July 2001

Analysis of Hazard Analysis Critical Control Point (HACCP) Survey Data

Final Report

Prepared for

Dr. David J. Zorn
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Economic Analysis Branch
Room 1058 Switzer Bldg.
200 C Street, SW
Washington, DC 20204

Prepared by

Mary K. Muth
Shawn A. Karns
Donald W. Anderson
Research Triangle Institute
Center for Economics Research
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1 Introduction

The Food and Drug Administration (FDA) is placing increasing emphasis on the use of Hazard Analysis and Critical Control Point (HACCP) systems to ensure the safety of foods. As a first step toward establishing HACCP as the preferred system for controlling foodborne risks, FDA finalized a rule in December 1995 requiring all seafood processors to implement HACCP by December 1997. Since that time, FDA has been considering HACCP requirements for juice plants.

Over a number of years, Research Triangle Institute (RTI), under contract with FDA, conducted studies to estimate the costs of implementing HACCP in food plants under FDA jurisdiction. The purpose of these studies was to determine the state of current food safety practices in the food processing industry and estimate the costs of moving from the pre-HACCP baseline to regulatory compliance. The project was conducted in the following three phases:

- Phase I: Collection of data on the 17,000 plants under FDA jurisdiction
- Phase II: Development of the costs of individual HACCP practices
- Phase III: Collection of data on baseline industry HACCP practices

Because the nature of the analyses required by FDA changes over time, the data collected from these efforts are most useful in a flexible analysis tool. Thus, the purpose of this task is two-fold:

- to provide a final report on the outcome of the three phases of the overall project, and

- to provide a Microsoft Access tool that combines the data from the three phases of the overall project and that can be used to analyze the effects of various regulatory options related to HACCP.

This report is organized as follows. Section 2 describes the results of the survey on HACCP practices in plants under FDA jurisdiction (Phase III) and includes a brief description of the sampling frame used to conduct the survey (from Phase I). Section 3 describes the results of the HACCP cost data collection process (from Phase II). Finally, Section 4 describes the interactive Microsoft Access tool that combines the data from the three phases of the project.

2 Results of the HACCP Practices Survey

In 1998, RTI administered a survey on HACCP practices to food processing plants in six industry segments under FDA jurisdiction. In this section, we describe the sample design, survey administration procedures, and selected summary statistics from the survey. These survey responses are incorporated, along with the HACCP cost data described in Section 3, into an Access database described in Section 4.

2.1 SAMPLE DESIGN

In this section, we describe the universe for the survey, the sample stratification, and the sample allocation.

2.1.1 Survey Universe

The universe for the survey is defined as the 13,060 establishments or plants in FDA's Official Establishment Inventory (OEI) database that manufacture or repackage food products for human consumption in the United States under FDA jurisdiction, with the exception of the seafood industry, for which a HACCP cost analysis has already been conducted.[1] Food importers and foreign processors are not part of the sampling frame, except for food importers that also either manufacture or repack.

[1]This universe excludes 179 plants contacted during the 1995 pretest, 6 plants contacted for cost data collection, and 619 plants identified by American Business Lists (ABL) that no longer exist.

To facilitate the sample design and selection, we supplemented the OEI database with some additional variables from American Business Lists (ABL).[2] We matched names and addresses of plants from the OEI database with plant and corporate parent company names and addresses from ABL and added to the OEI database the primary SIC code, number of employees, and annual revenue of the plant. We used the SIC codes to identify establishments that, although they are in the OEI database as manufacturers or repackers of a relevant product, are primarily retail establishments that will be exempt from HACCP. We used the employment and revenue data from ABL to identify small and large businesses according to SBA size standards for each four-digit SIC code.

2.1.2 Sample Stratification

The primary purpose of stratification is to ensure that substantive differences in key outcomes between population subdivisions are detected with acceptable statistical power. In this case, establishment size and industry are population subdivisions of particular interest because these characteristics will be important factors influencing the cost of HACCP.

We stratified the universe of 13,060 establishments into 47 food industries, or substrata, and grouped them into six broader food industry categories, or superstrata. These superstrata represent groupings of similar food industries identified by their primary four-digit SIC codes as follows:

1. Premarket Services and Other Products- agricultural services, crop preparation, animal feeds, wholesale groceries, and food warehousing
2. Animal Protein Products- meat and poultry processing and dairy products
3. Preserved/Additive/Supplement Products- canned, frozen, or dried fruits, vegetables, and other products and dietary supplements
4. Cereals/Grains/Baked Products- flour mills and plants that produce bread, pasta and other noodle products, nuts, snacks, and vegetable oils
5. Beverages/Sugared Products- cane and beet sugar, cane sugar refining, candy and chewing gum, alcoholic

[2]American Business Lists is now known as infoUSA.

beverages, bottled and canned soft drinks, flavorings, extracts, syrups, roasted coffee, ice

6. Products for Sensitive Consumers- baby food, infant formula, geriatric foods

Each of the six superstrata were stratified further into two size categories, plants owned by small companies and plants owned by large companies, resulting in 12 sampling strata. Because FDA is particularly interested in superstratum 6- Products for Sensitive Consumers- we surveyed all of the plants in this superstratum.

Table 2-1 shows the number of establishments or plants in the sampling universe by the 12 sampling strata. Appendix A describes in greater detail the industry and size stratification.

Table 2-1. Survey Universe, by Sampling Strata

	Number of Plants	
	Large	**Small**
Premarket Services and Other Products	697	3,565
Animal Protein Products	309	1,193
Preserved/Additive/Supplement Products	420	1,914
Cereals/Grains/Baked Products	445	1,972
Beverages/Sugared Products	519	1,980
Products for Sensitive Consumers	25	21
Subtotal	2,415	10,645
Total	13,060	

2.1.3 Sample Allocation

Our targeted number of respondents was 1,231. Our sample allocation was designed to yield 240 respondents from five of the six superstrata. The final superstratum, Products for Sensitive Consumers, was censused. Within each superstratum, we allocated the sample to maximize detectable differences between small and large establishments. Before selecting the sample, we sorted the frame by type of industry (the 47 substrata) within each sampling stratum. Then we selected a stratified systematic sample so that industries were proportionally represented within each superstratum/size combination.

Table 16 of the ICR assumed full-scale survey interviewing would begin early in 1997. When survey initiation was delayed approximately 1 year, we anticipated that some sampled firms would have now gone out of business or changed their operations and would no longer be a part of the eligible population for the study. Also, we felt the contact and response rates hypothesized in the ICR were the best possible rates the survey might experience. We initially assumed that we would be able to contact approximately 90 percent of large establishments and 80 percent of small establishments. Among those contacted, we assumed that approximately 80 percent of large and 75 percent of small establishments would complete the survey. These assumptions were based on previous survey experience with establishment samples drawn from lists provided by ABL.

Consequently, we estimated the worst contact and response rates we felt the study might attain and selected a much larger sample, which was divided into 10 waves in each superstratum. Thus, if the actual sample yield was between our best and worst assumptions, we could assign as many of the 10 waves as needed to obtain the desired number of completed interviews.

Initially, five waves were assigned for interviewing in each of the large superstrata and four waves were assigned in each of the small superstrata for an initial sample of 1,785 establishments or plants. Additional waves were released as the survey interviewing progressed; ultimately seven waves were used in each of the superstrata for a final sample size of 2,895 establishments or plants. Table 2-2 shows the initial and final sample sizes by sampling strata.

As we discuss later, more than one-third of the sampled plants were ineligible for the survey, and the contact and response rates for the eligible plants were close to our worst pre-survey assumptions. As a result of these factors, the number of completed interviews was considerably less than initially planned but still sufficient for most of the planned tabulations and analyses.

2.2 SURVEY ADMINISTRATION

In this section, we describe the survey administration procedures and present the survey response rates.

Table 2-2. Initial and Final Sample Sizes, by Sampling Strata

	Number of Plants			
	Initial Sample		Final Sample	
	Large	Small	Large	Small
Premarket Services and Other Products	130	212	182	371
Animal Protein Products	95	256	133	448
Preserved/Additive/Supplement Products	105	244	147	427
Cereals/Grains/Baked Products	110	240	154	420
Beverages/Sugared Products	115	232	161	406
Products for Sensitive Consumers	25	21	25	21
Subtotal	580	1,205	802	2,093
Total	1,785		2,895	

2.2.1 Survey Procedures

We pretested the survey instrument from Monday, December 1, through Monday, December 22, 1997, with a sample of 100 plants selected from RTI's Enhanced Establishment Database (EED). Based on the pretest, we made some minor revisions to the survey instrument and recruiting script. We conducted the full-scale interviewing over a 15-week period from January 27, 1998 through May 15, 1998.

Gordon S. Black Corporation (GSBC), as a subcontractor to RTI, conducted the full-scale survey using the three-step procedure described below.

First, establishments in the sample were called and screened for eligibility. Establishments had to meet the following criteria to be eligible for the survey:

- The plant must manufacture or repack food product for human consumption.
- The plant's primary industry classification must be from the 47 industries in the study.

If eligible, an appropriate contact person (e.g., plant manager, HACCP team leader, or QA manager) was identified and asked to participate in the survey. If the contact person agreed to participate, a date and time was scheduled for the follow-up telephone interview.

Next, GSBC mailed an introductory packet to those establishments recruited. The introductory packet included a cover letter on RTI letterhead, an information sheet, cue sheets to refer to during the telephone interview, and a list of definitions.

Finally, GSBC called respondents back at the scheduled time to conduct the follow-up telephone interview. On average, the follow-up telephone interview lasted about 30 minutes.

2.2.2 Survey Response

We completed a total of 595 interviews- 199 with large plants and 396 with small plants. Table 2-3 shows the number of completed interviews by sampling strata.

Table 2-3. Number of Completed Interviews, by Sampling Strata

	Number of Plants		
	Large	**Small**	**Total**
Premarket Services and Other Products	50	63	113
Animal Protein Products	40	90	130
Preserved/Additive/Supplement Products	45	88	133
Cereals/Grains/Baked Products	32	74	106
Beverages/Sugared Products	24	75	99
Products for Sensitive Consumers	8	6	14
Total	199	396	595

Table 2-4 presents the final disposition of the sample and the response rates by sampling strata. We present this information separately for the initial telephone interview and the follow-up telephone interview. For the initial telephone interview, we assigned each sample point a disposition of *recruit*, *refusal*, or *ineligible*. In the following cases, eligibility status could not be determined:

- The sample point was never contacted after eight call attempts or was contacted but did not complete the screening questions (e.g., the individual identified as the contact person was not available or asked to be called back).

Table 2-4. Final Disposition of Sample and Response Rates, by Sampling Strata

	Premarket Services and Other Products		Animal Protein Products		Preserved/ Additive/ Supplement Products		Cereals/ Grains/ Baked Products		Beverages/ Sugared Products		Products for Sensitive Consumers		Total		
	Large	Small	Large	Small	Large	Small	Large	Small	Large	Small	Large	Small	Large	Small	Total
Initial Telephone Interview															
Recruits	85	112	79	174	70	166	76	146	70	141	15	8	395	747	1,142
Refusals	45	88	30	105	32	100	44	107	45	113	6	4	202	518	719
Ineligibles	52	171	24	169	45	161	34	167	46	152	4	9	205	828	1,034
Total Sample	182	371	133	448	147	427	154	420	161	406	25	21	802	2,093	2,895
Eligibility Rate (%)	71.4	53.9	82.0	62.3	69.4	62.3	77.9	60.2	71.4	62.6	84.0	57.1	74.4	60.4	64.3
Recruitment Response Rate (%)	65.4	56.0	72.5	62.4	68.6	62.4	63.3	57.7	60.9	55.5	71.4	66.7	66.2	59.1	61.4
Follow-up Telephone Interview															
Respondents	50	63	70	90	45	88	32	74	24	75	8	6	199	396	595
Nonrespondents	35	49	39	84	25	78	44	72	46	66	7	2	196	351	547
Total Recruits	85	112	79	174	70	166	76	146	70	141	15	8	395	747	1,142
Survey Response Rate (%)	58.8	56.3	50.6	51.7	64.3	53.0	42.1	50.7	34.3	53.2	53.3	75.0	50.4	53.0	52.1
Overall Response Rate (%)	38.5	31.5	36.7	32.3	44.1	33.1	26.7	29.2	20.9	29.5	38.1	50.0	33.3	31.3	32.0

- The sample point was contacted but refused to participate prior to answering the screening questions.
- The sample point was contacted but there was a language barrier.

For sample points where the eligibility status was unknown, we estimated the proportion of eligibles among known eligibles and ineligibles and used this proportion to distribute the unknowns between eligibles (i.e., refusals) and ineligibles.

The "ineligibles" disposition includes the following:

- sample points that did not meet the screening criteria (e.g., plant does not manufacture or repack food product for human consumption),
- sample points for which a telephone number was not available from directory assistance,
- sample points for which the telephone number was disconnected,
- duplicates- sample points with the same facility address and telephone number,
- sample points that were contacted but were out of business, and
- a percentage of the sample points for which the eligibility status was unknown.

Recruits are those sample points that completed the initial telephone interview, agreed to participate, and then were scheduled for a follow-up telephone interview. Refusals are those sample points that were eligible for the survey but declined to participate (includes a percentage of the sample points for which the eligibility status was unknown).

The eligibility rate- the proportion of the total sample that was eligible for the survey- is calculated as follows:

$$\text{Eligibility Rate} = \frac{\text{Recruits}_{\text{Initial}} + \text{Refusals}_{\text{Initial}}}{\text{Total Sample}} \qquad (2.1)$$

The eligibility rate for all plants was 64 percent. This means that 64 percent, or 1,861 of the 2,895 sample points, met the eligibility criteria for participating in the survey. For large plants, the overall eligibility rate was 74 percent. The eligibility rates for each industry category ranged from 69 to 84 percent. For small plants, the overall eligibility rate was 60 percent, while the eligibility rates for each industry category ranged from 54 to 63 percent. The

majority of ineligibles were sample points that did not manufacture or repack food product for human consumption.

The recruitment response rate for the initial telephone survey- the proportion of the total number of eligible sample points that agreed to participate and scheduled a follow-up telephone interview- is calculated as follows:

$$\text{Recruitment Response Rate} = \frac{\text{Recruits}_{\text{Initial}}}{\text{Recruits}_{\text{Initial}} + \text{Refusals}_{\text{Initial}}} \qquad (2.2)$$

The recruitment response rate for all plants was 61 percent. For large plants, the recruitment response rate ranged from 61 to 73 percent, with a recruitment response rate of 66 percent for all large plants. For small plants, the recruitment response rate ranged from 56 to 67 percent, with a recruitment response rate of 59 percent for all small plants.

For the follow-up telephone interview, we assigned each sample point recruited for the follow-up telephone interview a disposition of *respondent* or *nonrespondent*. Respondents are sample points that completed the follow-up telephone interview, and nonrespondents are sample points that were recruited for the follow-up telephone interview but did not complete it.

The survey response rate for the follow-up telephone interview- the proportion of the recruits that completed the follow-up telephone interview- is calculated as follows:

$$\text{Survey Response Rate} = \frac{\text{Respondents}_{\text{Follow-up}}}{\text{Recruits}_{\text{Initial}}} \qquad (2.3)$$

The survey response rate for all plants was 52 percent. For large plants, the survey response rate ranged from 34 to 64 percent, with a survey response rate of 50 percent for all large plants. For small plants, the survey response rate ranged from 51 to 75 percent, with a survey response rate of 53 percent for all small plants.

The overall response rate is calculated as follows:

$$\text{Overall Response Rate} = \text{Recruitment Response Rate}_{\text{Initial}} \bullet \text{Survey Response Rate}_{\text{Follow-up}} \qquad (2.4)$$

The overall response rate for all plants was 32 percent. For large plants, the overall response rate ranged from 21 to 44 percent, with

an overall response rate of 33 percent for all large plants. For small plants, the overall response rate ranged from 29 to 50 percent, with an overall response rate of 31 percent for all small plants.

Although we did not complete our targeted number of interviews, the number of completes is sufficient for most of the planned tabulations and analyses. The shortfall in the number of respondents was caused by a combination of lower-than-expected eligibility rates and response rates. Our initial estimated eligibility rates were 90 percent for large plants and 80 percent for small plants. Our actual eligibility rates were much lower- 74 percent for large plants and 60 percent for small plants. Our eligibility rates were lower than anticipated because of the age of the sampling frame due to the delay in starting the full-scale interviews and inaccuracies in the initial OEI database. Many plants were either out of business or no longer manufacture or repack food product.

Our initial estimated response rates were 80 percent for large plants and 75 percent for small plants. Our actual response rates were much lower- 33 percent for large plants and 31 percent for small plants. The unanticipated poor response rates result from the following factors:

- The contact person for the survey, especially for small plants, was often the plant manager; thus, it was difficult for him/her to find time to complete the survey.
- Concerns about the legitimacy of the survey kept some plants from responding. Although we provided the OMB number, there were instances in which the number could not be verified.
- For some plants, especially large plants, concerns about legality issues kept companies from responding to the survey. Some plants had to get clearance from their legal department to participate.
- In many cases, we were referred to a different contact person for the follow-up telephone interview; thus, we had to start the recruiting process over again (i.e., contact the appropriate person, send the information package, and make the follow-up call).

For future surveys of food processing plants, we recommend sending a prenotification or alert letter from FDA or an industry trade group prior to calling companies. This would address the legitimacy concerns of respondents. In addition, we recommend

that a contact person be identified at FDA whom respondents can call if they have questions or concerns.

2.3 SELECTED RESULTS

In this section, we present selected results of the survey.[3] All results are weighted using the final survey weights adjusted for nonresponse. The weights were computed using a two-step procedure. First, we computed initial sampling weights to reflect the different probabilities of selection induced by the sampling design (i.e., by using different sampling rates in the various strata). Next, we adjusted the initial sampling weights for nonresponse to minimize the potential bias due to survey nonresponse. We adjusted the weights by weighting class using the 12 sampling strata as weighting classes. The weighting class adjustments ensure that, within each class, respondent weights sum to the population counts of eligible establishments. These adjustments, implemented with the computation and application of adjustment factors in each class, also tend to reduce nonresponse bias to the extent that weighting classes are homogeneous.

The differences between the strata are statistically significant if their confidence intervals do not overlap. For example, if the confidence interval around the point estimate for plants owned by large companies does not overlap the confidence interval around the point estimate for plants owned by small companies, then the differences between large and small are statistically significant at the 95 percent confidence level.

We describe the results from each of the three categories of costs below (HACCP plan development, food processing, and sanitation). The complete list of questions for food processing and sanitation is provided in Appendix C.

2.3.1 HACCP Training, Planning, and Implementation

Table 2-5 shows the percentage of plants by strata that have trained their staff in HACCP procedures, conducted a hazard analysis, written a HACCP plan, or implemented a HACCP plan for at least one product. The 95 percent confidence intervals show that there

[3]The survey results were also summarized in a presentation to FDA in January 1999. The overhead slides from that presentation are provided in Appendix B.

Table 2-5. Weighted Percentage of Plants Performing HACCP Training, Planning, and Implementation Activities

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
Have you or has any member of your staff received HACCP training?												
Premarket Services and Other Products	50	68.00	55.03	80.97	62	58.06	45.75	70.38	112	60.13	49.99	70.27
Animal Protein Products	40	85.00	73.90	96.10	90	73.33	64.17	82.50	130	76.30	68.86	83.74
Preserved/Additive/Supplement Products	45	88.89	79.68	98.10	87	67.82	57.97	77.66	132	72.00	63.81	80.19
Cereals/Grains/Baked Products	32	96.88	90.83	100.00*	73	64.38	53.37	75.40	105	71.80	62.86	80.73
Beverages/Sugared Products	22	63.64	43.48	83.80	75	38.67	27.61	49.72	97	44.02	34.12	53.93
Products for Sensitive Consumers	8	75.00	44.91	100.00*	6	66.67	28.84	100.00*	14	71.94	48.28	95.60
Overall	197	78.91	72.62	85.19	393	59.07	53.70	64.44	590	63.41	58.95	67.88
Has a hazard analysis been conducted for any product at this plant?												
Premarket Services and Other Products	48	66.67	53.29	80.04	61	44.26	31.76	56.76	109	48.83	38.42	59.24
Animal Protein Products	40	82.50	70.69	94.31	88	73.86	64.66	83.07	128	76.10	68.59	83.60
Preserved/Additive/Supplement Products	45	82.22	71.02	93.43	86	55.81	45.29	66.34	131	61.11	52.27	69.95
Cereals/Grains/Baked Products	31	100.00	100.00	100.00	71	61.97	50.65	73.30	102	70.62	61.43	79.82
Beverages/Sugared Products	22	63.64	43.48	83.80	75	40.00	28.88	51.12	97	45.07	35.14	55.00
Products for Sensitive Consumers	8	87.50	64.52	100.00*	6	66.67	28.84	100.00*	14	79.84	59.08	100.00*
Overall	194	77.81	71.41	84.21	387	52.42	46.93	57.91	581	57.97	53.36	62.57

(continued)

Table 2-5. Weighted Percentage of Plants Performing HACCP Training, Planning, and Implementation Activities (continued)

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
Has a HACCP plan been written for any product at this plant?												
Premarket Services and Other Products	50	62.00	48.51	75.49	61	31.15	19.49	42.80	111	37.65	27.83	47.47
Animal Protein Products	40	85.00	73.90	96.10	89	62.92	52.86	72.99	129	68.58	60.42	76.74
Preserved/Additive/Supplement Products	44	75.00	62.17	87.83	88	39.77	29.52	50.03	132	46.58	37.72	55.45
Cereals/Grains/Baked Products	31	93.55	84.88	100.00*	73	47.95	36.45	59.44	104	58.10	48.37	67.82
Beverages/Sugared Products	23	39.13	19.13	59.13	75	25.33	15.46	35.21	98	28.40	19.46	37.34
Products for Sensitive Consumers	8	87.50	64.52	100.00*	6	50.00	9.88	90.12	14	73.71	51.03	96.40
Overall	196	69.19	62.05	76.33	392	38.60	33.38	43.83	588	45.32	40.84	49.80
Has a HACCP plan been implemented for any product at this plant?												
Premarket Services and Other Products	50	62.00	48.51	75.49	61	32.79	20.97	44.60	111	38.94	29.03	48.86
Animal Protein Products	40	80.00	67.57	92.43	88	59.09	48.79	69.39	128	64.50	56.07	72.92
Preserved/Additive/Supplement Products	45	75.56	62.96	88.15	87	40.23	29.90	50.56	132	47.25	38.36	56.13
Cereals/Grains/Baked Products	31	87.10	75.26	98.93	74	44.59	33.24	55.95	105	53.96	44.23	63.68
Beverages/Sugared Products	22	36.36	16.20	56.52	74	28.38	18.08	38.68	96	30.11	20.91	39.31
Products for Sensitive Consumers	8	87.50	64.52	100.00*	6	50.00	9.88	90.12	14	73.71	51.03	96.40
Overall	196	67.06	59.83	74.29	390	38.72	33.47	43.97	586	44.93	40.44	49.42

[a]The 95 percent confidence intervals were calculated from the standard errors. Where the calculation resulted in a confidence interval lower than zero or greater than 100 percent, we truncated the interval. These instances are indicated with an asterisk.

are statistically significant differences between the plants owned by large companies and the plants owned by small companies. For example, about 79 percent of plants owned by large companies and 59 percent of plants owned by small companies answered "yes" to the question, "Have you or has any member of your staff received HACCP training?" The confidence intervals are sufficiently tight around each point estimate (73 to 85 for large, 54 to 64 for small) so that they do not overlap. Thus, there are significant differences between large and small plants. The confidence intervals for the industry strata are not as tight, in part due to the lower number of observations. Therefore, although we observe differences between plants owned by large and small companies with respect to the point estimates within each industry strata, in most cases, the confidence intervals overlap so that we cannot say that the differences are statistically significant.

