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Analysis and Evaluation of Food Manufacturing Practices Used to Address Allergen Concerns

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Introduction

According to the National Institutes of Health (NIH), 6 to 8% of children and up to 2% of adults in America suffer from food-related allergic reactions, which can range from mild itching to the more severe and sometimes fatal condition of anaphylaxis (NIH 2004). In August 2004 Congress responded to this significant public health concern by enacting the "Food Allergen Labeling and Consumer Protection Act" (FALCPA) (Pub. L. 108-282). The goal of this law is to ensure that foods that contain a major food allergen (defined by the law as milk, egg, finfish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans), or a derivative of these allergens (with certain exceptions) disclose the presence of the allergen on the product label using the "common or usual name" of the allergen source, so as to make it recognizable to the consumer.

FALCPA further required that the Secretary of Health and Human Services provide a comprehensive report on the problem of unintended residues of food allergens in processed foods. The report included findings on the manufacturing conditions and practices associated with foods becoming unintentionally contaminated with undeclared allergens. The report also addresses pre-FALCPA (which took effect Jan. 1, 2006) use of advisory labeling (such as "may contain") by food manufacturers, consumer preference for food product labeling and the effectiveness of the food industry's efforts to address cross-contact issues. FDA's report was sent to Congress in July 2006.

On September 23, 2004, the Food and Drug Administration (FDA) of the U.S. Dept. of Health and Human Services signed a 5-year contract with the Institute of Food Technologists (IFT) to pro-

vide scientific review and analysis of issues in food safety, food security, food processing, and human health. In February of 2005 FDA tasked IFT with assessing the state of manufacturing and labeling practices used by food manufacturers to address allergen concerns.

IFT assembled a group (Scientific & Technical Panel) to develop a strategy for accomplishing this task. The panel was comprised of experts in food allergens and/or food manufacturing and labeling practices. Subsequently, IFT implemented an allergen-related information acquisition strategy, obtaining a wealth of data and information from numerous manufacturers of a wide variety of food commodities. This report summarizes IFT's response to the manufacturing portion of Task Order #2.

Methods

The information included in this report was obtained via verbal discussions with food industry personnel. IFT sought the most knowledgeable person(s) responsible for allergen control and/or quality control within each company to take part in this discussion. For some companies, IFT spoke with representatives of several of the company's plants or facilities; for others, one representative (usually the equivalent of the Director of Food Safety or Director of Regulatory Affairs). Participation in the project was voluntary and participants were guaranteed anonymity. Nearly all of the participants or teams of participants were able to discuss all aspects of allergen control raised by IFT. All discussions were led using a structured discussion guide that was developed by the Scientific & Technical Panel and, except for one set of discussions, administered by the same 2 IFT staff throughout. Thus, all the representatives of companies and their plants/facilities responded to the same questions. Terms used when discussing allergen control, such as 'Allergen Control Program' (documented plan to address use of allergens) and 'cross-contact' (contact of a given ingredient/product with an allergen not intended for incorporation into that ingredient/product), were defined, when necessary, in general terms when posing the questions to participants. However, requests for clarification of such terms were rare. This was a voluntary, open-ended discussion pertaining to control of allergens in

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each individual food process environment. No documentation or proof of responses was required. Various methods were used to recruit participants, including invitation via various trade organizations, direct contact via IFT membership and direct contact via random internet searches for companies within the identified product categories.

IFT involved discussants representing small, medium, and large companies. Current FDA guidelines define company size as less than 500 (small) and greater than 500 (large). IFT included an additional category for companies employing 100 to 500 employees (medium) so as to provide greater stratification of results. Large and medium companies, however, were better represented than small companies. While IFT made tremendous efforts to ensure small companies were equally represented, many small companies simply declined the opportunity, often without explanation, to be included in the effort.

IFT met with 59 food companies. Some manufacture food products in one or more plants/facilities that comprise more than one food product category, in which case the data and information that IFT obtained appears with the data in subsequent tables for each respective food product category. Thus, the total number of food manufacturers associated with the food product categories captured in subsequent tables is larger ($n = 120$) than the total number of small, medium, and large food companies interviewed. In other words, 59 companies were interviewed providing information pertaining to 120 product types from 14 different categories. From this perspective (a single company manufacturing products corresponding to multiple categories), the information obtained for 13 of the product categories originated from small-sized companies, 21 from medium-sized companies, and 86 from large-sized companies.

Results

The 59 companies interviewed by IFT manufacture food products comprising 14 categories—baby food, infant formula, bakery products, beverages, candy/confections, cereal/pasta, dairy products/substitutes, desserts, fish/fish products, miscellaneous, mixed dishes, sauces/dips/gravies/condiments, snack foods, and soups. IFT obtained information on the 8 major food allergens associated with these products, the respective manufacturers' allergen control programs, and their purchasing, receiving, production, rework, clean-up, analytical testing, packaging, labeling, and employee training practices. During discussions with the food manufacturers, IFT also obtained input on research needs pertaining to control of allergens in the food manufacturing and distribution environments.

Food manufacturer and food product category information

Table 1 shows the number and percentage of companies in each of the 3 size categories (small, medium, and large). IFT put forth a purposeful effort to gather information from all 3 categories. However, due to the structure of certain food categories, the opportunity for inclusion of small and medium companies was difficult to impossible. The baby food and infant formula markets, for example, are dominated by a small number of companies (4 to 6) with most having greater than 500 employees. The largest proportion of companies that IFT spoke with are of size category 3 (large companies, > 500 employees), with 38 of 59 total companies (64%) that IFT spoke with, followed by category 2 (medium companies, 100 to 500 employees) comprising 14 companies (24%), and category 1 (< 100 employees) comprising 7 companies (12%).

The number of companies interviewed in each of the 14 food product categories is shown in Table 2. The categories of food products addressed are those that the Scientific & Technical Panel

Table 1—Number and percent of companies by size^a

Company size	Number of companies	Percent of companies
Category 1 (Small, < 100 employees)	7	12%
Category 2 (Medium, 100 to 500 employees)	14	24%
Category 3 (Large, > 500 employees)	38	64%

^aNumbers of companies reflect the number of food manufacturing companies included in IFT's task from FDA. Some of these companies manufacture in one or more facilities products comprising more than one food product category (for example, baby food, bakery products), in which cases the data and information that IFT obtained appears with the data in subsequent tables for each respective/pertinent food product category. Thus, total number of food manufacturers associated with all of the food product categories, captured in subsequent tables, is larger than the total number of small, medium, and large food companies ($n = 59$).

Table 2—Number of companies by food manufactured

Food product category ^a	Number of companies
Baby food	2
Infant formula	3
Bakery products	25
Beverages ^b	8
Candy/confections	10
Cereal/pasta	11
Dairy products/substitutes ^c	15
Desserts	8
Fish/fish products	7
Miscellaneous	7
Mixed dishes	6
Sauces/dips/gravies/condiments ^d	6
Snacks	7
Soups	5
Total	120

^aContents of food categories reflect NLEA, Attachment 26 (www.fda.gov/ora/inspect_ref/igs/nleaat26.html)

^bIncludes fruit juices

^cIncludes rice and soy beverages, butter, and margarine

^dIncludes pancake syrup, oils, and shortenings

Table 3—Percent and number of companies, by food manufactured and company size

Food product category	Company size		
	Category 1 (small) < 100 employees $n = 13$	Category 2 (medium) 100 to 500 employees $n = 21$	Category 3 (large) > 500 employees $n = 86$
	Percent (number)		
Baby food ($n = 2$)	0	0	100 (2)
Infant formula ($n = 3$)	0	0	100 (3)
Bakery products ($n = 25$)	16 (4)	4 (1)	80 (20)
Beverages ^a ($n = 8$)	0	37 (3)	62 (5)
Candy/confections ($n = 10$)	0	30 (3)	70 (7)
Cereal/pasta ($n = 11$)	36 (4)	9 (1)	54 (6)
Dairy products/substitutes ^b ($n = 15$)	20 (3)	27 (4)	53 (8)
Desserts ($n = 8$)	12 (1)	25 (2)	62 (5)
Fish/fish products ($n = 7$)	0	71 (5)	29 (2)
Miscellaneous ($n = 7$)	0	14 (1)	86 (6)
Mixed dishes ($n = 6$)	0	0	100 (6)
Sauces/dips/gravies/condiments ^c ($n = 6$)	17 (1)	0	83 (5)
Snack foods ($n = 7$)	0	14 (1)	86 (6)
Soups ($n = 5$)	0	0	100 (5)

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, and shortenings

believed to involve allergenic ingredients or allergen cross-contact potential (herein referred to as the "targeted food industry"). Ingredient manufacturers were intentionally excluded.

Table 3 shows the percent and number of companies manufacturing foods in each product category by company size. The specific types of food products made by the companies from which IFT obtained information as categorized by each of the 14 food product categories are detailed in Appendix 1.

Allergens

The prevalence of use of the major food allergens in food product categories is listed in Table 4 according to company size. Within each company size, the relative prevalence of each allergen's use is ranked from 1 (most used) to 8 (least used). Considering manufacturers of all sizes together, milk was the allergen found to be most commonly used in the food products included in this project (rank 1, 88%), followed by soy (rank 2, 84%), wheat (rank 3, 78%), eggs (rank 4, 72%), tree nuts (rank 5, 63%), peanuts (rank 6, 55%), finfish (rank 7, 27%), and crustacean shellfish (rank 8, 16%). Table 5 provides a breakdown of the 8 major food allergens across the 14 food product categories.

Allergen control programs

Information on whether or not the manufacturers have Allergen Control Programs (ACPs), and, if so, whether the ACPs or portions

thereof are considered in each companies' prerequisite programs or their Hazard Analysis & Critical Control Point (HACCP) plans, as well as the specific activities that are addressed by the ACPs, are shown in Table 6 and 7. The information is presented by company size and food product category. All of the small companies (n = 13) and medium companies (n = 21), and 94% (n = 81) of the large companies have ACPs.

IFT inquired about the method of integration of ACPs into either a prerequisite or HACCP program (Table 6). All of the small companies, 76% (n = 16) of the medium companies, and 86% (n = 74) of the large companies consider their ACPs in their prerequisite programs. Eighty-five percent (n = 11) of the small companies, 71% (n = 15) of the medium companies, and 80% (n = 69) of the large companies consider their ACPs in their HACCP plans. Some manufacturers have freestanding ACPs.

Many of the companies integrate their ACPs with their prerequisite plans and/or HACCP via 1, 2 or all 3 of the above mentioned methods, dependent on each company's HACCP philosophy. This is further explained in the following text specific to each category.

• **Baby food.** One manufacturer indicated integration via both the prerequisite program and identification of a CCP, whereas the oth-

Table 4—Prevalence of use of the major food allergens for all companies and by company size

Allergen	Prevalence (%) n = 120	Company Size		
		Category 1 (small) < 100 employees	Category 2 (medium) 100 to 500 employees	Category 3 (large) > 500 employees
Milk	88	69 [rank = 2]	81 [rank = 2]	95 [rank = 1]
Soy	84	85 [rank = 1]	86 [rank = 1]	85 [rank = 2]
Wheat	78	85 [rank = 1]	86 [rank = 1]	77 [rank = 3]
Eggs	72	69 [rank = 2]	62 [rank = 3]	76 [rank = 4]
Tree Nuts	63	46 [rank = 3]	62 [rank = 3]	67 [rank = 5]
Peanuts	55	31 [rank = 4]	38 [rank = 4]	62 [rank = 6]
Finfish	27	15 [rank = 5]	24 [rank = 5]	33 [rank = 7]
Crustacean Shellfish	16	0 [rank = 6]	24 [rank = 5]	19 [rank = 8]

Table 5—Percent and number of companies manufacturing products with the major food allergens by food manufactured and company size

	Allergen							
	Milk	Soy	Wheat	Eggs	Tree nuts	Peanuts	Finfish	Crustacean shellfish
	Percent (number)							
All companies (n = 120)	88 (106)	84 (101)	78 (94)	72 (86)	63 (76)	55 (66)	27 (33)	16 (19)
Company Size	Percent (number)							
Category 1 (small, < 100 employees) (n = 13)	77 (10)	92 (12)	92 (12)	77 (10)	54 (7)	39 (5)	15 (2)	0
Category 2 (medium, 100 - 500 employees) (n = 21)	86 (18)	91 (19)	91 (19)	67 (14)	62 (13)	38 (8)	29 (6)	24 (5)
Category 3 (large, > 500 employees) (n = 86)	91 (78)	81 (70)	73 (63)	72 (62)	65 (56)	62 (53)	29 (25)	16 (14)
Food Product Category	Percent (number)							
Baby Food (n = 2)	100 (2)	100 (2)	50 (1)	50 (1)	0	0	0	0
Infant Formula (n = 3)	100 (3)	100 (3)	0	0	0	0	0	0
Bakery products (n = 25)	96 (24)	96 (24)	96 (24)	96 (24)	80 (20)	72 (18)	28 (7)	0
Beverages ^a (n = 8)	75 (6)	75 (6)	63 (5)	63 (5)	63 (5)	50 (4)	0	0
Candy/confections (n = 10)	100 (10)	90 (9)	70 (7)	50 (5)	90 (9)	80 (8)	20 (2)	0
Cereal/pasta (n = 11)	64 (7)	55 (6)	100 (11)	64 (7)	64 (7)	27 (3)	9 (1)	0
Dairy products/substitutes ^b (n = 15)	93 (14)	87 (13)	60 (9)	60 (9)	67 (10)	53 (8)	13 (2)	7 (1)
Desserts (n = 8)	100 (8)	100 (8)	100 (8)	75 (6)	100 (8)	75 (6)	0	0
Fish/Fish Products (n = 7)	100 (7)	71 (5)	100 (7)	71 (5)	29 (2)	14 (1)	100 (7)	100 (7)
Miscellaneous (n = 7)	71 (5)	86 (6)	57 (4)	71 (5)	29 (2)	57 (4)	43 (3)	14 (1)
Mixed dishes (n = 6)	100 (6)	100 (6)	100 (6)	100 (6)	67 (4)	67 (4)	50 (3)	67 (4)
Sauces/dips/gravies/condiments ^c (n = 6)	100 (6)	100 (6)	83 (5)	100 (6)	50 (3)	67 (4)	100 (6)	33 (2)
Snack foods (n = 7)	100 (7)	86 (6)	86 (6)	71 (5)	100 (7)	100 (7)	29 (2)	0
Soups (n = 5)	100 (5)	100 (5)	100 (5)	100 (5)	40 (2)	20 (1)	60 (3)	80 (4)

