops that are milled into flour and oil are used as ingredients in processed food products and in recipes prepared by consumers. Milled foods are generally shelf stable. When used as ingredients by food processors, milled foods are shipped in bulk.
Types of Packaging	Paper and plastic bags and plastic and glass bottles for consumer products
Estimated Imports[a]	Wheat (2009/10): 10% of consumption Rice (2009/10): 15% of consumption Soybean oil: 0% of consumption Cottonseed oil: 0% of consumption Corn oil (2009): 2% of consumption
Reported Outbreaks, 2000–2008[b]	Number of outbreaks: 237 Number of individuals affected by outbreaks: 3,700
Estimated Consumption[c]	Daily grams per capita: Not available except for rice, which is 17 ± 8 (95% C.I.)
Production Plants[d]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	738	$2
20–99 employees	338	$22
100–499 employees	121	$257
500+ employees	16	$53,545

Notes

[a]Estimated from USDA/FAS Market & Trade Data and USDA/ERS Rice Yearbook and Oil Crops Yearbook.

[b]Estimated using CDC site http://wwwn.cdc.gov/foodborneoutbreaks

[c]Estimated using NHANES dietary recall data.

[d]Estimated using Dun & Bradstreet data.

Table C-9. Sugars & Sweets

	Assumptions and Data
Foods Included	Cane and beet sugar, syrups (e.g., maple, corn), candy, and chewing gum
Nature of Products	Natural sugar or artificial sweeteners are a primary ingredient in this category. Sugars and sweets are mostly solids, although syrups are a liquid. Most products are shelf stable.
Types of Packaging	Paper and plastic pouches or wraps
Estimated Imports[a]	Sugar (2010): 23% of consumption
Reported Outbreaks, 2000–2008[b]	Number of outbreaks: 98 Number of individuals affected by outbreaks: 2,373
Estimated Consumption[c]	Daily grams per capita: 13 ± 8 (95% C.I.) (Consumption is underestimated because it excludes sugar consumed as an ingredient in recipes.)
Production Plants[d]	

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	2,838	$0.5
20–99 employees	374	$5
100–499 employees	195	$50
500+ employees	47	$3,107

Notes

[a]Estimated from USDA/ERS Sugar and Sweeteners Yearbook.

[b]Estimated using CDC site http://wwwn.cdc.gov/foodborneoutbreaks

[c]Estimated using NHANES dietary recall data.

[d]Estimated using Dun & Bradstreet data.

Table C-10. Animal Feed / Pet Food

	Assumptions and Data
Foods Included	Animal feed for chickens, turkeys, cows, pigs, sheep, and fish and pet food for cats, dogs, and horses; includes pet treats.
Nature of Products	Animal feed and pet food are dry or canned, and are shelf stable. Feed ingredients might include grains, milling byproducts, added vitamins, minerals, fats/oils, and other nutritional and energy sources. Pet food might include meat, poultry, and grains.
Types of Packaging	Animal feed is often shipped in bulk or in large plastic or paper bags; pet food is sold in paper and plastic pouches and tin cans
Estimated Imports	While ingredients may be imported, the vast majority of animal feed and pet food used in the US is manufactured domestically.
Reported Outbreaks, 2000–2008	*Not available*
Estimated Consumption	*Not available*

Production Plants—Animal Feed[a]

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	1,307	$6
20–99 employees	470	$40
100–499 employees	67	$222
500+ employees	14	$20,043

Production Plants—Pet Food[a]

Size	No. of Plants	Average Annual Sales (Millions)
<20 employees	367	$0.4
20–99 employees	95	$8
100–499 employees	39	$48
500+ employees	7	$7,796

Notes

[a]Estimated using Dun & Bradstreet data.

EXPERT ELICITATION WORKSHEET
FOODBORNE ILLNESS ATTRIBUTION FOR THE FOOD SAFETY MODERNIZATION ACT

The overall purpose of this expert elicitation is to provide information to the Food and Drug Administration (FDA) to address foodborne illness attribution for the Food Safety Modernization Act. Under the Act, FDA must conduct a study that addresses the following two areas:

- the incidence of foodborne illness originating from each size and type of operation and the type of food facilities for which no reported or known hazard exists
- the effect on foodborne illness risk associated with commingling, processing, transporting, and storing food and raw agricultural commodities, including differences in risk based on scale and duration of such activities

Because the data to address these requirements are not available from published sources or existing databases, estimates are being obtained through this expert elicitation. We are asking you to provide values based on your experience and knowledge following an open discussion of each question. In the study report, you will be identified as a participant in the panel, but your specific responses will be aggregated with those of the other panel participants.

For this exercise, FDA has identified the following product categories and processing establishment sizes:

Product categories:

- Beverages
- Canned Foods
- Dairy Products
- Dry (Low Moisture) Foods
- Food Additives
- Fresh Produce
- Frozen Foods
- Milled Products
- Refrigerated Foods[16]
- Sugars & Sweets
- Animal Feed/Pet Food

[16] The Refrigerated Foods category was added on the day of the expert elicitation, at the suggestion of the experts.