Table 2-6 provides several details regarding HACCP training and the plants' familiarity with HACCP. The survey responses indicate that for plants that have received HACCP training, the managers and quality control personnel are most often trained. In about 51 percent of the plants, production workers are also trained. Plants owned by large companies are more likely to train their production staff, but this difference is not statistically significant. The most common source of HACCP training is an industry trade group.

Fourteen percent of the plants indicated that they are very familiar with HACCP, while 19 percent indicated that they are unfamiliar with HACCP. Plants owned by large companies are more likely to rank themselves as very familiar with HACCP, while plants owned by small companies are more likely to rank themselves as unfamiliar. These differences are statistically significant.

Table 2-7 shows the distribution of responses to the question, "In what year did your plant begin to implement a HACCP plan?" The responses indicate that relatively many plants implemented HACCP during the years 1991 through 1997. This table also shows that about 51 percent of the plants that have not yet implemented HACCP have no plans to do so if FDA does not require it.

Table 2-6. Weighed Responses to Questions about Training and Knowledge

	Large				Small				All Plants			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
For plants with HACCP training, which of the following types of employees have received HACCP training?												
Managers	159	93.86	89.95	97.77	241	89.31	84.93	93.69	400	90.55	87.19	93.92
Quality Control	159	81.26	74.68	87.84	241	73.90	67.53	80.27	400	75.90	70.91	80.89
Production Workers	159	58.63	50.47	66.78	241	48.04	41.03	55.04	400	50.92	45.34	56.50
Support Staff	159	29.70	22.22	37.17	241	19.70	14.32	25.08	400	22.43	17.99	26.87
Other	159	8.05	3.40	12.71	241	2.44	0.56	4.33	400	3.97	2.08	5.86
For plants with HACCP training, which of the following were the sources of training?												
Trade Group	159	38.45	30.44	46.46	241	44.04	37.03	51.05	400	42.51	36.95	48.08
Government Agency	159	12.51	7.13	17.90	241	24.16	18.23	30.10	400	20.99	16.40	25.57
College or University	159	24.87	17.88	31.86	241	35.02	28.52	41.53	400	32.26	27.16	37.36
Consultant or Consultant Firm	159	32.72	24.98	40.45	241	27.54	21.36	33.72	400	28.95	23.98	33.93
Independent Study	159	13.91	8.33	19.49	241	36.66	29.82	43.50	400	30.46	25.14	35.78
Other	159	39.37	31.36	47.38	241	14.26	9.69	18.83	400	21.10	16.96	25.25
On a scale of 1 to 5, how would you rank your plant's familiarity with HACCP?												
1 - Unfamiliar	198	9.93	5.09	14.76	394	21.70	17.12	26.27	592	19.10	15.36	22.84
2 - Somewhat Unfamiliar	198	12.22	7.15	17.29	394	17.73	13.67	21.79	592	16.52	13.16	19.87
3 - Neither Familiar nor Unfamiliar	198	26.88	20.39	33.36	394	26.50	21.71	31.30	592	26.58	22.58	30.59
4 - Somewhat Familiar	198	30.01	23.34	36.69	394	22.45	17.99	26.91	592	24.12	20.34	27.90
5 - Very Familiar	198	20.97	15.04	26.89	394	11.62	8.14	15.09	592	13.68	10.66	16.70

[a]The 95 percent confidence intervals were calculated from the standard errors. Where the calculation resulted in a confidence interval lower than zero or greater than 100 percent, we truncated the interval. These instances are indicated with an asterisk.

Table 2-7. Weighed Responses: Year of HACCP Implementation

	Large				Small				All Plants			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
In what year did your plant begin to implement a HACCP plan?												
1953	126	0.62	0.00*	1.83	153	0.00	0.00	0.00	279	0.20	0.00*	0.58
1964	126	0.00	0.00	0.00	153	0.74	0.00*	2.18	279	0.50	0.00*	1.48
1968	126	0.00	0.00	0.00	153	0.37	0.00*	1.09	279	0.25	0.00*	0.74
1971	126	0.00	0.00	0.00	153	0.37	0.00*	1.09	279	0.25	0.00*	0.74
1972	126	0.00	0.00	0.00	153	0.60	0.00*	1.78	279	0.41	0.00*	1.22
1973	126	1.46	0.00*	4.30	153	0.00	0.00	0.00	279	0.47	0.00*	1.38
1974	126	0.00	0.00	0.00	153	0.37	0.00*	1.09	279	0.25	0.00*	0.74
1975	126	0.25	0.00*	0.75	153	1.36	0.00*	4.00	279	1.01	0.00*	2.81
1977	126	0.62	0.00*	1.83	153	0.00	0.00	0.00	279	0.20	0.00*	0.58
1978	126	0.62	0.00*	1.83	153	0.46	0.00*	1.20	279	0.51	0.00*	1.15
1979	126	1.03	0.00*	3.03	153	0.71	0.00*	2.11	279	0.81	0.00*	1.96
1980	126	0.62	0.00*	1.83	153	0.60	0.00*	1.78	279	0.61	0.00*	1.50
1981	126	1.03	0.00*	3.03	153	0.00	0.00	0.00	279	0.33	0.00*	0.97
1983	126	0.62	0.00*	1.83	153	0.71	0.00*	2.11	279	0.68	0.00*	1.71
1984	126	0.00	0.00	0.00	153	1.21	0.00*	2.87	279	0.82	0.00*	1.96
1985	126	1.55	0.00*	3.73	153	0.00	0.00	0.00	279	0.49	0.00*	1.19
1986	126	1.63	0.00*	3.95	153	0.74	0.00*	2.18	279	1.02	0.00*	2.25
1987	126	1.03	0.00*	3.03	153	1.68	0.00*	3.64	279	1.47	0.00*	2.95
1988	126	0.87	0.00*	2.18	153	1.10	0.00*	2.71	279	1.03	0.00*	2.20

(continued)

Table 2-7. Weighed Responses: Year of HACCP Implementation (continued)

	Large				Small				All Plants			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
In what year did your plant begin to implement a HACCP plan? (continued)												
1989	126	1.20	0.00*	2.87	153	2.55	0.00*	5.46	279	2.12	0.07	4.18
1990	126	2.84	0.00*	5.84	153	3.78	0.73	6.83	279	3.48	1.20	5.77
1991	126	9.53	3.78	15.27	153	6.09	2.03	10.15	279	7.18	3.86	10.51
1992	126	7.58	2.38	12.79	153	5.23	1.20	9.25	279	5.98	2.77	9.19
1993	126	8.68	4.01	13.35	153	8.49	3.82	13.17	279	8.55	5.04	12.07
1994	126	11.09	5.02	17.15	153	9.60	4.38	14.82	279	10.07	6.03	14.12
1995	126	22.10	14.44	29.75	153	15.99	9.51	22.47	279	17.94	12.89	22.99
1996	126	12.39	6.48	18.30	153	17.74	11.07	24.40	279	16.03	11.11	20.95
1997	126	11.72	5.82	17.62	153	16.86	9.77	23.94	279	15.22	10.01	20.42
1998	126	0.94	0.00*	2.79	153	2.65	0.26	5.05	279	2.11	0.38	3.84
For plants with no HACCP plan, which of the following describes your plans regarding HACCP, if the government doesn't issue HACCP regulations?												
Intend to implement a HACCP plan within the next year	57	23.39	12.22	34.55	221	28.54	22.11	34.97	278	27.84	22.08	33.61
Intend to implement a HACCP plan within the next five years	57	38.72	25.30	52.15	221	18.69	13.18	24.19	278	21.41	16.26	26.56
Have no plans to implement HACCP	57	37.89	24.34	51.44	221	52.77	45.61	59.93	278	50.75	44.27	57.23

[a]The 95 percent confidence intervals were calculated from the standard errors. Where the calculation resulted in a confidence interval lower than zero or greater than 100 percent, we truncated the interval. These instances are indicated with an asterisk.

2.3.2 Sanitation Processes

Table 2-8 shows the responses to several questions about sanitation procedures. The responses indicate that about 76 percent of the plants have a written sanitation program, but there are significant differences between plants owned by large and small companies. Similarly, about 78 percent of plants have written records that verify sanitation inspections, but plants owned by large companies are more likely to have these written records than plants owned by small companies. There are some significant differences among the industrial strata; for example, all plants in the Products for Sensitive Consumers stratum conduct both of these sanitation procedures.

2.3.3 Other Food Safety Procedures

Table 2-9 shows the weighted results for some of the questions we asked about specific food safety procedures. Most of these procedures apply only to a portion of the plants. For example, only plants with refrigerated or frozen storage were asked the question, "Does your plant monitor the total amount of time that perishable raw materials are kept at room temperature…?" This reduces the number of observations and increases the standard errors on the estimates. As a result, the differences between plants owned by large companies and plants owned by small companies are statistically significant for only the first, second, and fourth questions in Table 2-9.

2.4 REFERENCES

Martin, S.A., D.W. Anderson, B.W. Wendling, and R.C. Lindrooth. 1998. "The FDA Enhanced Establishment Database." Prepared for the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition.

Table 2-8. Weighted Percentage of Plants Performing Selected Sanitation Procedures

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
Does your plant have a written sanitation program?												
Premarket Services and Other Products	49	83.67	73.29	94.05	63	65.08	53.27	76.89	112	68.84	59.12	78.55
Animal Protein Products	40	97.50	92.65	100.00*	89	84.27	76.68	91.86	129	87.66	81.81	93.51
Preserved/Additive/Supplement Products	45	97.78	93.46	100.00*	87	78.16	69.45	86.87	132	82.06	74.94	89.18
Cereals/Grains/Baked Products	32	96.88	90.83	100.00*	72	80.56	71.39	89.72	104	84.32	77.03	91.61
Beverages/Sugared Products	24	87.50	74.23	100.00*	74	59.46	48.24	70.68	98	65.96	56.52	75.40
Products for Sensitive Consumers	8	100.00	100.00	100.00	6	100.00	100.00	100.00	14	100.00	100.00	100.00
Overall	198	91.56	87.20	95.92	391	71.65	66.61	76.70	589	76.06	71.95	80.17
Are written records available to verify sanitation inspections of the plant?												
Premarket Services and Other Products	49	77.55	65.83	89.27	62	79.03	68.87	89.19	111	78.73	70.30	87.16
Animal Protein Products	39	94.87	87.93	100.00*	88	78.41	69.79	87.03	127	82.59	75.81	89.36
Preserved/Additive/Supplement Products	44	95.45	89.28	100.00*	87	72.41	62.99	81.83	131	76.91	69.12	84.70
Cereals/Grains/Baked Products	32	100.00	100.00	100.00	71	80.28	71.00	89.56	103	84.88	77.61	92.15
Beverages/Sugared Products	24	83.33	68.38	98.29	75	61.33	50.28	72.39	99	66.38	57.03	75.74
Products for Sensitive Consumers	8	100.00	100.00	100.00	6	100.00	100.00	100.00	14	100.00	100.00	100.00
Overall	196	88.81	83.89	93.72	389	74.42	69.70	79.14	585	77.60	73.75	81.46

[a]The 95 percent confidence intervals were calculated from the standard errors. Where the calculation resulted in a confidence interval lower than zero or greater than 100 percent, we truncated the interval. These instances are indicated with an asterisk.

Table 2-9. Weighted Percentage of Plants Performing Selected Food Safety Procedures

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
Does your plant require written vendor guarantees that any raw materials and ingredients received must meet specific requirements for contamination?												
Premarket Services and Other Products	48	79.17	67.64	90.69	60	58.33	45.82	70.84	108	62.64	52.35	72.93
Animal Protein Products	39	87.18	76.66	97.70	89	71.91	62.55	81.27	128	75.75	68.18	83.32
Preserved/Additive/Supplement Products	45	93.33	86.02	100.64	86	69.77	60.03	79.50	131	74.49	66.46	82.53
Cereals/Grains/Baked Products	32	96.88	90.83	102.92	73	75.34	65.43	85.26	105	80.25	72.32	88.19
Beverages/Sugared Products	24	83.33	68.38	98.29	74	74.32	64.34	84.31	98	76.41	67.97	84.86
Products for Sensitive Consumers	8	87.50	64.52	110.48	5	100.00	100.00	100.00	13	91.58	75.79	107.37
Overall	196	87.13	82.03	92.23	387	68.64	63.45	73.83	583	72.75	68.50	77.00
Does your plant conduct scheduled sample testing for microbiological contamination of any ingredients?												
Premarket Services and Other Products	49	65.31	51.94	78.67	62	45.16	32.74	57.58	111	49.29	38.96	59.61
Animal Protein Products	39	89.74	80.19	99.29	90	76.67	67.90	85.43	129	79.93	72.87	86.98
Preserved/Additive/Supplement Products	45	53.33	38.71	67.95	88	55.68	45.27	66.09	133	55.22	46.38	64.06
Cereals/Grains/Baked Products	31	58.06	40.64	75.49	74	50.00	38.57	61.43	105	51.78	42.06	61.49
Beverages/Sugared Products	23	56.52	36.20	76.84	74	36.49	25.49	47.49	97	40.98	31.17	50.79
Products for Sensitive Consumers	8	62.50	28.86	96.14	6	83.33	53.43	113.24	14	70.16	45.66	94.65
Overall	195	63.54	56.28	70.80	394	50.21	2.77	44.78	589	53.11	48.55	57.67

(continued)

Table 2-9. Weighted Percentage of Plants Performing Selected Food Safety Procedures (continued)

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
For plants with refrigerated or frozen storage, does your plant monitor the total amount of time that perishable raw materials are kept at room temperature, that is, outside a refrigerator or freezer?												
Premarket Services and Other Products	31	54.84	37.23	72.44	39	38.46	23.12	53.81	70	41.83	29.05	54.61
Animal Protein Products	26	46.15	26.90	65.41	69	39.13	27.56	50.70	95	40.71	30.73	50.68
Preserved/Additive/Supplement Products	30	70.00	53.52	86.48	48	54.17	40.00	68.33	78	57.82	46.20	69.43
Cereals/Grains/Baked Products	21	52.38	30.91	73.85	37	48.65	32.46	64.83	58	49.68	36.55	62.81
Beverages/Sugared Products	9	33.33	2.38	64.28	30	53.33	35.39	71.27	39	48.97	33.19	64.74
Products for Sensitive Consumers	4	50.00	0.76	99.24	3	33.33	0.00*	86.94	7	43.87	6.56	81.18
Overall	121	52.86	43.42	62.30	226	45.30	38.05	52.55	347	47.04	41.04	53.04
For plants with refrigerated or frozen storage, does your plant calibrate temperature devices to NIST?												
Premarket Services and Other Products	36	72.22	57.52	86.92	40	55.00	39.51	70.49	76	58.91	46.40	71.41
Animal Protein Products	34	79.41	65.76	93.07	80	77.50	68.31	86.69	114	77.97	70.27	85.67
Preserved/Additive/Supplement Products	23	69.57	50.67	88.46	48	50.00	35.79	64.21	71	53.65	41.48	65.83
Cereals/Grains/Baked Products	18	83.33	66.04	100.00*	33	45.45	28.39	62.52	51	55.64	41.65	69.63
Beverages/Sugared Products	9	44.44	11.83	77.06	36	25.00	10.79	39.21	45	28.67	15.42	41.92
Products for Sensitive Consumers	6	100.00	100.00	100.00	4	100.00	100.00	100.00	10	100.00	100.00	100.00
Overall	126	72.14	63.59	80.68	241	52.02	44.91	59.12	367	56.57	50.68	62.45

(continued)

Table 2-9. Weighted Percentage of Plants Performing Selected Food Safety Procedures (continued)

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
For plants with dry storage, does your plant use humidity-indicating devices?												
Premarket Services and Other Products	40	17.50	5.68	29.32	46	17.39	6.40	28.38	86	17.42	8.46	26.37
Animal Protein Products	36	8.33	0.00*	17.39	77	12.99	5.45	20.52	113	11.76	5.71	17.81
Preserved/Additive/Supplement Products	41	24.39	11.20	37.58	74	17.57	8.87	26.27	115	19.00	11.58	26.42
Cereals/Grains/Baked Products	30	20.00	5.64	34.36	69	17.39	8.42	26.37	99	17.98	10.31	25.65
Beverages/Sugared Products	20	45.00	23.12	66.88	58	34.48	22.21	46.76	78	37.04	26.29	47.79
Products for Sensitive Consumers	7	42.86	6.07	79.64	6	33.33	0.00*	71.18	13	39.06	12.17	65.94
Overall	174	23.65	16.65	30.66	330	20.12	15.38	24.87	504	20.94	16.94	24.93
For plants conducting product temperature control, does the plant have an established procedure for dealing with product and operations outside the established temperature tolerance limit?												
Premarket Services and Other Products	10	100.00	100.00	100.00	11	90.91	73.68	100.00*	21	92.99	79.62	100.00*
Animal Protein Products	13	92.31	77.62	100.00*	22	95.45	86.63	100.00*	35	94.47	86.85	100.00*
Preserved/Additive/Supplement Products	9	100.00	100.00	100.00	21	90.48	77.75	100.00*	30	92.10	81.49	100.00*
Cereals/Grains/Baked Products	10	100.00	100.00	100.00	12	91.67	75.81	100.00*	22	94.66	84.38	100.00*
Beverages/Sugared Products	1	100.00	100.00	100.00	11	90.91	73.68	100.00*	12	91.62	75.68	100.00*
Products for Sensitive Consumers	2	100.00	100.00	100.00	3	100.00	100.00	100.00	5	100.00	100.00	100.00
Overall	45	98.28	94.89	100.00*	80	91.67	84.68	98.67	125	93.25	87.83	98.67

(continued)

Table 2-9. Weighted Percentage of Plants Performing Selected Food Safety Procedures (continued)

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
For plants using food additives, does your plant measure the weight of food additives?												
Premarket Services and Other Products	19	78.95	60.46	97.44	16	93.75	81.79	100.00*	35	89.62	79.37	99.87
Animal Protein Products	8	87.50	64.38	100.00*	24	91.67	80.51	100.00*	32	90.82	80.75	100.00*
Preserved/Additive/Supplement Products	21	95.24	86.05	100.00*	34	91.18	81.56	100.00*	55	92.10	84.38	99.83
Cereals/Grains/Baked Products	12	91.67	75.89	100.00*	16	87.50	71.15	100.00*	28	88.90	76.80	100.00*
Beverages/Sugared Products	11	63.64	34.96	92.31	31	90.32	79.82	100.00*	42	83.70	72.52	94.87
Products for Sensitive Consumers	3	100.00	100.00	100.00	3	100.00	100.00	100.00	6	100.00	100.00	100.00
Overall	74	81.70	71.60	91.80	124	91.19	85.84	96.54	198	88.70	83.89	93.52
For plants that culture or ferment, does your plant use known starter cultures?												
Premarket Services and Other Products	10	80.00	54.89	100.00*	7	57.14	20.02	94.27	17	64.40	37.40	91.40
Animal Protein Products	17	100.00	100.00	100.00	41	97.56	92.78	100.00*	58	98.15	94.51	100.00*
Preserved/Additive/Supplement Products	5	80.00	44.49	100.00*	3	33.33	0.00*	87.35	8	54.06	16.25	91.87
Cereals/Grains/Baked Products	12	33.33	6.32	60.34	11	63.64	34.85	92.42	23	50.79	29.73	71.86
Beverages/Sugared Products	6	100.00	100.00	100.00	21	95.24	86.01	100.00*	27	96.24	88.92	100.00*
Products for Sensitive Consumers	3	100.00	100.00	100.00	0	0.00	0.00	0.00	3	100.00	100.00	100.00
Overall	53	75.96	63.40	88.52	83	81.41	70.92	91.90	136	79.80	71.55	88.05