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, and shortenings

Table 6—Information on companies, by size and food product category, having Allergen Control Programs (ACP)

	ACP	ACP as part of prerequisite program	ACP as part of HACCP program	Method of inclusion in HACCP	
				Control point(s)	Critical control point(s)
Company Size	Percent (number)				
Category 1 (small, < 100 employees) (n = 13)	100 (13)	100 (13)	85 (11)	0	38 (5)
Category 2 (medium, 100 to 500 employees) (n = 21)	100 (21)	76 (16)	71 (15)	14 (3)	29 (6)
Category 3 (large, > 500 employees) (n = 86)	94 (81)	86 (74)	80 (69)	35 (30)	56 (48)
Food Product Category	Percent (number)				
Baby food (n = 2)	100 (2)	50 (1)	50 (1)	50 (1)	50(1)
Infant formula (n = 3)	67 (2)	67 (2)	67 (2)	100 (3)	33 (1)
Bakery products (n = 25)	100 (25)	80 (20)	76 (19)	20 (5)	56 (14)
Beverages ^a (n = 8)	88 (7)	100 (8)	75 (6)	13 (1)	13 (1)
Candy/confections (n = 10)	90 (9)	80 (8)	90 (9)	90 (9)	50 (5)
Cereal/pasta (n = 11)	100 (11)	100 (11)	91 (10)	9 (1)	64 (7)
Dairy products/substitutes ^b (n = 15)	87 (13)	87 (13)	60 (9)	13 (2)	27 (4)
Desserts (n = 8)	100 (8)	100 (8)	75 (6)	38 (3)	25 (2)
Fish/fish products (n = 7)	100 (7)	29 (2)	71 (5)	0	57 (4)
Miscellaneous (n = 7)	100 (7)	100 (7)	71 (5)	14 (1)	71 (5)
Mixed dishes (n = 6)	100 (6)	100 (6)	100 (6)	50 (3)	67 (4)
Sauces/dips/gravies/condiments ^c (n = 6)	100 (6)	100 (6)	100 (6)	33 (2)	50 (3)
Snack foods (n = 7)	100 (7)	86 (6)	100 (7)	14 (1)	43 (3)
Soups (n = 5)	100 (5)	100 (5)	80 (4)	20 (1)	100 (5)

^aIncludes fruit juices^bIncludes rice and soy beverages, butter, and margarine^cIncludes pancake syrup, oils, and shortening

er does so based only on CP(s).

• **Infant formula.** Two companies indicated use of both the prerequisite plan and at least one CP to control allergens, whereas the 3rd does not use the prerequisite plan and rather uses CP(s) and CCP(s).

• **Bakery products.** Of the manufacturers interviewed, 8 integrate their ACP with HACCP through only the prerequisite plan, 7 use both the prerequisite and at least one CCP, 4 use CCP(s) only, 3 use the prerequisite plan along with both CP(s) and CCP(s), and 2 via prerequisite and CP(s).

• **Beverages.** Six integrate through the prerequisite plan only, one with both prerequisite and CP(s) and another prerequisite and CCP(s).

• **Cereals/pastas.** Six companies use both prerequisite plans and CCP(s), 4 use prerequisite only and 1 employs prerequisite, CP(s) and CCP(s) for allergen control.

• **Confections/candy.** Four companies stated that they integrate their ACP with HACCP via the prerequisite plan and at least one CP, 4 others use these plus CCP(s) and 1 other does not include the prerequisite plan and instead integrates via CP(s) and CCP(s).

• **Dairy products and substitutes.** Eight indicated use of prerequisite plans only, 3 prerequisite plus CCP(s), 1 prerequisite plus CP(s) and another uses all 3 (prerequisite, CP and CCP).

• **Desserts.** Four use prerequisite plans only, 2 combine that with CP(s), 1 uses prerequisite with CCP(s), 1 uses all 3, and 1 integrates using only CP(s).

• **Sauces/dips/gravies/condiments.** Of the companies IFT met with, 3 indicated integration of their ACP with HACCP via their prerequisite plan only, 2 use that plus CP(s) and CCP(s), and 1 via the prerequisite plan with at least one CCP.

• **Fish/fish products.** Four use CCP(s) and 2 integrate via the prerequisite plan.

• **Miscellaneous.** Four of the firms in this category stated use of both the prerequisite plan and CCP(s), 2 use prerequisite only, and 1 uses a prerequisite plan along with CP(s) and CCP(s).

• **Mixed dishes.** Two integrate via their prerequisite plan and CCP(s), 2 via those plus CP(s), 1 prerequisite plus CP(s), and 1 prerequisite only.

• **Snack foods.** Of the snack food companies, 4 indicated use of prerequisite only, 1 prerequisite plus CCP(s), and 1 uses prerequisite, CP(s) and CCP(s).

• **Soups.** Four soup companies indicated integrating their plans via prerequisite plan and CCP(s), and 1 uses those plus CP(s) as well.

The specific activities addressed by manufacturers' ACPs are shown in Table 7. IFT inquired about the integration of 8 specific items into ACPs and asked manufacturers if other items were included as well. The 8 items for which IFT inquired were purchasing, receiving, storage, production, rework, clean-up, labeling, and packaging.

The additional items that some companies mentioned that they address via their ACPs are training, segregation of animal feed scrap, maintenance, equipment design, research and development, sales/marketing, employee practices, scheduling (which the IFT Scientific & Technical Panel considers as part of production), consumer communications/complaints, and graphic design of labels/packages.

IFT also inquired about validation of ACPs—whether companies have validated their ACPs and if so, what aspect (receiving, scheduling, separation [for example, testing, sanitation], rework, or other) of the ACP they validate. This information is presented in Table 8. The majority of large companies (79%, n = 68) have validated their ACPs, while 62% (n = 13) of the medium companies and 46% (n = 6) of the small companies have done so.

The aspect of ACPs (receiving, scheduling, separation, and/or rework) that companies validate varies among the interviewed food product manufacturers. Many indicated that the separation aspect of an ACP was the only element that could be validated with any certainty (via analytical testing); however, some also indicated that reliance on testing may provide a false sense of assurance because testing is localized.

Purchasing practices

The percentage of companies requiring their suppliers to have ACPs and the percentage ensuring supplier compliance via regular supplier checks are shown in Table 9. Data are presented by company size and food product category manufactured. Ninety-two

percent (n = 12) of the small companies interviewed indicated that they require their suppliers to have ACPs and 77% (n = 10) ensure supplier compliance with their ACPs via checks, whereas 43% (n = 9) of the medium companies require supplier ACPs and 38% (n = 8) ensure compliance, and 88% (n = 76) of large companies require supplier ACPs and 71% (n = 61) ensure compliance.

A number of companies volunteered information on how they check for supplier compliance. Methods mentioned are audits

(via the company or third parties), vendor approvals, checklists, rotating supplier visits (with higher risk plants visited more frequently than others), maintenance of updated copies of supplier control programs, and certification of supplier allergen declaration. Some companies also mentioned the fact that while they do not require suppliers to have an ACP, they still perform regular checks on suppliers to ensure adequate allergen handling measures (among other GMPs) are in place.

Table 7—Information on companies, by size and food category, having Allergen Control Programs (ACPs)

Company Size	Items addressed by ACPs								
	Purchasing	Receiving	Storage	Production	Rework	Clean-up	Labeling	Packaging	Other
	Percent (number)								
Category 1 (n = 13) (small, < 100 employees)	77 (10)	69 (9)	69 (9)	100 (13)	54 (7)	77 (10)	100 (13)	100 (13)	0
Category 2 (n = 21) (medium, 100 to 500 employees)	67 (14)	62 (13)	67 (14)	100 (21)	62 (13)	100 (21)	100 (21)	100 (21)	24 (5)
Category 3 (n = 86) (large, s> 500employees)	90 (77)	94 (81)	93 (80)	94 (81)	93 (80)	94 (81)	94 (81)	93 (80)	48 (41)
Food Product Category	Percent (number)								
Baby food (n = 2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	50 (1)
Infant formula (n = 3)	100 (3)	100 (3)	100 (3)	100 (3)	67 (2), 1 NA	100 (3)	100 (3)	100 (3)	0
Bakery products (n = 25)	96 (24)	96 (24)	96 (24)	100 (25)	88 (22), 1 NA	96 (24)	100 (25)	100 (25)	40 (10)
Beverages ^a (n = 8)	63 (5), 1 NA	50 (4), 1 NA	63 (5), 1 NA	75 (6), 1 NA	63 (5), 1 NA	75 (6), 1 NA	75 (6), 1 NA	75 (6), 1 NA	13 (1), 1 NA
Candy/confections (n = 10)	100 (10)	100 (10)	100 (10)	100 (10)	100 (10)	100 (10)	100 (10)	90 (9)	20 (2)
Cereal/pasta (n = 11)	73 (8)	82 (9)	82 (9)	100 (11)	91 (10)	91 (10)	100 (11)	100 (11)	55 (6)
Dairy products/ substitutes ^b (n = 15)	73 (11)	67 (10)	73 (11)	87 (13)	67 (10), 2 NA	80 (12)	87 (13)	87 (13)	27 (4)
Desserts (n = 8)	100 (8)	88 (7)	88 (7)	100 (8)	75 (6), 2 NA	100 (8)	100 (8)	100 (8)	50 (4)
Fish/fish products (n = 7)	71 (5)	71 (5)	57 (4)	100 (7)	71 (5), 2 NA	100 (7)	100 (7)	100 (7)	29 (2)
Miscellaneous (n = 7)	100 (7)	100 (7)	86 (6)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	57 (4)
Mixed dishes (n = 6)	100 (6)	100 (6)	100 (6)	100 (6)	100 (6)	100 (6)	100 (6)	100 (6)	50 (3)
Sauces/dips/gravies/ condiments ^c (n = 6)	50 (3)	67 (4)	67 (4)	83 (5)	67 (4)	83 (5)	83 (5)	83 (5)	33 (2)
Snack foods (n = 7)	71 (5)	100 (7)	100 (7)	100 (7)	86 (6)	100 (7)	100 (7)	100 (7)	86 (6)
Soups (n = 5)	100 (5)	100 (5)	100 (5)	100 (5)	100 (5)	100 (5)	100 (5)	100 (5)	40 (2)

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, and shortenings

Table 8—Percent and number of companies, by size and food category, that have validated the efficacy of their Allergen Control Program (ACPs)

Company Size	ACPs validated	Aspect of ACP that is validated ^a				
		Receiving	Scheduling	Separation	Rework	Other
		Percent (number)				
Category 1 (small, < 100 employees) (n = 13)	46 (6)	30 (4)	30 (4)	46 (6)	23 (3)	30 (4)
Category 2 (medium, 100 to 500 employees) (n = 21)	62 (13)	14 (3)	24 (5)	48 (10)	5 (1)	38 (21)
Category 3 (large, > 500 employees) (n = 86)	79 (68)	45 (39)	45 (39)	63 (54)	44 (38)	38 (33)
Food Product Category	Percent (number)					
Baby food (n = 2)	100 (2)	50 (1)	100 (2)	100 (2)	50 (1)	50 (1)
Infant formula (n = 3)	67 (2)	0	0	67 (2)	0	0
Bakery products (n = 25)	84 (21)	32 (8)	36 (9)	40 (10)	32 (8), 2 NA	64 (16)
Beverages ^b (n = 8)	75 (6)	50 (4)	63 (5)	63 (5)	38 (3), 1 NA	38 (3)
Candy/confections (n = 10)	70 (7)	10 (1)	10 (1)	70 (7)	10 (1)	20 (2)
Cereal/pasta (n = 11)	91 (10)	73 (8)	73 (8)	91 (10)	64 (7), 1 NA	55 (6)
Dairy products/substitutes ^c (n = 15)	87 (13)	53 (8)	67 (10)	73 (11)	47 (7), 3 NA	53 (8)
Desserts (n = 8)	75 (6)	50 (4)	50 (4)	63 (5)	50 (4), 2 NA	38 (3)
Fish/fish products (n = 7)	14 (1)	0	0	14 (1)	0	0
Miscellaneous (n = 6)	57 (4)	57 (4)	43 (3)	57 (4)	43 (3)	29 (2)
Mixed dishes (n = 6)	50 (3)	17 (1)	17 (1)	33 (2)	17 (1)	0
Sauces/dips/gravies/condiments ^d (n = 6)	33 (2)	0	0	33 (2)	0	17 (1)
Snack foods (n = 7)	86 (6)	57 (4)	57 (4)	71 (5)	57 (4)	14 (1)
Soups (n = 5)	80 (4)	60 (3)	40 (2)	80 (4)	40 (2)	40 (2)

^aData are self reported.

^bIncludes fruit juices

^cIncludes rice and soy beverages, butter, and margarine

^dIncludes pancake syrup, oils, and shortenings

Receiving practices

Table 10 addresses whether manufacturers of each size and food product category require ingredient statements on all ingredients and specification of allergen presence in those statements. Participants were asked how they ensure accuracy of the ingredient statements, including method(s) of doing so, and whether suppliers have allergen identifier labels to indicate allergen presence. Procedures to prevent cross-contact of ingredients during transit or receiving, and use of dedicated ingredient storage facilities and/or separate ingredient storage are also addressed in Table 10.

Aside from those listed in the table, other mechanisms mentioned to ensure ingredient statement accuracy were affidavits sent by regulatory departments to ingredient suppliers, raw material information surveys, letters of continuing guarantee, notification by the supplier of any changes, ingredient lists checked every 2 y for changes, spot checks of products against lists, label review and approval/verification of labels against specification sheets, required annual allergen disclosure, and distribution of quality expectations manual to suppliers.

Several handling practices were discussed with participants. Sixty-two percent (n = 8) of the small, 38% (n = 8) of the medium, and 80% (n = 69) of the large companies add an allergen label (for example, bright colored sticker) to draw attention to allergenic ingredients.