Processing establishment sizes:

- Fewer than 20 employees
- 20–99 employees
- 100–499 employees
- 500 or more employees

DEFINITIONS

Commingling—(1) to combine product harvested on different days or from different growing areas (most common), or (2) to combine same product (and form) from containers with different container codes or different production lots, including rework.

Processing—making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. (Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, distilling, acidification, fermentation, labeling, or packaging.) This excludes processing that occurs on the farm.

Storage—holding of food ingredients and finished food products at all stages, including warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Transporting—movement of food ingredients or finished food products and loading, unloading, or storage incidental to the movement of food ingredients or finished food products. It includes all stages of shipping from the farm to initial processing, to ingredient manufacturing, to final product manufacturing, to a distribution center or warehouse, and to a retail establishment (grocery store, restaurant, or institution).

Mortality—number of deaths in a year attributable to a product.

Morbidity—number of people who suffer adverse health effects (illnesses or injuries) in a year that are at least serious enough to affect quality of life attributable to a product.

Number of Foodborne Illness Cases—total cases, including reported and unreported, of mortality and morbidity attributable to a product.

Foodborne Illness Severity—total reduction in quality of life, accounting for number of reported and unreported cases, severity of illness, and duration of illness, attributable to a product.

Duration of Activity—length of time from when food ingredients or finished food products begin an activity to when those products end the activity. For example, in processing, the duration of activity is the length of time from when the ingredients for a food product are added to the process when the final product is packaged. In transportation, the duration of activity is the length of time that the food ingredient or finished food product is loaded on a truck until it is unloaded at its destination.

Scale of Activity—relative volume of product handled during an activity. For example, it might refer to operating capacity of a processing establishment, storage warehouse, or truck used for hauling.

Note: Product definitions are provided in the Product Fact Sheets.

ASSUMPTIONS

In providing your estimates, please use the following assumptions to ensure that all panelists are responding in a similar context:

- **Consider average recent year**—Base your estimates on your knowledge of foodborne illness cases, outbreaks, and recalls for an average year over the past decade (approximately 2001–2011).
- **Include all sources of unintentional contamination**—Provide responses based on illnesses associated with any biological, chemical, radiological, or physical agent that is reasonably likely to cause morbidity or mortality in the absence of its control. This also includes allergens such as milk, egg, wheat, fish, crustacean shellfish, soybeans, peanuts, and tree nuts.
- **Exclude intentional contamination**—Provide responses based only on unintentional contamination of food; in other words, we are excluding bioterrorism or other intentional contamination events.
- **Aggregate all stages after the farm and before retail**—Provide responses based on aggregate foodborne illnesses associated with all stages of processing and preparation of food ingredients and finished food products after leaving the farm through warehousing or distribution centers; that is, exclude foodborne illnesses associated with farm-level production, food retailing, restaurants/foodservice, and home preparation. Assume that the product leaves the farm with whatever level of contamination is typical and that the product is handled at retail or by consumers using whatever practices are typical.
- **Aggregate all populations**—Provide responses based on aggregate foodborne illnesses for all populations, including adults, children, elderly, and other vulnerable populations.
- **Aggregate domestic production and imports**—Provide responses based on aggregate product volume for domestic and imported product, assuming the typical distribution of sources of the food in the marketplace.

BACKGROUND INFORMATION

1. Please indicate your level of experience or knowledge of the following:

Food	Level of Experience/Knowledge		
Beverages	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Canned & Preserved Foods	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Dairy Products`	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Dry Foods	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Food Additives	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Fresh Produce	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Frozen Foods	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Milled Products	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Sugars & Sweets	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Animal Feed	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
Pet Food	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive

2. Please indicate your level of experience or knowledge of the following for any type of food product:

Establishment Size	Level of Experience/Knowledge		
Fewer than 20 employees	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
20–99 employees	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
100–499 employees	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive
500 or more employees	☐ 1 Minimal / none	☐ 2 Moderate	☐ 3 Extensive

Notes & Comments:

FOOD PRODUCT RANKING

3. Based on your experience and knowledge, rank the food categories by their contributions to the annual number of cases of foodborne illness and severity of foodborne illness (morbidity and mortality combined).[17]

   (Assign 1 = highest number or severity to 10 = lowest number or severity. Please use each number only once in each column.)

Food Category	Total No. of Foodborne Illness Cases	Foodborne Illness Severity
Beverages		
Canned Foods		
Dairy Products		
Dry (Low Moisture) Foods		
Food Additives		
Fresh Produce		
Frozen Foods		
Milled Products		
Refrigerated Foods		
Sugars & Sweets		

Notes & Comments:

[17] Note that based on input from the experts during the in-person meeting, they provided responses for animal feed and pet food as an addendum to this table rather than as a separate exercise in question 10.

ESTABLISHMENT SIZE RANKING

4. Based on your experience and knowledge, rank the contribution of each establishment size, by food category, to the annual number of cases of foodborne illness.