(continued)

Table 2-9. Weighted Percentage of Plants Performing Selected Food Safety Procedures (continued)

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
For plants conducting drying, does your plant monitor the water activity level for specific tolerances during the drying process?												
Premarket Services and Other Products	9	66.67	35.09	98.24	9	44.44	11.16	77.73	18	49.91	23.34	76.47
Animal Protein Products	6	50.00	8.98	91.02	10	60.00	28.87	91.13	16	56.85	31.82	81.88
Preserved/Additive/Supplement Products	8	25.00	0.00*	55.76	10	60.00	28.87	91.13	18	50.30	25.33	75.27
Cereals/Grains/Baked Products	2	50.00	0.00*	100.00*	6	0.00	0.00	0.00	8	9.18	0.00*	27.09
Beverages/Sugared Products	1	0.00	0.00	0.00	5	60.00	15.98	100.00*	6	50.58	9.56	91.61
Products for Sensitive Consumers	3	0.00	0.00	0.00	1	0.00	0.00	0.00	4	0.00	0.00	0.00
Overall	29	45.65	25.87	65.43	41	44.90	27.51	62.30	70	45.09	31.13	59.05
For plants conducting baking, does your plant maintain time- and/or temperature-recording devices on baking equipment?												
Premarket Services and Other Products	6	33.33	0.00*	71.69	17	35.29	12.20	58.39	23	35.09	14.00	56.18
Animal Protein Products	1	100.00	100.00	100.00	1	100.00	100.00	100.00	2	100.00	100.00	100.00
Preserved/Additive/Supplement Products	3	100.00	100.00	100.00	11	54.55	24.63	84.46	14	59.80	32.66	86.94
Cereals/Grains/Baked Products	22	59.09	38.20	79.98	36	58.33	41.96	74.71	58	58.55	45.45	71.66
Beverages/Sugared Products	1	100.00	100.00	100.00	6	83.33	53.01	100.00*	7	85.57	58.99	100.00*
Products for Sensitive Consumers	0	N/A	N/A	N/A	0	N/A	N/A	N/A	0	N/A	N/A	N/A
Overall	33	59.53	42.27	76.79	71	51.17	38.64	63.70	104	52.84	42.21	63.48

(continued)

Table 2-9. Weighted Percentage of Plants Performing Selected Food Safety Procedures (continued)

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
For plants conducting pasteurization, has the adequacy of the pasteurization process been verified by an acknowledged expert?												
Premarket Services and Other Products	12	91.67	75.86	100.00*	5	60.00	16.59	100.00*	17	73.90	47.26	100.00*
Animal Protein Products	29	96.55	89.84	100.00*	66	93.94	88.12	99.76	95	94.60	89.92	99.27
Preserved/Additive/Supplement Products	8	100.00	100.00	100.00	17	88.24	72.75	100.00*	25	90.40	77.68	100.00*
Cereals/Grains/Baked Products	1	100.00	100.00	100.00	4	100.00	100.00	100.00	5	100.00	100.00	100.00
Beverages/Sugared Products	2	100.00	100.00	100.00	6	83.33	53.18	100.00*	8	87.28	63.76	100.00*
Products for Sensitive Consumers	4	100.00	100.00	100.00	3	66.67	12.73	100.00*	7	87.75	64.71	100.00*
Overall	56	96.00	90.39	100.00*	101	87.27	78.58	95.95	157	89.63	83.03	96.23
For plants that package and ship their products, is a "tamper-evident" seal used on the finished product packaging?												
Premarket Services and Other Products	48	54.17	40.03	68.31	62	53.23	40.77	65.68	110	53.42	43.07	63.76
Animal Protein Products	37	70.27	55.50	85.04	83	46.99	36.22	57.76	120	52.92	43.89	61.95
Preserved/Additive/Supplement Products	42	45.24	30.14	60.34	85	62.35	52.02	72.68	127	59.08	50.18	67.97
Cereals/Grains/Baked Products	31	35.48	18.59	52.38	64	43.75	31.56	55.94	95	41.72	31.61	51.82
Beverages/Sugared Products	22	68.18	48.66	87.70	70	62.86	51.50	74.21	92	64.06	54.22	73.91
Products for Sensitive Consumers	8	62.50	28.85	96.15	6	33.33	0.00*	71.17	14	51.78	25.36	78.20
Overall	188	54.17	46.59	61.74	370	54.48	48.88	60.07	558	54.41	49.74	59.08

(continued)

Table 2-9. Weighted Percentage of Plants Performing Selected Food Safety Procedures (continued)

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
Does your plant conduct destructive testing for seal integrity?												
Premarket Services and Other Products	45	60.00	45.64	74.36	58	48.28	35.38	61.18	103	50.64	39.92	61.36
Animal Protein Products	39	64.10	49.00	79.20	88	54.55	44.11	64.98	127	56.97	48.26	65.68
Preserved/Additive/Supplement Products	43	69.77	56.00	83.54	82	58.54	47.84	69.23	125	60.79	51.78	69.80
Cereals/Grains/Baked Products	29	44.83	26.67	62.98	66	46.97	34.89	59.05	95	46.48	36.28	56.68
Beverages/Sugared Products	22	68.18	48.66	87.70	71	40.85	29.38	52.31	93	46.96	36.79	57.14
Products for Sensitive Consumers	8	75.00	44.90	100.00*	6	83.33	53.42	100.00*	14	78.06	55.99	100.00*
Overall	186	61.26	53.78	68.73	371	49.35	43.74	54.95	557	51.96	47.27	56.66
For plants conducting metal detection, when critical limits are exceeded, which of the following does your plant do?												
Increase monitoring frequency	119	49.63	39.86	59.39	134	56.67	47.35	65.98	253	54.37	47.31	61.42
Search for source of metal	119	98.79	97.12	100.00*	134	100.00	100.00	100.00	253	99.60	99.03	100.00*
Recalibrate metal detector	119	75.48	67.11	83.86	134	72.26	63.34	81.18	253	73.33	66.74	79.92
Shut down processing line	119	79.73	71.83	87.63	134	82.51	75.22	89.81	253	81.60	76.06	87.14

(continued)

Table 2-9. Weighted Percentage of Plants Performing Selected Food Safety Procedures (continued)

	Large				Small				Total			
			95% Confidence Interval[a]				95% Confidence Interval[a]				95% Confidence Interval[a]	
	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)	(n)	Percentage	Low (%)	High (%)
For plants conducting microbial finished-product testing, are microbial specifications required by your customers?												
Premarket Services and Other Products	29	68.97	52.04	85.89	27	55.56	36.71	74.40	56	59.03	44.34	73.73
Animal Protein Products	37	67.57	52.40	82.73	71	57.75	46.20	69.30	108	60.55	51.20	69.90
Preserved/Additive/Supplement Products	22	72.73	54.02	91.44	41	53.66	38.31	69.00	63	57.56	44.67	70.45
Cereals/Grains/Baked Products	14	50.00	23.67	76.33	28	67.86	50.47	85.25	42	63.35	48.59	78.12
Beverages/Sugared Products	15	33.33	9.35	57.32	32	43.75	26.47	61.03	47	40.59	26.46	54.72
Products for Sensitive Consumers	6	100.00	100.00	100.00	4	25.00	0.00*	67.66	10	74.45	48.56	100.00*
Overall	123	59.19	49.68	68.70	203	55.30	47.63	62.98	326	56.33	50.16	62.51
For plants using refrigerated shipping, does your plant monitor internal temperature, ambient temperature, or the sufficiency of ice during distribution?												
Premarket Services and Other Products	27	70.37	53.03	87.71	28	75.00	58.85	91.15	55	73.89	60.92	86.87
Animal Protein Products	31	74.19	58.69	89.70	77	72.73	62.71	82.74	108	73.07	64.59	81.56
Preserved/Additive/Supplement Products	21	52.38	30.88	73.89	29	62.07	44.29	79.85	50	59.57	45.22	73.92
Cereals/Grains/Baked Products	3	66.67	12.96	100.00*	17	70.59	48.78	92.39	20	70.17	49.86	90.48
Beverages/Sugared Products	1	100.00	100.00	100.00	17	35.29	12.42	58.16	18	38.65	16.03	61.28
Products for Sensitive Consumers	3	33.33	0.00*	87.04	1	100.00	100.00	100.00	4	47.02	0.00*	96.37
Overall	86	67.84	57.64	78.04	169	67.27	59.26	75.29	255	67.39	60.72	74.07

[a]The 95 percent confidence intervals were calculated from the standard errors. Where the calculation resulted in a confidence interval lower than zero or greater than 100 percent, we truncated the interval. These instances are indicated with an asterisk.

3 Results of HACCP Cost Data Collection

In addition to surveying the industry on HACCP practices as described in Section 2, RTI developed estimates of the costs of instituting these practices in each industry segment/size category. In this section, we describe the expert panel method we used to obtain these estimates and the additional follow-up work we conducted to complete the estimates. We provide a summary of the cost estimates and describe the observed ranges of the cost data that were used to code the costs included in the Access database described in Section 4. We conclude by describing a spreadsheet tool that can be used to estimate the costs of any combination of HACCP and sanitation processes of interest.

3.1 EXPERT PANEL METHODOLOGY

Prior to developing the methodology for eliciting HACCP costs through the expert panel, RTI visited six plants in a variety of industries and conducted interviews with their quality control managers. During these site visits, we collected data on the costs to these plants of implementing many of the controls that could be included in a HACCP plan. However, it was impractical to visit a sufficient number of sites to represent the entire food industry. Thus, the information collected during the site visits was used as a reference for developing the expert panel methodology.

In this section, we describe the typical plants included in each industry segment/size category for which we collected data, the qualifications of the expert panel, and finally the process followed for eliciting individual cost estimates.

3.1.1 Typical Plant Descriptions

The definitions of typical plants in each industry segment/size category facilitated development of representative cost estimates for each category.

We designed the methodology to estimate costs separately for 12 different industry segment/size categories. The size designations are based on company-level Small Business Administration (SBA) definitions for the appropriate SIC code for each category. Although there is a wide range of products and plant sizes within each of the 12 categories, our goal was to obtain a representative cost estimate for each category for each HACCP practice. To facilitate obtaining a representative cost estimate, we developed a description of a typical plant within each category. These typical plant descriptions are provided in Table 3-1.

For each plant category, we then developed assumptions about the number of shifts and lines in a typical plant. In addition, we calculated the average number of employees and sales for plants in each category. These assumptions and estimates are provided in Table 3-2.

3.1.2 Expert Panel Qualifications

In recruiting the expert panel, we sought to involve individuals with experience in a range of plants under FDA's jurisdiction. The specific criteria used to select the panel of experts were based on obtaining

- ➤ coverage of each industry segment by at least one expert,
- ➤ a mix of academic and nonacademic participants, and
- ➤ a mix of scientists (microbiologists and chemists) and engineers (food technologists).

The expert panel was a mix of industry consultants and academics with experience in a range of plants under FDA jurisdiction.

The final panel of experts was composed of

- ➤ John McAnnelly, industry consultant, with greatest experience in animal proteins and cereals/grains/baked products;
- ➤ Don Corlett, industry consultant, with greatest experience in preserved/additive/supplement products, cereals/grains/baked products, and beverages/sugared products;
- ➤ Dan Farkas, Oregon State University, with greatest experience in preserved/additive/supplement products and cereals/grains/baked products;
- ➤ John Rushing, North Carolina State University, with greatest experience in animal proteins and preserved/additive/supplement products;

Table 3-1. Description of a Typical Plant in Each of the Twelve Industry Categories
The expert panel used these descriptions as the context for estimating the costs of HACCP and sanitation processes.

Industry Segment/ Size Category	Typical Plant Description
Premarket Services—Small	➤ Approximately 45 percent of plants are food wholesalers owned by companies with fewer than 100 employees. ➤ The next largest type of plant includes those that fall into "other food preparations" and have fewer than 500 employees.
Premarket Services—Large	➤ Over 50 percent of plants are food wholesalers owned by companies with more than 100 employees. ➤ The next largest type of plant includes agricultural services companies with more than $5 million in annual revenue.
Animal Protein Products—Small	➤ One-third of plants produce cheese products. ➤ Ice cream is the second largest category, followed by milk. ➤ All plants are owned by companies that employ fewer than 500 employees.
Animal Protein Products—Large	➤ The largest number of plants produce cheese products, followed by ice cream and milk. ➤ All plants are owned by companies that employ more than 500 employees.
Preserved/Additive/ Supplement Products—Small	➤ The largest number of plants can fruit, followed by plants that pickle fruits and vegetables. ➤ Plants that manufacture vitamins and other dietary supplements make up about 16 percent of this category. ➤ Plants that produce dried and dehydrated fruits and vegetables, frozen fruits, fruit juices, and vegetables are also represented in this segment. ➤ Most of the plants in this segment are owned by companies that employ fewer than 500 employees.
Preserved/Additive/ Supplement Products—Large	➤ This segment is dominated by plants that can fruit, followed by frozen fruits, fruit juices, and vegetables. ➤ Plants that manufacture vitamins and other dietary supplements make up about 11 percent of this segment. ➤ Most of the plants in this segment are owned by companies that employ more than 500 employees.
Cereals/Grains/Baked Products—Small	➤ This segment is dominated by bread and bakery products, followed by flour and other mill products. ➤ Snack foods and pasta products are also represented in this segment. ➤ Most plants in this segment are owned by companies that employ fewer than 500 employees.
Cereals/Grains/Baked Products—Large	➤ This segment is dominated by bread and bakery products, followed by flour and other mill products. ➤ Most of the plants in this segment are owned by companies that employ more than 500 employees.

(continued)

Table 3-1. Description of a Typical Plant in Each of the Twelve Industry Categories (continued)

Industry Segment/ Size Category	Typical Plant Description
Beverages/Sugared Products—Small	➤ This segment is led by plants that produce candy and chewing gum, followed by alcoholic beverages and bottled and canned soft drinks. ➤ Most plants in this segment are owned by companies that employ fewer than 500 employees.
Beverages/Sugared Products—Large	➤ This segment is dominated by plants that produce bottled and canned soft drinks. ➤ Most of the plants in this segment are owned by companies that employ more than 500 employees.
Products for Sensitive Consumers—Small	➤ This segment includes plants owned by small companies that produce baby food, infant formula, and geriatric foods. There are only 21 plants in this segment. ➤ Most are owned by companies that employ fewer than 500 employees.
Products for Sensitive Consumers—Large	➤ This segment contains plants owned by large companies that produce baby food, infant formula, and geriatric foods. There are only 25 plants in this segment. ➤ Most are owned by companies that employ more than 500 employees.

Table 3-2. Estimated Typical Plant Lines, Shifts, Employment, and Sales in Each of the Twelve Industry Categories

Based on the HACCP survey responses, we developed typical plant size estimates to provide the basis for the HACCP and sanitation process cost estimates.

Industry Segment/Size Category	Lines	Shifts	Employment	Sales (millions)
Premarket Services—Small	1	1	31	$11
Premarket Services—Large	3	2	287	$133
Animal Protein Products—Small	4	1	72	$28
Animal Protein Products—Large	8	2	486	$144
Preserved/Additive/Supplement Products—Small	1	2	83	$26
Preserved/Additive/Supplement Products—Large	4	2	776	$161
Cereals/Grains/Baked Products—Small	1	2	68	$32
Cereals/Grains/Baked Products—Large	6	3	459	$145
Beverages/Sugared Products—Small	2	2	55	$24
Beverages/Sugared Products—Large	6	2	391	$151
Products for Sensitive Consumers—Small	1	2	162	$67
Products for Sensitive Consumers—Large	3	2	1,483	$322

- John Surak, Clemson University, with greatest experience in animal proteins, preserved/additive/supplement products, and products for sensitive consumers; and
- Rick Stier, industry consultant, with greatest experience in premarket services and preserved/additive/supplement products.

Because they have been in hundreds of plants in a variety of industries and have helped many plants implement HACCP plans for numerous products, the HACCP experts are aware of the range of resources required to implement HACCP procedures.

3.1.3 Expert Panel Process

We recruited the panelists to spend 2 days at RTI to

- review the evidence on HACCP costs obtained from the six site visits,
- consider their own experience with HACCP, and then
- provide information about the resources (labor, capital, and materials) required to implement a variety of potentially required HACCP procedures.

Based on their backgrounds, the panelists were divided into two groups and assigned specific industry segments to address. For each industry segment, the panelists considered the costs of specific procedures in the following three categories:

- HACCP plan development and training,
- food processing, and
- sanitation.

The **HACCP plan development and training** section included questions on the

- startup costs associated with conducting a hazard analysis, developing a HACCP plan, and training employees on use of the plan and processes; and
- ongoing costs of periodically reviewing the HACCP plan and providing ongoing employee training.

The **food processing** section included questions on the following 15 processes:

- Receiving Raw Ingredients and Materials,
- Storing,
- Controlling Product/Temperature during Processing,
- Batching,

- ➤ Culturing and Fermenting,
- ➤ Drying,
- ➤ Low Water Activity Processing (i.e., salting, brining, preserving),
- ➤ Baking,
- ➤ Heat Treatment and Pasteurization,
- ➤ Irradiating,
- ➤ Packaging,
- ➤ Inspecting Container Seal Integrity,
- ➤ Detecting Metal,
- ➤ Testing Finished Product, and
- ➤ Distributing.

These processes represent the great majority of processes that are practiced by food processing plants, although not every process occurs for all industry segments or for all plants within an industry segment. Within each of these processes are several practices that plants may or may not include in a HACCP plan (see Appendix C for a complete listing). For each of these individual practices, we asked the panelists to provide estimates of both startup and ongoing costs for a representative plant in each industry segment/size category.

The **sanitation** section included practices that plants may already conduct under Good Manufacturing Practices (GMPs). However, if a plant is not currently conducting these practices under GMPs, they may be required to include them in a HACCP plan (see Appendix C for a complete listing of practices). Again, we asked the panelists to provide estimates of both startup and ongoing costs for a representative plant in each industry segment/size category.

The types of costs associated with HACCP practices include labor, capital, and material costs.

Costs for each practice (within HACCP plan development, food processing, and sanitation) can be grouped into the following types:

- ➤ Labor costs—based on the types of workers, the number of hours for each worker, and the hourly wage for each worker;
- ➤ Capital costs—based on the additional equipment needed to implement a particular practice (if a plant would not already have it), the cost of the equipment, and its expected life; and
- ➤ Material costs—based on the types, numbers, and per unit costs of materials.

We asked the consultants to first consider these cost estimates on a single shift/single line basis and then on a per plant basis for a plant with a typical number of lines and a typical number of shifts for the industry segment/size category. The consultants then discussed these types of costs for each of the industry segments to which they were assigned and provided us with a consensus agreement of their cost estimate by practice.

3.1.4 Expert Panel Follow-Up

Due to the limited time and the large number of practices to be covered, we did not obtain cost estimates for every practice across all industry segment/size categories. In cases where the costs of a particular practice were likely to be similar across other industry segments in the same size classification, we transferred those costs to fill in missing cost estimates. Once this process was completed, we worked with one of the panelists, John Rushing, to complete the remaining cost estimates. We also verified that (1) particular practices are not applicable for an industry segment and thus the cost estimates should be blank, and (2) remaining blank cost estimates indicated that there are no additional costs associated with the practice beyond what plants are currently doing.

3.2 COST ESTIMATE SUMMARY

Through the expert panel process described above, we obtained point estimates for year one and ongoing costs of HACCP practices in each of the 12 industry segment/size categories. Across the industry segment/size categories, the highest cost practices were associated with

- a pasteurization flow diversion system for low temperature product,
- tamper evident packaging,
- microbiological testing, and
- sanitation (several practices).

However, many practices had zero costs because plants are already conducting the practice, or some have positive costs at start-up but zero costs on an ongoing basis.

Because plants that have implemented HACCP or sanitation plans conduct different sets of practices as part of those plans, we

developed a method to obtain weighted-average industry costs by size and industry segment. For plants that said they had implemented HACCP, we estimated average industry costs by industry segment as

We developed weighted average industry costs for HACCP and sanitation practices to facilitate comparisons of costs across plant sizes and industry segments.

$$\sum_{i=1}^{n} \begin{pmatrix} \text{weighted percentage} \\ \text{of plants conducting} \\ \text{practice i} \end{pmatrix} * \begin{pmatrix} \text{cost estimate} \\ \text{for practice i} \end{pmatrix}$$

where the "weighted percentage of plants conducting practice i" is the sum of the survey weights of plants conducting practice i divided by the sum of the survey weights of plants with HACCP.[1] We followed the same procedure both for the HACCP plan costs and for HACCP practice costs. Similarly, we calculated weighted average industry costs for sanitation practices based on the set of practices that plants with sanitation plans said they were conducting.[2] The resulting average cost estimates are presented in Table 3-3. The costs tend to be higher for small plants than for large plants with substantial variation among industry segments.

We also compared these cost estimates to the average annual sales estimates as reported by plants in the survey (see Table 3-4). In general, year one and ongoing costs as a percentage of sales are as follows:

- HACCP plan cost estimates averaged less than 0.1 percent,
- HACCP practice cost estimates averaged between 1 and 3 percent, and
- sanitation practice cost estimates averaged between 1 and 4 percent of sales.

In all cases, the cost estimates as a percentage of sales are higher for small than for large plants.

Because the year one costs of the HACCP plan, HACCP practices, and sanitation practices are similar in concept to capital purchase and installation costs, we compared these costs to annual capital expenditures for each of the industry segments. In Table 3-5, we list the NAICS codes (and their associated SIC codes) on which we

[1] We assumed a plant had implemented HACCP if it answered yes to question Q7A, "Has a HACCP plan been implemented for any product at this plant?"

[2] We assumed a plant had implemented a sanitation plan if it answered yes to question Q201B, "Does your plant have a written sanitation program?"

Table 3-3. Weighted Average Costs for Developing a HACCP Plan, Conducting HACCP Practices, and Conducting Sanitation Practices

The cost estimates for HACCP and sanitation practices vary by industry segment and size of the company.

	Small Plant		Large Plant	
Industry Segment	**Year 1**	**Ongoing**	**Year 1**	**Ongoing**
HACCP Plan				
Premarket Services	$18,000	$3,000	$23,000	$6,000
Animal Protein Products	$19,000	$3,000	$28,000	$9,000
Preserved/Additive/Supplement Products	$20,000	$3,000	$37,000	$14,000
Cereals/Grains/Baked Products	$19,000	$3,000	$29,000	$9,000
Beverages/Sugared Products	$18,000	$3,000	$25,000	$7,000
Products for Sensitive Consumers	$21,000	$4,000	$50,000	$23,000
HACCP Practices				
Premarket Services	$246,000	$208,000	$1,260,000	$1,094,000
Animal Protein Products	$784,000	$673,000	$2,822,000	$2,402,000
Preserved/Additive/Supplement Products	$409,000	$372,000	$1,531,000	$1,450,000
Cereals/Grains/Baked Products	$304,000	$274,000	$2,291,000	$2,138,000
Beverages/Sugared Products	$705,000	$662,000	$1,936,000	$1,852,000
Products for Sensitive Consumers	$553,000	$469,000	$1,512,000	$1,262,000
Sanitation				
Premarket Services	$238,000	$190,000	$1,223,000	$1,171,000
Animal Protein Products	$1,009,000	$789,000	$3,316,000	$3,242,000
Preserved/Additive/Supplement Products	$430,000	$386,000	$1,647,000	$1,589,000
Cereals/Grains/Baked Products	$415,000	$372,000	$3,514,000	$3,438,000
Beverages/Sugared Products	$757,000	$717,000	$2,276,000	$2,215,000
Products for Sensitive Consumers	$578,000	$396,000	$1,273,000	$1,219,000

Note: The weights for calculating the weight averages are based on the proportion of surveyed plants with a HACCP plan or with a sanitation program that conduct each of the practices listed in the survey.

Table 3-4. Cost-to-Sales Ratios for Developing a HACCP Plan, Conducting HACCP Practices, and Conducting Sanitation Practices[a]

Cost-to-sales ratios for HACCP practices vary from 0.4 to 2.7 percent on an annual basis, and the cost-to-sales ratios for sanitation practices vary from 0.4 to 3.0 percent.

	Small Plant		Large Plant	
Industry Segment	**Year 1 (%)**	**Ongoing (%)**	**Year 1 (%)**	**Ongoing (%)**
HACCP Plan				
Premarket Services	0.16	0.02	0.02	0.01
Animal Protein Products	0.07	0.01	0.02	0.01
Preserved/Additive/Supplement Products	0.08	0.01	0.02	0.01
Cereals/Grains/Baked Products	0.06	0.01	0.02	0.01
Beverages/Sugared Products	0.07	0.01	0.02	0.01
Products for Sensitive Consumers	0.03	0.01	0.02	0.01
HACCP Practices				
Premarket Services	2.24	1.89	0.95	0.82
Animal Protein Products	2.80	2.40	1.96	1.67
Preserved/Additive/Supplement Products	1.57	1.43	0.95	0.90
Cereals/Grains/Baked Products	0.95	0.86	1.58	1.48
Beverages/Sugared Products	2.94	2.76	1.28	1.23
Products for Sensitive Consumers	0.83	0.70	0.47	0.39
Sanitation				
Premarket Services	2.17	1.73	0.92	0.88
Animal Protein Products	3.61	2.82	2.30	2.25
Preserved/Additive/Supplement Products	1.65	1.49	1.02	0.99
Cereals/Grains/Baked Products	1.30	1.16	2.42	2.37
Beverages/Sugared Products	3.16	2.99	1.51	1.47
Products for Sensitive Consumers	0.86	0.59	0.40	0.38

[a]Ratios were calculated using the following average company sales of the survey respondents:

	Company Sales ($millions)	
Industry Segment	**Small**	**Large**
Premarket Services (SIC)	$11	$133
Animal Protein Products	$28	$144
Preserved/Additive/Supplement Products	$26	$161
Cereals/Grains/Baked Products	$32	$145
Beverages/Sugared Products	$24	$151
Products for Sensitive Consumers	$67	$322

Table 3-5. Average Annual Capital Expenditures for the Predominate NAICS Code for Each Industry Segment

The costs of implementing HACCP and sanitation programs can be compared to the average capital expenditures for small and large plants.

						Small			Large		
Industry Segment	Primary SIC	SIC Definition	Primary NAICS	NAICS Definition	SBA Size	Number of Establishments	Total Capital Expenditures (10^3)	Avg. Capital Expenditures per Establishment (10^3)	Number of Establishments	Total Capital Expenditures (10^3)	Avg. Capital Expenditures per Establishment (10^3)
Premarket Services	2091, 2092, 2099	Other Food Preparations	311999	All Other Miscellaneous Food Manufacturing	500	838	221,371	264	14	58,806	4,200
Animal Protein Products	2022	Cheese	311513	Cheese	500	518	427,898	826	6	57,992	9,665
Preserved/ Additive/ Supplement Products	2033	Canned Fruits, Vegetables, Preserves, Jams, Jellies	311421	Canned Fruits & Vegetables	500	807	399,381	495	17	134,814	7,930
Cereals/Grains/ Baked Products	2051	Bread & Other Bakery Products, Except Cookies & Crackers	311812	Commercial Bakery Products	500	2,708	503,020	186	58	222,008	3,828
Beverages/ Sugared Products	2086	Bottled & Canned Soft Drinks	312111	Soft Drink Manufacturing	500	588	737,573	1,254	18	90,414	5,023
Products for Sensitive Consumers	2023	Condensed & Evaporated Milk	311514	Dry, Condensed, & Evaporated Milk	500	208	208,921	1,004	5	52,754	10,551

Source: U.S. Census Bureau. 1999 and 2000. "1997 Census: Manufacturing Industry, Series." Various issues.

based the annual capital expenditure estimates for each industry segment. Using data from the 1997 Census, we calculated average capital expenditures for small and large plants (assuming the plant and the company are the same entity). We then use these average capital expenditure estimates to calculate the ratios in Table 3-6. According to these ratios, the year one and ongoing costs as a percentage of annual capital expenditures are as follows:

- HACCP plan cost estimates averaged less than 10 percent,
- HACCP practice cost estimates averaged between 29 and 164 percent, and
- sanitation practice cost estimates averaged between 12 to 224 percent of annual capital expenditures.

As in Tables 3-3 and 3-4, the cost estimates as a percentage of annual capital expenditures are higher for small than for large plants.

We categorized the cost estimates from the expert panel into ranges for small and large plants.

Because the point estimates that we used for the calculations in Tables 3-3, 3-4, and 3-6 are indicative of the costs that might be incurred by a typical plant, they may not be appropriate for every plant in each category. Therefore, we also developed cost ranges for each practice and then reclassified the cost estimates into these ranges. These cost ranges also facilitate comparisons across practices. The following breakpoints were used for the cost ranges, which are loosely based on the 33rd and 67th percentile of costs within each category:

- Small plants
  - ✓ Low cost—$1 to $2,499
  - ✓ Medium cost—$2,500 to $4,999
  - ✓ High cost—$5,000 and up
- Large plants
  - ✓ Low cost—$1 to $4,999
  - ✓ Medium cost—$5,000 to $24,999
  - ✓ High cost—$25,000 and up

We used these cost ranges to categorize both year one and ongoing costs.

Table 3-6. Cost-to-Annual Capital Expenditure Ratios for Developing a HACCP Plan, Conducting HACCP Practices, and Conducting Sanitation Practices[a]

As a percentage of annual capital expenditures, the year 1 costs of HACCP practices range from 19 to 164 percent, and the year 1 costs of sanitation practices range from 12 to 223 percent.

Industry Segment	Small Plant Year 1 (%)	Large Plant Year 1 (%)
HACCP Plan		
Premarket Services	6.7	0.6
Animal Protein Products	2.3	0.3
Preserved/Additive/Supplement Products	4.1	0.5
Cereals/Grains/Baked Products	10.4	0.7
Beverages/Sugared Products	1.4	0.5
Products for Sensitive Consumers	2.1	0.5
HACCP Practices		
Premarket Services	93.2	30.0
Animal Protein Products	94.9	29.2
Preserved/Additive/Supplement Products	82.6	19.3
Cereals/Grains/Baked Products	163.7	59.9
Beverages/Sugared Products	56.2	38.5
Products for Sensitive Consumers	55.0	14.3
Sanitation		
Premarket Services	90.2	29.1
Animal Protein Products	122.2	34.3
Preserved/Additive/Supplement Products	86.8	20.8
Cereals/Grains/Baked Products	223.6	91.8
Beverages/Sugared Products	60.4	45.3
Products for Sensitive Consumers	57.5	12.1

[a]Ratios were calculated assuming the following average annual capital expenditures (based on the predominate SIC code for each segment):

	Capital Expenditures ($thousands)	
Industry Segment	**Small**	**Large**
Premarket Services	$264	$4,200
Animal Protein Products	$826	$9,665
Preserved/Additive/Supplement Products	$495	$7,930
Cereals/Grains/Baked Products	$186	$3,828
Beverages/Sugared Products	$1,254	$5,023
Products for Sensitive Consumers	$1,004	$10,551

Table 3-7 summarizes the percentage of practices in each of the cost categories by industry segment/size. As noted above, some practices have no costs associated with them because the practices are not applicable for the industry segment or because plants are already conducting the practice regardless of HACCP requirements. For *small* plants producing premarket services, preserved/additive/supplement products, cereals/grains/baked products, or products for sensitive consumers, the greatest number of year one and ongoing costs are *low* cost practices. In comparison, for *small* plants producing animal protein products or beverages/sugared products, the greatest number of year one and ongoing costs are *high* cost practices. For *large* plants, the distribution of costs for each industry segment is more even across the low, medium, and high cost categories. However, just as with the small plants, *large* plants producing premarket services, preserved/additive/supplement products, and products for sensitive consumers have the greatest number of *low* cost practices. In comparison, *large* plants producing cereals/grains/baked products and beverages/sugared products have the greatest number of high cost practices. *Large* plants producing animal protein products have a relatively even distribution of costs across the cost categories.

To provide a sense of the level of costs within individual practice categories, Table 3-8 describes the typical level of costs in small and large plants across industry segments. While many practice categories tend to have a mix of costs, other categories are more easily classified into specific cost ranges. In particular, cold storage and metal detection practices are generally low cost, and packaging and sanitation practices are generally high cost.

The cost ranges for each individual practice within the industry segment/size categories are provided in the database of survey and cost information described in Section 4.

Table 3-7. Percentage of Practices by Cost Category for Each Industry Segment/Size Category
Depending on the plant size and industry segment, we classified the costs of each individual practice as low, medium, and high.

	Small Plant[a]							
	Year 1 (%)				Ongoing (%)			
Segment	None[b]	Low	Medium	High	None[b]	Low	Medium	High
Premarket Services	6	59	9	27	17	59	6	18
Animal Protein Products	6	35	10	49	16	37	8	39
Preserved/Additive/ Supplement Products	10	37	22	31	20	36	21	23
Cereals/Grains/Baked Products	7	39	22	32	17	38	21	24
Beverages/Sugared Products	20	21	10	49	29	21	8	42
Products for Sensitive Consumers	9	35	22	34	20	34	22	24
	Large Plant[c]							
	Year 1 (%)				Ongoing (%)			
Segment	None[b]	Low	Medium	High	None[b]	Low	Medium	High
Premarket Services	6	39	36	19	17	34	33	16
Animal Protein Products	7	33	27	33	17	31	22	30
Preserved/Additive/ Supplement Products	9	36	34	21	19	32	31	18
Cereals/Grains/Baked Products	9	24	26	41	19	19	25	37
Beverages/Sugared Products	20	24	26	30	29	21	24	26
Products for Sensitive Consumers	8	39	34	19	19	35	30	16

[a]Small plant cost categories: Low = $1 to $2,499; Medium = $2,500 to $4,999; and High = $5,000 and up.

[b]None indicates that either the practices are not applicable for the industry segment or there are no incremental costs associated with the practice.

[c]Large plant cost categories: Low = $1 to $4,999; Medium = $5,000 to $24,999; and High = $25,000 and up.

Table 3-8. Typical Level of Costs for HACCP Processes and Practices Across Industry Segments
Each HACCP process comprises several practices that we characterized based on their cost estimate ranges.

	Small Plant[a]		Large Plant[b]	
Processes	**Year 1**	**Ongoing**	**Year 1**	**Ongoing**
HACCP Plan	Low	Low	Low	Low–Medium
Food Processing				
Receipt	Medium–High	Medium–High	Medium–High	Medium–High
Storage—Cold	Low	Low	Low	Low
Storage—Dry	Low	Low	Low–Medium	Low–Medium
Temperature Control	Low–High	Low–High	Low–High	Low–High
Batching	High	High	High	Medium–High
Culturing and Fermenting	High	High	Medium	Medium
Drying	Low	Low	Low–Medium	Medium
Low Water Activity Processing	Low	Low	Low–Medium	Low–Medium
Baking	High	High	Low–Medium	Medium
Pasteurization	Low–High	Low	Low–Medium	Low
Thermal Heat Treatment	Low	Low	Low	Low–High
Irradiation	High	Low	Medium	Low
Packaging	High	High	High	High
Seal Integrity	High	High	Medium–High	Medium–High
Metal Detection	Low	Low	Low	Low
Finished Product Testing	High	Low	Low	Low
Refrigerated Shipping	Low	Low	Low–Medium	Low–Medium
Sanitation	High	High	High	High

[a]Small plant cost categories: Low = $1 to $2,499; Medium = $2,500 to $4,999; and High = $5,000 and up.

[b]Large plant cost categories: Low = $1 to $4,999; Medium = $5,000 to $24,999; and High = $25,000 and up.

3.3 HACCP COST ESTIMATION TOOL

Because FDA may be interested in estimating the costs of a number of different combinations of HACCP or sanitation processes, we created a cost estimation tool, which accompanies this report, in

Microsoft Excel. We describe the design of the spreadsheet, provide instructions for an example, and provide hints for working with PivotTables in Microsoft Excel below.

3.3.1 Spreadsheet Design

FDA can use the HACCP cost estimation spreadsheet to estimate the costs of any combination of HACCP practices by size of plant and industry segment.

The HACCP cost estimation spreadsheet is made up of eight worksheets. These eight worksheets include a summary worksheet, six input worksheets (corresponding to the six industry segments), and a data worksheet. The purpose of these worksheets is as follows:

- The **Summary** worksheet displays the HACCP costs of user selected HACCP or sanitation practices by industry segment. These costs are displayed using the built-in PivotTable tool in Microsoft Excel.
- The six input worksheets—**Premarket**, **Preserved**, **Cereals**, **Beverages**, and **Sensitive**—correspond to the six industry segments. The user chooses any combination of HACCP or sanitation practices in the input worksheets by clicking on the **checkboxes** next to the practice or procedure that the user wants to include in the cost estimates. Each input worksheet also has a **Clear** button located at the top of Column D. The **Clear** button clears all the checkboxes in its associated worksheet. Before you start a new cost estimation, you should clear each input worksheet. (Although it is not necessary, you can also then clear the **Summary** worksheet by clicking anywhere in the Pivot Table and then selecting **Refresh Data** in the **Data** menu.)
- The **Data** worksheet contains the cost estimates of the HACCP or sanitation practices for each of the industry segments as obtained during the expert elicitation process. The six input worksheets are linked to the **Data** worksheet, and the PivotTable in the **Summary** worksheet is built from the **Data** worksheet. Note that the user should never need to alter the **Data** worksheet.

With this basic structure, the user can then develop cost estimates in any required combination.

3.3.2 Estimating HACCP Costs (An Example)

Use the following procedures to obtain an estimation of the costs of HACCP Training, Hazard Analysis, and Creating a HACCP Plan for the Premarket and Beverages industry segments:

- In each of the six input worksheets, **Click** on the **Clear** button.

- In the **Premarket** worksheet, **Click** the **Checkbox** next to the control description labeled **HACCP Training**, **Click** the **Checkbox** next to **Hazard Analysis**, and **Click** the **Checkbox** next to **HACCP Plan**. These are the first three practices listed in the spreadsheet.
- In the **Beverages** worksheet, repeat the same operations that you performed in the **Premarket** worksheet.
- In the **Summary** worksheet, **Click** anywhere in the PivotTable. Then select **Refresh Data** from the **Data Menu**. The PivotTable will update the cost estimates based on your current choices.

The default display in the **Summary** worksheet will show the combined cost estimates for both industry segments. To see each segment individually, select the industry segment of industry from the **Industry** drop-down box.

3.3.3 Tips on Working with PivotTables

PivotTables allow you to interactively change the arrangement of your results. The **Summary** PivotTable is made up of page, row, and data fields. The purpose of each of these fields is as follows:

- The **Page** field is located in cell B3 of the **Summary** worksheet. This field filters the data in the table by breaking the PivotTable into seven pages: a page for each of the six industry segments and a page that displays the total of all the industry segments.
- The **Row** fields define the headings for the rows and also control the level of detail displayed in the table. The row fields included in the PivotTable are **Section**, **Process**, **Control Description**, and **Choice**.
- The **Data** fields are the year 1 and ongoing costs for small and large plants, respectively. The **Data** fields are displayed as columns.

Selecting **Toolbars** from the **View Menu** and then selecting **PivotTable** will display a PivotTable toolbar. The toolbar contains buttons that perform many of the actions listed in Section 3.3.3.

To **Hide Detail** in the table, **Double-Click** under the **Row Heading** that will be the lowest level of detail shown in the table. Using the results from the example above, **Double-Click** the cell directly beneath the row heading **Process**. The Control Description detail will be hidden.

To **Show Detail** in the table, **Double-Click** under the **Row Heading** that is the lowest level of detail shown in the table. To show the hidden Control Descriptions, **Double-Click** the cell directly beneath the row heading **Process**. The **Control Description** detail will be shown.

4 HACCP Survey and Cost Database

The HAACP Practices and Costs Database (HACCP-PCD) combines the plant information in the EED with the HACCP survey responses and costs described in Sections 2 and 3. RTI developed the database in Microsoft Access. The relational nature of the database allows us to link the data from these three sources thus providing FDA with a convenient method of viewing, manipulating, and analyzing the responses to the HACCP industry survey. In this section, we describe the database tables, describe the database forms, and provide example queries.

4.1 DATABASE TABLES

The database tables can be separated into two categories-plant-related tables and survey-related tables. The two sets of tables are linked through the Plant Data table in the database. Figure 4-1 provides an overview of the plant-related tables and shows how they are linked. Plant-related tables were previously described in Martin et al. (2000) and thus are not described in detail here.

An overview of the survey-related tables and their linkages is provided in Figure 4-2. Due to the length of the HACCP industry survey, the survey was divided into its individual sections, and Section 2 was further divided into its 15 process modules. Each survey section is an individual table within the database for a total of 19 survey section tables. We describe the survey section tables and supporting tables below.

Figure 4-1. Overview of Plant-Related Tables

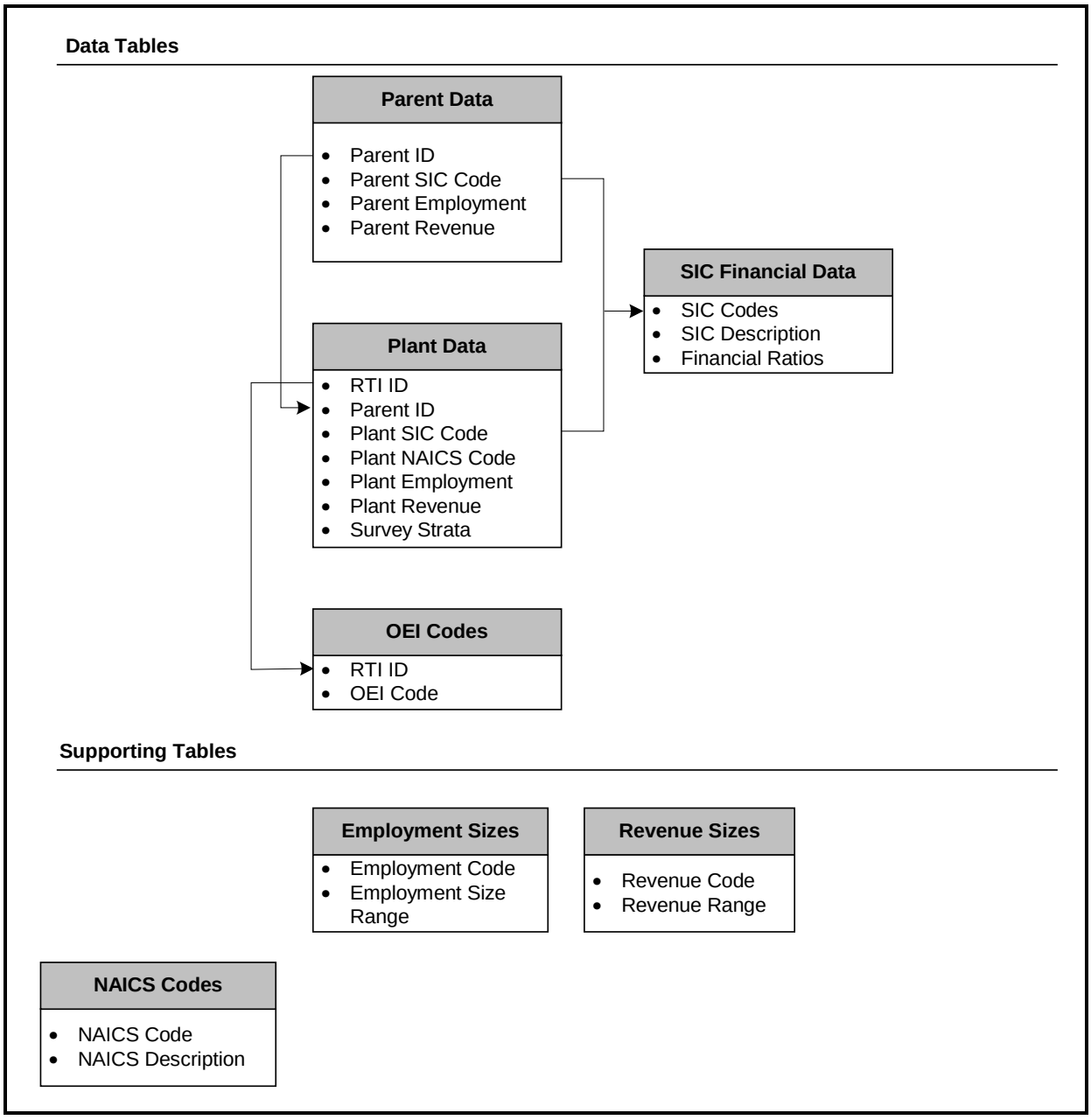
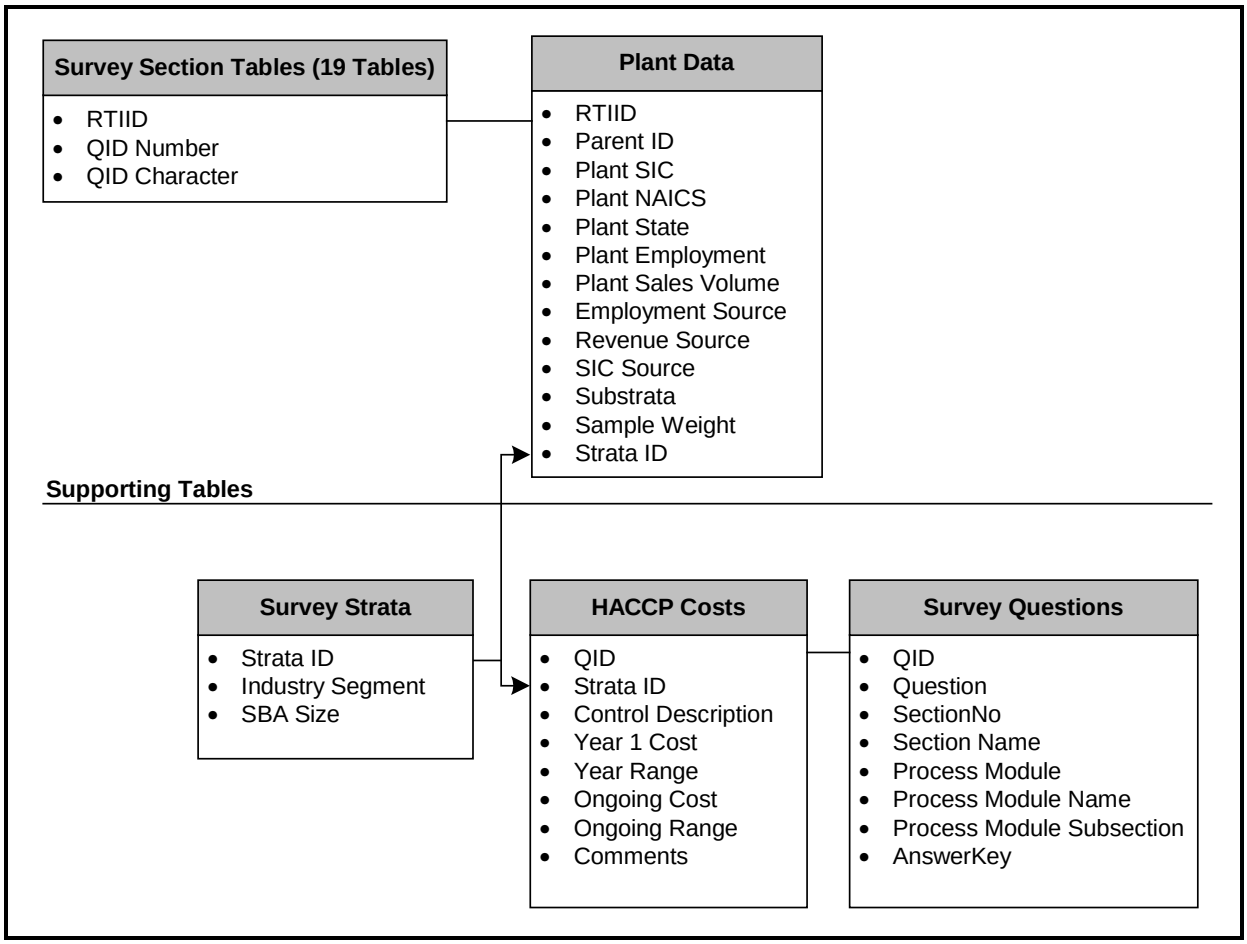


Figure 4-2. Overview of Survey-Related Tables



4.1.1 Survey Section Tables

Table 4-1 lists the 19 survey section tables and the corresponding section name used in the survey. We created all of the survey section tables in a similar format. Specifically, each table contains the unique identifier assigned by RTI (RTIID) and two response fields for each survey question in the table. The first response field is a numerical response to the survey question (i.e., 1, 2, etc.). The second response field is a character response to the survey question (i.e., yes, no, etc.). The character response field name repeats the numerical field name but has a "char" appended to the end. For example, field Q60A contains the numerical response, and field Q60Achar contains the character response to question 60A of the survey.

Table 4-1. The HACCP-PCD Survey Section Tables

HACCP-PCD Table Name	Section No.	HACCP Industry Survey Section Name
Introduction Responses	Intro	Introductory Questions
Section 1 Responses	1	HACCP Utilization
Section 2A Responses	2A	Receiving Raw Ingredients and Materials
Section 2B Responses	2B	Storing
Section 2C Responses	2C	Controlling Product/Temperature During Processing
Section 2D Responses	2D	Batching
Section 2E Responses	2E	Culturing and Fermenting
Section 2F Responses	2F	Drying
Section 2G Responses	2G	Low Water Activity Processing
Section 2H Responses	2H	Baking
Section 2I Responses	2I	Heat Treatment and Pasteurization
Section 2J Responses	2J	Irradiating
Section 2K Responses	2K	Packaging
Section 2L Responses	2L	Inspecting Container Seal Integrity
Section 2M Responses	2M	Detecting Metal
Section 2N Responses	2N	Testing Finished Product
Section 2O Responses	2O	Distributing
Section 3 Responses	3	Sanitation Procedures
Section 4 Responses	4	Plant Organization, Products and Markets

4.1.2 Supporting Tables

The HACCP_PCD contains several supporting tables that contain HACCP cost information, the survey questions, and sample stratification (Table 4-3 through Table 4-5):

- Table 4-3: **HACCP costs** as obtained from the expert panel for each industry segment and size,
- Table 4-4: the text of the **HACCP survey questions**, and
- Table 4-5: the descriptions of the **HACCP survey strata**.

Table 4-3. Fields in the HACCP Costs Table

Field Name	Data Type	Description
QID	Character	Question identification number
Strata ID	Numeric	Unique identifier for the 12 survey strata
Control Description	Character	Brief description of the HACCP control
Year 1 Cost	Character	Indicates low, medium, or high year 1 costs
Year 1 Range	Character	Cost range for low, medium, and high year 1 costs
Ongoing Cost	Character	Indicates low, medium, or high ongoing costs
Ongoing Range	Character	Cost range for low, medium, and high ongoing costs
Comments	Character	Comments from the cost data collection process

Table 4-4. Fields in the Survey Questions Table

Field Name	Data Type	Description
QID	Character	Question identification number
Question	Character	Question as it appeared on the survey instrument
Section No.	Character	Number of survey section (Introduction and Sections 1-4)
Section Name	Character	Name of survey section
Process Module	Character	Alphabetic list of process modules within Section 2
Process Module Name	Character	Name of process module within Section 2
Process Module Subsection	Character	Name of subsection within a process module
Answer Key	Character	Lists response fields associated with question

Table 4-5. Fields in the Survey Strata Table

Field Name	Data Type	Description
Strata ID	Numeric	Unique identifier for the 12 survey strata
Industry Segment	Character	Industry segment associated with strata (6 segments)
SBA Size	Character	Size of plant by SBA definitions (small or large)

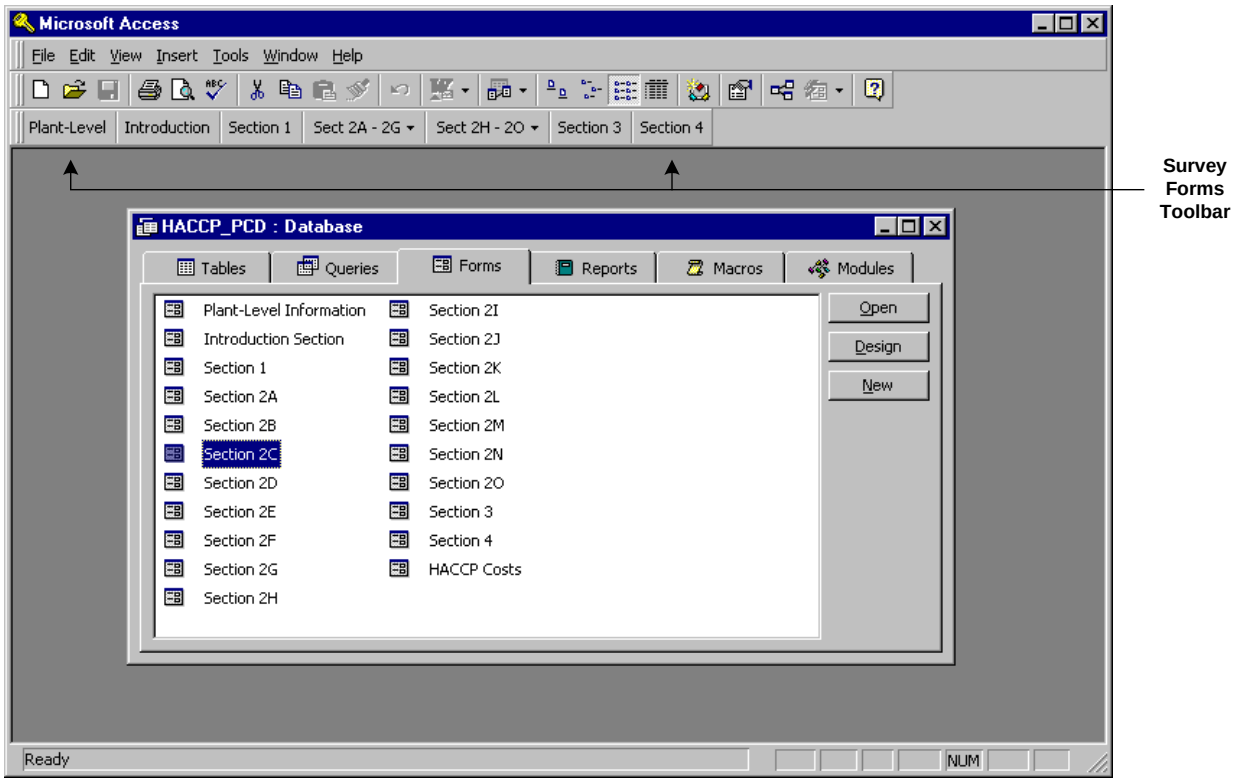
4.2 DATABASE FORMS

Enhanced Feature. The toolbar is programmed to look for an open form before opening a new form. If a form is already open when you select a new form, the new form will open to the same record as the first form. For example, if Section 1 form is open to Record 35 (RTI ID 1035), the Section 2C form will open to the same record.

The database forms consist of a Plant-Level Information form, HACCP Costs forms, and Survey Section forms. Due to the size of the survey, a separate form was created for each of the 19 sections of the survey.

Figure 4-3 lists the forms available in the database. Note that the Survey Section forms and the Plant-Level Information form can be opened in two ways: by clicking on a form listed in the forms window or on the Survey Forms toolbar across the top of the window. Due to the length of Section 2, the Survey Forms toolbar provides drop-down menus that allow you to choose individual process models (Section 2A-2G and Section 2H-2O). The toolbar will allow you to open a form from anywhere within the database.

Figure 4-3. HACCP-PCD Database Forms

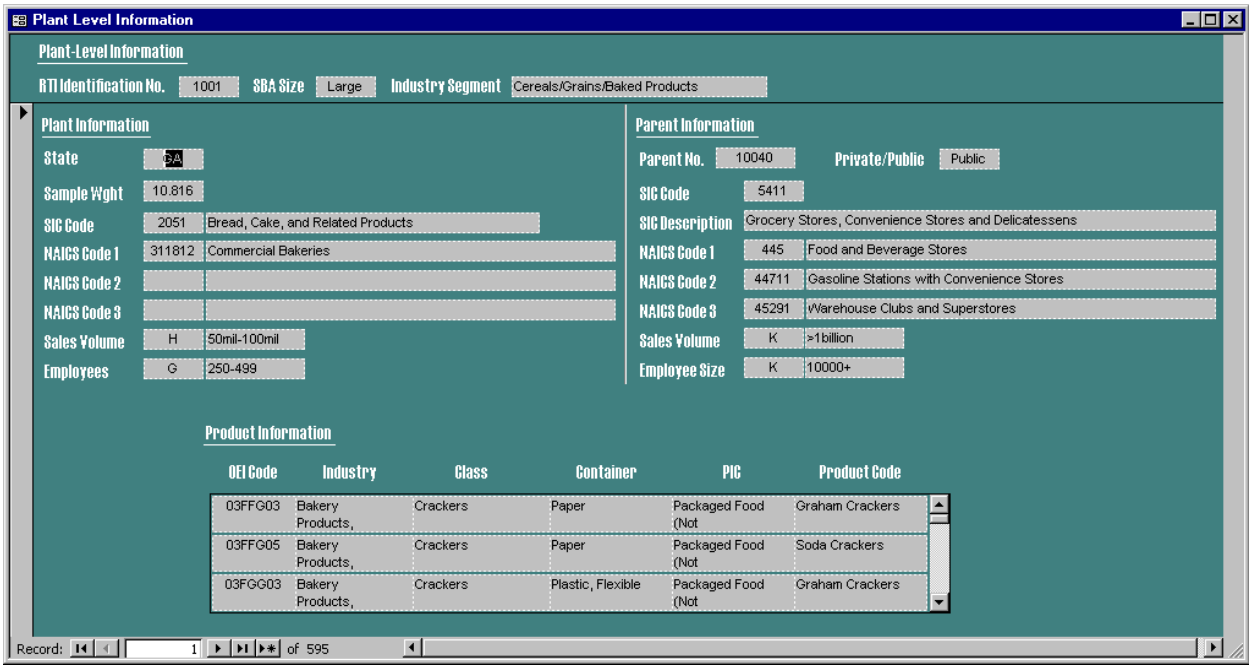


4.2.1 Plant-Level Information Form

Figure 4-4 shows a representative observation from the Plant-Level Information form. The Plant-Level Information form contains

- ➤ the RTI identification number and the strata of the plant (size and industry segment);
- ➤ the state, sample weight, SIC code, NAICS codes, sales volume, and number of employees of the plant;
- ➤ the SIC code, NAICS codes, sales volume, number of employees, and public/private designation of the parent company; and
- ➤ the Official Establishment Inventory (OEI) descriptions of the products produced at the plant.

Figure 4-4. Representative Observation from Plant-Level Information Form

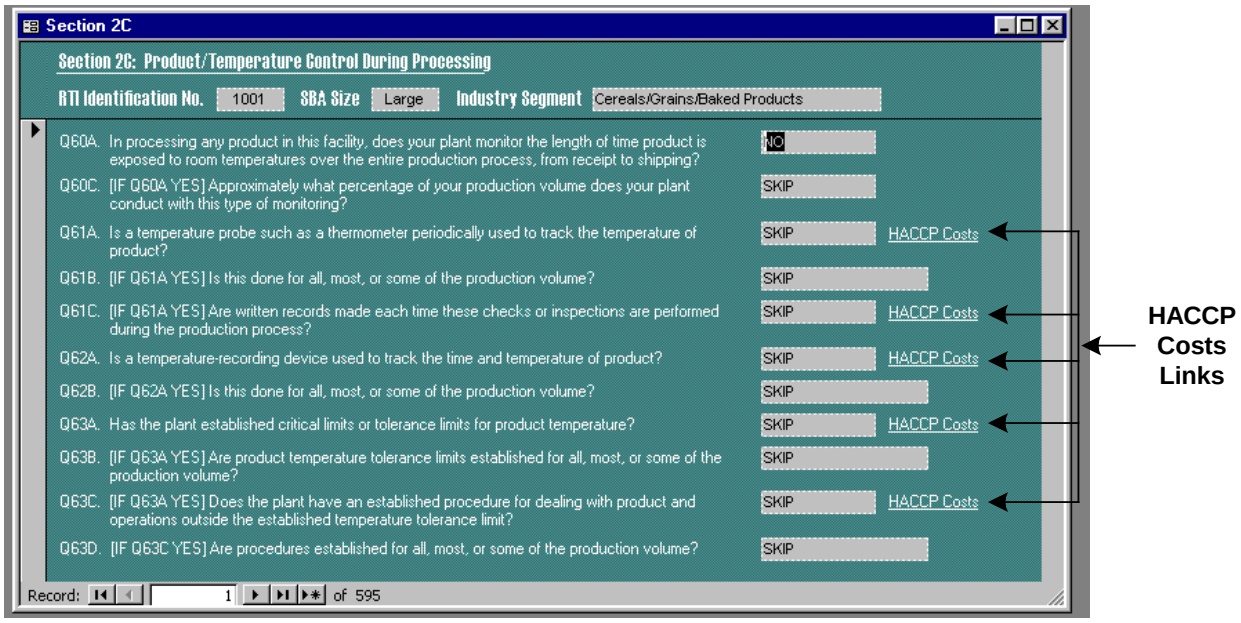


4.2.2 Survey Section Forms

The Survey Section forms were created using a similar format across all sections. Figure 4-5 shows a representative observation from the Section 2C form. Each Survey Section form contains

- ➤ the RTI identification number and the strata of the plant (size and industry segment),
- ➤ the survey questions and responses for that section of the survey, and

Figure 4-5. Representative Survey Section Form (Section 2C)



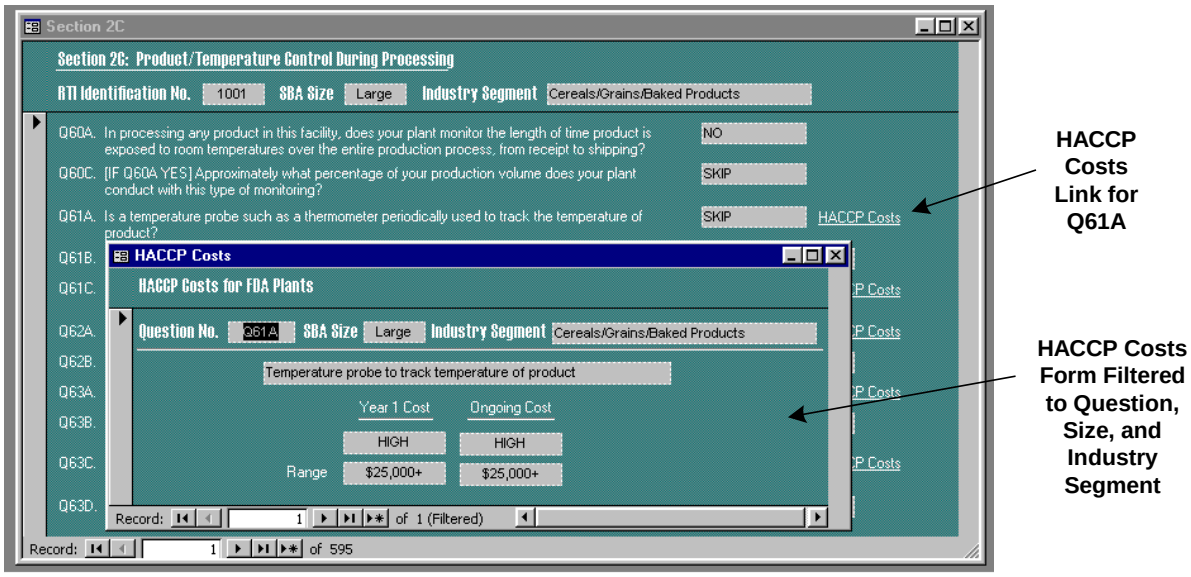
- ➤ links to the HACCP cost information for each HACCP practice question.

To view the HACCP Costs for a particular question, click on the words **HACCP Costs**. The HACCP Costs form will open to the costs for that question and the SBA size and industry segment of the observation. For example, Figure 4-6 shows the year 1 and ongoing cost ranges for a large Cereal/Grains/Baked Products plant that uses a temperature probe to track the temperature of a product (Q61A).

4.3 EXAMPLE DATABASE QUERIES

RTI has selected eight custom queries typical of those the FDA might be interested in conducting. In this section, we provide instructions on how to create and run these custom queries. All of the example queries are saved in the database for easy reference.

Figure 4-6. HACCP Costs Form Opened to Costs for Question 61A



4.3.1 Example Query 1: Obtain the Average Number of Products Produced

Use the following procedures to obtain the average number of products produced by industry segment and SBA size. Each bold word (or words) below indicates a key that you will click on as you conduct the query.

- ➤ Click on the **Query** tab, then click on the **New** button, and choose **Design View**.
- ➤ From the list of tables, choose **Introduction Responses** table and click on **Add**, choose **Plant Data** table and click on **Add**, and choose **Survey Strata** table and click on **Add**. Click on **Close**.
- ➤ On the Survey Strata table on the upper portion of the screen, double-click the **Industry Segment** and **SBA Size** fields.
- ➤ In the next blank column, in the cell labeled Field, type the following: **Total Plants:=[Introduction Responses]![QNA]**
- ➤ In the next blank column, in the cell labeled Field, type the following: **Avg # of Different Products:=[Introduction Responses]![QNA]**
- ➤ Click on the ∑ button located on the toolbar. This will display a new row titled "Total" in each column.
- ➤ In the column labeled Total Plants, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list

of choices. Click on **Count** to obtain the average number of products.

- ➤ In the column labeled Avg # of Different Products, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list of choices. Click on **Avg** to obtain the average number of products.
- ➤ To run the query, click on the **!** button located on the toolbar.

4.3.2 Example Query 2: Obtain Information on HACCP Plans and Implementation

Use the following procedures to obtain the number of plants by industry segment and SBA size that have conducted a hazard analysis and/or written a HACCP Plan and/or implemented a HACCP Plan. Each bold word (or words) below indicates a key that you will click on or words you will type as you conduct the query.

- ➤ Click on the **Query** tab, then click on the **New** button, and choose **Design View**.
- ➤ From the list of tables, choose **Section 1 Responses** table and click on **Add**, choose **Plant Data** table and click on **Add**, and choose **Survey Strata** table and click on **Add**. Click on **Close**.
- ➤ On the Survey Strata table on the upper portion of the screen, double-click the **Industry Segment** and **SBA Size** fields.
- ➤ In the next blank column, in the cell labeled Field, type the following: **Total Plants:=[Section 1 Responses]![RTIID]**
- ➤ To calculate the number of plants that have conducted a hazard analysis:
  - ✓ In the next blank column, *right* click and choose **Build** (with the Magic Wand icon) from the shortcut menu. This will open the Expression Builder.
  - ✓ Within the Expression Builder, in the blank text box type the following: **Hazard Analysis?: = iif([Section 1 Responses]![Q5Achar]="yes",1,0)**
  - ✓ Click **OK**.
- ➤ To calculate the number of plants that have written a HACCP Plan:
  - ✓ In the next blank column, *right* click and choose **Build** from the shortcut menu.
  - ✓ Within the Expression Builder, in the blank text box type the following: **HACCP Plan?: = iif([Section 1 Responses]![Q7Achar]="yes",1,0)**
  - ✓ Click **OK**.

- ➤ To calculate the number of plants that have implemented a HACCP Plan:
  - ✓ In the next blank column, *right* click and choose **Build** from the shortcut menu.
  - ✓ Within the Expression Builder, in the blank text box, type the following: **Plan Implemented?: = iif([Section 1 Responses]![Q8Achar]="yes",1,0)**
  - ✓ Click **OK**.
- ➤ Click on the ∑ button located on the toolbar. This will display a new row titled "Total" in each column.
- ➤ In the column labeled Total Plants, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list of choices. Click on **Count** to obtain a count of plants.
- ➤ In the columns labeled Hazard Analysis?, HACCP Plan?, and Plan Implemented?, click on **Group By**, then the ↓, and then **Sum**.
- ➤ To run the query, click on the **!** button located on the toolbar.

4.3.3 Example Query 3: Obtain the Number of Plants that Package and Ship

Use the following procedures to obtain the number of plants that package and ship product by industry segment and SBA size. Each bold word (or words) below indicates a key that you will click on or text that you will type as you conduct the query.

- ➤ Click on the **Query** tab, then click on the **New** button, and choose **Design View**.
- ➤ From the list of tables, choose **Section 2K Responses** table and click on **Add**, choose **Plant Data** table and click on **Add**, and choose **Survey Strata** table and click on **Add**. Click on **Close**.
- ➤ On the Survey Strata table on the upper portion of the screen, double-click the **Industry Segment** and **SBA Size** fields.
- ➤ In the next blank column, in the cell labeled Field, type the following: **Plants that Ship Own Product:=[Section 2K Responses]![Q150AChar]**
- ➤ On the Section 2K Responses table on the upper portion of the screen, double-click the **Q150AChar** field. In the Section 2K Responses column, do the following:
  - ✓ Click on the **Checkbox** to deselect it.
  - ✓ In Criteria cell, type **yes**.
- ➤ Click on the ∑ button located on the toolbar. This will display a new row titled "Total" in each column.

- ➤ In the column labeled Plants that Ship Own Product, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list of choices. Click on **Count** to obtain a count of plants.
- ➤ In the column labeled Q150Achar, click on **Group By** and then **Where**.
- ➤ To run the query, click on the **!** button located on the toolbar.

4.3.4 Example Query 4: Obtain the Costs of Code-Marking Product

Use the following procedures to obtain the number of plants and the costs associated with code-marking finished product number by industry segment and SBA size. The results of this query can be used in conjunction with the results of Query 3 to determine the proportion of plants that package finished product that also code-mark their product. Each bold word (or words) below indicates a key that you will click on or text that you will type as you conduct the query.

- ➤ Click on the **Query** tab, then click on the **New** button, and choose **Design View**.
- ➤ From the list of tables, choose **Section 2K Responses** table and click on **Add**, choose **Plant Data** table and click on **Add**, choose **Survey Strata** table and click on **Add**, choose **HACCP Costs** table and click on **Add**, and choose **Survey Questions** table and click on **Add**. Click on **Close**.
- ➤ On the Survey Strata table on the upper portion of the screen, double-click the **Industry Segment** and **SBA Size** fields.
- ➤ In the next blank column, in the cell labeled Field, type the following: **# Code Package:=[Section 2K Responses]![Q151AChar]**
- ➤ On the HACCP Costs table on the upper portion of the screen, double-click the **Year 1 Range**, **Ongoing Range**, **Year 1 Cost**, and **Ongoing Cost** fields.
- ➤ On the Section 2K Responses table on the upper portion of the screen, double-click the **Q151AChar** field. In the Section 2K Responses column, do the following:
  - ✓ Click on the **Checkbox** to deselect it.
  - ✓ In Criteria cell, type **yes**.
- ➤ On the Survey Questions table on the upper portion of the screen, double-click the **QID** field. In the Survey Questions column, do the following:
  - ✓ Click on the **Checkbox** to deselect it.

- ✓ In Criteria cell, type **Q151A**.

➤ Click on the ∑ button located on the toolbar. This will display a new row titled "Total" in each column.

➤ In the column labeled # Code Package, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list of choices. Click on **Count** to obtain a count of plants.

➤ In the columns labeled Q151AChar and QID, click on **Group By** and then **Where**.

➤ To run the query, click on the **!** button located on the toolbar.

4.3.5 Example Query 5: Obtain the Number of Plants that Package and Ship by SIC Code

This query duplicates Query 3 except that the information will be provided by SIC code instead of industry segment and size. Each bold word (or words) below indicates a key that you will click on or text that you will type as you conduct the query.

➤ Click on the **Query** tab, then click on the **New** button, and choose **Design View**.

➤ From the list of tables, choose **Introduction Responses** table and click on **Add**, choose **Section 2K Responses** and click on **Add**, choose **Plant Data** table and click on **Add**, and choose **Survey Strata** table and click on **Add**. Click on **Close**.

➤ In the next blank column, in the cell labeled Field, type the following: **SIC Code:=[Introduction Responses]![QKA]**

➤ In the column labeled SIC Code, in the criteria cell, type **>0**.

➤ On the Survey Strata table on the upper portion of the screen, double-click the **Industry Segment** and **SBA Size** fields.

The remainder of the instructions is identical to Steps 4 and beyond for Query 3.

➤ In the next blank column, in the cell labeled Field, type the following: **Plants that Ship Own Product:=[Section 2K Responses]![Q150AChar]**

➤ On the Section 2K Responses table on the upper portion of the screen, double-click the **Q150AChar** field. In the Section 2K Responses column, do the following:

- ✓ Click on the **Checkbox** to deselect it.
- ✓ In Criteria cell, type **yes**.

➤ Click on the ∑ button located on the toolbar. This will display a new row titled "Total" in each column.

- ➤ In the column labeled Plants that Ship Own Product, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list of choices. Click on **Count** to obtain a count of plants.
- ➤ In the column labeled Q150Achar, click on **Group By** and then **Where**.
- ➤ To run the query, click on the **!** button located on the toolbar.

4.3.6 Example Query 6: Obtain the Costs of Code-Marking Product by SIC Code

This query duplicates Query 5 except that the information will be provided by SIC code instead of industry segment and size. The results of this query can be used in conjunction with the results of Query 5 to determine the proportion of plants that package finished product that also code-mark their product. Each bold word (or words) below indicates a key that you will click on or text that you will type as you conduct the query.

- ➤ Click on the **Query** tab, then click on the **New** button, and choose **Design View**.
- ➤ From the list of tables, choose **Introduction Responses** table and click on **Add**, choose **Section 2K Responses** table and click on **Add**, choose **Plant Data** table and click on **Add**, choose **Survey Strata** table and click on **Add**, choose **HACCP Costs** table and click on **Add**, and choose **Survey Questions** table and click on **Add**. Click on **Close**.
- ➤ In the next blank column, in the cell labeled Field, type the following: **SIC Code:=[Introduction Responses]![QKA]**
- ➤ In the column labeled SIC Code, in the criteria cell, type **>0**.
- ➤ On the Survey Strata table on the upper portion of the screen, double-click the **Industry Segment** and **SBA Size** fields.

The remainder of the instructions is identical to Steps 4 and beyond for Query 4.

- ➤ In the next blank column, in the cell labeled Field, type the following: **# Code Package:=[Section 2K Responses]![Q151AChar]**
- ➤ On the HACCP Costs table on the upper portion of the screen, double-click the **Year 1 Range**, **Ongoing Range**, **Year 1 Cost**, and **Ongoing Cost** fields.
- ➤ On the Section 2K Responses table on the upper portion of the screen, double-click the **Q151AChar** field. In the Section 2K Responses column, do the following:

- ✓ Click on the **Checkbox** to deselect it.
- ✓ In Criteria cell, type **yes**.

➤ On the Survey Questions table on the upper portion of the screen, double-click the **QID** field. In the Survey Questions column, do the following:

- ✓ Click on the **Checkbox** to deselect it.
- ✓ In Criteria cell, type **Q151A**.

➤ Click on the ∑ button located on the toolbar. This will display a new row titled "Total" in each column.

➤ In the column labeled # Code Package, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list of choices. Click on **Count** to obtain a count of plants.

➤ In the columns labeled Q151AChar and QID, click on **Group By** and then **Where**.

➤ To run the query, click on the **!** button located on the toolbar.

4.3.7 Example Query 7: Obtain the Plants that Produce Juice

Use the following procedures to obtain the plants that produce juice by SBA size. The results of this query will be used as the starting point for Query 8. Each bold word (or words) below indicates a key that you will click on or text that you will type as you conduct the query.

➤ Click on the **Query** tab, then click on the **New** button, and choose **Design View**.

➤ From the list of tables, choose **Introduction Responses** table and click on **Add**, choose **Plant Data** table and click on **Add**, choose **Survey Strata** table and click on **Add**, and choose **OEI Codes** table and click on **Add**. Click on **Close**.

➤ On the Introduction Responses table on the upper portion of the screen, double-click the **RTIID** field.

➤ On the Survey Strata table on the upper portion of the screen, double-click the **SBA Size** field.

➤ In the next blank column, in the cell labeled Field, type the following: **Plant Products:=[Introduction Responses]![VQNCA]**

*To find the plants that produce juice, the query will look for the word **juice** in two separate fields: VQNCA (main product listed by respondent) and Product Class Description (Part of OEI Code).*

- ➤ On the Introduction Responses table on the upper portion of the screen, double-click the **VQNCA** field. In the Introduction Responses column, do the following:
  - ✓ Click on the **Checkbox** to deselect it.
  - ✓ In **first** line of the Criteria field, type **Like "*juice*"**.
- ➤ On the OEI Codes table on the upper portion of the screen, double-click the **Product Class Description** field. In the OEI Codes column, do the following:
  - ✓ Click on the **Checkbox** to deselect it.
  - ✓ In **second** line of the Criteria field, type **Like "*juice*"**.

Note: Staggered criteria fields, like the ones above, signal to Access that the criteria statement is an OR statement. The query will return any plant that has juice in the VQNCA field OR in the Product Class Description field.

- ➤ Click on the ∑ button located on the toolbar. This will display a new row titled "Total" in each column.
- ➤ In the columns labeled Plant Products and Product Class Description, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list of choices. Click on **Where**.
- ➤ To run the query, click on the **!** button located on the toolbar.

4.3.8 Example Query 8: Obtain the Number of Plants that Produce and Pasteurize Juice

This query uses the results of Query 7 to calculate the number of plants that produce juice and of those plants, the number of plants that pasteurize. Each bold word (or words) below indicates a key that you will click on or text that you will type as you conduct the query.

- ➤ Click on the **Query** tab, then click on the **New** button, and choose **Design View**.
- ➤ Click on the **Queries** tab. From the list of queries, choose **ExQuery7** query and click on **Add**. Click on the **Tables** tab. From the list of tables, choose **Section 2I Responses** table and click on **Add**. Click on **Close**.
- ➤ On the **ExQuery7** query on the upper portion of the screen, double-click the **SBA Size** field.
- ➤ In the next blank column, in the cell labeled Field, type the following: **# Juice Plants:=[ExQuery7]![RTIID]**
- ➤ To calculate the number of plants that pasteurize, do the following:

- ✓ In the next blank column, *right* click and choose **Build** from the shortcut menu.
- ✓ Within the Expression Builder, in the blank text box type the following: **# Pasteurize: = iif([Section 2I Responses]![Q120Achar]="yes",1,0)**
- ✓ Click **OK**.

➤ Click on the ∑ button located on the toolbar. This will display a new row titled "Total" in each column.

➤ In the column labeled # Juice Plants, click on **Group By** to get a drop-down list arrow. Then click on the ↓ to display a list of choices. Click on **Count** to obtain a count of plants.

➤ In the columns labeled # Pasteurize, click on **Group By**, then the ↓, and then **Sum**.

➤ To run the query, click on the **!** button located on the toolbar.

4.3.9 A Note on Hidden Queries

The HACCP-PCD contains 25 queries that have been developed by RTI to run the forms described in Section 4.2. Since the user should not need to revise these queries, we have hidden the queries from the database window view. This gives a cleaner appearance to the database window. If the user would like to examine the hidden queries then go to the toolbar and click **Tools-Options-View-Show-Hidden Objects**.

4.4 REFERENCES

Martin, S.A., D.W. Anderson, B. Wendling, and R.C. Lindrooth. January 1998. "The FDA Enhanced Establishment Database: Working Paper." Prepared for U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition.

Appendix A: Industry and Size Stratification

As mentioned in Section 2, this appendix describes the industry and size stratification for the survey of HACCP practices.

A.1 INDUSTRY STRATIFICATION

Although OEI product codes were used to define the scope of the survey, RTI used SIC codes to stratify the sample by industry for several reasons. First, the OEI file allows multiple OEI product codes for each plant with no indication of which is the primary product. However, each plant is assigned only one primary SIC code, determined by the primary activity of the plant. Second, SIC codes distinguish among manufacturing plants, growers, wholesale establishments, and retail establishments. However, OEI industries are based on product. OEI product codes are augmented by three establishment type codes for each plant that do not indicate which activity (e.g., manufacturing and labeling) is most important. That is, if an establishment does both manufacturing and retail, we cannot determine which is the primary activity. Third, other data, such as those gathered by the U.S. Census Bureau, that we may use in analyzing the implications of the cost estimates are published by SIC code.

The only exception to our use of SIC codes for stratification is for food industry 46. This industry includes any establishments that manufacture or pack/repack infant formula, baby food, or geriatric foods. We used an establishment's OEI product code to identify all plants that process these foods. Because FDA is particularly interested in the results of the survey for this industry, we have designated this industry as a superstrata, and each establishment will be surveyed. Table A-1 provides a description of each of the superstrata and substrata, as defined by SIC codes and, in the case of the last superstrata, OEI product codes. Table A-1 also shows the number of plants in each superstrata and substrata, and the percentage of the survey universe each represents.

Table A-1. Superstrata for FDA HACCP Practices Survey

Superstrata	SIC Codes	Description	Frequency	Percent
		Superstrata 1: Premarket Services and Other Products		
1	0133-0721, 0724-0831	Agriculture services, except crop preparation for market	150	1.1
2	0723	Crop preparation for market	506	3.9
17	2047, 2048	Animal feeds	51	0.4
34	2091, 2092, 2099	Other food preparations	1215	9.3
37	5032-5122, 5153-5199	Wholesale trade, except groceries	339	2.6
38	5141	Wholesale groceries, general	236	1.8
39	5142	Wholesale groceries, packed frozen foods	51	0.4
40	5143	Wholesale groceries, dairy products	69	0.5
41	5145	Wholesale confectionery	99	0.8
42	5148	Wholesale fresh fruits	482	3.7
43	5144, 5146, 5147	Wholesale trade in meat and poultry	54	0.4
44	5149	Other wholesale trade in groceries	679	5.2
45	4221-4226, 4213, 4783	Food warehousing and food transport	57	0.4
47	2211-2759, 2911-2992, 3081-3999, 4731, 4822, 4941,6061-9999	Other primary SIC codes not directly related to food	274	2.1
		Superstrata 2: Animal Protein Products		
3	2011, 2013, 2015	Meat and poultry processing	147	1.1
4	2021	Butter	101	0.8
5	2022	Cheese	477	3.7
6	2023	Dry, condensed, evaporated dairy products	130	1.0
7	2024	Ice cream	371	2.8
8	2026	Milk	276	2.1

(continued)

Table A-1. Superstrata for FDA HACCP Practices Survey (continued)

Superstrata	SIC Codes	Description	Frequency	Percent
		Superstrata 3: Preserved/Additive/Supplement Products		
9	2032	Canned specialties	192	1.5
10	2033	Canned fruit	644	4.9
11	2034	Dried and dehydrated fruits, vegetables, and soup mixes	254	1.9
12	2035	Pickled fruits and vegetables	358	2.7
13	2037	Frozen fruits, fruit juices and vegetables	154	1.2
14	2038	Other frozen specialties	234	1.8
35	2812-2823, 2836-2899	Chemicals, except vitamins, etc.	135	1.0
36	2833-2834	Vitamins, minerals, proteins, and unconventional dietary supplements	363	2.8
		Superstrata 4: Cereals/Grains/Baked Products		
15	2041, 2044, 2045, 5046	Flour and other mill products	453	3.5
16	2043	Cereal breakfast foods	45	0.3
18	2051	Bread and bakery	1173	9.0
19	2052, 2053	Other bakery products	209	1.6
24	2068	Salted nuts and seeds	66	0.5
25	2074, 2075, 2076	Vegetable oil mills	111	0.8
26	2077, 2079	Other oils	64	0.5
31	2096	Potato chips, corn chips and other snacks	160	1.2
33	2098	Macaroni, spaghetti, vermicelli, and noodles	136	1.0

(continued)

Table A-1. Superstrata for FDA HACCP Practices Survey (continued)

Superstrata	SIC Codes	Description	Frequency	Percent
		Superstrata 5: Beverages/Sugared Products		
20	2061, 2063	Cane and beet sugar	55	0.4
21	2062	Cane sugar refining	54	0.4
22	2064, 2067	Candy and chewing gum	614	4.7
23	2066	Chocolate	82	0.6
27	2082-2085	Alcoholic beverages	501	3.8
28	2086	Bottled and canned soft drinks	726	5.6
29	2087	Other flavoring extracts and syrups	271	2.1
30	2095	Roasted coffee	112	0.9
32	2097	Ice	84	0.6
		Superstrata 6: Products for Sensitive Consumers		
46	OEI Codes 40 and 41F[a]	Baby food, infant formula, and geriatric foods	46	0.4
Total			13,060	100

[a]Any plant for which any of its OEI product codes was 40 or 41F is included in this stratum.

A.2 SIZE STRATIFICATION

The SBA classifies companies as small based on the size of the entire company. Because the OEI data on size are only for a specific plant, we had to obtain parent company information on employment and/or revenue to correctly classify each plant as part of a small or large company.

To obtain parent company data for plants in the survey universe, we sent ABL the OEI data records and requested (among other variables) the name, address, employment size (in ranges), and sales receipts (in ranges) of parent company firms with plants in the survey universe. ABL matched 2,212 records to ultimate parents. The parent company data for these 2,212 plants were merged with the survey universe. Of the remaining records, 7,193 plants were matched but did not have a larger parent company. For these records, the plant and parent company were the same entity, so we

used plant-level ABL data to define the plant's size. For plants that were in the OEI database but not the ABL database, we imported size data as described in Martin et al. (1998).

Using SBA size standards, each of the 13,060 plants in the survey universe was classified as parts of small or large businesses based on the employment size or annual revenues of each plant's parent company. The SBA size standards represent the largest size a firm can be, in terms of either the number of employees or annual receipts, and still remain eligible as a small business for various types of federal assistance. When a plant did not have a parent company (i.e., when a record in the EED survey universe did not match with an ultimate parent in the ABL database), the employment size or annual revenues of the plant were used to categorize the plant. If a plant's parent company had a sales volume or employment size that exceeded the SBA size standard for the plant's primary four-digit SIC code, the firm was categorized as large. Conversely, a plant whose parent company had an employment size or sales volume less than or equal to the SBA size standard for the plant's primary four-digit SIC code was classified as small. Table A-2 provides a listing of SBA size standards for the four-digit SIC codes found in the survey universe.

Because ABL data on employment size and sales volume were in ranges that did not coincide with SBA size standards for a particular four-digit SIC code, 36 of the 13,060 plants in the survey universe were not initially categorized as small or large using the method described above. For example, the SBA size standard for SIC 2046, wet corn milling, is 750 employees. However, there is not an ABL employment size range that breaks at 750; the relevant ABL employment range is 500 to 999 employees. Thus, for plants in SIC code 2046 with parent companies with employment of 500 to 999, we could not determine if the plant was large or small.

In such cases where the SBA size standard did not precisely coincide with an employment or sales range, we categorized the plant as small. In addition, there were three plants with four-digit SIC codes (9199, 9621, 9721) for which the SBA does not determine size standards. We categorized these plants as small or large based on whether the plant or its parent company had annual receipts of $5 million or more. Finally, the SBA size standard for

Table A-2. Size Definitions by SIC Code

SIC Codes	SBA Size Standard
0133-0191, 0212-0241, 4822, 4941	$500,000 in sales
6531	$1,500,000 in sales
0711-0831, 6221, 6411, 6513, 7011, 7033, 7231, 7261, 7319-7342, 7359, 7384, 7319-7342, 7359, 7384, 7389, 7542-7699, 7832-8222, 8322-8699, 8732, 8734, 8748-9999	$5,000,000 in sales
7381	$9,000,000 in sales
7374	$18,000,000 in sales
4213, 4221-4226, 4731, 4783	$18,500,000 in sales
7819	$21,000,000 in sales
6061	$100,000,000 in assets
5032-5199	100 employees
2011-2026, 2033-2041, 2044-2045, 2047-2051, 2053-2061, 2064-2075, 2077, 2082-2084, 2086-2099, 2281-2284, 2399-2599, 2655, 2671-2759, 2836, 2842-2861, 2875-2891, 2899, 2992, 3081-3089, 3274, 3412-3479, 3523, 3556, 3559, 3565, 3569, 3581, 3589, 3599, 8731	500 employees
2046, 2052, 2062, 2063, 2079, 2085, 2621, 2657, 2821, 2841, 2865	750 employees
2032, 2043, 2076, 2211, 2812-2819, 2822, 2869, 3275, 3312, 3411	1,000 employees

[a]The EED does not contain information on company assets. The two firms in the sampling universe from this SIC code were categorized as large or small based on annual sales of $5 million.

firms in SIC code 6061, federally chartered credit unions, is $100 million in assets. Because the sampling frame does not contain information on assets, the two establishments in SIC 6061 were classified based on the size of the firm's annual receipts. The establishment was classified as large if receipts were greater than $5 million. This is the most common size standard (not based on assets) for financial, insurance, and real estate firms.

Appendix B: Presentation on Industry's HACCP Progress and Plans

As mentioned in Section 2, RTI presented the results of the HACCP survey to FDA in January 1999. The presentation provided an overview of the survey procedures and results. The overhead slides for the presentation are provided in this section.

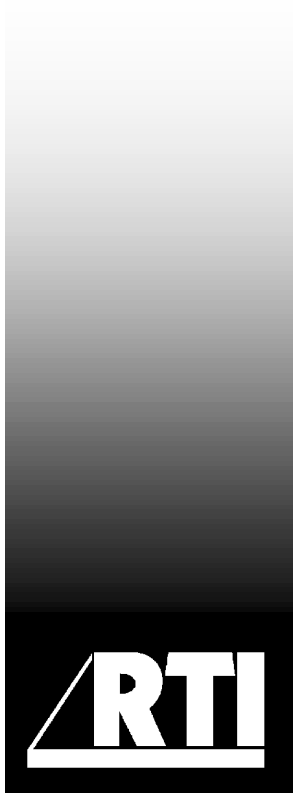
HACCP: Industry's Progress and Plans

Presented to **Center for Food Safety and Applied Nutrition**
Food and Drug Administration

Presented by **Sheila A. Martin**
Donald W. Anderson

January 11, 1999

Research Triangle Institute
P.O. Box 12194 · 3040 Cornwallis Road
Research Triangle Park, NC 27709



Overview

- **Objectives**
- **Primary Findings**
- **Approach**
- **Survey Procedures**
- **Results**
- **Conclusions**

Objectives

- **Describe current HACCP-related practices in industry**
- **Explore HACCP differences among different industry segments**
- **Support analysis of regulatory initiatives**

Primary Findings

- **45 percent of all plants report implementing HACCP**
- **Plants that have HACCP also conduct more HACCP-related practices**
- **Many companies not currently practicing HACCP report that they plan to implement HACCP in the future**
- **Industries leading HACCP implementation:**
  - ✓ **Products for Sensitive Consumers**
  - ✓ **Animal Protein Products**
- **Small companies lag behind large companies in HACCP implementation**

Approach

- **Collect practices data from a national sample of food processing plants**
- **Use survey results to forecast future HACCP adoption**
- **Conceptual Problem: How do we define the required practices?**
- **Solution: Define complete set of possibly required HACCP-related practices and build a flexible model**

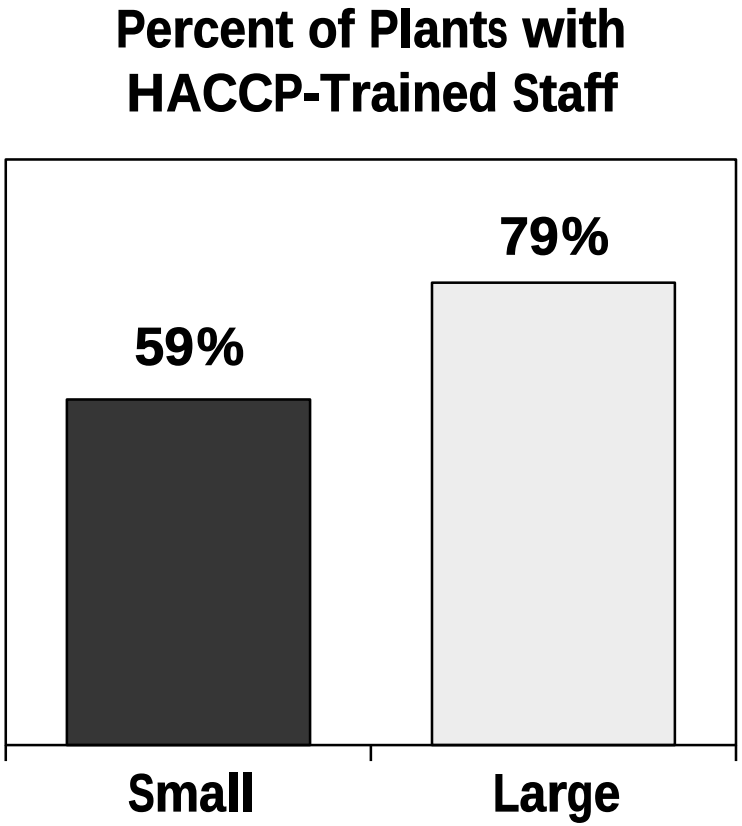
Survey Instrument

- **HACCP Development and Training**
- **Food Safety Practices for Each Manufacturing Process**
  - ✓ **Receiving**
  - ✓ **Storing (Refrigerated and Dry)**
  - ✓ **Controlling Product/Temperature During Processing**
  - ✓ **Batching**
  - ✓ **Culturing and Fermenting**
  - ✓ **Drying**
  - ✓ **Low Water Activity Processing**
  - ✓ **Baking**
  - ✓ **Pasteurization**
  - ✓ **Heat Treatment**
  - ✓ **Irradiation**
  - ✓ **Packaging**
  - ✓ **Inspecting Container Seal Integrity**
  - ✓ **Metal Detection**
  - ✓ **Testing Finished Product**
  - ✓ **Refrigerated Distribution**
- **Sanitation**

Sample Design

- **Final sample size: 595 plants**
- **Response rate: 32 percent**
- **Results estimated by company size and industry**
- **Contacts:**
  - ✓ **Plant managers**
  - ✓ **HACCP managers**
  - ✓ **Quality assurance managers**

Results:
HACCP Training

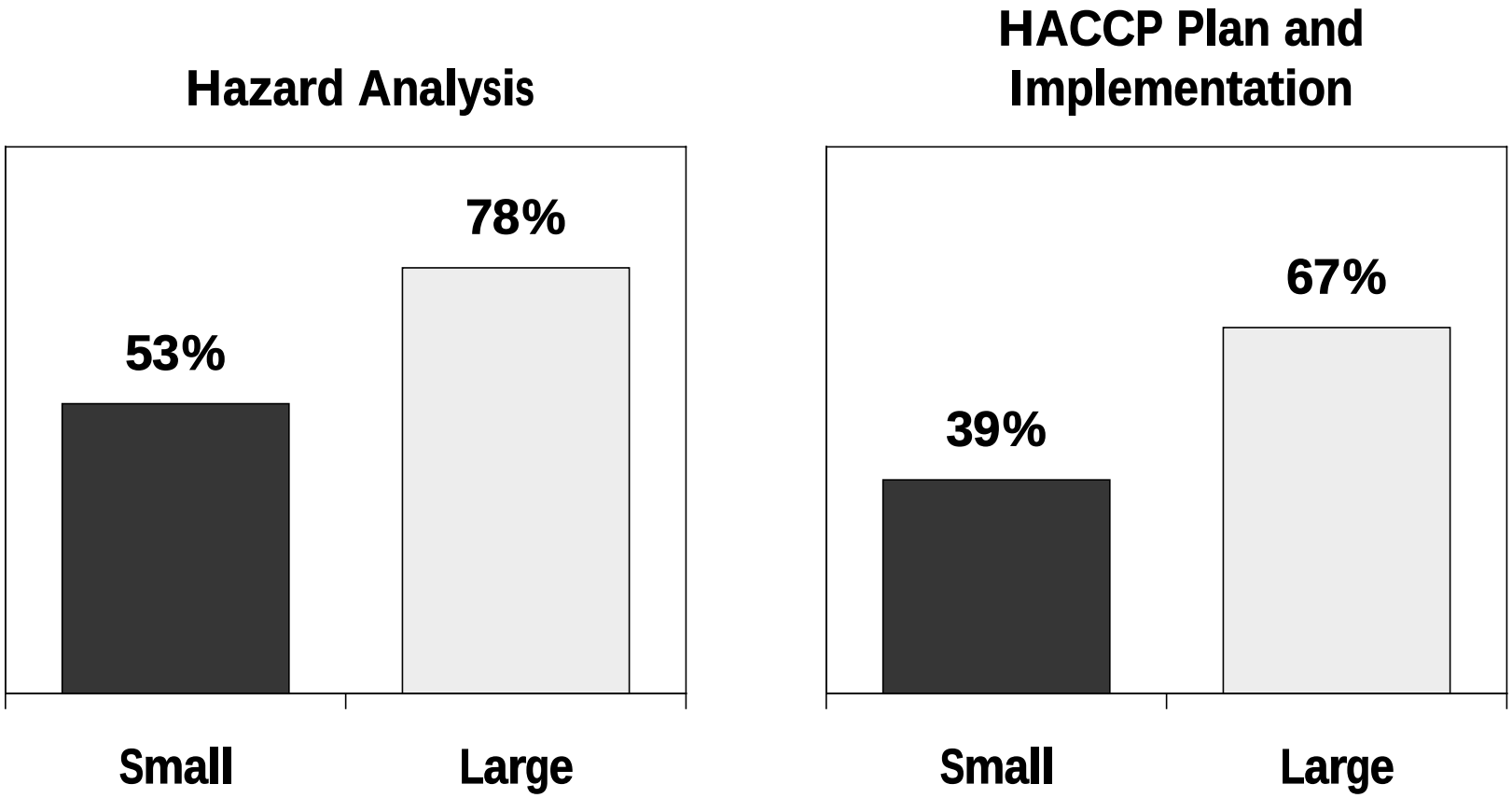


Highest Industry: Animal Protein Products
Lowest Industry: Beverages/Sugared Products

Results:
Percent of Plants with HACCP-Trained Staff

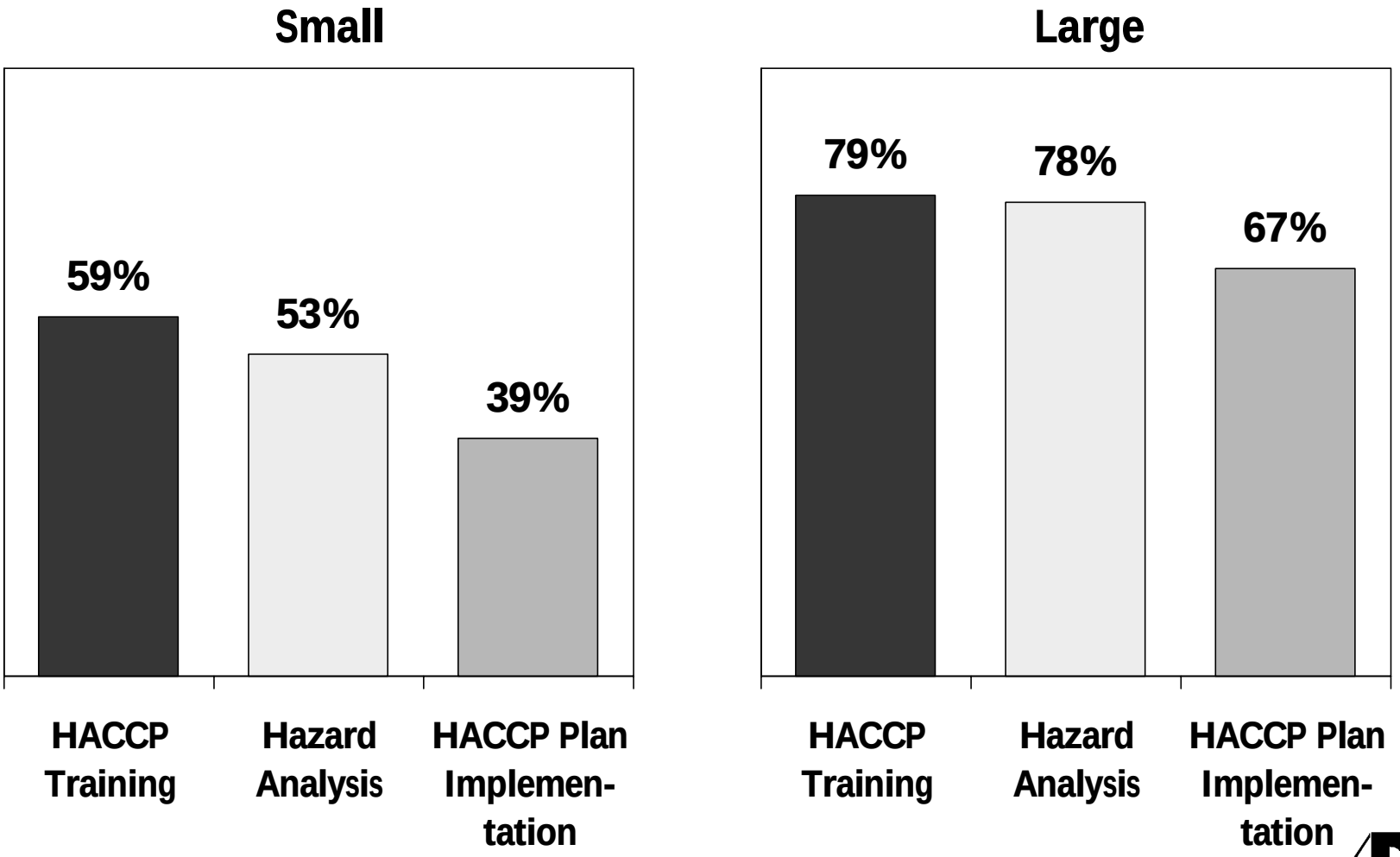
Industry Segment	Small	Large	Total
Premarket Services and Other Products	58	68	60
Animal Protein Products	73	85	76
Preserved/Additive/ Supplement Products	68	89	72
Cereal/Grains/Baked Products	64	97	72
Beverages/Sugared Products	39	64	44
Products for Sensitive Consumers	67	75	72
Overall	59	79	63

Results:
HACCP Implementation (I)

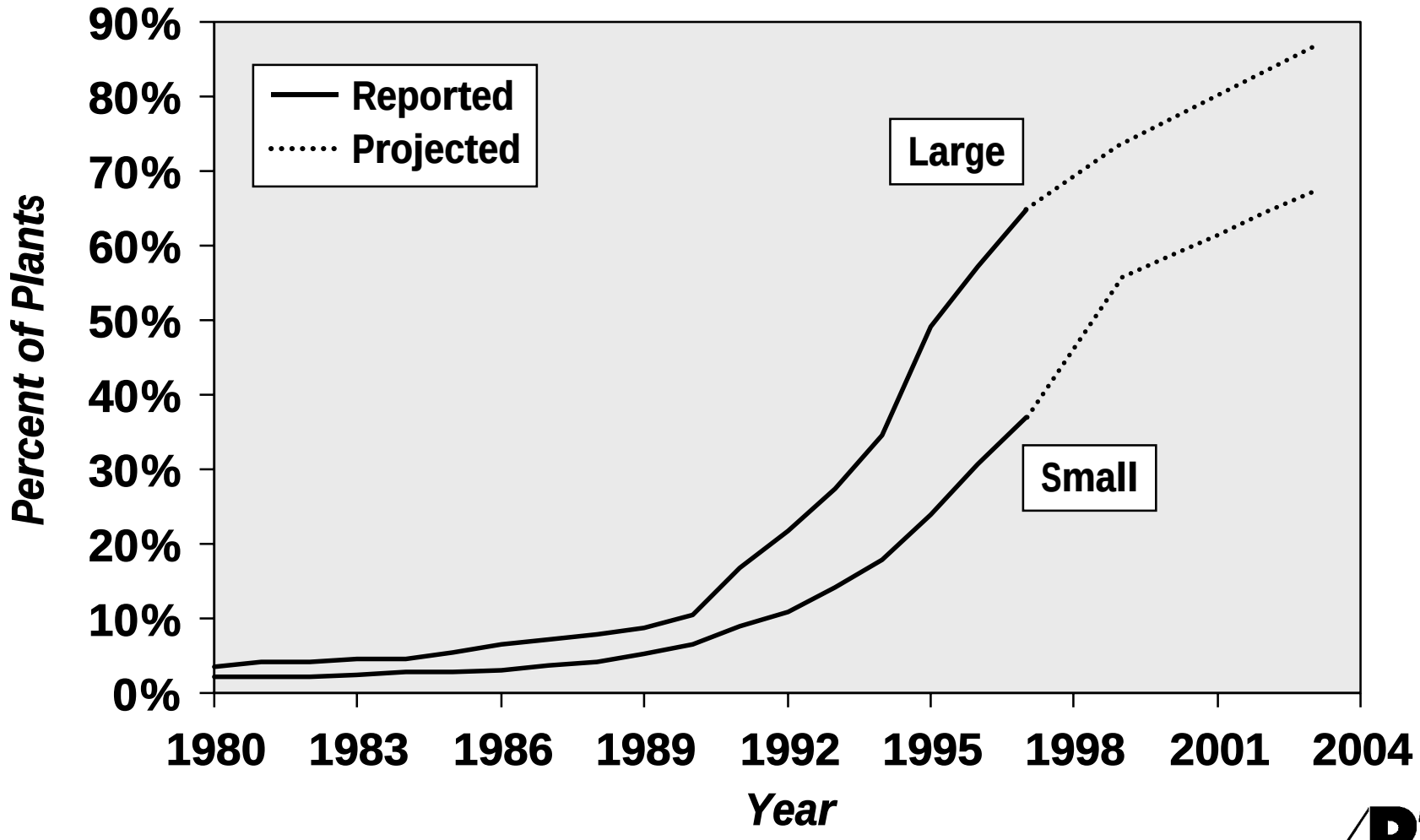


Highest Industry: Products for Sensitive Consumers
Lowest Industry: Beverages/Sugared Products

Results: HACCP Implementation (II)

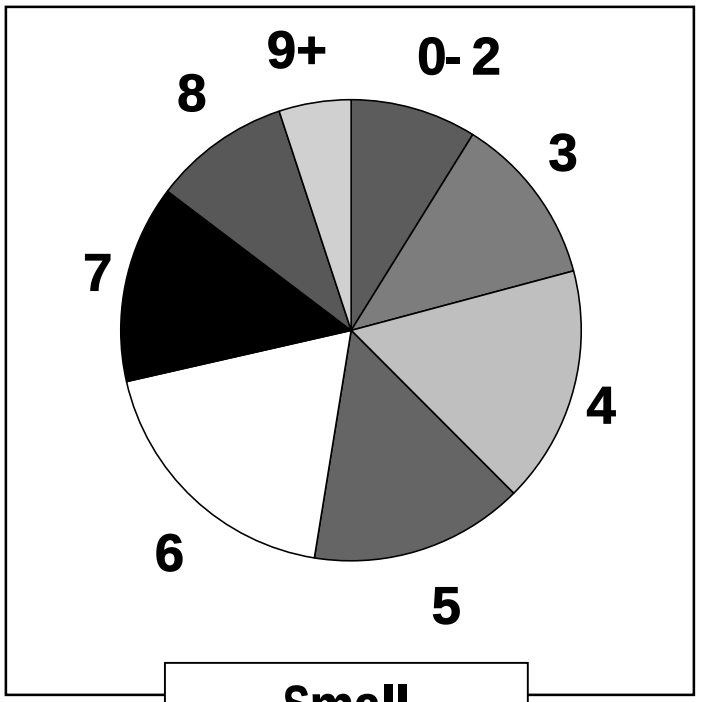


Results:
HACCP Diffusion

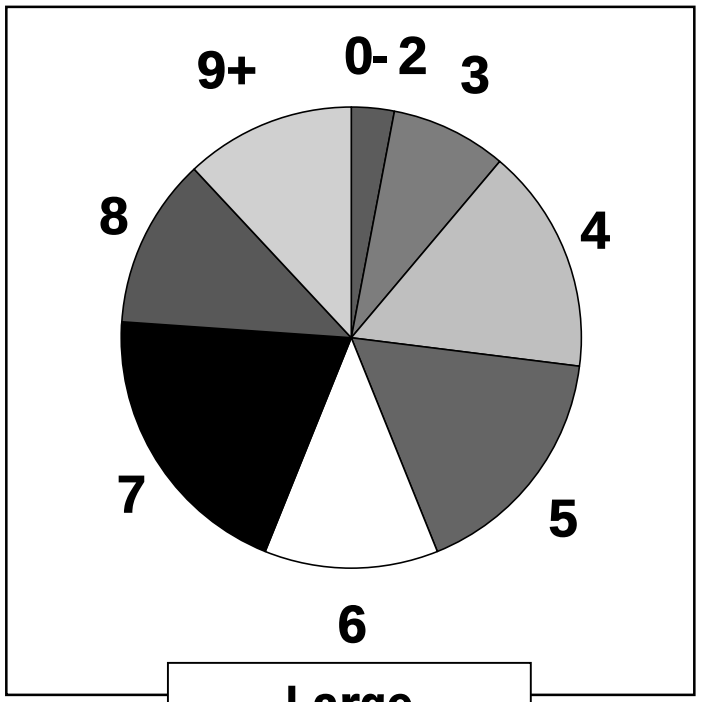


Results:
Process Complexity

Number of Nonstandard Processes



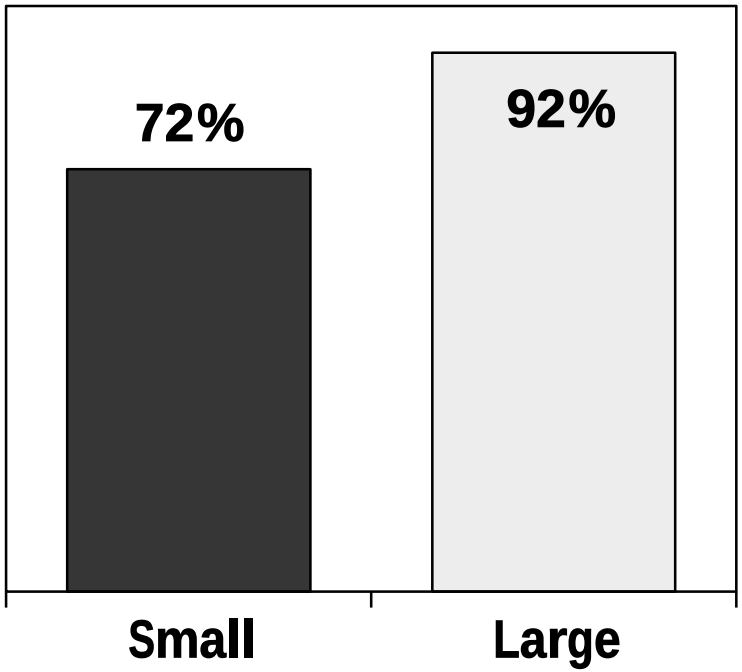
Small
Average = 5.5
Median = 6



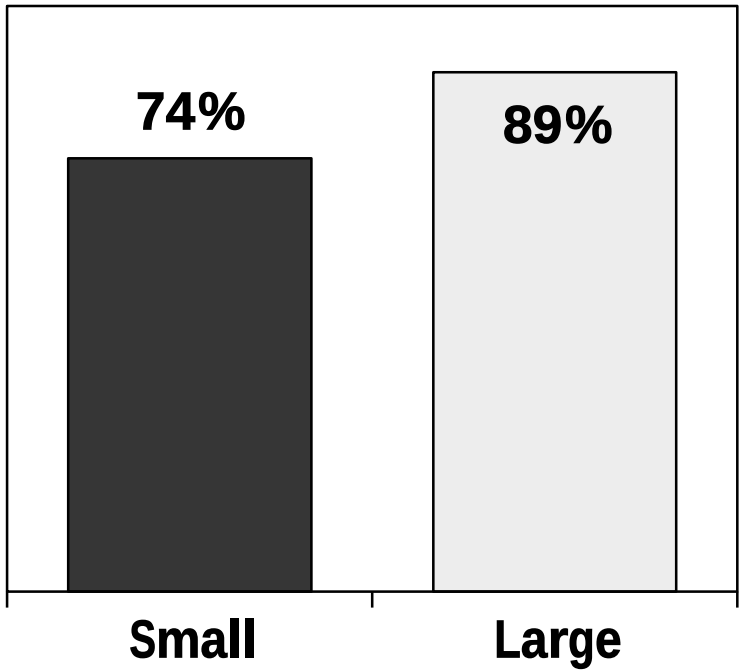
Large
Average = 6.2
Median = 6

Results:
Sanitation Practices

Plant Has a Written Sanitation Program



Plant Keeps Records to Verify Sanitation Inspections



Results:
Top 10 HACCP-Related Practices

Practice	Percent of Plants Conducting Practice*	
	Small	Large
Maintaining thermometers on pasteurization equipment	99	100
Maintaining thermometers on refrigerators and freezers	98	98
Visual inspection of incoming food ingredients	98	98
Physical separation of hazardous chemicals from food ingredients	97	99
Maintaining thermometers on ovens	98	97
Maintaining written records for finished product microbial testing	97	99
Establishing critical limits for metal detector	94	97
Conducting evaluation of product held due to exceeding critical limits for metal	97	96
Conducting scheduled testing and calibration of metal detectors	93	97
Maintaining thermometers on heat treatment equipment	92	100

*As a percentage of plants for which this process is relevant

Results:
Bottom 10 HACCP-Related Practices

Practice	Percent of Plants Conducting Practice*	
	Small	Large
Testing for sulfites	30	35
Conducting microbial testing of equipment surfaces	27	42
Using automated temperature alarms or temperature recording devices during refrigerated distribution	22	45
Maintaining written records for automated temperature alarms in distribution	19	37
Requiring sanitation records for deliveries	23	34
Using innoculum from previous cultures for culturing and fermenting	20	22
Maintaining relative humidity-indicating devices for dry finished products	20	24
Daily monitoring of humidity indicating devices	13	13
Maintaining written records for monitoring and calibrations of humidity indicating devices	12	16
Calibration of humidity-indicating devices	9	11

*As a percentage of plants for which this process is relevant

Results: Overall Performance of HACCP-Related Practices

	Average Number of Relevant Practices	Average Number of Practices Conducted	Ratio: Conducted/ Relevant
Plants Implementing HACCP	79	58	.73
Plants Not Implementing HACCP	72	40	.54
Industry Average	75	48	.63

Results: Overall Performance of HACCP-Related Practices by Industry

	Small			Large		
Industry Segment	**Relevant**	**Conducted**	**Ratio**	**Relevant**	**Conducted**	**Ratio**
Premarket Services and Other Products	72	42	.57	77	53	.66
Animal Protein Products	84	59	.69	85	65	.76
Preserved/Additive/ Supplement Products	75	50	.66	81	61	.75
Cereal/Grains/Baked Products	73	46	.62	81	61	.74
Beverages/Sugared Products	68	38	.55	69	45	.64
Products for Sensitive Consumers	78	60	.74	82	63	.78
Industry Average	74	46	.61	78	56	.70

Concluding Observations

- **The baseline adoption of HACCP in many industries is almost certainly being influenced by the promulgation of HACCP rules for other industries**
- **Consequently, some industry segments are adopting HACCP faster than others**
- **Large firms are adopting HACCP and HACCP-related practices at a faster rate than smaller firms**
- **Many small plants must catch up with their large counterparts in their sanitation practices**
- **In many cases, HACCP implementation will require more significant changes in small firms than in large firms**
- **Without FDA regulation, some plants have no plans or incentives to adopt HACCP practices**

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Appendix C: Food Processing and Sanitation Survey Questions

The food safety practices covered in the survey include those associated with food processing and with sanitation. Table C-1 lists the survey questions related to food processing, and Table C-2 lists the survey questions related to sanitation. Selected results from these survey questions were presented in Section 2 and Appendix B of the report. These survey questions are also the basis for the cost estimates developed in Section 3. All of the survey question responses are incorporated into the database presented in Section 4.

Table C-1 Food Processing Practices Covered by the Survey

Receiving	
Q21A.	Does your plant require written vendor guarantees that any raw materials and ingredients received must meet specific requirements for biological, chemical, or physical contamination?
Q22A.	Does your plant conduct scheduled sample testing for microbiological contamination of any ingredients?
Q23A.	Does your plant conduct sample testing on a scheduled basis of any ingredients for chemical contamination?
Q25A.	Does your plant measure the temperature of REFRIGERATED ingredients upon arrival?
Q25C.	Does your plant measure the temperature of FROZEN ingredients upon arrival?
Q25E.	Does your plant require TEMPERATURE records for each delivery from the transportation company?
Q26A.	Does your plant require SANITATION records for any delivery from the transportation company?
Q27A.	Does your plant visually inspect the condition of incoming packaged food ingredients for damaged containers?
Q28A.	Does your plant maintain specification sheets that describe acceptable limits for all incoming food and packaging materials?
Q29A.	Does your plant have established procedures for handling raw materials that do not meet your specifications for incoming food and packaging materials?
Q30A.	Are written records made each time any of the checks or inspections described above are performed for raw materials or ingredients?
Storing	
Q40B.	Are hazardous chemicals such as sanitizers stored in a separate room or closet from food ingredients?
Q41A.	Are perishable raw materials that are not immediately processed stored in refrigeration or freezer units?
Q42A.	Does your plant monitor the total amount of time that perishable raw materials are kept at room temperature, that is, outside refrigerator or freezer unit?

(continued)

Table C-1 Food Processing Practices Covered by the Survey (continued)

Storing (continued)	
Q43A.	Does your plant maintain physically separate refrigerated and frozen storage facilities for finished products and raw products?
Q44A.	Does your plant use TEMPERATURE-INDICATING devices or thermometers for refrigeration/freezer units?
Q45A.	Does your plant use TEMPERATURE-RECORDING devices or thermometers with printers for refrigeration/freezer units?
Q46A.	Does your plant use automated temperature alarms for refrigeration/freezer units?
Q47A.	Using a response of yes or no, does your plant do EITHER of the following to check that proper storage temperatures are maintained: monitor temperature-recording devices daily OR conduct multiple visual checks of temperature-indicating devices daily?
Q47C.	Are written records maintained for these checks to ensure proper storage temperatures?
Q48A.	Does your plant calibrate temperature devices to NIST (National Institute of Standards Technology) standards?
Q49A.	Are written records made each time the checks or inspections we've discussed are performed in refrigerated/frozen storage?
Q51.	Does your plant maintain separate storage facilities for dry finished products and dry raw ingredients?
Q52A.	Does your plant use humidity-indicating devices (such as hygrometers or hygroscopes) to monitor relative humidity for dry finished products and/or raw ingredients?
Q53A.	Does your plant monitor humidity-indicating devices daily?
Q54A.	Does your plant calibrate humidity-indicating devices to U.S. standards such as NIST?
Q55A.	Are written records made when monitoring or calibrations are performed for dry storage?
Controlling Product/Temperature During Processing	
Q61A.	Is a temperature probe such as a thermometer periodically used to track the temperature of product?
Q61C.	Are written records made each time these checks or inspections are performed during the production process?
Q62A.	Is a temperature-recording device used to track the time and temperature of product?
Q63A.	Has the plant established critical limits or tolerance limits for product temperature?
Q63C.	Does the plant have an established procedure for dealing with product and operations outside the established temperature tolerance limit?

(continued)

Table C-1 Food Processing Practices Covered by the Survey (continued)

Batching	
Q71A.	Does your plant monitor the pH level for each lot?
Q72A.	Does your plant check the accuracy of your pH meter against NIST standards?
Q73A.	Does your plant measure the weight of food additives?
Q74A.	Does your plant test for sulfites?
Q75A.	Does your plant periodically verify the batching process using chemical analysis?
Q76A.	Are written records made each time these food additive checks or inspections are performed?
Culturing and Fermenting	
Q81A.	Does your plant use known starter cultures?
Q82A.	Does your plant use inoculum from previous cultures?
Q83A.	Does your plant monitor pH or acidity development at any point during fermentation?
Q84A.	Does your plant conduct procedures to inhibit culture growth after a specific length of time?
Q85A.	Are written records made each time these culturing or fermenting checks or inspections are performed?
Drying	
Q91A.	Does your plant monitor the water activity level for specific tolerances during the drying process?
Q91C.	Are written records of this water activity level for specific tolerances during the drying process?
Q92A.	Does your plant monitor the moisture level for specific tolerances during the drying process?
Q92C.	Are written records of this moisture level maintained?
Q93.	Has the adequacy of the drying process been verified by an acknowledged expert, for example, university extension agent or food technology consultant, to ensure that the appropriate water activity or moisture level is attained for shelf stability?
Low Water Activity Processing	
Q101A.	Does your plant measure the quantity of water activity reducing agents (such as water, salt, or sugar) by either volume or weight for each lot?
Q101C.	Are written records of these measurements maintained?
Q102A.	Does your plant monitor the length of the low water activity process for each lot or batch?
Q102C.	Are written records of this monitoring maintained?
Q103A.	If scales are used for weighing ingredients, are the scales calibrated using a standard set of weights (such as NIST-traceable weights)?
Q104A.	Does your plant monitor the water activity level for specific tolerances during the low water activity process?
Q104C.	Are written records of this water activity monitoring maintained?
Q105A.	Does your plant monitor the moisture level for specific tolerances during the low water activity process?

(continued)

Table C-1 Food Processing Practices Covered by the Survey (continued)

Low Water Activity Processing (continued)	
Q105C.	Are written records of this moisture level monitoring maintained?
Q106A.	Does your plant check the accuracy of your water activity meter against U.S. standards such as NIST?
Q107.	Has the adequacy of the water activity process been verified by an acknowledged expert, for example, university extension agent or food technology consultant, to ensure proper reduction in microorganisms?
Baking	
Q111A.	Does your plant maintain temperature-indicating devices such as thermometers on baking equipment?
Q112A.	Does your plant maintain time- and/or temperature-recording devices on baking equipment?
Q113.	Does your plant check the accuracy of temperature-indicating devices daily?
Q114A.	Does your plant calibrate temperature-recording and temperature-indicating devices to U.S. standards such as NIST?
Q115A.	Are written records made each time the checks or inspections are performed during the baking process?
Q116.	Has the adequacy of the baking process been verified by an acknowledged expert, for example, university extension agent or food technology consultant?
Pasteurization	
Q121A.	Does your plant repasteurize any previously pasteurized ingredients before use such as milk or egg products?
Q122A.	Does your plant maintain temperature-indicating devices such as thermometers on pasteurization equipment?
Q123A.	Does your plant maintain time- and/or temperature-recording devices on pasteurization equipment?
Q124B.	Does your plant maintain a metering pump upstream from a holding pump?
Q124D.	Does your plant maintain a flow-diversion system to divert low temperature product?
Q125A.	Are written records made each time the checks or inspections are performed during the pasteurization process?
Q126.	Has the adequacy of the pasteurization process been verified by an acknowledged expert, for example, university extension agent or food technology consultant, to ensure proper reduction in microorganisms?
Heat Treatment	
Q131A.	Does your plant maintain temperature-indicating devices such as thermometers on heat treatment equipment?
Q131C.	Are written records maintained regarding temperature inspections?
Q132A.	Does your plant maintain time- and/or temperature-recording devices on heat treatment equipment?

(continued)

Table C-1 Food Processing Practices Covered by the Survey (continued)

Heat Treatment (continued)	
Q133A.	Does your plant check the accuracy of time- and/or temperature-recording devices daily?
Q134A.	Does your plant calibrate temperature-recording and temperature-indicating devices against standards such as NIST?
Q134C.	Are written records maintained regarding calibrations?
Q135A.	Has a cooling-rate study been conducted to establish that product is cooled within a certain period of time sufficient to prevent microbial growth or decomposition of heat treated products?
Q136A.	Does your plant check the length of time required to cool the product following heat treatment until it reaches an appropriate internal temperature?
Q137A.	Does your plant check the product temperature at the completion of the cooling period?
Q137C.	Are written records maintained for cooled product time and temperatures?
Q138.	Has the adequacy of the heat treatment process been verified by an acknowledged expert, for example, university extension agent or food technology consultant, to ensure proper reduction in microorganisms?
Irradiation	
Q141.	Has the adequacy of the irradiation process been verified by an acknowledged expert, for example, university extension agent or food technology consultant, to ensure proper reduction in microorganisms?
Packaging	
Q151A.	Is the finished product package code-marked to identify the plant where the product was packed and the date and time (lot or period) of packing?
Q151B.	Is there a procedure to check that the code is legible and corresponds to the production batch?
Q152A.	Is a "tamper-evident" seal used on the finished product packaging?
Q153A.	Does the supplier test the packaging material for compatibility with the food product to make sure that packaging material dyes do not bleed onto product and produce a potentially hazardous chemical reaction?
Q153B.	Does your plant receive a letter of guarantee from the supplier regarding this test?
Q154A.	Is there a procedure to check that the ingredient statement on the label has been checked against the formulation?
Q155A.	Is the SHIPPING container code-marked to identify the plant where the product was packed and the date and time (lot or period) of packing?
Q155B.	Is there a procedure to check that the code is legible and corresponds to the production batch?
Inspecting Container Seal Integrity	
Q161A.	Does your plant visually inspect containers from either the sealing machines or sealing heads on each sealing machine for container integrity?
Q162A.	Does your plant conduct destructive testing for seal integrity?

(continued)

Table C-1 Food Processing Practices Covered by the Survey (continued)

Metal Detection	
Q171A.	Are critical limits or tolerance levels established for sizes or amounts of metal detected by these duties?
Q171B.	Are limits established for all, most, or some of the production volume in metal detection?
Q172A.	When critical limits are exceeded, does your plant shut down the processing line?
Q172B.	Does your plant hold product until an investigation of the metal's origin is complete?
Q172C.	Is the held product evaluated and its disposition determined by quality control?
Q173A.	Are electronic or magnetic metal detectors tested or calibrated on a scheduled basis?
Q174A.	Are written records made each time the checks or inspections that we've discussed are performed for the metal detection process?
Testing Finished Product	
Q181A.	Does your plant have microbial specifications for your finished products?
Q182A.	Does your plant conduct microbial testing of your finished product on a scheduled basis?
Q183A.	Are written records made each time the tests that we discussed in finished product testing are performed?
Refrigerated Distribution	
Q191A.	Does your plant monitor internal temperature, ambient temperature, or the sufficiency of ice during distribution?
Q191C.	Are written records maintained?
Q192A.	Does your plant use automated temperature alarms or temperature-recording devices during distribution?
Q192C.	Are written records maintained?

Table C-2. Sanitation Practices Covered by the Survey

Sanitation
Q201A. Does your plant use a sanitation inspection procedure or check list?
Q201B. Does your plant have a written sanitation program?
Q203A. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Sampling product or visually inspecting for filth, decomposition mold, or other foreign material?
Q203B. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Inspecting health and personal cleanliness of employees?
Q203C. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Verifying sanitary condition of employees' gloves and outer garments?
Q203D. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Preventing food contamination from hair and foreign objects?
Q203E. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Verifying sanitary practices by processing employees during operations, such as verifying hand washing upon entry and reentry to the processing area?
Q203F. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Implementing a schedule for cleaning and sanitizing the plant and all food contact surfaces?
Q203G. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Cleaning and sanitizing all utensils?
Q203H. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Cleaning and sanitizing all equipment surfaces?
Q203I. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Preventing food contamination with cleaning chemicals?
Q203J. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Evaluating the sanitary condition of all utensils and food contact surfaces of equipment immediately after each cleaning and sanitizing operation?
Q203K. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Establishing sanitary zones around finished product handling areas that exclude objects and employees that have come into contact with waste, raw materials, or other sources of contamination?
Q203L. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Erecting physical barriers between raw product and finished product areas to prevent cross-contamination of product or personnel?
Q203M. (Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Implementing a system to ensure that supplies and equipment are not shared between raw product and finished product processing areas, such as color-coding supplies or equipment by area of use?

(continued)

Table C-2. Sanitation Practices Covered by the Survey

Sanitation (continued)	
Q203N.	(Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Establishing a system for keeping raw products and cooked products separate in storage areas?
Q203O.	(Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Protecting the product from water sources such as overhead condensation, drips from refrigeration coils, or improper drainage?
Q203P.	(Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Inspecting plant and surrounding outside area to identify and eliminate waste, overgrown weeds, insect breeding grounds, or inadequately drained areas?
Q203Q.	(Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Employing a pesticide applications operator?
Q203R.	(Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Requiring the operator be licensed?
Q203S.	(Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Analyzing water supplies to detect microbiological and chemical contamination and to determine that water is potable?
Q203T.	(Does the written sanitation program or the inspection checklist contain Good Manufacturing Practices (GMPs) such as): Segregating hazardous substances from food manufacturing and food storage areas?
Q207.	Does your plant conduct microbial testing of the sanitary condition of all equipment's surfaces that come in contact with food?
Q214.	Has the plant established policy and procedures ensuring the education and training of food handlers and supervisors regarding proper personal hygiene and sanitary practices?
Q215.	Has the plant established tolerance limits for enforcing the sanitation checklist procedures that we've discussed in sanitation and GMPs?
Q216.	Has the plant established procedures for dealing with failures in the sanitation program or exceeding specified sanitation limits?
Q217.	Are written records available to verity sanitation inspections of the plant?