Far more companies have procedures in place to prevent cross-contact of ingredients at receiving than do for prevention during transit. While all 13 of the small companies, 76% (n = 16) of the medium companies, and 84% (n = 72) of the large companies have procedures to prevent ingredient cross-contact at receiving, none of the small companies, only 10% (n = 2) of the medium companies, and 36% (n = 31) of the large companies have procedures in place specifically to prevent cross-contact in transit.

Table 9—Percent and number of companies, by size and food product category, requiring Allergen Control Programs (ACPs) of suppliers and ensuring compliance

Company Size	Ensure	
	Require supplier ACPs	supplier compliance via routine checks
Company Size	Percent (number)	
Category 1 (small, < 100 employees) (n = 13)	92 (12)	77 (10)
Category 2 (medium, 100 to 500 employees) (n = 21)	43 (9)	38 (8)
Category 3 (large, > 500 employees) (n = 86)	88 (76)	71 (61)
Food Product Category	Percent (number)	
Baby food (n = 2)	100 (2)	100 (2)
Infant formula (n = 3)	100 (3)	100 (3)
Bakery products (n = 25)	88 (22) ^c	72 (18) ^c
Beverages ^a (n = 8)	50 (4) ^c	38 (3) ^c
Candy/confections (n = 10)	40 (4)	40 (4)
Cereal/pasta (n = 11)	91 (10)	64 (7)
Dairy products/substitutes ^b (n = 15)	80 (12)	53 (8)
Desserts (n = 8)	88 (7) ^c	75 (6) ^c
Fish/fish products (n = 7)	86 (6) ^c	71 (5) ^c
Miscellaneous (n = 7)	86 (6)	71 (5)
Mixed dishes (n = 6)	100 (6)	100 (6)
Sauces/dips/gravies/condiments ^d (n = 6)	67 (4)	50 (3)
Snack foods (n = 7)	86 (6)	71 (5)
Soups (n = 5)	100 (5)	80 (4)

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cManufacturer(s) reported that although an ACP is not required of suppliers, the company requests allergen declaration and regularly certifies its accuracy.

^dIncludes pancake syrup, oils, shortenings

A practice (GMP) common to all participants was inspection at receiving. Incoming ingredient shipments are manually/visually inspected prior to and during unloading to ensure integrity of packaging (bags, boxes, bag-in-box, barrels, shrink wrap, pallets, and so on). Any breach of package integrity can initiate refusal of shipment. Segregation of ingredients (mixed shipment/partial loads) was also noted as commonplace to reduce possibility for cross-contact in transit.

Table 10 also includes data pertaining to ingredient storage. Dedicated storage facilities were a rare occurrence (especially if bulk storage is excluded) among the food companies IFT met with. None of the small companies, 1 of the medium companies, and 18 of the large companies indicated use of dedicated storage facilities. Three of the 8 dessert manufacturers use dedicated storage facilities, while 25% (n = 2) of the beverage manufacturers, 20% each of the bakery product manufacturers (n = 5), dairy product/substitute manufacturers (n = 3), and soup manufacturers, 18% (n = 2) of the cereal/pasta manufacturers, 17% (n = 1) of the mixed dish manufacturers, and 14% (n = 1 each) of the miscellaneous product and snack food manufacturers do so. None of the baby food manufacturers, infant formula manufacturers, candy/confection manufacturers, or fish/fish product manufacturers use dedicated storage facilities.

Separate ingredient storage, on the other hand, was a common occurrence. Seventy-one percent of the small companies (n = 5) and medium companies (n = 10) and 81% (n = 70) of the large companies use separate ingredient storage. Both of the baby food manufacturers and all of the infant formula (n = 3), mixed dish (n = 6), and snack food manufacturers (n = 7) use separate ingredient storage. A large majority of the bakery product (84%), candy/confection (90%), cereal/pasta (82%), miscellaneous product (86%), and soup manufacturers (80%) use separate ingredient storage, while 75% (n = 6) of the dessert manufacturers, 67% of the dairy product/substitute manufacturers (n = 10) and sauces/dips/gravies/condiments manufacturers (n = 4), 50% (n = 4) of the beverage manufacturers, and 14% (n = 1) of the fish/fish product manufacturers use separate ingredient storage (which in some cases may be due to a lack of breeding application, thereby reducing potential for cross-contact).

Production practices

The percentage and number of companies, by size and food product category, that have identified potential allergen sources (including ingredients, processing aids, rework, product carry-over from shared equipment, and clean-in-place [CIP] fluid) within manufacturing/production is shown in Table 11. Ninety-two percent (n = 12) of the small companies, 95% (n = 20) of the medium companies, and 95% (n = 82) of the large companies have identified potential allergen sources.

Table 12 shows the percentage and number of companies, by food product category, that have identified specific points in the manufacturing process where cross-contact could occur, the specific points, and the examples of control practices that companies use to address cross-contact at these points. Nearly all of the manufacturers with whom IFT spoke have identified such points. The numerous potential cross-contact points identified, via free-form comments (without specifics being solicited/ prompted by IFT), by the manufacturers of food products in the 14 categories are listed in Table 12 along with examples of practices used to control cross-contact at the specific points mentioned by the companies.

Table 13 displays the percentage and number of companies, by size and food product category that exclude certain allergens from facilities, dedicate either facilities or lines, and their line dedication measures. Sixty-nine percent (n = 9) of the small companies, 43% (n = 9) of the medium companies, and 62% (n = 53) of the large companies indicated that certain allergens are intention-

Table 10—Percent and number of companies, by size and food category, having certain ingredient and handling practices

Require ingredient statements on all ingredients		Require specification of allergen presence in ingredient statements	Mechanism(s) for ensuring ingredient statement accuracy						Procedures to prevent ingredient cross-contact at receiving				Use dedicated ingredient storage facilities	Use separate ingredient storage	
			Allergen question-naire	COA (certificate of analysis)		Specific- cations	Company evalu- ations	Other ^a							
Percent (number)															
Company Size				77 (10)	77 (10)				31 (4)	31 (4)	15 (2)	38 (5)	62 (8)	0	100 (13)
Category 1 (small, < 100 employees) (n = 13)			77 (10)	77 (10)	31 (4)	31 (4)	15 (2)	38 (5)	62 (8)	0	100 (13)	0	71 (5)		
Category 2 (medium, 100 to 500 employees) (n = 21)			76 (16)	57 (12)	43 (9)	10 (2)	24 (5)	14 (3)	19 (4)	38 (8)	10 (2)	76 (16)	7 (1)	71 (10)	
Category 3 (large, > 500 employees) (n = 86)			73 (63)	90 (77)	80 (77)	80 (69)	37 (32)	60 (52)	41 (35)	23 (20)	80 (69)	36 (31)	84 (72)	21 (18)	81 (70)
Food Product Category															
Percent (number)															
Baby food (n = 2)			100 (2)	100 (2)	100 (2)	50 (1)	0	0	100 (2)	100 (2)	0	100 (2)	0	100 (2)	
Infant formula (n = 3)			100 (3)	67 (2)	100 (3)	67 (2)	33 (1)	67 (2)	0	33 (1)	33 (1)	100 (3)	0	100 (3)	
Bakery products (n = 25)			76 (19)	76 (19)	88 (22)	84 (21)	32 (8)	72 (18)	36 (9)	8 (2)	76 (19)	20 (5), 2 NA	80 (20)	20 (5), 1 NA	84 (21)
Beverages ^b (n = 8)			63 (5)	63 (5)	88 (7)	50 (4)	25 (2)	38 (3)	25 (2)	25 (2)	38 (3)	38 (3)	75 (6)	25 (2)	50 (4)
Candy/confections (n =10)			70 (7)	70 (7)	60 (6)	60 (6)	40 (4)	30 (3)	30 (3)	20 (2)	50 (5)	10 (1), 1 NA	90 (9)	0	90 (9)
Cereal/pasta (n = 11)			27 (3)	55 (6)	91 (10)	73 (8)	45 (5)	45 (5)	36 (4)	9 (1)	73 (8), 1 NA	9 (1), 3 NA	82 (9), 1 NA	18 (2), 1 NA	82 (9)
Dairy products/ ^c substitutes ^c (n = 15)			53 (8)	73 (11)	73 (11)	80 (12)	40 (6)	53 (8)	40 (6)	27 (4)	67 (10)	20 (3)	87 (13)	20 (3)	67 (10)
Desserts (n = 8)			88 (7)	100 (8)	88 (7)	88 (7)	38 (3)	63 (5)	50 (4)	50 (4)	75 (6)	50 (4)	100 (8)	38 (3), 1 NA	75 (6)
Fish/fish products (n = 7)			100 (7)	86 (6)	100 (7)	43 (3)	14 (1)	0	71 (5)	14 (1)	29(2)	0	43 (3)	0	14 (1)
Miscellaneous (n = 7)			86 (6)	71 (5)	100 (7)	71 (5)	29 (2)	43 (3)	14 (1)	43 (3)	100 (7)	0	100 (7)	14 (1)	86 (6)
Mixed dishes (n = 6)			83 (5)	100 (6)	83 (5)	83 (5)	17 (1)	33 (2)	50 (3)	17 (1)	83 (5)	67 (4)	100 (6)	17 (1)	100 (6)
Sauces/dips/gravies/condiments ^d (n = 6)			67 (4)	67 (4)	100 (6)	83 (5)	100 (6)	33 (2)	33 (2)	17 (1)	83 (5)	50 (3)	100 (6)	0	67 (4)
Snack foods (n = 7)			57 (4)	57 (4)	100 (7)	71 (5)	14 (1)	43 (3)	43 (3)	14 (1)	100 (7)	57 (4)	71 (5)	14 (1)	100 (7)
Soups (n = 5)			80 (4)	80 (4)	100 (5)	80 (4)	40 (2)	40 (2)	60 (3)	40 (2)	100 (5)	40 (2)	80 (4)	20 (1)	80 (4)

^aPlease refer to text for details on the other methods used to ensure ingredient statement accuracy.

^bIncludes fruit juices

^cIncludes rice and soy beverages, butter, and margarine

^dIncludes pancake syrup, oils, shortenings

Table 11—Percent and number of companies, by size and food product category, that have identified potential allergen sources within manufacturing/production, and sources

	Identified potential allergen sources	Allergen source					
		Ingredients	Processing aids	Rework	Product carry-over from shared equipment	CIP (clean-in-place) fluid	Other
Company Size		Percent (number)					
Category 1 (small, < 100 employees) (n = 13)	92 (12)	92 (12)	69 (9)	31 (4)	69 (9)	15 (2)	15 (2)
Category 2 (medium, 100 to 500 employees) (n = 21)	95 (20)	90 (19)	67 (14)	67 (14)	95 (20)	38 (8)	14 (3)
Category 3 (large, > 500 employees) (n = 86)	95 (82)	95 (82)	94 (81)	91 (78)	93 (80)	51 (44)	17 (15)
Food Product Category		Percent (number)					
Baby food (n = 2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	50 (1), 1 NA	50 (1)
Infant formula (n = 3)	100 (3)	100 (3)	100 (3)	67 (2), 1 NA	100 (3)	67 (2), 1 NA	33 (1)
Bakery products (n = 25)	100 (25)	100 (25)	96 (24)	92 (23), 2 NA	100 (25)	32 (8), 1 NA	12 (3)
Beverages ^a (n = 8)	75 (6)	75 (6)	75 (6)	63 (5), 1 NA	75 (6)	63 (5)	13 (10)
Candy/confections (n = 10)	80 (8)	80 (8)	80 (8)	80 (8)	80 (8)	60 (6), 2 NA	50 (5)
Cereal/pasta (n = 11)	91 (10)	82 (9), 1 NA	73 (8), 1 NA	73 (8), 1 NA	91 (10)	36 (4), 6 NA	9 (1)
Dairy products/substitutes ^b (n = 15)	93 (14)	93 (14)	80 (12), 1 NA	53 (8), 3 NA	73 (11)	60 (3), 1 NA	13 (2)
Desserts (n = 8)	100 (8)	100 (8)	88 (7), 1 NA	75 (6), 1 NA	100 (8)	88 (7), 1 NA	13 (1)
Fish/fish products (n = 7)	100 (7)	100 (7)	86 (6), 1 NA	57 (4), 3 NA	100 (7)	7 NA	0
Miscellaneous (n = 7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	29 (2), 4 NA	29 (2)
Mixed dishes (n = 6)	100 (6)	100 (6)	100 (6)	100 (6)	100 (6)	50 (3), 3 NA	33 (2)
Sauces/dips/gravies/condiments ^c (n = 6)	100 (6)	100 (6)	83 (5)	83 (5)	83 (5)	17 (1), 4 NA	0
Snack foods (n = 7)	100 (7)	100 (7)	86 (6)	100 (7)	100 (7)	57 (4), 3 NA	0
Soups (n = 5)	100 (5)	100 (5)	80 (4)	100 (5)	80 (4)	40 (2), 3 NA	20 (1)

^aIncludes fruit juices^bIncludes rice and soy beverages, butter, and margarine^cIncludes pancake syrup, oils, shortenings

ally excluded from their facilities.

However, none of the small companies dedicate facilities to avoid cross-contact, only 1 of the medium companies does so, and 12 large companies do so. Dedication of process lines is a more common practice. Two of the small companies dedicate specific lines for products containing or excluding allergens, using walls (n = 2), distance (n = 2), air handling (n = 2), or other means (n = 2) to do so. Four of the medium companies dedicate specific lines. Some do so using either walls (n = 1), distance (n = 1), or other means (n = 1). Fifty-one of the large companies dedicate specific lines via walls (n = 35), curtains (n = 20), distance (n = 31), air handling (n = 15), and other means (n = 8).

Other measures used to maintain dedication of lines volunteered by some companies include reminder signs, plexiglass shielding (positioned to enhance separation), enclosed equipment system, covered conveyors, and production on separate floors.

Manufacturers' usage of tools, containers, and other items dedicated to allergen or non-allergen use to control cross-contact is shown, by company size and food product category, in Table 14. IFT inquired about dedicated usage of several specific items—bins, totes, pans, utensils, sanitation tools, sampling devices, and/or maintenance tools—and inquired about use of other cross-contact safeguards—uniforms and/or smocks, gloves, defined traffic patterns, dedicated employees, and/or product shielding. Eight of the 13 small companies dedicate 1 or more of the identified items for allergen-containing products. Eleven of the 21 medium companies and 58 of the 86 large companies dedicate one or more of the specific items for allergen containing products.

Table 15 shows the extent of use of scheduling strategies and matrices and the number of companies that indicated using either of 3 specific types of scheduling strategies. The specific scheduling strategies that IFT asked manufacturers about were:

- Strategy 1: addition of allergen-containing ingredients to product as late as possible in manufacturing operations;
- Strategy 2: running of allergen-containing formulations at the end of shifts or on separate days; and
- Strategy 3: running of allergen-containing formulations in successive batches or long runs to minimize clean-up/changeover operations.

All of the small and medium companies and 81 of the 86 large companies employ a scheduling strategy as part of their overall effort to control allergen cross-contact. Most indicated that they consider scheduling a primary defense against unintentional cross-contact. Two of the 13 small companies, more than half (13 of the 21) of the medium companies, and 64 of the 86 large companies use a scheduling matrix (also referred to as a “run sequence chart”, this varies slightly from company-to-company, but is basically a spreadsheet used to organize process runs so as to minimize potential for cross-contact, maximize effectiveness of sanitation practices, and indicate necessary sanitation practices dependent on the allergen composition of the next production run).

Less than half (46%) of the small companies utilize Strategy 1. This strategy is not available to some operations due to the nature of the product they produce (for example, milk proteins often require hydration to function in a formulation, which is a time consuming step) or the system to produce it (for example, enclosed systems). Most use Strategy 2 (92%) and Strategy 3 (85%). Similarly, 43% of the medium companies employ Strategy 1, 90% run Strategy 2 and 71% run Strategy 3. Sixty-four percent (n = 55) of the large companies use Strategy 1, 87% (n = 75) use Strategy 2 and 70% (n = 60) implement Strategy 3.

The prevalence (by size and food product category) of co-packer ACP requirements and the regular evaluation of specific co-packer activities are shown in Table 16. IFT inquired about whether the companies use co-packers, and if so, whether they regularly evalu-

Table 12—Percent and number of companies, by food product category, that have identified specific points in the manufacturing process where cross-contact could occur

Food Product Category	Percent (number) that have identified specific points	Specific points identified	Examples of control practices used
Baby food (n = 2)	100 (2)	kettles, fill heads, drum dryers	scheduling (2), defined areas, sanitation, push-through, shields, labeling
Infant formula (n = 3)	100 (3)	holding tanks, lines, fillers, non-CIP equipment (those that must be dry cleaned) sources of cross-contact (before ingredients reach line, other)	sanitation (3), scheduling (2), segregation (1), validation (1), visual inspection (1), purging of line (1), use of CIP (3)
Bakery products (n = 25)	100 (25)	mixers (14), shared equipment (10), packaging equipment (10), dividers (9), conveyors (8), ingredient scaling (8), proofer (6), cooler (6), slicer (6), racks (6), piping (6), dough troughs (6), pans (6), belts (4), ovens (2), enrobing (2), freezer (2), changeovers (2), rounder, extruder, sheeter, baking room, crossed lines, shared storage containers, dough pump, dead spots, scoops, sifters, depositer, sieves	scheduling (16), sanitation (14), training (4), storage segregation (4), visual inspection (3), allergen testing (3), color-coding (3), push-through (2), equipment design (2), tarps under conveyors (2), labeling (2), vacuum, line separation, shields, distance, production layout, eliminate crossed lines, allergen profiling, scraping, segregated steam room for cleaning, color-code rework, dedicated areas, dedicate maintenance tools, harmonization ^d
Beverages ^a (n = 8)	75 (6), 2 NA	filler (4), shared equipment (3), storage tanks (3), blending (2), pumps (2), lines (2), pasteurization, homogenization, liquifiers, batch tanks	sanitation (4), scheduling (4), allergen testing (4), visual inspection (3), flushing
Candy/confections (n = 10)	90 (9)	enrober (6), packaging (4), panning (4), shared lines (3), coating (2), molding (2), belts, ovens, temper unit, piping, refining, spraying systems, conveyors, changeovers	scheduling (6), sanitation (5), dedicated lines (4), flushing (2), wet cleaning where possible (2), segregation (2), dry cleaning, disassembly of equipment to clean, product formulation, labeling, dedicated equipment, wrap products prior to packaging, dedicated employees, inspection, allergen testing, single-use storage bags
Cereal/pasta (n = 11)	100 (11)	belts (3), mixers (3), particulates (2), packaging (2), shared lines (2), conveyors (2), scales (2), residue, piping, ovens, handling, rework, baking room, egg feeder, shared equipment, driers, shakers, sifters, crossed lines, reuse of storage containers, changeover, reuse of frying oil	sanitation (8), scheduling (4), separation (4), visual inspection (3), shielding (3), vacuum (2), dedication (2), eliminate cross-overs (2), pressure washing, disassembly of equipment for cleaning, flush with cornstarch, equipment design, allergen testing
Dairy products/substitutes ^b (n = 15)	87 (13)	shared equipment (5), fillers (5), blending (4), pasteurization (3), homogenization (3), storage tanks (2), shared lines (2), liquifiers, batch tanks, packaging equipment, ingredient receiving	scheduling (9), sanitation (7), allergen testing (5), inspection (3), flushing, dedication, shields, separation, supplier contact
Desserts (n = 8)	100 (8)	shared equipment (4), fillers (4), pumps (3), storage tanks (3), lines (3), duct work, cooling systems, changeovers, fruit feeders, varigators	sanitation (7), scheduling (4), allergen testing (2), inspection (2), production layout
Fish/fish products (n = 7)	100 (7)	batter/breader equipment (7), freezer (2), fryer (2), packaging (1), conveyor (1)	scheduling (7), sanitation (7), pre-requisites (2), filter oil (1), validation test (1), receipt of original containers at specific line assignments (1), equipment design (1), equipment flexibility (1), inspection (1)
Miscellaneous (n = 7)	100 (7)	shared equipment (2), piping, utensils, common tanks, crossed lines, reuse of storage containers, changeovers	sanitation (4), scheduling (4), equipment design (2), eliminate 'dead spots,' allergen testing, eliminate crossed lines, segregated storage
Mixed dishes (n = 6)	100 (6)	shared equipment (2), filler, mixer, conveyors, dead spots, spice rooms	sanitation (5), scheduling (4), equipment design (2), allergen testing, visual inspection, dedicated lines, segregated storage
Sauces/dips/gravies/condiments ^c (n = 6)	100 (6)	piping (2), filler, mixer, scales, utensils, common tanks, spice room, shared lines, reused fry oil, conveyors	sanitation (4), scheduling (4), allergen profiling, color-coding, elimination of 'dead spots,' segregated storage, shielding, visual inspection, labeling
Snack foods (n = 7)	100 (7)	packaging (2), conveyors (2), belts, ovens, dryers, enrobers, mixers, shared equipment, crossed lines, reuse of storage containers, changeovers, dead spots, reuse of fry oil	sanitation (7), visual inspection (3), equipment design (3), walls (2), scheduling (2), allergen testing (2), dedication, training, color-coding, segregated storage, eliminate cross-overs, labeling
Soups (n = 5)	100 (5)	spice rooms, dead spots, shared lines	scheduling (4), sanitation (3), separation, equipment design, segregated storage

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, shortenings

^dThe practice of intentionally putting allergens in the product.

Table 13—Percent and number of companies, by size and food product category, that dedicate facilities or lines to avoid cross-contact

Company Size	Exclude certain allergens from facilities	Dedication to specific facility	Dedication to specific line					
			Yes	Dedication measures				
				Walls	Curtains	Distance	Air handling	Other
			Percent (number)					
Category 1 (n = 13) (small, < 100 employees)	69 (9)	0	15 (2)	15 (2)	0	15 (2)	15 (2)	15 (2)
Category 2 (n = 21) (medium, 100 to 500 employees)	43 (9)	5 (1)	19 (4)	5 (1)	0	5 (1)	0	5 (1)
Category 3 (n = 86) (large, > 500 employees)	62 (53)	14 (12)	59 (51)	41 (35)	23 (20)	36 (31)	17 (15)	9 (8)
Food Product Category			Percent (number)					
Baby food (n = 2)	100 (2)	0	0	50 (1), 1 NA	1 NA	1 NA	50 (1), 1 NA	1 NA
Infant formula (n = 3)	33 (1)	0	67 (2)	33 (1), 1 NA	33 (1), 1 NA	67 (2), 1 NA	67 (2), 1 NA	1 NA
Bakery products (n = 25)	72 (18)	4 (1)	60 (15)	36 (9), 3 NA	20 (5), 3 NA	32 (8), 3 NA	12 (3), 3 NA	4 (1), 3 NA
Beverages ^a (n = 8)	25 (2)	0	0	7 NA	7 NA	7 NA	7 NA	7 NA
Candy/confections (n = 10)	80 (8)	50 (5)	60 (6)	50 (5), 1 NA	20 (2), 1 NA	40 (4), 1 NA	1 NA	20 (2), 1 NA
Cereal/pasta (n = 11)	82 (9)	18 (2)	73 (8)	64 (7), 2 NA	45 (5), 2 NA	55 (6), 2 NA	18 (2), 2 NA	27 (3), 2 NA
Dairy products/substitutes ^b (n = 15)	27 (4)	0	20 (3)	7 (1), 11 NA	11 NA	20 (3), 11 NA	7 (1), 11 NA	7 (1), 11 NA
Desserts (n = 8)	50 (4)	0	13 (1)	13 (1), 7 NA	7 NA	13 (1), 7 NA	7 NA	7 NA
Fish/fish products (n = 7)	100 (7)	0	14 (1)	0	0	0	0	14 (1)
Miscellaneous (n = 7)	57 (4)	14 (1)	71 (5)	57 (4), 1 NA	29 (2), 1 NA	14 (1), 1 NA	43 (3), 1 NA	29 (2)
Mixed dishes (n = 6)	67 (4)	17 (1)	50 (3)	33 (2), 2 NA	2 NA	50 (3), 2 NA	17 (1), 2 NA	2 NA
Sauces/dips/gravies/condiments ^c (n = 6)	33 (2)	17 (1)	33 (2)	33 (2), 4 NA	33 (2), 4 NA	17 (1), 4 NA	17 (1), 4 NA	4 NA
Snack foods (n = 7)	57 (4)	29 (2)	86 (6)	57 (4), 1 NA	43 (3), 1 NA	57 (4), 1 NA	29 (2), 1 NA	1 NA
Soups (n = 5)	40 (2)	0	60 (3)	20 (1), 2 NA	2 NA	40 (2), 2 NA	20 (1), 2 NA	20 (1), 2 NA

^aIncludes fruit juices^bIncludes rice and soy beverages, butter, and margarine^cIncludes pancake syrup, oils, shortenings

ate co-packers for 8 specific activities—purchasing function integrity, supplier reliability, proper raw material receiving and storage, formulation reliability, processing reliability, packaging operation reliability, sanitation program adequacy, and accuracy and consistency of labeling practices. Twelve of the 13 small companies, 20 of the 21 medium companies, and 74 of the 86 large companies use co-packers; all 12 of the small companies using co-packers, 19 of the medium companies, and all 74 of the large companies using co-packers require their co-packers to have ACPs.

Companies often reported “non-applicable” for activities if they purchased and/or stored ingredients and raw materials for co-packers, had co-packers use the same suppliers and formulas they used, and supplied labels and packages to co-packers or performed packaging and labeling at their own company. Other activities of co-packers that some companies mentioned evaluating are monitoring of adherence to a no-shared-equipment rule, changeover, employee training, GMPs, training/auditing, general food safety, random sampling of equipment and/or products.

The rework-related practices that companies have and their rework container cleaning methods are listed, by company size and food product category, in Table 17. Rework is considered “clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food” (21 CFR, Ch. 1, Part 110). There are several caveats to the responses in this section.

- First, companies frequently indicated that they use rework within shift and/or within the same exact product so as to avoid the potential for cross-contact, thereby eliminating the need for segregation in storage because said rework would not be stored.
- Second, many companies indicated that they either do not use rework, or do not store rework (unused portions would be discarded).
- Third, many companies indicated they use either single-use con-

tainers and/or single-use liners to protect containers and thereby avoid cross-contact and eliminate the need for cleaning of totes.

The cleaning practices used by the 3 different sizes of companies and manufacturers of the 14 categories of food products are shown in Table 18. A variety of practices may be used for cleaning lines and equipment coming into contact with allergen-containing ingredients and products. There are practical/physical limitations specific to each product category that result in noted differences in clean-up practices. The cleaning practices that are more commonly used across company size and food product manufacturing categories are water, detergents/chemicals, equipment disassembly, CIP, and COP (clean-out-of-place). Also, the greater majority of companies interviewed (13 of 13 small, 19 of 21 medium and 74 of 86 large) indicated that their employees follow written SSOPs (Sanitation Standard Operating Procedures) for allergen control.

As for the prevalence of validation of cleaning methods to ensure that allergen residue potential is minimized, the majority of the small, medium, and large companies (85%, 86%, and 85%, respectively) indicated that they validate their cleaning methods (Table 18). This was an open-ended question with participants offering up methods of validation ranging from “visually clean” to outsourcing of samples for ELISA testing to in-house testing of equipment swabs and final products.

IFT inquired of the manufacturers what procedures they use to verify that equipment is cleaned thoroughly, specifically asking about visual inspections, ELISA, protein detection, bioluminescence/ATP, lateral flow devices, and other methods that might be used. Table 19 shows the procedures used, by company size and food product category. Across all size and food product categories, visual inspection is by far the most commonly used verification method, followed by ELISA and bioluminescence/ATP, with far fewer using protein detection or lateral flow devices.

Frequency of use of the verification procedures varied among the

Table 14—Percent and number of companies, by size and food product category, that use dedicated tools, containers, and other items to control cross-contact

Use dedicated items	Use of dedicated containers, tools							Use of other dedicated items						
	Bins	Totes	Pans	Utensils	Sanitation		Main-tenance tools	Other	Uniforms, smocks	Gloves	Defined traffic patterns	Dedicated employees	Product shielding	Other
					tools	devices								
Company Size														
Category 1 (n = 13) (small, < 100 employees)	54 (7)	62 (8)	54 (7)	54 (7)	38 (5)	15 (2)	15 (2)	0	31 (4)	54 (7)	31 (4)	15 (2)	77 (10)	0
	24 (5)	19 (4)	14 (3)	52 (11)	38 (8)	43 (9)	10 (2)	0	33 (7)	52 (11)	43 (9)	52 (11)	29 (6)	14 (3)
	67 (58)	64 (55)	59 (51)	63 (54)	47 (40)	34 (29)	21 (18)	10 (9)	29 (25)	47 (40)	52 (45)	56 (48)	50 (43)	24 (21)
Food Product Category														
Baby food (n = 2)	50 (1)	50 (1)	50 (1)	50 (1)	50 (1)	50 (1)	50 (1)	0	50 (1)	50 (1)	50 (1)	50 (1)	50 (1)	50 (1)
Infant formula (n = 3)	67 (2)	67 (2)	67 (2)	33 (1)	33 (1)	33 (1)	0	0	67 (2)	67 (2)	67 (2)	0	67 (2)	0
Bakery products (n = 25)	76 (19)	68 (17)	56 (14), 1 NA	68 (17)	52 (13)	44 (11), 3 NA	20 (5)	4 (1)	32 (8)	56 (14)	40 (10)	48 (12)	60 (15)	20 (5)
Beverages ^a (n = 8)	13 (1), 1 NA	13 (1), 1 NA	13 (1), 1 NA	13 (1)	0	13 (1)	0	0	13 (1)	38 (3), 2 NA	13 (1)	25 (2)	13 (1), 1 NA	13 (1)
Candy/confections (n = 10)	90 (9)	90 (9)	90 (9)	90 (9)	80 (8)	70 (7), 1 NA	60 (6)	0	60 (6)	80 (8)	80 (8)	100 (10)	60 (6)	20 (2)
Cereal/pasta (n = 11)	64 (7), 1 NA	73 (8), 1 NA	45 (5), 2 NA	73 (8)	73 (8)	36 (4), 2 NA	18 (2)	9 (1)	18 (2)	27 (3)	45 (5)	36 (4)	73 (8)	9 (1)
Dairy products/substitutes ^b (n = 15)	20 (3), 1 NA	20 (3), 1 NA	20 (3), 1 NA	27 (4)	33 (5)	20 (3), 1 NA	7 (1)	7 (1)	27 (4)	47 (7)	33 (5)	40 (6)	27 (4)	7 (1)
Desserts (n = 8)	38 (3)	38 (3)	38 (3)	50 (4)	25 (2)	25 (2)	13 (1)	13 (1)	38 (3), 1 NA	50 (4), 1 NA	50 (4), 1 NA	50 (4), 1 NA	25 (2), 1 NA	13 (1), 1 NA
Fish/fish products (n = 7)	14 (1), 2 NA	2 NA	2 NA	29 (2), 1 NA	0	0	0	0	57 (6), 1 NA	57 (6), 1 NA	57 (6), 1 NA	57 (6), 1 NA	43 (3), 1 NA	14 (1)
Miscellaneous (n = 7)	86 (6)	86 (6)	86 (6)	71 (5)	43 (3)	29 (2)	43 (3)	29 (2)	29 (2)	71 (5)	71 (5)	57 (4)	71 (5)	43 (3)
Mixed dishes (n = 6)	83 (5)	83 (5)	83 (5)	83 (5)	33 (2)	17 (1)	17 (1)	17 (1)	0	33 (2)	83 (5)	83 (5)	67 (4)	33 (2)
Sauces/dips/gravies/condiments ^c (n = 6)	83 (5)	83 (5)	83 (5)	67 (4)	33 (2)	33 (2)	0	17 (1)	0	0	17 (1)	50 (3)	50 (3)	17 (1)
Snack foods (n = 7)	43 (3)	43 (3)	43 (3)	71 (5)	71 (5)	43 (3), 1 NA	14 (1)	14 (1)	29 (2)	43 (3)	57 (4)	57 (4)	43 (3)	57 (4)
Soups (n = 5)	100 (5)	80 (4)	80 (4)	100 (5)	60 (3)	40 (2)	20 (1)	40 (2)	20 (1)	40 (2)	60 (3)	40 (2)	40 (2)	20 (1)

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, shortenings

Table 15—Percent and number of companies, by size and food product category, using scheduling strategies

	Use schedule strategy	Use schedule matrix	Type of strategy used		
			Strategy 1 ^d	Strategy 2 ^e	Strategy 3 ^f
Company Size	Percent (number)				
Category 1 (small, < 100 employees) (n = 13)	100 (13)	15 (2)	46 (6)	92 (12)	85 (11)
Category 2 (medium, 100 to 500 employees) (n = 21)	100 (21)	62 (13)	43 (9)	90 (19)	71 (15)
Category 3 (large, > 500 employees) (n = 86)	94 (81)	74 (64)	64 (55)	87 (75)	70 (60)
Food Product Category	Percent (number)				
Baby food (n = 2)	100 (2)	100 (2)	2 NA	100 (2)	100 (2)
Infant formula (n = 3)	100 (3)	100 (3)	3 NA	100 (3)	100 (3)
Bakery products (n = 25)	100 (25)	68 (17)	64 (16), 3 NA	96 (24)	92 (23)
Beverages ^a (n = 8)	75 (6)	50 (4)	50 (4), 1 NA	75 (6)	50 (4)
Candy/confections (n = 10)	100 (10)	60 (6)	90 (9)	90 (9)	100 (10)
Cereal/pasta (n = 11)	91 (10)	64 (7)	64 (7), 2 NA	82 (9)	64 (7)
Dairy products/substitutes ^b (n = 15)	87 (13)	40 (6)	47 (7)	87 (13)	53 (8)
Desserts (n = 8)	100 (8)	38 (3)	88 (7)	100 (8)	63 (5)
Fish/fish products (n = 7)	100 (7)	100 (7)	71 (5), 2 NA	86 (6), 1 NA	100 (7)
Miscellaneous (n = 7)	100 (7)	71 (5)	43 (3), 1 NA	71 (5)	43 (3)
Mixed dishes (n = 6)	100 (6)	83 (5)	67 (4), 2 NA	83 (5)	67 (4)
Sauces/dips/gravies/condiments ^c (n = 6)	100 (6)	67 (4)	50 (3), 3 NA	83 (5)	33 (2)
Snack foods (n = 7)	100 (7)	71 (5)	57 (4)	100 (7)	71 (5)
Soups (n = 5)	100 (5)	100 (5)	20 (1) 2 NA	80 (4)	60 (3)

^aIncludes fruit juices^bIncludes rice and soy beverages, butter, and margarine^cIncludes pancake syrup, oils, shortenings^dAddition of allergen-containing ingredients to product as late as possible in the process^eAllergen-containing formulations run at end of shift or separate day^fAllergen-containing formulations run in successive batches or long runs**Table 16—Percent and number of companies, by size and food product category, addressing allergens with co-packers**

	Use Co-Packers	Require ACPs of Co-Packers	Percent regularly evaluating specific activities of co-packers								
			Purchasing function integrity	Supplier reliability	Proper raw material receiving, storage	Formulation reliability	Processing reliability	Packaging operation reliability	Sanitation program adequacy	Accuracy, consistency of labeling practices	Other
Company Size	Percent (number)										
Category 1 (n = 13) (small, < 100 employees)	92 (12)	100 (12)	58 (7)	75 (9)	83 (10)	100 (12)	100 (12)	100 (12)	100 (12)	83 (10)	17 (2)
Category 2 (n = 21) (medium, 100 to 500 employees)	95 (20)	95 (19)	55 (11)	60 (12)	80 (16)	80 (16)	80 (16)	80 (16)	80 (16)	75 (15)	20 (4)
Category 3 (n = 86) (large, > 500 employees)	86 (74)	100 (74)	84 (62)	84 (62)	96 (71)	95 (70)	99 (73)	97 (72)	100 (74)	85 (63)	34 (25)
Food Product Category	Percent (number)										
Baby food (n = 2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	50 (1), 1 NA	100 (2)
Infant formula (n = 3)	67 (2)	100 (2)	2 NA	2 NA	50 (1), 1 NA	2 NA	50 (1), 1 NA	50 (1), 1 NA	100 (2)	100 (2)	0
Bakery products (n = 25)	92 (23)	100 (23)	74 (17), 1 NA	65 (15), 3 NA	91 (21), 1 NA	91 (21), 1 NA	96 (22)	96 (22)	96 (22)	83 (19), 1 NA	22 (5)
Beverages ^a (n = 8)	88 (7)	71 (5)	57 (4)	71 (5), 1 NA	86 (6)	86 (6)	86 (6)	86 (6)	86 (6)	86 (6)	29 (2)
Candy/confections (n = 10)	100 (10)	80 (8)	70 (7)	60 (6), 1 NA	80 (8)	80 (8)	90 (9)	80 (8), 1 NA	90 (9)	70 (7), 2 NA	10 (1)
Cereal/pasta (n = 11)	91 (10)	100 (10)	90 (9), 1 NA	80 (8)	100 (10)	100 (10)	100 (10)	100 (10)	100 (10)	80 (8), 1 NA	30 (3)
Dairy products/ substitutes ^b (n = 15)	87 (13)	100 (13)	62 (8), 1 NA	85 (11), 1 NA	92 (12)	100 (13)	100 (13)	100 (13)	100 (13)	92 (12), 1 NA	23 (3)
Desserts (n = 8)	88 (7)	86 (6)	71 (5)	100 (7), 1 NA	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	29 (2)
Fish/fish products (n = 7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	57 (4)
Miscellaneous (n = 7)	100 (7)	57 (4)	57 (4)	71 (5)	71 (5)	71 (5)	71 (5)	71 (5)	71 (5)	43 (3), 2 NA	43 (3)
Mixed dishes (n = 6)	100 (6)	100 (6)	83 (5)	83 (5)	83 (5)	83 (5)	83 (5)	83 (5)	83 (5)	83 (5)	17 (1)
Sauces/dips/gravies/ condiments ^c (n = 6)	83 (5)	100 (5)	40 (2)	60 (3)	60 (3)	80 (4)	80 (4)	80 (4)	80 (4)	80 (4)	0
Snack foods (n = 7)	86 (6)	100 (6)	100 (6)	83 (5)	100 (6)	100 (6)	100 (6)	100 (6)	100 (6)	67 (4)	67 (4)
Soups (n = 5)	100 (5)	100 (5)	80 (4)	80 (4)	80 (4)	80 (4)	80 (4)	80 (4)	80 (4)	60 (3), 1 NA	20 (1)

^aIncludes fruit juices^bIncludes rice and soy beverages, butter, and margarine^cIncludes pancake syrup, oils, shortenings

Table 17—Percent and number of companies using rework and their rework practices

	Use rework	Use like-like policy	Clearly label rework product	Segregate rework in storage	Prevent contamination of totes	Rework container cleaning method(s) used			
						Wet clean ^d	Air	Vacuum	Wipe downs
Company Size	Percent (number)								
Category 1 (n = 13) (small, < 100 employees)	54 (7)	100 (7)	71 (5)	15 (2)	38 (5)	15 (2)	15 (2)	8 (1)	15 (2)
Category 2 (n = 21) (medium, 100 to 500 employees)	67 (14)	100 (14)	78 (11)	43 (9)	62 (13)	14 (3)	0	5 (1)	10 (2)
Category 3 (n = 86) (large, > 500 employees)	92 (79)	100 (79)	95 (75)	64 (55)	74 (64)	66 (57)	2 (2)	1 (1)	7 (6)
Food Product Category	Percent (number)								
Baby food (n = 2)	50 (1)	100 (1)	100 (1)	100 (1)	100 (1)	100 (1)	0	0	0
Infant formula (n = 3)	67 (2)	100 (2)	100 (2)	50 (1), 1 NA	100 (2)	1 NA	0	0	50 (1), 1 NA
Bakery products (n = 25)	92 (23)	100 (23)	87 (20), 1 NA	52 (12), 2 NA	65 (15), 5 NA	83 (19), 2 NA	9 (2), 2 NA	13 (3), 2 NA	22 (5), 2 NA
Beverages ^a (n = 8)	63 (5)	100 (5)	90 (4)	90 (4)	100 (5)	60 (3), 2 NA	2 NA	2 NA	2 NA
Candy/confections (n = 10)	100 (10)	100 (10)	100 (10)	90 (9)	40 (4)	60 (6), 4 NA	10 (1), 4 NA	4 NA	4 NA
Cereal/pasta (n = 11)	82 (9)	100 (9)	89 (8)	44 (4), 1 NA	67 (6), 1 NA	56 (5), 4 NA	11 (1), 4 NA	11 (1), 4 NA	22 (2), 4 NA
Dairy products/ substitutes ^b (n =15)	67 (10)	100 (10)	80 (8), 1 NA	70 (7), 2 NA	80 (8), 2 NA	50 (5), 5 NA	5 NA	5 NA	5 NA
Desserts (n = 8)	75 (6)	100 (6)	100 (6)	100 (6)	83 (5), 1 NA	50 (3), 1 NA	2 NA	2 NA	2 NA
Fish/fish products (n = 7)	57 (4)	100 (4)	100 (4)	100 (4)	100 (4)	50 (2), 2 NA	1 NA	1 NA	1 NA
Miscellaneous (n = 7)	100 (7)	100 (7)	100 (7)	57 (4)	100 (7)	71 (5), 1 NA	0	0	14 (2)
Mixed dishes (n = 6)	100 (6)	100 (6)	100 (6)	83 (5)	100 (6)	83 (5), 1 NA	1 NA	1 NA	1 NA
Sauces/dips/gravies/ condiments ^c (n = 6)	100 (6)	100 (6)	83 (5)	67 (4), 1 NA	67 (4)	67 (4), 2 NA	2 NA	2 NA	2 NA
Snack foods (n = 7)	100 (7)	100 (7)	86 (6), 1 NA	29 (2), 1 NA	71 (5), 1 NA	100 (7)	0	14 (1)	29 (2)
Soups (n = 5)	100 (5)	100 (5)	80 (4), 1 NA	60 (3), 1 NA	80 (4), 1 NA	60 (3), 2 NA	2 NA	2 NA	2 NA

^aIncludes fruit juices.

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, shortenings

^dIncludes COP, CIP, water, sanitizer, detergent, steam, and other related wet cleaning methods.

Table 18—Percent and number of companies, by size and food product category, having certain cleaning practices for lines and equipment in contact with allergen-containing ingredients and products

	Cleaning practices											
	Equipment dis- SSOPs ^d	assembly	Water	Deter- gents, chemicals	COP (clean- out-of- place)	CIP (clean- in- place)	Air	Vacuum	Wipe/ brush downs	Push- through	Other	Cleaning methods validated
Company Size	Percent (number)											
Category 1 (n = 13) (small, < 100 employees)	100 (13)	85 (11)	69 (9)	100 (13)	38 (5)	31 (4)	38 (5)	62 (8)	77 (10)	62 (8)	15 (2)	85 (11)
Category 2 (n = 21) (medium, 100 to 500 employees)	90 (19)	90 (19)	100 (21)	86 (18)	62 (13)	81 (17)	43 (9)	24 (5)	62 (13)	14 (3)	19 (4)	86 (18)
Category 3 (n = 86) (large, > 500 employees)	86 (74)	92 (79)	93 (80)	93 (80)	84 (72)	83 (71)	49 (42)	51 (44)	63 (54)	44 (38)	6 (5)	85 (73)
Food Product Category	Percent (number)											
Baby food (n = 2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	100 (2)	50 (1)	50 (1)	50 (1)	100 (2)	0	100 (2)
Infant formula (n = 3)	100 (3)	100 (3)	33 (1)	67 (2)	100 (3)	100 (3)	33 (1)	67 (2)	67 (2)	0	0	100 (3)
Bakery products (n = 25)	88 (22)	92 (23)	92 (23)	92 (23)	76 (19)	76 (19), 1 NA	60 (15)	64 (16)	92 (23)	48 (12)	4 (1)	88 (22)
Beverages ^a (n = 8)	63 (5)	75 (6)	75 (6)	75 (6)	75 (6)	75 (6)	0	0	0	25 (2), 2 NA	13 (1)	75 (6)
Candy/confections (n = 10)	100 (10)	90 (9)	90 (9)	80 (8)	30 (3), 1 NA	50 (5), 1 NA	50 (5)	70 (7)	100 (10)	50 (5), 2 NA	10 (1)	100 (10)
Cereal/pasta (n = 11)	73 (8)	91 (10)	82 (9)	91 (10)	64 (7), 1 NA	27 (3), 1 NA	73 (8), 1 NA	91 (10), 1 NA	100 (11)	64 (7), 1 NA	0	91 (10)
Dairy products/ substitutes ^b (n = 15)	80 (12)	80 (12)	93 (14)	100 (15)	60 (9)	87 (13)	1 NA	7 (1), 1 NA	13 (2), 1 NA	33 (5), 1 NA	13 (2)	80 (12)
Desserts (n = 8)	100 (8)	100 (8)	100 (8)	100 (8)	88 (7)	88 (7), 1 NA	13 (1), 1 NA	1 NA	38 (3), 1 NA	50 (4), 1 NA	0	100 (8)
Fish/fish products (n = 7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	100 (7)	14 (1)	100 (7)	7 NA	0	86 (6)
Miscellaneous (n = 7)	100 (7)	100 (7)	100 (7)	100 (7)	86 (6)	86 (6)	57 (4)	43 (3)	57 (4)	43 (3)	29 (2)	86 (6)
Mixed dishes (n = 6)	100 (6)	100 (6)	100 (6)	100 (6)	100 (6)	100 (6)	50 (3)	67 (4)	67 (4)	33 (2), 1 NA	17 (1)	83 (5)
Sauces/dips/gravies/ condiments ^c (n = 6)	100 (6)	83 (5), 1 NA	83 (5), 1 NA	100 (6)	67 (4)	100 (6)	50 (3)	50 (3)	50 (3)	17 (1)	33 (2)	50 (3)
Snack foods (n = 7)	86 (6)	86 (6)	100 (7)	86 (6)	86 (6)	71 (5)	57 (4)	71 (5)	71 (5)	43 (3)	14 (1)	86 (6)
Soups (n = 5)	80 (4)	100 (5)	100 (5)	100 (5)	100 (5)	100 (5)	60 (3)	80 (4)	40 (2)	60 (3)	20 (1)	80 (4)

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, shortenings

^dSanitation Standard Operating Procedures

manufacturers, from nightly or after every cleanup (for example, for visual inspections), to periodically (for example, for ATP), routinely (for example, for ELISA), annually, randomly, infrequently, and quarterly. Some companies volunteered information about additional verification methods that they use; these other methods are lactose testing and use of a fiber optic scope/boroscope for piping inspection.

Analytical testing

IFT also posed additional questions to determine how companies integrate analytical testing practices with their ACPs. The percentage of companies, by size and food product category, who include analytical testing in their ACPs, is shown in Table 20, along with frequency of testing and specific material tested. More

Table 19—Percent and number of companies, by size and food product category, and their equipment cleaning verification procedures

	Verification procedures					
	Visual inspections	ELISA	Protein detection	Bioluminescence/ATP	Lateral flow devices (dipsticks)	Other
Company size	Percent (number)					
Category 1 (small, < 100 employees) (n = 13)	100 (13)	15 (2)	0	38 (5)	15 (2)	31 (4)
Category 2 (medium, 100 to 500 employees) (n = 21)	90 (19)	38 (8)	0	43 (9)	0	10 (2)
Category 3 (large, > 500 employees) (n = 86)	93 (80)	52 (45)	14 (12)	44 (38)	10 (9)	13 (11)
Food Product Category	Percent (number)					
Baby food (n = 2)	100 (2)	50 (1)	0	50 (1)	50 (1)	50 (1)
Infant formula (n = 3)	100 (3)	33 (1)	0	33 (1)	0	0
Bakery products (n = 25)	88 (22)	24 (6)	4 (1)	36 (9)	8 (2)	12 (3)
Beverages ^a (n = 8)	75 (6)	63 (5)	25 (2)	63 (5)	0	0
Candy/confections (n = 10)	100 (10)	70 (7)	10 (1)	40 (4)	10 (1)	0
Cereal/pasta (n = 11)	100 (11)	36 (4)	0	36 (4)	18 (2)	18 (2)
Dairy products/substitutes ^b (n = 15)	87 (13)	47 (7)	20 (3)	60 (9)	7 (1)	13 (2)
Desserts (n = 8)	100 (8)	50 (4)	38 (3)	63 (5)	0	25 (2)
Fish/fish products (n = 7)	100 (7)	14 (1)	0	0	0	0
Miscellaneous (n = 7)	100 (7)	71 (5)	0	57 (4)	29 (2)	43 (3)
Mixed dishes (n = 6)	100 (6)	67 (4)	33 (2)	50 (3)	0	17 (1)
Sauces/dips/gravies/condiments ^c (n = 6)	100 (6)	33 (2)	0	17 (1)	0	0
Snack foods (n = 7)	86 (6)	71 (5)	0	43 (3)	14 (1)	14 (1)
Soups (n = 5)	100 (5)	60 (3)	0	60 (3)	20 (1)	40 (2)

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, shortenings

Table 20—Percent and number of companies, by size and food product category, and their analytical testing practices (as part of ACPs)

	Conduct testing	Frequency of testing		Material/area tested							Finished product	Other
		Routine	Periodic	Ingred- ients	Sanitation	Equipment surface ^d	Water rinse ^d	Push through ^d				
Company Size				Percent (Number)								
Category 1 (n = 13) (small, < 100 employees)	77 (10)	31 (4)	38 (5)	46 (6)	77 (10)	38 (5)	15 (2)	0	54 (7)	15 (2)		
Category 2 (n = 21) (medium, 100 to 500 employees)	71 (15)	24 (5)	48 (10)	5 (1)	71 (15)	48 (10)	24 (5)	0	24 (5)	14 (3)		
Category 3 (n = 86) (large, > 500 employees)	83 (71)	34 (29)	58 (50)	30 (26)	77 (66)	65 (56)	48 (41)	27 (23)	34 (29)	8 (7)		
Food Product Category				Percent (Number)								
Baby food (n = 2)	100 (2)	100 (2)	50 (1)	0	100 (2)	50 (1)	50 (1), 1 NA	0	50 (1)	0		
Infant formula (n = 3)	100 (3)	33 (1)	67 (2)	0	100 (3)	100 (3)	33 (1)	0	67 (2)	0		
Bakery products (n = 25)	76 (19)	20 (5)	60 (15)	52 (13)	60 (15)	52 (13)	32 (8)	28 (7)	40 (10)	12 (3)		
Beverages ^a (n = 8)	75 (6)	25 (2)	50 (4)	0	75 (6)	63 (5)	25 (2)	0	13 (1)	13 (1)		
Candy/confections (n = 10)	100 (10)	20 (2)	90 (9)	30 (3)	90 (9)	90 (9)	30 (3), 1 NA	10 (1), 2 NA	60 (6)	0		
Cereal/pasta (n = 11)	73 (8)	27 (3)	55 (6)	36 (4)	82 (9)	64 (7)	36 (4)	36 (4)	27 (3)	9 (1)		
Dairy products/substitutes ^b (n = 15)	87 (13)	33 (5)	53 (8)	20 (3)	87 (13)	60 (9)	53 (8)	13 (2), 2 NA	27 (4)	7 (1)		
Desserts (n = 8)	100 (8)	38 (3)	63 (5)	25 (2)	100 (8)	75 (6)	50 (4)	13 (1), 1 NA	25 (2)	25 (2)		
Fish/fish products (n = 7)	43 (3)	0	43 (3)	0	43 (3), 1 NA	0	14 (1), 1 NA	0	0	0		
Miscellaneous (n = 7)	57 (4)	57 (4)	29 (2)	14 (1)	71 (5)	29 (2)	57 (4)	14 (1)	57 (4)	14 (1)		
Mixed dishes (n = 6)	67 (4)	67 (4)	33 (2)	33 (2)	83 (5)	83 (5)	67 (4)	33 (2)	33 (2)	17 (1)		
Sauces/dips/gravies/ condiments ^c (n = 6)	67 (4)	17 (1)	50 (3)	17 (1)	50 (3)	33 (2)	17 (1)	0	17 (1)	0		
Snack foods (n = 7)	71 (5)	43 (3)	57 (4)	43 (3)	86 (6)	86 (6)	57 (4)	57 (4)	43 (3)	29 (2)		
Soups (n = 5)	60 (3)	60 (3)	20 (1)	20 (1)	80 (4)	60 (3)	60 (3)	20 (1)	40 (2)	0		

^aIncludes fruit juices

^bIncludes rice and soy beverages, butter, and margarine

^cIncludes pancake syrup, oils, shortenings

^dThese components were specifically identified by some (not all) participants that test for effectiveness of sanitation

than half of the small, medium, and large companies (77%, 71%, and 83%, respectively) conduct testing within their ACPs. More companies conduct the testing periodically than do so routinely. Among the various materials/items tested, components of sanitation are tested by far most frequently, including equipment surfaces, water rinse, and push-through. Some participants indicated that testing is used to ensure proper sanitation, but did not continue to specify which component of sanitation is tested. Testing of finished products and/or ingredients was much less common. Several indicated that they test intermediate foods (in-process) and monitor dishwasher effectiveness via testing of washed surfaces, and one company mentioned using air plate counts to monitor sanitation effectiveness.

Packaging practices

IFT asked company representatives whether their company has measures in place to ensure that product is always placed in the intended package (correct product – package match) and if checks are in place to ensure that labels accurately reflect formulation. Findings relating to such packaging practices are detailed in Table 21. IFT specifically asked companies about such measures as bar code readers and specific design; upon doing so, IFT found that more of the companies have other measures in place to ensure product – package match. Manual checks (up to 3 different check points, typically checked by different employees and including sign-offs) were the most commonly mentioned “other” methods to ensure product – package match. Some indicated that they employ bar code scanners as well as manual checks.

Additional measures that some companies mentioned using include verification check with cross-reference to computer database, quality control sign-off, allergen training for packaging suppliers, label control as part of HACCP, cans scanned for dough match with sampling, product number matches, color-coding, optical cameras, procedures for operators to ensure colored tick marks line up with machines, audit finished product, next day

panel tests, and line cleared/purged before beginning new products. Also mentioned: discarding of old packaging or labeling before new items brought in, scheduling, proofread labels, CCP for bulk packages, specific code numbers, run rules for label suppliers, vertical cut so all labels must be same, nutrition group review of labels for accuracy, regulatory checks and balances, and no mixed product lots. Note, as with all of the information provided that IFT has deemed “other”, this was volunteered information that may be used by many of the companies interviewed.

All of the small and medium companies and all of the large companies answering the question (6 company representatives were unsure) have measures to ensure labels accurately reflect formulation.

IFT went on to inquire how many manufacturers label interior containers (for example, small pouches and/or packages inside containers of final product) to indicate allergen content (when applicable). Typically such packages are not meant for individual retail sale. Only a few of the small, medium, and large companies (23%, 29%, and 31%, respectively) label interior containers. Of those that do not, most indicated that they either (1) rely on the exterior package for labeling or (2) are limited by size of the interior individual packages. Three of the small companies, 6 of the medium companies, and 27 of the large companies label interior containers. This question did not apply to all companies (see Table 21) because many indicated they do not produce multi-packaged products. Others may package individual portions in a larger bag or box; however, due to the very small size of those portions, they find it impractical to add additional labeling.

Employee training practices

Information pertaining to allergen-related training programs and the frequency of the training are shown, by size and food product category, in Table 22. Generally, more companies train production and sanitation personnel and new hires than train purchasing, receiving, research and development, marketing and sales, maintenance, and other employees. Frequency of training among

Table 21—Percent and number of companies, by size and food product category, and their allergen-related packaging practices

	Ensure correct product–package match			Measures in place to ensure labels reflect formulation	Label interior containers	
	Measures in place	Method used				
		Bar code readers	Specific design ^a			Other (including manual)
Company Size		Percent (number)				
Category 1 (n = 13) (small, < 100 employees)	100 (13)	31 (4)	15 (2)	85 (11)	100 (13)	23 (3)
Category 2 (n = 21) (medium, 100 to 500 employees)	100 (21)	5 (1)	19 (4)	100 (21)	100 (21)	29 (6)
Category 3 (n = 86) (large, > 500 employees)	99 (85), 1 NA	56 (48)	47 (40)	78 (67)	93 (80), 6 NA	31 (27)
Food Product Category		Percent (number)				
Baby food (n = 2)	100 (2)	50 (1)	50 (1)	50 (1)	100 (2)	1 NA
Infant formula (n = 3)	100 (3)	100 (3)	67 (2)	67 (2)	100 (3)	33 (1), 2 NA
Bakery products (n = 25)	100 (25)	32 (8)	20 (5)	72 (18)	88 (22)	24 (6), 4 NA
Beverages ^b (n = 8)	88 (7)	25 (2)	38 (3)	75 (6)	75 (6)	25 (2), 3 NA
Candy/confections (n = 10)	100 (10)	30 (3)	30 (3)	100 (10)	100 (10)	40 (4), 2 NA
Cereal/pasta (n = 11)	100 (11)	55 (6)	18 (2), 1 NA	64 (7)	100 (11)	27 (3), 2 NA
Dairy products/substitutes ^c (n = 15)	100 (15)	33 (5)	47 (7)	80 (12)	87 (13)	27 (4), 5 NA
Desserts (n = 8)	100 (8)	50 (4)	50 (4)	100 (8)	100 (8)	25 (2), 2 NA
Fish/fish products (n = 7)	100 (7)	14 (1)	1 NA	100 (7)	100 (7)	29 (2), 2 NA
Miscellaneous (n = 7)	100 (7)	43 (3)	57 (4)	100 (7)	100 (7)	14 (1), 1 NA
Mixed dishes (n = 6)	100 (6)	67 (4)	67 (4)	100 (6)	100 (6)	50 (3)
Sauces/dips/gravies/condiments ^d (n = 6)	100 (6)	67 (4)	67 (4)	83 (5)	100 (6)	33 (2), 2 NA
Snack foods (n = 7)	100 (7)	86 (6)	57 (4)	71 (5)	100 (7)	71 (5)
Soups (n = 5)	100 (5)	60 (3)	60 (3)	80 (4)	100 (5)	20 (1)

^aSpecific design to allow easy identification of mixed packaging

^bIncludes fruit juices

^cIncludes rice and soy beverages, butter, and margarine

^dIncludes pancake syrup, oils, shortenings

Table 22—Percent and number of companies, by size and food product category, and their allergen-related employee training practices

	Employees involved in training									Frequency of training
	New hires	Purchasing	Receiving	Research and development	Marketing and sales	Production	Sanitation	Maintenance	Other	
Company Size	Percent (number)									
Category 1 (n = 13) (small, < 100 employees)	85 (11)	69 (9)	69 (9)	69 (9)	31 (4)	100 (13)	100 (13)	62 (8)	23 (3)	^d (8), ^e (2), ^g (1)
Category 2 (n = 21) (medium, 100 to 500 employees)	86 (18)	57 (12)	71 (15)	76 (16)	43 (9)	95 (20)	86 (18)	57 (12)	5 (1)	^d (17)
Category 3 (n = 86) (large, > 500 employees)	83 (71)	58 (50)	83 (71)	72 (62)	42 (36)	83 (71)	83 (71)	80 (69)	38 (33)	^d (55), ^e (5), ^f (2)
Food Product Category	Percent (number)									
Baby food (n = 2)	100 (2)	100 (2)	100 (2)	100 (2)	50 (1)	100 (2)	100 (2)	100 (2)	50 (1)	ⁱ (1), ^e (1)
Infant formula (n = 3)	67 (2)	33 (1)	67 (2)	33 (1)	33 (1)	67 (2)	67 (2)	67 (2)	0	^d (1), ^o (1), ¹ NA
Bakery products (n = 25)	76 (19)	60 (15)	76 (19)	72 (18)	44 (11)	80 (20)	80 (20)	68 (17)	20 (5)	^d (15), ^e (1), ^f (1)
Beverages ^a (n = 8)	75 (6)	63 (5)	63 (5)	63 (5), ¹ NA	38 (3), ¹ NA	75 (6)	75 (6)	63 (5)	38 (3)	^d (4)
Candy/confections (n = 10)	100 (10)	60 (6), ¹ NA	80 (8)	30 (3)	100 (10)	90 (9)	90 (9)	40 (4)	0	^d (6), ^f (1), ^j (2), ^k (1)
Cereal/pasta (n = 11)	73 (8)	55 (6)	55 (6)	64 (7)	36 (4)	73 (8)	73 (8)	64 (7)	27 (3)	^d (5), ^e (1), ^k (1), ^l (1)
Dairy products/substitutes ^b (n = 15)	80 (12)	67 (10)	73 (11)	73 (11)	40 (6)	87 (13)	87 (13)	67 (10)	27 (4)	^d (7), ^e (1), ^g (1), ^j (1)
Desserts (n = 8)	88 (7)	100 (8)	100 (8)	100 (8)	75 (6)	100 (8)	100 (8)	100 (8)	50 (4)	^d (5), ^j (1), ^k (1), ^m (1)
Fish/fish products (n = 7)	86 (6)	14 (1)	86 (6)	86 (6)	14 (1)	86 (6)	71 (5)	29 (2)	14 (1)	^d (7)
Miscellaneous (n = 7)	100 (7)	57 (4)	86 (6)	57 (4)	14 (1)	100 (7)	100 (7)	100 (7)	29 (2)	^d (2), ^e (2), ^j (1), ^l (1)
Mixed dishes (n = 6)	100 (6)	67 (4)	100 (6)	83 (5)	50 (3)	100 (6)	100 (6)	100 (6)	50 (3)	^d (4), ^j (1)
Sauces/dips/gravies/condiments ^c (n = 6)	83 (5)	33 (2)	83 (5)	50 (3)	50 (3)	100 (6)	100 (6)	83 (5)	33 (2)	^d (2), ^j (2), ⁿ (1)
Snack foods (n = 7)	86 (6)	57 (4)	86 (6)	86 (6)	57 (4)	86 (6)	86 (6)	71 (5)	57 (4)	^d (2), ^l (1), ^j (1)
Soups (n = 5)	80 (4)	60 (3)	80 (4)	60 (3)	40 (2)	80 (4)	80 (4)	80 (4)	20 (1)	^d (2), ^e (1), ^j (1)

^aIncludes fruit juices^bIncludes rice and soy beverages, butter, and margarine^cIncludes pancake syrup, oils, shortenings^dTraining is conducted annually.^eTraining is conducted quarterly.^fTraining conducted two times per year^gTraining is conducted at monthly meetings.^hTraining frequency depends on plant policy.ⁱTraining is annual for most employees and periodic for others.^jTraining is provided annually and as needed.^kTraining frequency varies depending on job function/type.^lTraining frequency is annual at a minimum.^mTraining frequency is annual and a retraining certificate for HACCP programⁿTraining frequency is annual, as part of food safety training.^oTraining is conducted periodically.

the various sizes of companies and manufacturers of various food product categories ranges from monthly to annually.

Discussion

This report provides an assessment of allergen control practices within the targeted food industry (those companies that manufacture products in the 14 categories established by the Scientific & Technical Panel). The information upon which this report is based was collected within a short timeframe (6 months to complete) from verbal inquiries (information was self-reported) of companies representing 14 food categories using a structured assessment approach. Participation in the project was voluntary, meaning that responding companies were willing to provide information to IFT. As directed by the Statement of Work, this project collected information from FDA-regulated finished product food manufacturers (with the focus on primary rather than contract manufacturers).

Responses were received from a disproportionate number of larger companies; only 12% of companies were categorized as small whereas 64% of companies were classified as large (Table 1). It could be argued that larger companies have greater awareness of allergen issues and more resources to develop and implement allergen control practices and that the small companies included in this project are more likely (than those not included) to have implemented appropriate allergen control measures. It could further be argued that companies would be most willing to be included if they perceived themselves to have reasonably good allergen control measures in place. Recruiting of small companies (< 100 employees) was difficult, with only 7 (of more than 75) companies contacted agreeing to participate in the project. Fur-

thermore, the low response rate from small companies may have been due to a lack of manpower resources and/or lack of familiarity with the IFT organization as compared to larger firms. The disproportionate number of large companies may have more impact in some categories than others because the distribution of small companies is much greater in certain categories, for example, bakeries compared with baby food manufacturers. In some categories, small companies may not exist (baby food, infant formula manufacturers) or are less prevalent (soups) in the U.S. food marketplace with only a handful of companies dominating. That said, IFT did achieve national representation of the food industry that is likely reflective of supermarket shelves (that being dominated by large companies). Also, broader company size distribution was achieved in 4 key categories: baked goods, cereal/pasta, dairy products and substitutes, and desserts (Table 3).

Allergen awareness in the food industry has increased in recent years. However, this project represents one of the first systematic attempts to define the level of awareness and the implementation of allergen control practices. Two to 25 companies in each of 14 product categories were interviewed (Table 2). A diversity of food product categories were included, and a wide range of finished food companies were represented within each category, providing a good range of the targeted segments of the U.S. food industry leading to a reasonable assessment of allergen awareness and allergen control practices. Each of the 8 major food allergens was represented in various product categories and for various companies (Table 4).

Milk, soy, wheat, and eggs were the most commonly used allergens by the companies involved in this project, with tree nuts and peanuts used by 63% and 55% of the companies, respectively (Table 4). The frequency of use of the 8 major allergens varied by

product category (Table 5), hence the allergen risk assessment and the nature of the ACP may likewise vary. The appearance of an allergenic food in a particular category may not always reflect the same degree of risk, for example, soy flour compared with soy lecithin or fish compared with fish gelatin. Soy flour is known to contain allergenic protein and also tends to be used at much higher levels in product formulations, whereas soy lecithin used in foods would contain far lower levels of protein and thereby may not pose a risk in many applications. Fish gelatin and fish both contain appreciable levels of fish protein but the allergen level of fish gelatin (derived from fish skins) is lower than the allergen level in fish muscle tissue. Furthermore, fish gelatin is used at much lower levels than fish in most product formulations. These realities could influence the level of allergen risk for specific products, and thereby the potential for cross-contact and necessity of allergen control measures.

The vast majority (115 of 120) of food product types included in this report were produced by companies with some form of Allergen Control Program (ACP) in place (Table 6). While no previous industry assessments have been conducted that would allow comparisons, the Panel feels that the high percentage of companies with ACPs likely represents a substantial increase over the past 10 to 15 y. The Panel believes that this high percentage also reflects a very high level of allergen awareness in the targeted food industry. Of the 5 companies that did not report the existence of an ACP, the nature of the products/ingredients of 4 of them did not dictate the need for an ACP (because they either do not contain an allergen or have the same allergen in all products manufactured at that site) and the 5th company indicated that they are in the process of designing/implementing an ACP.

The Panel feels that the implementation of ACPs into prerequisite programs and consideration in HACCP is an emerging trend that has been widely adopted in recent years. This held true for many of the food companies IFT interviewed (Table 6). Most food companies indicated that allergen control is included as part of their prerequisite programs and many integrate allergen control into HACCP. The data in Table 6 show that some companies have elements of allergen control as control points (CP) or critical control points (CCP) within HACCP. Half of the manufacturers integrating their ACPs into HACCP do so via CCPs as opposed to CPs. Many of the companies indicated that their CCPs mostly relate to product-package matching. A few large companies indicated that they integrate their ACP into HACCP when dealing with only one allergen, but rely on their prerequisite programs when manufacturing products containing multiple allergens. Others indicated that the method of integration varies, dependent on the facility (for example, its infrastructure, capabilities, products manufactured, and so on).

The Panel asserts that the overall effectiveness of these ACPs, whether part of HACCP or not, is variable and impossible to assess based upon this interview process alone. For all sizes of companies, the areas of production, labeling, packaging, and cleanup were a focus of the ACP (Table 7). However, small- and medium-sized companies tended to focus less attention on other areas including rework, purchasing, receiving, and storage. By contrast, larger companies tended to be more comprehensive and involve all areas within their ACPs (Table 7). Some variation was also noted between different product categories, but that may reflect upon the assessment of the comparative level of allergen risk.

Companies were asked how they knew that their ACPs were effective (validated). This question appeared to generate confusion among some respondents. Although most of the companies verified the effectiveness of portions of their ACPs (Table 19), it was apparent that the overall assessment of their ACP effectiveness was difficult to accomplish. While the data from this question are reported in Table 8, the Panel believes that the interpretation of these data requires some care. Well-recognized criteria to validate

overall ACPs and some of the components of ACPs have not been developed. For example, the Panel suggests that the validation of the overall ACP should ideally be tied to health impacts on food-allergic consumers (consumer complaints should be trending down). If threshold doses for specific allergenic foods were established and accepted by FDA, then analysis for the presence or absence of residues of these allergens in packaged food products could be directly linked to the comparative effectiveness of ACPs and their component segments. The metrics of success for various components of ACPs are variable and easier to assess in some cases (equipment cleanup, employee training) than in others (line separation, segregation in storage facilities).

Most companies indicated that they require their suppliers to have ACPs (Table 9). The majority ensures that the program is in compliance either by conducting checks (audits) or outsourcing such checks (3rd party audits). There is wide variability in the nature of the checks (audits) that are performed.

The majority of companies indicated the use of allergen control measures on ingredients and their handling (Table 10). Again, such control measures varied widely, with heavy dependence on the success of the supplier/manufacturer relationship. Information on the presence of allergens in ingredients is sought by the majority of food companies. Allergen questionnaires sent to suppliers are frequently used to obtain this information. Auditing of suppliers is also done with relatively high frequency to assure compliance. Several product categories (for example, cereal/pasta) ranked lower in this regard than many of the other categories, but this may be because certain raw materials are agricultural commodities obtained in very large amounts via bulk transport (for example, rail cars filled with wheat or corn). Ingredient statements may not always be required on such bulk ingredients.

Very few food companies have practices aimed at prevention of cross-contact during transit of ingredients (Table 10). However, this may not be particularly critical because most ingredients arrive in closed containers that are unlikely to allow much opportunity for cross-contact. Some companies do attempt to flag the presence of allergenic ingredients so that they can be quickly identified upon receipt although that practice is more common among large companies than among small- and medium-sized companies. In some cases this imbalance may be related to the greater number of products produced by large companies, thereby requiring handling of more ingredients.

Dedicated storage facilities were used by only about 16% of all responding companies, and qualitative information from the interviews indicates that this may in part reflect bulk storage of items such as raw milk and flour. However, segregated storage within facilities was a frequently used practice (Table 10). Most companies indicated that (post-receipt inspection) ingredients are moved to designated areas that are separated by distance and that allergens are not stored above other ingredients (so as to further minimize potential for cross-contact). The exception was for fish and fish products manufacturers where the nature of the raw material and its acquisition may not foster such practices.

With respect to ACPs, targeted food companies have clearly put considerable effort into the identification of the sources of common allergens (Table 11). The vast majority of food companies have identified the main sources of allergens, namely intentional ingredients and carryover from use of shared equipment. A greater percentage of larger companies have delved further into the allergen composition of processing aids. Rework is more commonly identified as a potential source of allergens by larger companies; this may be because fewer small- and medium-sized companies use rework and/or that they are producing fewer products at once, eliminating the need for labeling of rework (Table 17). CIP fluid was also identified as a source of allergens by 51% of large companies but a smaller percentage of small- and medium-sized companies (Table 18).

Food companies have also identified the points in the manufacturing process where allergen cross-contact is most likely to occur (Table 12). This table was generated from a free-form discussion; information was shared, not solicited. Therefore, it should not be considered comprehensive. Scheduling, sanitation, segregation/dedication, and equipment design are very frequently used control measures. The type of cleaning (Table 18) is quite variable depending upon the nature of the product. The Panel believes that harmonization (for example, intentional inclusion of a specific allergenic food in all formulations made on shared equipment) is a newer trend identified by a minority of the interviewed food companies. The use of harmonization could eliminate the need to consider advisory labeling but also would further restrict product choices for allergic consumers.

A majority of companies make some effort (for example, use of co-packers, reformulation to eliminate/avoid use of allergen ingredients, or rejection of new products that introduce a previously not present allergen) to exclude certain allergens from their facilities. However, the dedication of facilities to specific allergenic or non-allergenic foods is an uncommon practice (Table 13). Dedication appears more common among larger companies with multiple facilities and processing lines producing similar products. Thus, the limited sampling of smaller companies in this interview process may skew the data to make dedication seem more common than it actually is. Eight of the 11 dedicated facilities identified were dedicated to either non-soy-containing products or peanut-only products (Table 13), but this dedication could be happenstance in some cases. The Panel notes that due to the wide distribution of processed foods, dedication of facilities in particular is an economically unfeasible option that limits its practical implementation.

Use of dedicated processing lines is a more common practice, but again more so among large companies. Table 13 indicates that 2 of 13 small companies, 4 of 21 medium-sized companies and 51 of 86 large-sized companies have a least 1 dedicated line. One must consider this carefully so as to not overstate this result. The overall prevalence of the use of dedicated lines was rather small; this result simply indicates that each of these companies has one or more dedicated lines, which likely accounts for a very small percentage of their overall production. Segregation of dedicated processing lines can be achieved in various ways including walls, curtains, air handling, and distances (Table 13). The Panel believes that air handling is a less effective element of ACPs than walls, curtains, and distances. That is because likely levels of allergen cross-contact arising from dust would be inconsequential with the possible exception of unclean idle processing lines (which should be cleaned before startup).

From Table 10 and 11, it is clear that food companies have focused appropriately on the major risks associated with allergenic foods (allergen sources and allergen cross-contact from shared equipment). However, Table 14 indicates that fewer companies have focused on secondary sources of cross-contact. Secondary product contact items (bins, totes, pans, utensils, sanitation tools, sampling devices, and maintenance tools) and employee cross-contact (employees and their traffic patterns, uniforms, gloves) tended to receive less attention in ACPs. While this may give the appearance that some ACPs are not as comprehensive as others, the importance of these factors varies considerably depending on the risk analysis in the individual manufacturing facility. The observation was made that such practices are particularly common in the candy/confections segment, where wet cleaning approaches are not possible (due to the low moisture content necessary to make chocolate) nor advisable (due to microbiological food safety concerns) in chocolate confection facilities. Verification of the effectiveness of some of the practices, for example, dedication of maintenance tools, would be difficult to evaluate in the Panel's opinion. The Panel notes that allergen control practices are still

evolving in this area and that color-coding and other approaches have been more widely implemented in recent years. The Panel further believes that some of these secondary areas such as uniforms, smocks, and gloves are likely less important than other factors such as dedicated totes and bins.

Scheduling is a frequently employed and pivotal strategy in the vast majority of ACPs. Virtually all of the interviewed, targeted food companies employ scheduling as a key element of their ACP (Table 15). The Panel feels that proper scheduling is a good practice to minimize allergen cross-contact. The majority of medium-sized and large companies use a scheduling matrix approach. The most frequently used scheduling strategies involve (1) the scheduling of allergen-containing formulations at the end of manufacturing runs or shifts which typically would allow for full sanitation afterwards and (2) the use of long manufacturing runs for individual formulations which minimizes changeovers and allergen cleanup. Fewer companies use the strategy of addition of allergens to the product formulation as late in the process as possible, which has the advantage of minimizing the equipment surface area that is potentially in contact with the allergen. This is likely because this strategy is simply not feasible in the manufacturing of many products. For example, in some cases, the processing system is enclosed and prohibits the late addition of certain ingredients.

The vast majority of interviewed food companies use co-packers (also known as co-manufacturers, custom processors, or toll manufacturers). All but one of the companies using co-packers requires the co-packer to have an ACP (Table 16). Most co-packers are expected to have ACPs because they are considered an extension of the targeted manufacturer's operations. Sanitation program adequacy, packaging operation reliability, processing reliability, formulation reliability, and proper raw material receiving/storage are particular areas for the co-packers that are regularly evaluated by these companies. Purchasing function reliability, supplier reliability, and accuracy and consistency of labeling practices are less frequently assessed by these companies (typically because the packaged goods company provides these functions) but are still evaluated by a majority of the companies IFT met with.

The majority of companies interviewed use rework (Table 17). Rework is more commonly used by the large- and medium-sized companies than by the small companies included in this project. All targeted food companies using rework employ a "like-into-like" strategy (to prevent the presence of undeclared allergens in products arising from rework), with some implementing an even more stringent "exact-into-exact" policy. Rework is a particularly important area to control because the Panel believes that the inappropriate use of rework can lead to the presence of comparatively high levels of undeclared allergens. Rework has been implicated as a cause of allergic reactions in several episodes (Kemp and Lockey 1996; Taylor and Hefle 2000). Some of the companies did not report labeling of rework or segregated storage of rework but this was often because these companies had adopted the practice of using the rework during the same shift in which it was generated, thereby eliminating the need for such labeling or storage. It was observed that rework containers were usually cleaned using wet sanitation, which the Panel considers an appropriate approach. Alternatively, several manufacturers indicated that rework containers were not reused or were protected using disposable liners.

Most of the targeted food companies have SSOPs to delineate their cleaning practices in their ACPs (Table 18). The most common practice in allergen cleaning is the use of water and detergents/chemicals, although such practices are not needed or possible in all industry segments or on all of the equipment in other segments. Even though the data in Table 18 appear to demonstrate that wet cleaning and CIPs are used by a large percentage of the targeted companies, it is important to recognize that such practices may involve only portions of the equipment areas within

some segments. Some segments of the food industry (for example, chocolate, confections, baking, and cereal/pasta) do not use wet sanitation approaches in certain areas because of other safety/quality considerations. Equipment disassembly is very frequently used to aid in the cleaning process and the Panel believes that this can represent a particular challenge to the affected companies in terms of time, cost, and potential difficulties. In some cases, the equipment is not intended to be disassembled (for example, piping where it cannot be subjected to CIP). Therefore, push-through (also described as purging or flushing, dependent on the nature of the product being manufactured) is often used in such circumstances to minimize allergen cross-contact. The majority of the interviewed food companies indicated that they have validated the effectiveness of their allergen cleaning approaches (Table 18).

The most common approach to the verification of cleaning effectiveness is visual inspection, which was used by virtually all companies interviewed (Table 19). A substantial number of the large companies supplement using other means (ELISA, protein detection, bioluminescence/ATP, and lateral flow devices) to evaluate cleaning effectiveness. The Panel notes that “visually clean” is a good approach for verification when cleaning practices have been validated. In some product categories and cases, specific allergen assays (ELISAs) are not available (finfish, crustacean shellfish, some tree nuts), so visual inspection may be the main option. All of the tests discussed in the interview are not of equal value in the assessment of allergen cleaning. The validity/ specificity of certain of these test methods (protein detection, bioluminescence/ATP) for the detection of allergen residues is, at best, unproven. These tests do have value as measures of overall sanitation effectiveness and can be used as preliminary screening to be followed up by ELISAs or lateral flow devices, which represent the most specific methods for detection of allergen residuals. One company offered a novel approach that may have potential merit for wider application, for example, fiber optic devices to evaluate the cleaning of piping.

Analytical testing procedures are performed by a majority of the interviewed food companies, with most of those doing so on a periodic basis (Table 20). They appear to be used to validate the effectiveness of various components of the ACP, mostly for various aspects of equipment changeover practices, rather than for finished product testing (which for discrete or particulate contamination is similar to finding a ‘needle in a haystack’). The use of analytical testing approaches to assess the presence of allergens in ingredients is done by fewer than 50% of the interviewed compa-

nies but this may be because they are confident about the use of other approaches on ingredients (audits of suppliers, allergen questionnaires, and so on).

Nearly all companies indicated that efforts are made to assure that products are matched with the proper packages (Table 21). The exception was a single-ingredient product that contained no allergens. The Panel would note that such practices are particularly important because mismatched product and packaging can represent a considerable hazard to allergic consumers; mismatched product is a frequent cause of allergen recalls (Vierk and others 2002). Where companies include allergen control as a CCP in their HACCP programs, product-package matches and labeling are frequently identified as a CCP. Various approaches are used for product-package matching. Manual inspection was used most frequently, particularly for small- and medium-sized companies. Bar code readers were used by a majority of large companies but were much less commonly used by small- and medium-sized companies, which may represent a cost factor. All companies indicated that they assure that the formula matches the label (excluding those for which such matching was not necessary due to production of a single ingredient product or a single product) (Table 21). The labeling of interior containers to indicate the presence of allergens is not so widely practiced (Table 21) but this likely represents the fact that interior containers are not included in many food products or that they are not the primary selling unit, that is, “Not intended for retail sale.”

The majority of interviewed food companies do training of employees related to allergens on an annual basis (Table 22). Training was most widespread for production, sanitation, and newly hired employees and was noted by many companies to be a critical aspect of a successful ACP. The training of other categories of employees was more variable.

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Appendix 1—Food products manufactured by companies, by size and food product category

Food product category	Company Size		
	Small (< 100 employees) (n = 13)	Medium (100 to 500 employees) (n = 21)	Large (> 500 employees) (n = 86)
Baby food (n = 2)			Baby food (food intended for children < 2 y): stews, pureed foods, bakery products, juices
Infant formula (n = 3)			Infant formula and medicinal nutrition products
Bakery products (n = 25)	Cookies, dry mixes, bakery products, whole grain-based products	Crackers, cookies	Jelly fruit-filled toaster pastries, other pastries, cookies, baked goods, bread products (for example, rolls, buns, breads, muffins, biscuits, and so on), frozen and refrigerated dough products (for example, cookie dough, pizza dough, pie crusts, bread, rolls, buns, and so on)
Beverages (n = 8)		Single strength juices (that is, orange juice), fortified drinks, lemonade, iced tea, other beverages	Beverages, beverage bases, syrups, and flavors, juices (that is, orange juice), water, and so on
Candy/confections (n = 10)		Chocolate and non-chocolate candy, fundraising chocolates, confections	Chocolate and non-chocolate candy, confections, gums, mints, other candy, chocolate drops, chunks, liqueurs, coatings, confectionary coatings, ice cream coatings
Cereal/pasta (n = 11)	Pasta, flour, whole grain-based products, oatmeal, cereal	Pasta, egg noodles, macaroni	Cereals, ready-to-eat cereal, food service cereal, instant oatmeal, milled products
Dairy products and substitutes (n = 15)	Cheese substitutes, “dairy case” products, instant cocoa	Milk, flavored milk, cottage cheese, cultured milk products, cream, egg nog, soy milk drinks, yogurt, soy yogurt, smoothie	Milk, soy milk, yogurt, soy beverages, rice beverages, cottage cheese, cream cheese, natural and processed cheeses sour cream, butter, margarine
Desserts (n = 8)	Desserts and pastries	Frozen yogurt	Frozen desserts, ice cream, frozen yogurt, popsicles, dessert toppings including whipped topping
Fish/fish products (n = 7)		Shellfish, shrimp, oysters, crab meat, crab cakes, cakes, fillets (including smoked, grilled, breaded, battered, stuffed, and so on), steaks, soups, sauces/seasonings, pasta, entrees, dips, appetizers	Fillets (including battered, breaded, stuffed, and so on), roe, scallops, shrimp, other shellfish, entrees
Miscellaneous (n = 7)		Spices, flavor blends, dry blends, spice blends	Peanut butter, meat analogs (typically made with soy)
Mixed Dishes (n = 6)			Frozen dishes and foods, pre-made sandwiches, entrees (some meat containing), side dishes (often rice-containing or pasta-containing)
Sauces/dips/gravies/condiments (n = 6)	Condiments, mayonnaise, dressings, sprays, oils, shortening		Pancake syrup, other syrups, condiments, jam, jellies, sauces, pasta sauce, marinades
Snack foods (n = 7)		Snack bars	Snacks, snack mix, snack bars, corn chips, other chips, nuts and mixed nuts, popcorn
Soups (n = 5)			Canned soups, dry soup mixes

Appendix 2—Acronym Dictionary

Acronym	Explanation	Acronym	Explanation
ATP	Adenosine Triphosphate	FARRP	Food Allergen Research & Resource Program (Univ. of Nebraska)
ACPs	Allergen Control Programs	FDA	Food and Drug Administration
COA	Certificate of Analysis	FPA	Food Products Association
CIP	Clean In Place	GMPs	Good Manufacturing Practices
COP	Clean Out Of Place	HACCP	Hazard Analysis Critical Control Point
CP	Control Point	IFT	Institute of Food Technologists
CCP	Critical Control Point	NA	Not Applicable
ELISA	Enzyme-Linked Immunosorbent Assay	SSOPs	Sanitation Standard Operating Procedures
FALCPA	Food Allergen Labeling & Consumer Protection Act		