(Assign 1 = highest number of cases to 4 = lowest number of cases. Please use each number only once in each column.)

Establishment Size	Beverages	Canned Foods	Dairy Products	Dry (Low Moisture) Foods	Food Additives	Fresh Produce	Frozen Foods	Milled Foods	Refrigerated Foods	Sugars & Sweets
Fewer than 20 employees										
20–99 employees										
100–499 employees										
500 or more employees										

Notes & Comments:

NO REPORTED OR KNOWN HAZARD

5. For each food, indicate your level of agreement with the statement that no reported or known hazard exists.

Food Category	Level of Agreement				
Beverages	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Canned Foods	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Dairy Products	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Dry (Low Moisture) Foods	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Food Additives	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Fresh Produce	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Frozen Foods	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Milled Products	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Refrigerated Foods	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Sugars & Sweets	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree

Notes & Comments:

ATTRIBUTION BY ACTIVITY

6. For each food, provide an estimated percentage of annual number of cases of foodborne illness likely attributable to each of the following activities. *If you enter a percentage in the "all other" column, please write in at least one activity associated with the estimated percentage.*

Food Category	Commingling	Processing	Transporting	Storing	All Other	Describe "All Other"	Total
Beverages	%	%	%	%	%		100%
Canned Foods	%	%	%	%	%		100%
Dairy Products	%	%	%	%	%		100%
Dry (Low Moisture) Foods	%	%	%	%	%		100%
Food Additives	%	%	%	%	%		100%
Fresh Produce	%	%	%	%	%		100%
Frozen Foods	%	%	%	%	%		100%
Milled Products	%	%	%	%	%		100%
Refrigerated Foods	%	%	%	%	%		100%
Sugars & Sweets	%	%	%	%	%		100%

Notes & Comments:

SCALE & DURATION OF ACTIVITY

7. Across all foods combined, indicate the importance of the scale of activity in contributing to the number of cases of foodborne illness. In other words, does larger scale (or volume) of activity contribute to more cases of foodborne illness?

Activity	Contribution of "Scale of Activity" to Number of Cases of Foodborne Illness				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

8. Across all foods combined, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?[18]

Activity	Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

[18] Based on feedback from the experts during the in-person meeting, this question was broken out by food category (shown following this original set of questions). They did not provide responses to the combined question.

ANIMAL FEED & PET FOOD

9. For each product and population, indicate your level of agreement with the statement that no reported or known hazard exists from exposure to animal feed and pet food.

Product by Population	Level of Agreement				
Human Illness from Animal Feed	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Human Illness from Pet Food	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Animal Illness from Animal Feed	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree
Animal Illness from Pet Food	☐ 1 Strongly disagree	☐ 2 Disagree	☐ 3 Neutral	☐ 4 Agree	☐ 5 Strongly agree

Notes & Comments:

10. Relative to each of the food categories included in this exercise, how similar is the degree to which exposure to animal feed and pet food contributes to illness in humans?[19]

Food Category	Contribution of Exposure to Animal Feed and Pet Food to Human Illness Compared to Each Food				
Beverages	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Canned Foods	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Dairy Products	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Dry (Low Moisture) Foods	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Food Additives	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Fresh Produce	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Frozen Foods	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Milled Products	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Refrigerated Foods	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more
Sugars & Sweets	☐ 1 Substantially less	☐ 2 Somewhat less	☐ 3 About the same	☐ 4 Somewhat more	☐ 5 Substantially more

Notes & Comments:

[19] Based on feedback from the experts during the in-person meeting, the experts provided their responses within question 3 rather than in this separate table.

11. For each product, provide an estimated percentage of annual number of cases of foodborne illness in animals likely attributable to each of the following activities.

If you enter a percentage in the "all other" column, please write in at least one activity associated with the estimated percentage.

Category	Commingling	Processing	Transporting	Storing	All Other	Describe "All Other"	Total
Animal Illness from Animal Feed	%	%	%	%	%		100%
Animal Illness from Pet Food	%	%	%	%	%		100%

Notes & Comments:

8a. For **beverages**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?[20]

Activity	Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

[20] This question was broken out separately by food category based on the feedback from the experts during the in-person meeting.

8b. For **canned foods**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

8c. For **dairy foods**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	**Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness**				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

8d. For **dry (low moisture) foods**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

8e. For **food additives**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	**Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness**				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

8f. For **fresh produce**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

8g. For **frozen foods**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	**Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness**				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

8h. **For milled and pressed foods**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

8i. For **refrigerated foods**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	**Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness**				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments:

8j. For **sugars and sweets**, indicate the importance of duration of activity in contributing to the number of cases of foodborne illness. In other words, does longer duration of activity contribute to more cases of foodborne illness?

Activity	Contribution of "Duration of Activity" to Number of Cases of Foodborne Illness				
Commingling	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Processing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Transporting	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Storing	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important
Other (specify):_____	☐ 1 Not at all important	☐ 2 Somewhat important	☐ 3 Important	☐ 4 Very important	☐ 5 Extremely important

Notes & Comments: