Food Allergen Labeling and Consumer Protection Act of 2004
Public Law 108-282

Report to

The Committee on Health, Education, Labor, and Pensions
United States Senate

And

The Committee on Energy and Commerce
United States House of Representatives

Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
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Executive Summary

This report was prepared by the Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA), in response to the directive to the Secretary of Health and Human Services in section 204 of the Food Allergen Labeling and Consumer Protection Act of 2004. The report addresses multiple issues relating to cross-contact with food allergens during food manufacture and distribution and the use of, and consumer preferences about, advisory labeling.

The Occurrence of Cross-Contact and Use of CGMP

Foods may become unintentionally contaminated with major food allergens at almost any step of manufacturing prior to final packaging due to a number of factors. Dedicated facilities or production lines may help to control the occurrence of cross-contact but the use of such arrangements is limited due to cost, equipment utilization needs, and space limitations. It is difficult to estimate the prevalence of cross-contact. The available information indicates, however, that most food manufacturers and processors are aware of the potential for cross-contact in their operations, which is one indication of the perceived likelihood of such contamination.

The use of current good manufacturing practice (CGMP) is critical to the reduction and elimination of cross-contact, which would likely be implemented through a firm's allergen control plan. An effective allergen control plan is generally tailored to the particular facility and uses a combination of control procedures to eliminate or reduce the risk of cross-contact.

Use of Advisory Labeling by Food Producers

The available information indicates that food manufacturers use five basic advisory statements, with numerous variations of the five statements that communicate comparable information: "Produced in a plant that processes...[allergen(s)];" "May contain traces of...[allergen(s)];" "May contain...[allergen(s)];" "Produced on shared equipment that processes...[allergen(s)];" and "[Allergen(s)] traces." These statements vary by format as well as content. Less than one-fifth of the surveyed facilities use advisory labeling. Peanut and tree nuts are the allergens most often associated with facilities that use advisory labeling. The available information also suggests that a high proportion of facilities have cross-contact control measures in place regardless of whether the firm uses advisory labeling.

Consumer Preferences for Food Allergen Labeling

FDA contracted for a survey of food allergic consumers and their caregivers, with a control group, to evaluate consumer preferences for advisory labeling. Four advisory statements were tested: "Allergy Information: May Contain Peanuts;" "May contain peanuts;" "Manufactured on the same equipment as foods that contain peanut;" and "Produced in a facility with an allergy control plan. The possibility of contact with allergenic ingredients has been minimized. May still contain trace amounts of peanut." Surveyed consumers preferred "Allergy Information: May contain peanuts" over the other three statements. The results are consistent with prior product label research showing that consumers prefer information preceded by signal words and generally view this information as more credible.

FDA also contracted for an experiment to compare the effects of the four label statements identified above on consumers' food purchase or consumption intent decisions. The results indicate that consumers found the two shorter advisory statements to be less helpful and less believable, and thought that products bearing these statements were more likely to contain peanuts. In contrast, consumers found the two longer statements to be more believable and more helpful, and thought that products bearing one of the longer statements were less likely to contain peanuts.

FDA's Allergen-focused Inspections

During FY2002 to FY2004, FDA conducted over 2,000 allergen-focused inspections. These inspections assessed the following practices at inspected facilities: receipt of allergenic ingredients; review of product labels; equipment characteristics, equipment cleaning practices, and equipment cleaning efficacy checks; handling of rework; and inspection of finished product labels. Although FDA's inspections did not specifically determine whether facilities were "in compliance" or "out of compliance," the results, discussed in detail in the body of the report, provide valuable information about the food industry's awareness of food allergens in the manufacturing environment and facilities' practices designed to manage the risks posed by allergens.

Allergen Recalls

FDA reviewed and analyzed five years of agency information on voluntary recalls involving undeclared food allergens. During FY1999 to FY 2004, there were 462 recall actions due to the presence of undeclared allergens in a food. In terms of food product categories, bakery products, ice cream products, and fishery products represented the three largest groups of recalls. In terms of particular undeclared allergens, egg, milk, peanut, and tree nut ingredients were the four allergens most frequently associated with recall actions.

Current Efforts to Control Cross-contact

As explained in the body of the report, the results of FDA's allergen-focused inspections should not be generalized to all food production facilities. However, the findings suggest that a certain percentage of facilities do attempt to address potential concerns associated with the use of allergens in food products; the extent to which a firm does so varies and depends on the control measure or activity assessed. But FDA's inspections also suggest that a certain percentage of facilities do not apply control measures in the handling and use of allergens; the degree to which these gaps may contribute to the unintended presence of allergens in food, and the degree to which those allergens are associated with adverse health effects, is not known. These gaps do suggest areas for improvement in food manufacturing to protect against allergen cross-contact, including increasing awareness among all firms of the potential for allergen cross-contact in food manufacturing.

I. Introduction

Section 204 of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282) requires the Secretary of Health and Human Services (the Secretary) to submit to the Senate Committee on Health, Education, Labor, and Pensions and to the House Committee on Energy and Commerce a report on food allergens. The report is to address multiple issues relating to cross-contact with food allergens[1] during food manufacture and distribution and to address the use of, and consumer preferences about, advisory labeling.[2]

This report was prepared in response to the FALCPA mandate for the Secretary by the Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA). In drafting this report, CFSAN relied on the following sources of information:

- Information gathered during allergen-focused domestic inspections conducted by FDA in FY2002. This information concerns 1,470 facilities[3] for which the inspection information was largely complete. CFSAN subsequently performed a comprehensive analysis of these data, "Results of Targeted Allergen Inspections of Food Manufacturing Firms."[4]
- Information gathered by additional FDA inspections conducted in FY2003 and FY2004. This information concerns 372 facilities and was also analyzed by FDA, although not as comprehensively as the FY2002 inspection data.
- The response to a task order issued to the Institute of Food Technologists (IFT) under an existing contract with CFSAN. The task order was tailored to elicit information from the food industry specifically for this report. The IFT report, entitled "Analysis and Evaluation of the Current Manufacturing and Labeling Practices Used by Food Manufacturers to Address Allergen Concerns," was submitted to FDA in August 2005, and was based on information assembled by IFT earlier that year.[5]

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[1] Cross-contact occurs when a residue or other trace amount of a food allergen is present on a food contact surface, production machinery, or is air-borne, and unintentionally becomes incorporated into a product not intended to contain the allergen. Cross-contact may also result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment. FDA considers the term "cross-contact" to be synonymous with "cross-contamination," a term sometimes used to describe these circumstances. This report uses the term "cross-contact" because that is the term that Congress used in FALCPA.

[2] The purpose of advisory labeling is generally to alert food allergic consumers to the possibility of allergen cross-contact. Although these labels vary by content, common formulations include "This product was processed on machinery used to process (allergen)" and "May contain (allergen)."

[3] The questionnaire used by investigators in these inspections and the subsequent FDA analysis of the inspection results use the term "firm" to describe an individual manufacturing location. This is consistent with the customary practice of FDA's field offices. However, this report uses, where appropriate, the term "facility" to describe an individual manufacturing location because the term "firm" might inappropriately suggest a company, such as a corporation, not an individual manufacturing location.

[4] FDA field investigators inspected approximately 1800 domestic facilities that produce foods containing one of the eight most common food allergens (peanuts, soybeans, tree nuts, milk, egg, wheat, fish, and Crustacea) and completed a questionnaire designed to address various aspects of food production at the inspected facilities.

[5] IFT utilized a six member Scientific and Technical Panel to obtain information through interviews of personnel from 59 food manufacturing firms (38 "large" firms (> 500 employees), 14 "medium" firms (100-500 employees), and 7 "small" firms (< 100 employees).) The 59 firms produce food in 14 food product categories (baby food, infant formula, bakery products, beverages, candy/confections, cereal/pasta, dairy products/substitutes, desserts, fish/fish products, mixed dishes, sauces/dips/gravies/condiments, snack foods, soups, and miscellaneous.) In the IFT report and discussions of it, the term "firm" refers to a company as a whole, not a individual manufacturing location.

- The results of an August 2005 consumer survey conducted by Knowledge Networks, Inc., under contract with FDA, to determine consumer preferences regarding advisory labeling. Respondents were 739 food allergic adults or caregivers of food allergic individuals and 504 non-food allergic individuals.
- The results of a September 2005 experiment conducted by Synovate, Inc., under contract with FDA, to determine consumer preferences regarding advisory labeling. Participants were 1,000 food allergic adults or caregivers of food allergic individuals and 1,000 non-food allergic individuals. Participants, randomly assigned to groups, responded to questions about believability, helpfulness, and consumption for one of the tested advisory statements.

II. Section 204(1): The Occurrence of Cross-Contact

Section 204(1) of the FALCPA provides that the report to Congress analyze "the ways in which foods, during manufacturing and processing, are unintentionally contaminated with major food allergens,"[6] including contamination caused by the use of "the same production line to produce both products for which major food allergens are intentional ingredients and products for which major food allergens are not intentional ingredients ... and the ways in which foods produced on dedicated production lines are unintentionally contaminated with major food allergens." Section 204(1) also provides that the report estimate "how common the [identified] practices are in the food industry, with breakdowns by food type as appropriate."

Foods may become unintentionally contaminated with major food allergens at almost any step of manufacturing prior to final packaging. Unintentional allergen contamination can occur during manufacturing as a result of allergens in raw ingredients or in processing aids, from the use of reworked product that contains allergens, as a result of allergen carry-over from the use of shared equipment, and from clean-in-place fluid used to clean shared equipment. Nearly all companies surveyed by IFT identified potential sources of unintentional allergen contamination during their manufacturing and processing operations, regardless of firm size and food product category manufactured. Table 1 shows the specific points identified by surveyed companies as sources of unintentional cross-contact during manufacturing and processing.

Dedicated facilities or dedicated production lines are used by the food industry to exclude specific allergens from food products in which the allergens are not intended as ingredients. However, such use is limited due to cost, equipment utilization needs, and space limitations. Frequently, processing facilities exclude certain allergens from their facilities. The IFT survey shows that large companies are more likely than their medium-size or small-size counterparts to dedicate facilities to avoid cross-contact. Facilities more commonly dedicate specific production lines to avoid cross-contact during production by using physical barriers (such as walls, curtains, or distance) or air handling as a means of isolating the production line.

It is difficult to determine the true prevalence of unintentional contamination with major food allergens for several reasons. Visual observation is not always a reliable means to determine whether allergen cross-contact is actually occurring. Certainly, there are instances where an individual (either a firm employee or an FDA investigator) might observe the potential for cross-contact with an allergen, such as residual peanut butter on a shared production line after

[6] FALCPA defines "major food allergen" as one of eight foods or food groups (peanut, milk, egg, wheat, soy, tree nuts, fish, and Crustacean shellfish) or an ingredient that contains protein derived from one of the eight. "Highly refined oils" and ingredients derived from them are excluded from the definition of "major food allergen." 21 U.S.C. 321(qq).

cleaning, and infer that allergen-free products subsequently processed on that line could become contaminated. However, many instances of cross-contact are not readily observable. For example, an otherwise responsible manufacturer could be producing a food product using a raw ingredient that contains an undeclared allergenic ingredient or processing aid. Without knowledge of the presence of this allergen, the manufacturer could produce food products believed to be free of unintended allergens. Finally, consumer complaints and adverse events are likely to greatly underestimate the true prevalence of unintended allergens in foods, particularly when those allergens are not declared. Ordinarily, for an undeclared allergen to be detected by the consumer, a sensitive consumer must ingest the allergen-contaminated food, experience a noticeable allergic reaction, recognize the food as the cause of the reaction, and report the incident to the manufacturer or to food safety officials. Given that only a small percentage of consumers have a food allergy and that not all allergen-contaminated foods will cause an easily recognizable reaction in sensitive consumers (due to different thresholds for a noticeable effect in different individuals), it is likely that many allergen-contaminated foods go undetected by consumers.

Although it is difficult to estimate the prevalence of the unintentional contamination of foods with major allergens, it is useful to examine, as an indication of the perceived risk of such unintentional contamination, the extent to which food manufacturers and processors recognize the risk of allergen-cross-contact and implement preventive measures. Significantly, nearly all the food manufacturers and processors surveyed by IFT identified potential allergen sources within their operations. These manufacturers and processors identified as a potential allergen source raw materials, processing aids, rework product,[7] carry-over from shared equipment, clean-in-place fluid, and miscellaneous potential sources. Similarly, nearly all these food manufacturers and processors have allergen control programs in place to prevent the unintentional contamination of their products by major allergens. Given the widespread recognition of the risks and the extent to which the industry has implemented control programs, it is likely that there is a significant risk of allergen cross-contact where appropriate preventive measures are absent.

[7] As a verb, "rework" refers to the practice of reintroducing food product material that has been through some or all of the manufacturing process into an earlier stage of the production process of a subsequently produced food product. As a noun or adjective, "rework" refers to the food product material that is reintroduced into the production process.

Table 1. Points in the Manufacturing Process Where Cross-Contact Can Occur (by food category)		
Food Product Category	**Specific Points Identified**	**Examples of Control Practices Used**
Baby Food	kettles, fill heads, drum dryers	scheduling, defined areas, sanitation, push-through, shields, labeling
Infant Formula	holding tanks, lines, fillers, non-CIP equipment (those that must be dry cleaned), other sources of cross-contact (before ingredients reach line)	sanitation, scheduling, segregation, validation, visual Inspection, purging of line, use of clean in place fluid
Bakery Products	mixers, shared equipment, packaging equipment, dividers, conveyors, ingredient scaling, proofer, cooler, slicer, racks, piping, dough troughs, pans, belts, ovens enrobing, freezer, changeovers rounder, extruder, sheeter, baking room, crossed lines, shared storage containers, dough pump, dead spots, scoops, sifters, depositer, sieves	scheduling, sanitation, training, storage segregation, visual inspection, allergen testing, color-coding, push-through, equipment design, tarps under conveyors, labeling, vacuum, line separation, shields, distance, production layout, eliminate crossed lines, allergen profiling, scraping, segregated steam room for cleaning, color-code rework, dedicate areas, dedicate maintenance tools, harmonization [d]
Beverages [a]	filler, shared equipment, storage tanks, blending, pumps, lines, pasteurization, homogenization, liquefiers, batch tanks	sanitation, scheduling, allergen testing, visual inspection, flushing
Candy/Confections	enrober, packaging, panning, shared lines, coating, molding, belts, ovens, temper unit, piping, refining, spraying systems, conveyors, changeovers	scheduling, sanitation, dedicated lines, flushing, wet cleaning where possible, segregation, 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	belts, mixers, particulates, packaging, shared lines, conveyors, scales, 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, scheduling, separation, visual inspection, shielding, vacuum, dedication, eliminate cross-overs, pressure washing, disassembly of equipment for cleaning, flush with cornstarch, equipment design, allergen testing

Dairy Products/Substitutes [b]	shared equipment, fillers, blending, pasteurization, homogenization, storage tanks, shared lines, liquifiers, batch tanks, packaging equipment, ingredient receiving	scheduling, sanitation, allergen testing, inspection, flushing, dedication, shields, separation, supplier contact
Desserts	shared equipment, fillers, pumps, storage tanks, lines, duct work, cooling systems, changeovers, fruit feeders, varigators	sanitation, scheduling, allergen testing, inspection, production layout
Fish/Fish Products	batter/breader equipment, freezer, fryer, packaging, conveyor	scheduling, sanitation, pre-requisites, filter oil, validation test, receipt of original containers at specific line assignments, equipment design, equipment flexibility, inspection
Miscellaneous	shared equipment, piping, utensils, common tanks, crossed lines, reuse of storage containers, changeovers	sanitation, scheduling, equipment design, eliminate 'dead spots,' allergen testing, eliminate crossed lines, segregated storage
Mixed Dishes	shared equipment, filler, mixer, conveyors, dead spots, spice rooms	sanitation, scheduling, equipment design, allergen testing, visual inspection, dedicated lines, segregated storage
Sauces/Dips/Gravies/ Condiments [c]	piping, filler, mixer, scales, utensils, common tanks, spice room, shared lines, reused fry oil, conveyors	sanitation, scheduling, allergen profiling, color-coding, elimination of 'dead spots,' segregated storage, shielding, visual inspection, labeling
Snack Foods	packaging, conveyors, belts, ovens, dryers, enrobers, mixers, shared equipment, crossed lines, reuse of storage containers, changeovers, dead spots, reuse of fry oil	sanitation, visual inspection, equipment design, walls, scheduling, allergen testing, dedication, training, color-coding, segregated storage, eliminate cross-overs, labeling
Soups	spice rooms, dead spots, shared lines	scheduling, sanitation, separation, equipment design, segregated storage

[a] Includes fruit juices
[b] Includes rice and soy beverages, butter, and margarine
[c] Includes pancake syrup, oils, shortenings

III. Section 204(2): Role of Current Good Manufacturing Practice in Controlling Cross-Contact

Section 204(2) of the FALCPA provides that the report to Congress address "whether good manufacturing practices or other methods can be used to reduce or eliminate cross-contact of foods with the major food allergens."

The use of current good manufacturing practice is critical to the reduction and elimination of unintentional contamination of foods with major allergens. There is no known processing technology that could be used to exclude, automatically or continuously, major allergens from all foods at risk of contamination. Nearly all the food manufacturers and processors surveyed by IFT have an allergen control plan. An effective allergen control plan uses a combination of control procedures to eliminate or reduce the risk of unintentional contamination of foods with major allergens. In addition, allergen control plans are generally tailored to each manufacturing or processing facility to address risk factors that are unique to particular ingredients, products, and manufacturing processes.

CGMP to control allergen cross-contact would likely be implemented through a firm's allergen control plan. The value of an allergen control plan is widely recognized by the U.S. food industry. In response to a Federal Register notice of public meetings[8] that requested comments and information on FDA's CGMP regulations for foods, many comments recommended that those regulations (21 CFR Part 110) be amended to require allergen controls. The following comments related to allergen controls were reported by the Foods CGMP Modernization Working Group in its 2005 report, "Foods CGMP Modernization – A Focus on Food Safety"[9]:

> One commenter noted that "The current regulations contain a number of provisions that relate to preventing contamination in the food processing environment, but there is no explicit mention of food allergens." This commenter recommended that the agency amend the CGMP regulation to require food processors to develop and adopt allergen control practices within their facilities, yet keep the regulatory requirement flexible so that manufacturers can adapt control practices to their unique requirements.
>
> One commenter wrote that "The primary elements of an allergen control plan would include: identification of ingredients containing food allergen(s); management of these ingredients (*e.g.*, physical segregation); process controls; verified cleaning processes; label controls and label review; and employee training."
>
> Another commenter wrote that the following preventive controls are needed: "...1) revision of current GMPs to include guidelines regarding rework and shared equipment, 2) guidance on the need for employee training regarding food

[8] 69 FR 29220 (May 21, 2004) and 69 FR 40312 (July 2, 2004).

[9] Foods CGMP Modernization Working Group. 2005. Foods CGMP Modernization - A Focus on Food Safety. http://www.cfsan.fda.gov/~dms/cgmps3.html The Foods CGMP Modernization Working Group was formed by CFSAN in 2002 to examine the food CGMP regulations in 21 CFR Part 110 and to determine whether those regulations need modernization.

allergies, and 3) guidance on the use of precautionary ('may contain') statements." This commenter concluded by writing that "It is imperative that any revisions made to address food allergens must be mandatory (*i.e.*, 'shall') as opposed to optional (*i.e.*, 'should')."

Another commenter recommended that 21 CFR 110.80 "...be revised to include a separate section requiring an allergen control program for those processing plants that handle any of the eight common allergens. The allergen control plan should address the following: Training of processing and supervisory personnel; Separation of allergenic ingredients during storage and processing; Cleaning and Sanitation of processing equipment; Scheduling of production runs to enhance physical separation and time separation; Reworking ingredients and finished products; Product label review; and Supplier control program for ingredients and packaging."

The IFT report states that "It is the opinion of the Scientific & Technical Panel that the opportunities for the presence of undeclared allergens are minimized when current Good Manufacturing Practices (GMPs) are followed. GMPs appear to be effective in reducing or eliminating cross-contact and other allergen-related errors." With respect to the value of GMPs, the IFT report listed the following conclusions drawn by the Scientific & Technical Panel from analysis of the information collected:

- "Most food companies include allergen control as part of their prerequisite program"
- "Most of the food companies have SSOPs (Sanitation Standard Operating Procedures) to delineate their cleaning practices in their ACPs" (allergen control plans)
- "The majority of the targeted food companies have validated the effectiveness of their allergen cleaning approaches"
- "The majority of included food companies train employees on an annual basis on topics related to allergens"

IV. Section 204(3): Use of Advisory Labeling by Food Producers

Section 204(3) of the FALCPA provides that the report to Congress describe "the various types of advisory labeling (such as labeling that uses the words 'may contain') used by food producers; ... the conditions of manufacture of food that are associated with the various types of advisory labeling; and ... the extent to which advisory labels are being used on food products."

A. Types of advisory labeling used by food producers

The information in this section is based on data from the report of FDA's FY2002 allergen-focused inspections, from the analysis of FDA's FY2003/2004 allergen-focused inspections, and from the IFT report.

1. Information from FDA Inspections

During the FY2002 inspections, FDA investigators recorded the advisory statements used on food products by approximately 170 of the 247 facilities that used advisory labeling. The advisory statements identified by the investigators were of five basic types as follows:

- "Produced in a plant that processes...[allergen(s)]"

- "May contain traces of...[allergen(s)]"
- "May contain...[allergen(s)]"
- "Produced on shared equipment that processes...[allergen(s)]"
- "[Allergen(s)] traces"

Both groups of FDA inspections documented numerous variations of these basic advisory statements communicating comparable information. In addition to variations in content, the format of different facilities' statements varied widely.

The FDA inspection information showed that a number of firms used a single type of advisory statement on the labels of one or more of their products. Several firms, however, used a combination of different advisory statements for one or more of their products. The most common combinations of advisory statements used, in descending order, were as follows:

1. May contain...[allergen(s)] / Produced in a plant that processes...[allergen(s)]
2. May contain...[allergen(s)] / May contain traces of...[allergen(s)]
3. May contain...[allergen(s)] / Produced on shared equipment that processes...[allergen(s)]
4. May contain traces of...[allergen(s)] / Produced in a plant that processes...[allergen(s)]
5. May contain traces of...[allergen(s)] / Produced on shared equipment that processes...[allergen(s)]
6. May contain...[allergen(s)]/ May contain traces of..... / Produced on shared equipment that .....
7. Produced on shared equipment that processes...[allergen(s)] / Produced in a plant that.....
8. May contain traces of...[allergen(s)] / Produced on shared equipment that.../ Produced in a plant that...
9. May contain...[allergen(s)]/ Produced on shared equipment that processes.../ Produced in a plant that...

2. Information from the IFT report

The IFT panel surveyed the labeling practices of the 59 food manufacturing companies that participated in the IFT discussions to determine the frequency of use of the following four advisory labeling statements:

- "Contains [allergen]"
- "Manufactured in a facility that processes [allergen]"
- "May contain [allergen]"
- "Processed on equipment that also processes [allergen]"

IFT reported that the majority of surveyed companies used at least one of the foregoing advisory statements. However, in most cases, the advisory statements were used for a minority of a firm's products. In addition, IFT found that firms generally used a "Contains [allergen]" statement to identify only allergens listed in the ingredient statement.

B. Conditions of food manufacture associated with various types of advisory labeling.

1. Firms' Reasons for Use of Advisory Labeling

a) Information from FDA inspections

While conducting the allergen-focused inspections in FY2002, FDA investigators collected information related to the reason(s) facilities use advisory statements about the possible presence of food allergens. Facilities identified the following reasons (summarized by general category) for using advisory labeling:[10]

1. The firm used advisory labeling to advise consumers of the potential allergen(s) exposure or related hazard/safety issues.
2. The firm recognized the potential for cross-contact in its production of finished product.
3. The firm wanted to notify consumers of conditions under which food product is manufactured and the potential for cross-contact.
4. The firm used finished product label(s) that they were told to use or approved by the firm's headquarters or corporate office.
5. The regulatory or legal department of the firm or its corporation recommended or required the advisory statement.
6. The firm used advisory labeling as a self-protective measure (for example, due to liability or other concerns.)
7. The firm transferred an advisory statement from incoming raw material or bulk product to the finished product label.
8. The firm used advisory labeling to keep up with industry trends or practices.
9. The firm used advisory labeling to avoid the expense of multiple labels for related products or boxes of different product assortments.
10. A contract manufacturer used finished product label as directed or advised by the client firm.
11. The firm used advisory labeling to follow the advice of their industry trade association.
12. The firm believed that consumers want allergen information on product labels.
13. Use of labeling with an advisory statement was requested by a private label manufacturer.
14. A consumer requested allergen label information to his/her own specification for a privately-labeled product.

b) Information from the IFT report

The IFT panel asked those companies that use advisory labeling to explain why they use advisory statements on their products. The reasons provided to IFT were similar to several

[10] The order in which these categories are presented is not significant.

reasons identified by FDA's inspections.[11] In addition, several firms surveyed by the IFT panel explained that they used advisory statements because their ingredient suppliers used such statements.

2. Manufacturing Conditions Associated with Advisory Labeling[12]

FDA evaluated data from the FY2002 allergen-focused inspections to determine the manufacturing conditions related to production equipment and those related to processing practices for facilities using advisory labeling and then compared those conditions to the conditions at facilities not using advisory labeling.[13] The factors evaluated by investigators related to equipment used in manufacturing are shown in Table 2 below. Table 3 shows the equipment-related control measures used in manufacturing to prevent allergen cross-contact that the investigators evaluated at the inspected facilities. These control measures include one or more of the following: dedicated equipment, shared equipment with clean up in between a production run of a food containing a food allergen ingredient, or production on shared equipment with allergen formulations scheduled to run last.

Table 2. Equipment-related issues for facilities using advisory labeling compared with those facilities not using advisory labeling.

Equipment issues evaluated during allergen inspection of 1,470 facilities*	**Facilities that used advisory labeling n=247 % (number)**	**Facilities that did not use advisory labeling n=1,207 % (number)**
Firm used equipment-related control measures to prevent allergen cross-contact of products not intended to contain an allergen	87% (214)	79% (959)
Equipment was **not** cleanable and easily accessible in firm	13% (31)	4% (50)
Firm did **not** check the efficacy of cleaning food contact surfaces	14% (35)	17% (208)
After an allergen run and subsequent equipment cleaning, build up of residual material or pockets of residue in equipment corners that could contain an allergen from the previous run.	20% (50)	11% (136)

*Information on whether a firm used advisory labeling was missing for six facilities and considered "not applicable" for ten facilities.

[11] Of the reasons identified by the FDA inspections, numbers 1, 2, 3, 12, 13, and 14 were also identified by the IFT report.

[12] For the information presented in this section, it is important to bear in mind that FDA inspected many sectors of the food industry and the facilities inspected varied in terms of size, production practices, firm environment, equipment, and products. These variations may have had some effect on the use of advisory labeling.

[13] This section includes four tables that are related to one another in the follow way. Table 2 contains questionnaire items (put in declarative form for the reader) from the equipment portion of the inspections, and Table 4 contains questionnaire items (put in declarative form for the reader) from the processing portion of the inspections. In terms of interrelationships, Table 3 is a subset of Table 2, and Table 5 is a subset of Table 4. Specifically, if an investigator responded that a firm used equipment-related control measures to prevent allergen cross-contact of products (Table 2, second row), then s/he further specified which equipment-related control measures were used (Table 3). Similarly, if an investigator observed that a firm was likely to have cross-contact occur in the firm during processing (Table 4, second row), then s/he further specified what type of cross-contact was likely (Table 5).

The results suggest that a high proportion of facilities have control measures in place to prevent cross-contact regardless of whether the firm uses advisory labeling. Two equipment issues (equipment not readily cleanable/not easily accessible and build-up of residual material containing allergen(s) after equipment cleaning) appear to be associated slightly more frequently with facilities using advisory labeling than with facilities not using such labeling. A similar comparison of the two categories of facilities inspected in FY2003/2004 was consistent with the results from the FY2002 inspections.

FDA evaluated the FY2002 inspection data for facilities using equipment-related control measures to prevent allergen cross-contact of products to determine the types of control measures employed. Results are shown in Table 3. A higher proportion of facilities using advisory labeling employed the various cross-contact control measures than did facilities not using advisory labeling. The findings from the FY2003/2004 inspections were comparable except for facilities employing dedicated equipment.[14]

Table 3. Allergen cross-contact equipment-related control measures for facilities using advisory labeling compared with those of facilities not using advisory labeling.

Among facilities that used control measures to prevent allergen cross-contact of products not intended to contain an allergen n=1,183*	**Facilities that used advisory labeling n=214 % (number)**	**Facilities that did not use advisory labeling n=959 % (number)**
Dedicated Equipment	40% (85)	31% (301)
Shared equipment with clean up in between allergen run	81% (174)	75% (721)
Production on shared equipment with production scheduled to run allergen formulation last	43% (93)	32% (309)

* Information on whether a firm used advisory labeling was missing for six facilities and considered "not applicable" for four facilities.

FDA also evaluated cross-contact issues related to processing practices in relation to the use of advisory labeling; the results for the FY2002 inspections are shown in Table 4. The processing practices evaluated by investigators in the FY2002 inspections are shown in Table 4. More than twice the proportion of facilities that used advisory labeling were considered by the investigators to be likely to have cross-contact occur in the firm during processing, compared to facilities that did not use advisory labeling.[15] However, there was little difference between the two groups of facilities with respect to handling exposed product on the processing line to protect against allergen cross-contact. The findings of the FY2003/2004 inspections were

[14] For FY2003/2004, 24 percent of facilities using advisory labeling had dedicated equipment, whereas 34 percent of facilities not using advisory labeling had dedicated equipment. Information was missing or not applicable for 6 facilities with control measures.

[15] In evaluating firms and their practices for the likelihood of cross-contact, the FDA investigators relied on their prior training and experience. Before the allergen-focused inspections were initiated, these investigators also received additional training which was aimed at, among other things, helping these experienced investigators to provide consistent observations and apply consistent judgment specifically about the allergen-related issues addressed in the inspection.

generally consistent with the findings of the FY2002 inspections although the difference between the two groups on likelihood of cross-contact was not as great.

Table 4. Processing issues or practices of facilities using advisory labeling compared with those of facilities not using advisory labeling.

Processing issues or practices evaluated during allergen inspection of 1,470 facilities*	**Facilities that used advisory labeling n=247 % (number)**	**Facilities that did not use advisory labeling n=1,207 % (number)**
Cross-contact likely to occur in firm during processing	46% (113)	21% (252)
The unpackaged, exposed product on the processing line was handled in a way that protects against allergen cross-contact	79% (196)	75% (906)

*Information on whether a firm used advisory labeling was missing for six facilities and considered "not applicable" for ten facilities.

For the facilities considered by the investigators as likely to have cross-contact during processing, the investigators also evaluated whether there were allergen residues on equipment during processing, a build-up of allergen residues above the processing zones, or airborne food particles present during processing. As reflected in Table 5, specific cross-contact problems were nearly the same for facilities that used advisory labeling, compared to facilities that did not use advisory labeling. Similarly, the data from the FY2003/2004 inspections showed no particular pattern on these cross-contact issues.

Table 5. Cross-contact control problems during processing for facilities using advisory labeling compared with those facilities not using advisory labeling.

Among facilities with cross-contact likely to occur during processing n=369*	**Facilities that used advisory labeling n=113 % (number)**	**Facilities that did not use advisory labeling n=252 % (number)**
Residue of allergen product on equipment during processing	86% (97)	84% (211)
Build-up of allergen product above the processing zones	15% (17)	16% (41)
Airborne food particles	28% (32)	35% (88)

* Information on whether a firm used advisory labeling in this subset of data was missing for two facilities and "not applicable" for two facilities.

C. Extent to which advisory labels are being used on food products

FDA's allergen-focused inspections collected information on the prevalence of advisory statements related to food allergens. Of the 1,454 allergen-focused inspections conducted in FY2002 and analyzed by FDA for which use of advisory labeling determinations were made, 17 percent of these facilities used some form of advisory statement on the labels of their finished products relating to the presence of allergens.[16] Similarly, of the 372 allergen-focused inspections conducted in FY2003/2004 and analyzed by FDA, 18 percent of all facilities used an

[16] Advisory labeling was defined in FDA's allergen inspection questionnaire as follows: "Advisory labeling is a statement such as 'this product was processed on machinery that was also used to process products containing (allergen)' or 'may contain (allergen).'"

advisory statement of some type. In each group of inspections, the percentage of facilities that used allergen advisory statements increased with an increase in firm size.[17]

In addition, data from FDA's FY2002 allergen-focused inspections show that facilities manufacturing certain products (such as chocolates) were more likely to use allergen advisory statements in their labels.[18] FDA also evaluated the percentage of facilities that utilized advisory labeling according to the allergens contained in their food products. Peanut and tree nuts[19] were the allergens most often associated with facilities that used advisory labeling followed by soy, milk, egg, wheat, Crustacean shellfish, and fish.[20]

FDA did not evaluate facilities' use of advisory labeling by the type of product manufactured for the FY2003/2004 allergen-focused inspections because such estimates would have been unreliable due to small numbers of facilities inspected.

V. Section 204(4): Consumer Preferences for Food Allergen Labeling

Section 204(4) of the FALCPA provides that the report to Congress describe the advisory labeling preferences of consumers with food allergies and their caretakers with respect to statements about the risk of allergen cross-contact. FDA's review of the available research found no information on consumer preferences for cross-contact information on food labels. Accordingly, FDA selected an appropriate method to collect these data, developed an appropriate survey instrument, and contracted with a consumer research firm to administer the survey. FDA also developed an experimental study as a complementary test of the survey results on consumer preferences.[21]

A. The FDA-sponsored survey of consumer preferences

The FDA-sponsored survey sampled a pre-existing panel of respondents who participate in surveys using the Internet. This is a probability-based Internet panel, the constituents of which were recruited from a variety of sources so that the panel closely reflects U.S. population demographics. Internet access was not a requirement for inclusion in the panel.

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[17] For example, the FY2002 data show that 12% of smaller (Category 1) firms, 16 percent of mid-size (Category 2) firms, and 23 percent of the larger (Category 3) firms used some sort of advisory statement in their product labels.

[18] For example, facilities manufacturing chocolate products were the most likely to use allergen advisory statements (53 percent). Chocolate manufacturers were followed by firms that produced candy (47 percent), those producing nut products (32 percent), and those making snack food products (19 percent). For firms making other types of food products, the fraction of firms that used allergen advisory statements ranged from 0 to 15 percent.

[19] In the FY2002 inspections, almonds, chestnuts, macadamia nuts, pecans, walnuts, hazelnuts (filberts), cashews, Brazil nuts, pistachios, hickory nuts, and pine nuts were considered to be "tree nuts."

[20] Thirty-five percent of firms using advisory labeling used peanuts in their products and 29 percent used tree nuts. Fifteen to 20 percent of firms utilizing advisory labeling used wheat, egg, milk, or soy ingredients, and 5 to 7 percent of firms using fish or Crustacean shellfish used advisory labels.

[21] A consumer survey usually consists of a list of questions given to a randomly chosen sample of individuals from a known population. Survey questions generally query attitudes and opinions, and the results produce statistically derived estimates of how the entire population would respond to the questions. In contrast, experiments are conducted with individuals who have been randomly assigned to groups. Each group receives one set of stimuli (e.g., a product label containing an advisory statement) and completes a task using those stimuli. Differences between the groups on the tasks indicate differences between the stimuli.

In the survey, FDA asked two groups of individuals to identify their preferences for food labeling advisory statements intended to communicate information about the possibility of food allergen cross-contact. The first group consisted of food allergic individuals (n=530) and caregivers of food allergic individuals (n=209).[22] The second group was composed of individuals who identified themselves as neither having a food allergy nor providing care to a person with a food allergy (n=504).

All survey respondents were shown mock food labels similar to actual food product labels. Each mock-up contained one of four advisory statements. Respondents were asked to rank order their preferences by selecting their first choice from among the four statements, then their second choice, and so on. Three of the four advisory statements were based on statements currently found on food product labels in the marketplace. A fourth statement, developed for the FDA-sponsored survey, described manufacturing controls designed to reduce the likelihood of the presence of the allergen in the food. The purpose of this statement was to test whether consumers would prefer specific advisory information about food manufacturing processes and the potential for cross-contact. Most advisory statements currently in the marketplace do not specify the nature and potential source of such cross-contact.

Because they are frequently used as a food ingredient, peanuts were selected as the allergenic ingredient identified in the advisory statement for this study. Also, for sensitive individuals, exposure to peanuts may cause a very serious reaction (including anaphylaxis), and advisory statements on food labels regarding peanuts are increasingly common in the market place. The following four advisory statements were tested:

A. "Allergy Information: May Contain Peanuts."
B. "May contain peanuts."
C. "Manufactured on the same equipment as foods that contain peanut."
D. "Produced in a facility with an allergy control plan. The possibility of contact with allergenic ingredients has been minimized. May still contain trace amounts of peanut."

The data were analyzed using nonparametric procedures to test for rank position and significance. There were no significant differences between the food allergic group and the non-allergic group either in the magnitude or the ordering of their preferences for all of the statements. "Allergy Information: May contain peanuts" was preferred over the other three statements. "Manufactured on the same equipment as foods that contain peanut." was preferred second, and "May Contain Peanuts" was ranked third. The statement that assured an allergen control plan, "Produced in a facility with an allergen control plan..." was the least preferred of the four statements.

The results are consistent with prior research on product labels which has shown that consumers prefer information to be preceded by signal words and generally view this information as more credible than information not accompanied by signal words.[23] Signal words

[22] Respondents identified as food allergic or caregivers to food allergic persons were selected based on self-reported allergic reactions (of the survey respondent or of a person cared for by the respondent) to any of the eight foods or food groups identified by FALCPA.

[23] Wogalter, Michael S., Michael J. Kalsher, and Raheel Rashid. 1999. "Effect of Signal Word and Source Attribution on Judgments of Warning Credibility and Compliance Likelihood" *International Journal of Industrial Ergonomics*. 24:185-192.

are also time-savers for shoppers, who want to be able to scan a food product label quickly and locate the information they need to make informed purchase decisions.

B. Consumer Reactions to Food Allergen Labeling Options

1. 2005 Allergen Labeling Experiment – Key Findings

This section presents the results from an experimental study addressing consumers' reactions to the same four advisory statements tested in the allergen survey study. The purpose of the experiment was to test the viability of the survey results on consumer preferences. The experiment compared the effects of the different label statements on consumers' food purchase or consumption intent decisions. Participants were randomly assigned to experimental groups; each group evaluated a single label containing either one of the advisory statements or an "experimental control" (a label without an advisory statement.)

The experimental data were collected using a web-enabled panel of consumers.[24] There were two groups of respondents in the experiment: a group of self-reported food allergic[25] persons and caregivers to food allergic persons (n=1,000), and a control group of non-food allergic persons (n=1,000). The advisory statements were tested using two mock products: a chocolate candy bar and a seafood casserole. Neither product was labeled as containing peanut as an ingredient. Each respondent viewed a single label condition (e.g., a candy bar with an advisory statement) and was asked to answer questions appearing on his/her screen. There were approximately 100 individuals in each experimental group from each of the two groups of respondents.

The respondents were first asked to decide whether the product they were looking at contained peanuts (a "recognition measure"). The only reference to peanut on the product label was in the advisory statement, except that the control label had no advisory statement. Figure 1 displays results for the seafood casserole product and Figure 2 displays results for the candy bar product.

Advisory statements do not state definitively that the product contains the food identified in the statement (which, in this experiment, is peanut.) Instead, these statements suggest the possible presence of the food (in this experiment, peanut) in the product due to cross-contact. Therefore, the factually correct answer to the first question is "cannot be certain" for those products with an advisory label statement. On the product without such a statement (i.e., the control), if consumers rely only on the product label information, which does not include peanut as an ingredient, the most accurate answer is "no."

Interestingly, about 35 percent of people who saw the no-statement control label for the seafood casserole and 30 percent of those who saw the no-statement control candy bar label said that either the products contained peanuts or they were not certain. The similarity in the patterns for the no-statement control across the two products suggests that, in general, a substantial number of people will be skeptical about the absence of peanut in a product, even where peanut is not mentioned in the ingredient list or otherwise on the food label.

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[24]The panels for the experiment and the consumer preference survey reported in Section A above had different respondents.

[25] A person was considered "food allergic" if he/she reacted to any of the eight foods or food groups identified in FALCPA.

Figure1. Recognition Measure - Does this Seafood Product Contain Peanuts?

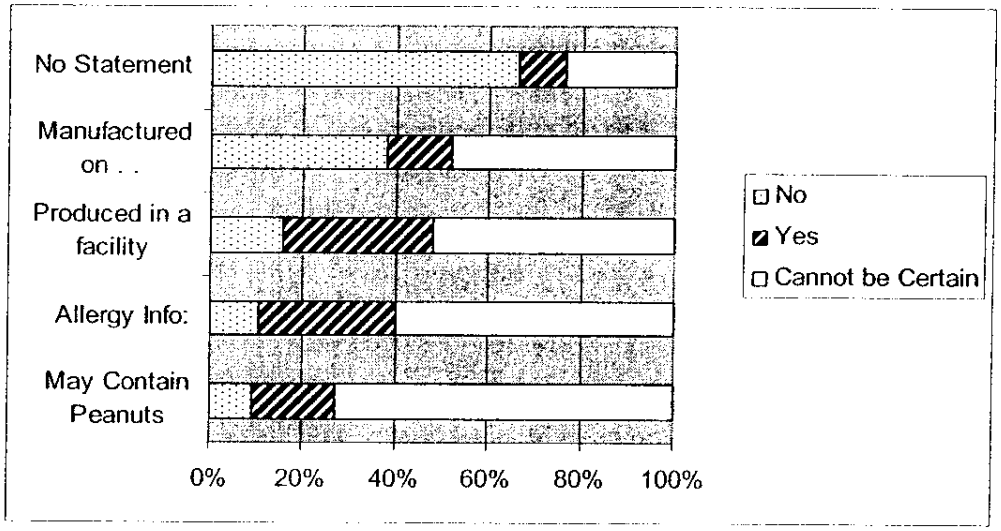
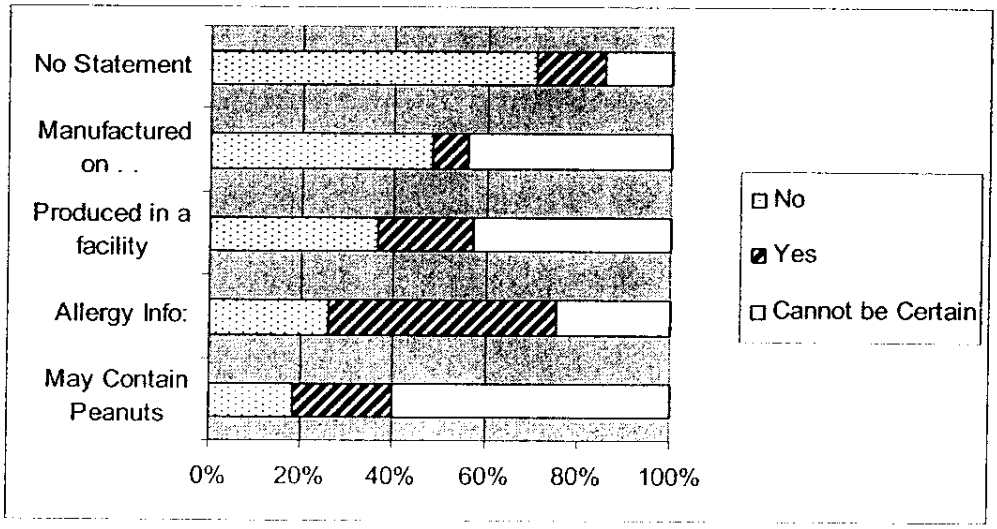


Figure 2. Recognition Measure - Does this Candy Bar Product Contain Peanuts?



The statement "Allergy Information: May Contain Peanuts" appears to have made a difference for respondents who saw the candy bar label in that about 50 percent of them concluded that the candy bar contains peanut. In contrast, only about 25 percent of respondents who saw the seafood casserole label concluded that the casserole contains peanuts. Because chocolate candy often contains peanut, it is likely that the signal words "Allergy Information" suggested to respondents an increased likelihood of the presence of peanuts in the candy bar. The statement "May Contain Peanuts" elicited more "cannot be certain" responses than any of the other statements. For this form of advisory statement, 70 percent of those who saw the seafood casserole label and 60 percent of those who saw the candy bar label responded that they could not be certain about the presence of peanut in the product in question.

Following the first "recognition measure," subjects were asked another question about recognition and a series of questions to rate the believability[26] and helpfulness[27] of the statements. They were also asked whether they would eat or serve the product to someone with a minor allergy to peanut and whether they would eat or serve the product to someone with a severe allergy to peanut ("consumption measures"). The questions in this part of the experiment differ from the first "recognition measure" in that respondents were asked to answer in degrees of likelihood, which permits a comparison of means across label conditions.

The results provided in Table 6 reflect combined data for the two food products and the two groups of respondents. There were no differences in results between the food allergic and non-food allergic groups. Similarly, differences in responses by product (candy and seafood casserole) were negligible.

Table 6 depicts the mean scores for each label condition (far left column) for each of the measures (top row). What becomes apparent when looking at these results is that the ratings for some of the label conditions seem to cluster. Subjects who saw the "May Contain Peanuts." label and those who saw the "Allergy Information: May contain peanut." label gave these two labels comparable ratings. Similarly, those who saw the "Manufactured on" label and those who saw the "Produced in a facility" label gave these two labels very similar ratings.

Subjects who saw the "May contain" label and those who saw the "Allergy Information" label rated them as significantly more likely to contain peanut than did those who saw the two other statements and the no-statement control. The "May contain. . ." and "Allergy Information" labels were also rated as significantly less believable and significantly less helpful than the two other labels containing advisory statements. (Groups evaluating the control labels were not asked to respond to the "believability" or "helpful" questions.) Those subjects who saw the "May contain" and the "Allergy Information" labels were also significantly less likely to serve the product to someone with a minor or severe peanut allergy than those who saw the "Manufactured on" or the "Produced in" labels. Subjects who saw the no-statement control label reported that they were significantly more likely than those who saw any of the four advisory statement labels to serve the product to someone with a peanut allergy.

[26] Beltramini, Richard F., and Kenneth R. Evens. 1985. "Perceived Believability of Research Results Information in Advertising." Journal of Advertising. 14:18-24, 31.

[27] Helpfulness was measured using a five-point, semantic differential, anchored by "helpful" and "not helpful" at respective ends. Subjects were asked to rate the statement about peanuts on the label using the scale.

Table 6. Means* on the Effectiveness Measures for Each Label Condition.

LABEL CONDITION	Likely to Contain[+]	Believability Scale[+]	Statement is Helpful[+]	Would Serve to Someone with a Minor Peanut Allergy[+]	Would Serve to Someone with a Severe Peanut Allergy[+]
No-Statement Control	2.3	n/a	n/a	3	2.4
May Contain Peanuts	3.2	3.2	3.1	1.5	1.1
Allergy Info: May Contain	3.3	3.3	3.1	1.6	1.1
Manufactured on the Same Equipment	2.7	3.7	3.7	2	1.2
Produced in a Facility with an Allergen Control Plan	2.6	3.6	3.6	2.1	1.2

[+] $p<.01$ *Range for all scales is 1 – 5. Higher numbers are more positive.

2. Discussion of results

There are some important qualifiers to the conclusions from this experiment. The statements tested in this experiment focused on the presence of peanut. Peanut allergy can produce among the most severe allergic responses, and even those not directly affected by this food allergy appear to be aware of the seriousness of peanut ingestion by sensitive individuals. Thus, it is possible that subjects might have responded differently had a food allergen other than peanut been the subject of the advisory statements.

Also, although these results are statistically significant, the differences in ratings among the label conditions on each measure are small. All of the ratings for the recognition, believability, and helpfulness measures cluster around "3," the midpoint in the scale. For the believability and helpfulness measures, subjects rated all four advisory statements more believable and more rather than less helpful. Across all the label conditions, subjects were unlikely to serve the product to someone with a peanut allergy.

VI. Section 204(5)(A) & (B): FDA's Allergen-focused Inspections

Section 204(5) of the FALCPA provides that the report to Congress include information on FDA's inspection of food manufacturing and processing facilities, including the number of facilities and food labels that were "found to be in compliance or out of compliance with respect to cross-contact of foods with residues of major food allergens and the proper labeling of major food allergens." As noted, in FY2002, FDA conducted over 1,800 allergen-focused inspections, and subsequently conducted comparable inspections at 372 facilities during FY2003/2004. These inspections did not specifically determine whether inspected facilities were "in compliance" or "out of compliance." Nevertheless, the results of these inspections, which are discussed in detail below, provide valuable information about the food industry's awareness of food allergens in the manufacturing environment and facilities' practices designed to manage the risks posed by such allergens.

A. INTRODUCTION

Facilities inspected in FY2002 included those manufacturing chocolate and candy products, bakery products (including crackers and cookies), ice cream, processed or shelled nut products, trail mixes, snack foods, breakfast cereals, macaroni and noodle products (fresh or dry), and salad dressings. FDA specifically targeted for inspection facilities with a manufacturing environment that created the possibility of cross-contact. The targeted inspections included facilities producing, within the same facility, similar food products, one of which contained an allergen and one of which did not contain the allergen (e.g., a single facility producing bakery products with and without egg ingredients or producing chocolate products with and without nut ingredients.) These inspections also included facilities using shared equipment or production lines to process both products containing allergens and products not containing allergens, and facilities using shared equipment that was not cleaned between allergen and non-allergen runs or with shared equipment that was dry-cleaned (i.e., without water) between allergen and non-allergen runs.

The data from the FY2002 inspections provide an overview of the practices of a group of facilities that were selected based on the above criteria. Importantly, because the facilities were not selected in an entirely random fashion, the data collected from the FY2002 inspections are not, in the statistical sense, a representative random sample of all facilities using the most common food allergens. Thus, the results should not be generalized to the larger population of all food production facilities.

The FDA investigators were instructed to conduct the inspection of a facility during production of the food(s) of interest. The investigators were also strongly encouraged to observe, where appropriate and possible, change-over from production of allergen containing product(s) to product(s) not containing allergen. These inspections were to determine and assess the following three items: (1) the allergens, along with the general practices, procedures, and processes a facility utilized in producing food products; (2) a facility's measures and controls to prevent conditions associated with allergen cross-contact; and (3) whether the labels of food products formulated to contain allergens correctly declared the presence of these ingredients.[28] The results discussed below are based on the 1,470 facilities for which the inspection information was largely complete.

B. RESULTS FROM THE FY2002 INSPECTIONS

1. Facility size and allergen use

Inspected facilities were categorized by size based on the reported annual sales volume for each facility; ten size categories were used. For this report, the ten size categories were collapsed into three broader categories, identified as Category 1, 2, or 3. Category 2 facilities (annual sales of $500,000 to $9,999,999) represented the largest fraction at 44.7 percent of all facilities; Category 3 facilities (annual sales volume of $10,000,000 or more) represented 30.2

[28] Inspections identified the specific food products evaluated during the inspection and gathered information on aspects of production, including product development, receiving (e.g., raw materials), equipment, processing, testing, and labeling finished products. Investigators examined finished food product labels for up to ten products formulated to contain any of the eight food allergens, concentrating on products with the highest production volume. These examinations verified that allergenic ingredients (including processing aids) were listed in the ingredient statement and confirmed that the ingredient was present in the finished product by reviewing batch records or through direct observation.

percent of the facilities; and Category 1 (annual sales volume of $0 to $499,999) represented 25.1 percent of the facilities.[29]

FDA evaluated the 1,470 facilities for the use and handling of food allergens during food manufacturing. Of the 1,470 facilities, 96.8 percent facilities used one or more of the eight most common food allergens as an ingredient, 62.7 percent used ingredients containing one or more of the eight as a sub-ingredient, and 47.1 percent used ingredients derived from one or more of the eight.

For all inspected facilities manufacturing food products containing any of the eight most common food allergens, milk was the allergen most frequently used, followed by wheat and egg. Milk and wheat also ranked first and second, respectively, across all facility size categories in terms of use. Soy, tree nuts, and peanut ranked fourth, fifth, and sixth, respectively. Fish and Crustacea were the two food allergens least used in food products, ranking seventh and eighth, respectively, for all facilities and across all facility size categories. For larger (Category 3) and smaller (Category 1) facilities, there are differences observed in the use of soy.[30] Tree nuts were used more frequently by the smaller (Category 1) facilities than by the larger (Category 3) facilities.

2. Receipt of allergenic ingredients[31]

FDA's inspections evaluated two aspects of facilities' receiving practices: the identification and segregation of allergenic ingredients and the use of bulk storage for such ingredients. When receiving raw materials for products, 55 percent of the facilities that used allergenic food as ingredients identified ingredients as allergens or segregated these ingredients, or both. Smaller facilities were less likely than larger facilities to identify or segregate allergenic ingredients.[32] Twenty-nine percent of the inspected facilities identified bulk tanks storing allergenic ingredients, managed such tanks, or both.[33] Bulk tanks for allergenic ingredients were identified or otherwise appropriately managed more frequently by the larger (Category 3) facilities than by the mid-size (Category 2) and smaller (Category 1) facilities.

FDA's inspections also evaluated facilities' receipt of allergenic sub-ingredients.[34] Of the facilities that used ingredients containing any of the eight most common food allergens as sub-ingredients, 48 percent identified or segregated, or identified and segregated, ingredients containing allergenic sub-ingredients. Smaller facilities were somewhat less likely to identify or

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[29] Because annual sales data were missing for one facility, the percentages of facilities by size are based on a total of 1469 firms.

[30] For the larger (Category 3) facilities, soy was the third most common allergen used with 67 percent of Category 3 facilities using soy, while for the smaller (Category 1) facilities, soy was ranked sixth (used by 36 percent of facilities) and for the mid-size (Category 2) facilities, soy ranked fifth (used by 45 percent of facilities.)

[31] The data in this portion of the "Receiving" section are drawn from the inspection of those facilities that reported using any of the eight most common food allergens as an ingredient. Approximately 97 percent of inspected facilities (1423 of 1470) used one or more of the eight as an ingredient. (The remaining 3 percent of facilities only used one of the eight as a sub-ingredient, only used an ingredient derived from a major food allergen, or both.)

[32] Sixty-three percent of the larger (Category 3) facilities, 53 percent of mid-size (Category 2) facilities, and 47 percent of the smaller (Category 1) facilities identified or segregated, or identified and segregated, allergenic ingredients upon receipt.

[33] For 30 percent of the facilities evaluated, the investigators determined that bulk storage was not applicable to their use of allergenic ingredients.

[34] For example, a facility producing breaded fish might receive and use a breading mixture (the ingredient) that contains wheat (an allergenic sub-ingredient.)

segregate allergenic sub-ingredients.[35] Sixteen percent of the facilities that used ingredients containing allergenic sub-ingredients reported that they identified or otherwise appropriately managed bulk tanks storing ingredients that contained allergenic sub-ingredients.[36] Bulk tanks for ingredients containing major food allergens as sub-ingredients were identified or otherwise appropriately managed more frequently by the larger (Category 3) facilities than by the mid-size (Category 2) or smaller (Category 1) facilities.

3. Monitoring ingredient statements in finished product labels

During the FY2002 inspections, FDA investigators asked facilities about monitoring the accuracy of ingredient statements in labels received for finished food products. Sixty-five percent of these facilities stated that finished product labels are checked when received to confirm the accuracy of the ingredient statement, including verification that the cartons of labels do not contain a mixture of different labels, compared to 29 percent that stated they did not check labels upon receipt.[37] Of this 29 percent of facilities, one-third did check labels prior to using them. Taken together, 75 percent of all facilities confirmed the accuracy of label ingredient statements either upon receipt of the labels or prior to their use.

4. Equipment

a) Cleaning Practices

The FDA inspections evaluated equipment cleaning practices used by food production facilities both in terms of control measures and efficacy checks. Eighty percent of all facilities applied one or more control measures to production equipment to prevent allergen cross-contact.[38] Equipment-related control measures to prevent cross-contact were used most frequently in the larger (Category 3) facilities with 89 percent of those facilities applying one or more of such measures, compared to 79 percent of the mid-size (Category 2) facilities and 72 percent of the smaller (Category 1) facilities.

Manufacturing facilities used several types of equipment-related control measures. Of the facilities that applied such measures, 33 percent used dedicated equipment, 76 percent used shared equipment with clean-up between manufacture of the allergen-containing product and manufacture of the product without an allergenic ingredient ("clean-up"), 34 percent used shared equipment with production of the allergenic product scheduled last ("production scheduling"), and 7 percent used other methods.

Of the facilities that practiced control measures to prevent allergen cross-contact associated with production equipment, one-third of those facilities used dedicated equipment, with a slightly higher percentage of the larger (Category 3) and smaller (Category 1) facilities using such equipment. Larger size facilities were more likely than smaller facilities to use clean-up and production scheduling.

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[35] Fifty-two percent of the larger (Category 3) facilities, 47 percent of the mid-size (Category 2) facilities, and 42 percent of the smaller (Category 1) facilities identified or segregated ingredients containing allergenic sub-ingredients.

[36] For 37 percent of the facilities evaluated, the investigators determined that bulk storage was not applicable to their use of allergenic sub-ingredients.

[37] Of the 1470 facilities inspected, checking labels was deemed "not applicable" for 4 percent of all facilities, it could not be determined for 0.4 percent of facilities, and an answer was missing for 1 percent of facilities.

[38] FDA investigators reported that for 2 percent of facilities, this question was not applicable; for 0.1 percent, no answer could be determined; and no response was provided for 1 percent of the facilities.

b) Cleaning effectiveness checks

Eighty-three percent of all facilities checked the effectiveness of their cleaning of food contact surfaces. Of these facilities, 95 percent used visual examination to check such efficacy, 25 percent used a microbiological test, 5 percent used a chemical assay for allergens, and 6 percent used other tests. Larger size facilities were more likely than smaller facilities to confirm the efficacy of their cleaning in some way.[39]

5. Cleaning and equipment characteristics

FDA investigators evaluated whether facilities' production equipment was easily accessible and cleanable. The inspections found that a majority of all facilities, 93 percent (1,370 of 1,470) had easily accessible and cleanable equipment. Equipment in less than 6 percent of the inspected facilities was deemed to be not easily accessible or cleanable.[40]

One situation that may result in allergen cross-contact is a build-up or pockets of residual food material on equipment even after cleaning. In 13 percent of all facilities inspected, FDA investigators observed a build-up of residue on equipment, which residue could have contained an allergen. There was a slight variation across facility sizes in the incidence of residue build-up on equipment.[41]

6. Potential cross-contact during processing

a) Possible routes of cross-contact

During the FY2002 inspections, FDA investigators assessed whether allergen cross-contact was likely to occur during processing of food products. The investigators considered that such cross-contact was likely to occur in 25 percent of all inspected facilities. There was a slight trend for facilities with the highest sales volume to have a lower likelihood of cross-contact.[42] The investigators evaluated the nature of this potential cross-contact, focusing on three possible sources of contamination: residues of allergen-containing product on equipment, build-up of product above the processing zone, and presence of airborne food particles. Overall, equipment residues were judged to be the most likely source of cross-contact, followed by airborne food particles, and build-up of product above the processing zone.

FDA evaluated the relationship between facility size and the foregoing three potential routes of cross-contact. Facility size was a minor factor in whether a facility was considered likely to have cross-contact due to residues on equipment.[43] Airborne food particles as a

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[39]Seventy-four percent of the smaller (Category 1) facilities, 80 percent of mid-size (Category 2) facilities, and 93 percent of larger (Category 3) facilities performed a cleaning effectiveness check of some type.

[40]For the balance (17) of the 1470 facilities, responses to this evaluation were missing, "not applicable," or "could not be determined."

[41]FDA investigators observed residues in 13 percent of larger (Category 3) facilities, 15 percent of mid-size (Category 2) facilities, and 10 percent of smaller (Category 1) facilities. FDA investigators could not make the equipment residue evaluation in 4 % of inspections, the question was deemed "not applicable" to the facilities in 4 percent of inspections, or a response to this question was missing for 1 percent of inspections.

[42] Twenty-two percent of the larger (Category 3) facilities, 27 percent of the mid-size (Category 2) facilities, and 26 percent of the smaller (Category 1) facilities were considered likely to experience allergen cross-contact during processing.

[43]Equipment residues were considered likely to be a source of cross-contact for a similar percentage of facilities in each size category.

potential source of cross-contact were considered more likely for mid-size (Category 2) facilities.[44] Finally, larger (Category 3) facilities were considered somewhat less likely to have product build-up above processing zones when compared to mid-size and smaller facilities.[45]

b) Handling of unpackaged exposed product

FDA investigators evaluated processing line practices and determined that 76 percent of all facilities handled unpackaged, exposed product in a way to protect it against cross-contact with an allergen.[46] The percentage of facilities that handled product in this way was greater in facilities with higher sales volumes.

c) Rework of semi-finished or finished product

Of the 1,470 facilities inspected, 34 percent reworked semi-finished or finished product. Fifty-four percent of larger (Category 3) facilities, 28 percent of mid-size (Category 2) facilities, and 20 percent of smaller (Category 1) facilities reworked semi-finished or finished product. Facilities with higher sales volumes were more likely to rework product.

FDA investigators collected information on three rework control measures. For 92 percent of the facilities that reworked semi-finished or finished product, the reworked product was added back only to products containing the same allergen(s). About half of the facilities determined the amount of rework at the beginning and end of production and reconciled these amounts. Nearly three-fourths of the facilities had control measures to ensure that labels for finished product that included allergen-containing rework had accurate ingredient information.

A larger fraction of the larger (Category 3) facilities utilized measures to control use of rework. Ninety-five percent of larger (Category 3) facilities controlled rework by adding it back to like product, compared to 90 percent of mid-size (Category 2) facilities and 85 percent of smaller (Category 1) facilities. Similarly, 68 percent of larger (Category 3) facilities controlled rework by reconciling the amount of rework incorporated, compared to 43 percent of mid-size (Category 2) facilities and 31 percent of smaller (Category 1) facilities. Finally, eighty-six percent of larger (Category 3) facilities used rework-related control measures to ensure accurate ingredient information on finished product labels, compared to 62 percent of mid-size (Category 2) facilities and 63 percent of smaller (Category 1) facilities. Facilities with larger sales volumes were more likely to engage in practices to control rework compared to facilities with smaller sales volumes.

One means by which some facilities that rework semi-finished or finished product controlled rework was by applying specific measures to rework storage containers. Facilities generally used one or more of the following ways to control these containers: dedicated containers, identified container contents, or segregated containers. Larger (Category 3) facilities

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[44] Airborne food particles were considered likely to be a source of cross-contact in 38 percent of mid-size (Category 2) facilities compared to 27 percent of the smaller (Category 1) facilities and 29 percent of the larger (Category 3) facilities.

[45] Only 11 percent of the larger (Category 3) facilities were considered likely to have cross-contact resulting from such product build-up compared to 17 percent of the mid-size (Category 2) and 17 percent of the smaller (Category 1) facilities.

[46] Eighty-six percent of the larger (Category 3) facilities, 73 percent of mid-size (Category 2) facilities, and 69 percent of the smaller (Category 1) facilities handled exposed product during processing in a way to prevent cross-contact.

were slightly more likely to handle rework containers in one of these ways compared to the smaller and mid-size (Categories 1 and 2) facilities.

7. Facilities' inspection of finished package labels

Sixty-eight percent of all facilities inspected finished product packages prior to distribution to ensure that an allergen-containing product was properly labeled. Larger facilities were more likely than smaller ones to inspect the labeling on the finished product packages. Seventy-nine percent of the larger (Category 3) facilities, 65 percent of the mid-size (Category 2) facilities, and 61 percent of the smaller (Category 1) facilities inspected such labeling.

C. RESULTS FROM THE FY2003/2004 INSPECTIONS

In FY2003 and FY2004, FDA conducted allergen-focused inspections at 372 facilities. As was the case with the FY2002 inspections, of the three size categories, mid-size (Category 2) facilities were the highest proportion of facilities inspected.[47] Of the 372 facilities, 96.0 percent used one or more of the eight most common food allergens as an ingredient, 54.6 percent facilities used ingredients that contained one or more of the eight as a sub-ingredient, and 37.6 percent facilities used ingredients derived from one or more of the eight. Consistent with the findings of the FY2002 inspections, milk and wheat were the most common food allergens used by facilities, and fish and Crustacea were the least common food allergens used by facilities.[48]

The results of FDA's FY2003/2004 inspections were similar to the results of the FY2002 inspections with respect to receiving, equipment, processing, testing and labeling. For example, 57 percent of facilities inspected in FY2003/2004 using allergens as ingredients identified or segregated such ingredients after receiving raw materials; in FY2002, the corresponding percentage was 55 percent. Likewise, like the FY2002 inspections, larger facilities inspected in FY2003/2004 were more likely to identify or segregate allergenic ingredients.

For FY2003/2004, 79 percent of the inspected facilities used one or more control measures associated with production equipment to prevent allergen cross-contact compared to 8 percent of the FY2002 facilities. In the FY2003/2004 inspections, of the facilities that tried to control cross-contact from equipment, 33 percent used dedicated equipment, 74 percent used shared equipment with clean up in between manufacture of the allergen containing product and the non-allergen containing product, 41 percent used shared equipment with production scheduled to run allergenic product last, and 8.5 percent used other methods; the corresponding percentages for FY2002 were 33 percent, 76 percent, 34 percent, and 7 percent. Ninety-four percent of facilities inspected in FY2003/2004 (versus 93 percent in the FY2002 inspections) had easily accessible and cleanable equipment. Again, as with the FY2002 inspections, the use of equipment-related control measures was higher in the facilities with greater sales volumes.

The results for likelihood of cross-contact during processing were consistent between the two groups of inspections. For facilities inspected in FY2003/2004, FDA investigators judged that 24 percent were likely to have cross-contact during processing compared to 25 percent in

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[47] Sales volume information was missing for four of the 372 facilities. Thus, the percentage of facilities in each size category is based on 368 facilities. Of these facilities, forty-two percent were mid-size (Category 2) facilities, 29.1 percent were smaller (Category 1) facilities, and 28.5 percent were larger (Category 3) facilities.

[48] Milk was used at 74 percent of the inspected facilities, and wheat was used at 62 percent of inspected facilities. Fish was used at only 12 percent of the inspected facilities and *Crustacea* were used at only 7 percent of the inspected facilities.

FY2002. Like the FY2002 inspections, mid-size (Category 2) facilities were more likely to be assessed as having airborne food particles as a source of cross-contact than either smaller (Category 1) or larger (Category 3) facilities. Finally, a slightly lower percentage of the larger (Category 3) facilities inspected in FY2003/2004 had build-up above the processing zone as a potential source of cross-contact during processing compared to mid-size (Category 2) and smaller (Category 1) facilities.

Another strong parallel between the FY2002 and FY2003/2004 inspections is the fact that 73 percent of the FY2003/2004 facilities were found to handle unpackaged, exposed product in a manner to protect against cross-contact. For FY2003/2004, the percentage of facilities that controlled product in this way was higher in facilities with larger sales volume.

Finally, the FY2003/2004 inspection results were consistent with the earlier inspections in terms of the facilities' inspection of finished product labels.[49] In both sets of inspections, larger facilities were more likely than smaller ones to inspect finished product labels prior to distribution to ensure that allergen-containing products were properly labeled.

VII. Section 204(5)(C): Allergen Recalls

Section 204(5)(C) of the FALCPA provides that the report address the "number of voluntary recalls, and their classifications, of foods containing undeclared major food allergens." FDA reviewed and analyzed five years of agency information on voluntary recalls involving undeclared food allergens. The results of this analysis are discussed below.

A. Background

Under FDA regulations, a recall is defined as a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action. 21 CFR 7.3(g). The relative level of health hazard attributed by FDA to each recalled product is reflected in an assigned recall classification number (*i.e.*, I, II, or III). A class I recall is defined as a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. Class II recalls involve situations in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Finally, Class III recalls entail situations in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. 21 CFR 7.3(m). For each recall action, FDA works with the recalling firm to develop a recall strategy and to monitor the progress of the recall. Among other things, this strategy determines whether public warnings should be issued, the level in the distribution chain to which recalls are extended, and the extent to which checks are performed by the firm, FDA, or both, to ensure that consignees have received notification of the recall and have taken appropriate actions.

For every recall or recall action, FDA maintains a record of information about the recalled product. Details captured in the recall record include the reason for the recall, the strategy employed by the manufacturer or distributor to remove the product from distribution,

[49] For FY2003/2004, 75 percent of all facilities inspected finished product labeling to ensure that an allergen-containing product was properly labeled; the corresponding percentage for the FY2002 inspections was 68 percent.

and the actions FDA took in processing the recall. In addition, each record contains information pertaining to adverse events, if any, reported by consumers or others to the firm or to FDA. Data collected on food recalls can be used to identify common problems and trends occurring in the food industry, and can be used to inform the public and the food industry of recurring hazards so that appropriate steps can be taken to prevent future occurrences.

B. Methods

The information in this section of the report is based on a review of FDA recall records for recall actions classified as Class I or Class II for FY1999 through FY2004 to identify recalls that occurred because of the presence of an undeclared food allergen.[50] Class III recalls were excluded because, by definition, these recalled products are not likely to have caused adverse health consequences. Each record was reviewed to determine the following: the type of product recalled; the nature of the problem that led to the recall; and the recall classification (I or II). Data were then entered into a database and analyzed using SAS software.

C. Results

During FY1999 to FY 2004, there were 462 recall actions due to the presence of undeclared allergens in a food. Of these recall actions, nearly three-fourths (n=352; 76.2 percent) were deemed Class I and about one-fourth (n=110; 23.8 percent) were deemed Class II (Table 7). Of the recall actions due to undeclared allergens, bakery products and ice cream products had the larger number of recalls between FY1999 and FY2004 (Table 8). Undeclared egg and milk ingredients were the most frequent undeclared allergens associated with recall actions (Table 9).

Table 7: Number and percent of recall actions due to undeclared major food allergens, by year and class (n=462)

Year	Class I	Class II	Total
1999	52 (75.4%)	17 (24.6%)	69 (100%)
2000	40 (64.5%)	22 (35.5%)	62 (100%)
2001	35 (53.0%)	31 (47.0%)	66 (100%)
2002	98 (87.5%)	14 (12.5%)	112 (100%)
2003	66 (79.5%)	17 (20.5%)	83 (100%)
2004	61 (87.1%)	9 (12.9%)	70 (100%)
Total	**352 (76.2%)**	**110 (23.8%)**	**462 (100%)**

[50]Only recall actions involving food products were reviewed; cosmetic and other non-food related recalls were excluded from consideration. Of recall actions involving food products, FDA reviewed those involving the following allergens: peanut, tree nut, egg, milk, wheat, soy, fish, and Crustacea. These are eight food or food groups identified by FALCPA.

Table 8: Number and percent of recall actions between FY1999-FY2004 due to undeclared major food allergens, by industry (n=462)

Industry	# of recall actions	% of total
Bakery products	141	30.5
Ice cream products	49	10.6
Fishery/seafood products	43	9.3
Multiple food dinner products	43	9.3
Chocolate products	33	7.1
Snack food products	25	5.4
Non-chocolate candy products	20	4.3
Prepared salad products	14	3.0
Dressing/Condiments	10	2.2
Nuts/seeds	9	1.9
Dietary foods	8	1.7
Noodle products	8	1.7
Soup	7	1.5
Vegetable protein products	5	1.1
Vegetable products	5	1.1
Beverages	5	1.1
Cheese products	5	1.1
Multiple types of products in one action	9	1.9
All other products*	24	5.2
Total	**462**	**100**

* Products which had fewer than five recall actions from FY1999-FY2004.

Table 9: Number and percent of recall actions between FY1999-FY2004 due to undeclared major food allergens, by industry and type of allergen (n=462)*

Industry	Peanut	Tree nut	Egg	Milk	Wheat	Soy	Fish	Crustacea
Bakery products (n=141)	22 (15.6%)	40 (28.4%)	49 (34.8%)	43(30.5%)	3 (2.1%)	6 (4.3%)	0	0
Ice cream products (n=49)	28 (57.1%)	12 (24.5%)	11 (22.5%)	1 (2.0%)	4 (8.2%)	0	0	0
Fishery/seafood (n=43)	0	0	31 (72.1%)	7 (16.3%)	16 (37.2%)	7 (16.3%)	6 (14.0%)	5 (11.6%)
Multiple food dinner products (n=43)	1 (2.3%)	2 (4.7%)	26 (60.5%)	14 (32.6%)	8 (18.6%)	6 (14.0%)	0	0
Chocolate products (n=33)	12 (36.4%)	7 (21.2%)	5 (15.2%)	14 (42.4%)	0	0	0	0
Snack food products (n=25)	9 (36.0%)	4 (16.0%)	0	12 (48.0%)	0	4 (16.0%)	0	0
Non-chocolate candy (n=20)	12 (60.0%)	3 (15.0%)	3 (15.0%)	5 (25.0%)	1 (5.0%)	1 (5.0%)	0	0
Prepared salads (n=14)	1 (7.1%)	0	9 (64.3%)	1 (7.1%)	3 (21.4%)	0	0	1 (7.1%)
Dressing/Condiments (n=10)	0	0	6 (60.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	0
Nuts/seeds (n=9)	4 (44.4%)	7 (77.8%)	0	0	0	0	0	0
Dietary foods (n=8)	3 (37.5%)	2 (25.0%)	0	2 (25.0%)	0	1 (12.5%)	0	0
Noodle products (n=8)	0	0	7 (87.5%)	1 (12.5%)	0	1 (12.5%)	0	0
Soup (n=7)	0	0	3 (42.8%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0	1 (14.3%)
Vegetable protein products (n=5)	0	0	1 (20.0%)	2 (40.0%)	2 (40.0%)	0	0	0
Vegetable products (n=5)	1 (20.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	0	0
Beverages (n=5)	0	0	1 (20.0%)	4 (80.0%)	0	0	1 (20.0%)	0
Cheese products (n=5)	0	0	5 (100%)	0	0	1 (20.0%)	0	0
Multiple food products in one action (n=9)	1 (11.1%)	1 (11.1%)	7 (77.8%)	1 (11.1%)	1 (11.1%)	0	0	0
All other products** (n=24)	0	8 (33.3%)	5 (20.8%)	9 (37.5%)	3 (12.5%)	2 (8.3%)	1 (4.2%)	0
Total (n=462)	**94 (20.3%)**	**87 (18.8%)**	**170 (36.8%)**	**120 (26.0%)**	**45 (9.7%)**	**32 (6.9%)**	**9 (1.9%)**	**7 (1.5%)**

* Recall actions may have more than one type of undeclared allergen

** Products which had fewer than five recall actions from FY1999-FY2000.

VIII. Section 204(6): Current Efforts to Control Cross-contact

Section 204(6) of the FALCPA provides that this report "assess the extent to which the Secretary and the food industry have effectively addressed cross-contact issues." As noted earlier, the data from FDA's FY2002 inspections[51] provide an overview of a group of facilities that were selected based on certain criteria and not in an entirely random fashion. As such, the data are not a representative sample of all facilities using the most common food allergens. Thus, the results should not be generalized to all food production facilities. Nevertheless, the results of these inspections provide some insight into current efforts to address the risks of food allergen cross-contact.

In particular, several findings suggest that at least some food manufacturing facilities are aware of the potential concerns associated with the use of allergens in the food production environment. For example, 90% of all facilities used wet cleaning for equipment and 83% used some method (such as a visual check) to verify the effectiveness of food contact surface cleaning. In addition, more than three-fourths of all facilities used some sort of control measures with equipment, and handled unpackaged, exposed product during processing so as to protect against allergen cross-contact. Also, only 13 percent of all inspected facilities "reworked" a mixture of allergen-free and allergen-containing food product, and 34 percent "reworked" semi-finished or finished product. Last, 68 percent of all facilities inspected the finished product prior to distribution to ensure proper labeling of an allergen-containing product.

Significantly, however, other findings suggest that some facilities do not appear to recognize that certain practices, procedures, and processes during food manufacturing may contribute to cross-contact and result in problems with undeclared allergens. For example, the handling of allergenic materials at the receiving stage does not appear to be fully recognized as a potential source of cross-contact in that 55 percent or fewer facilities have measures to identify or segregate allergenic ingredients upon receipt, or to identify or manage these ingredients in bulk containers after receipt.

Taken together, these findings suggest that a certain percentage of facilities do attempt to address potential concerns associated with the use of allergens in food products. But the extent to which a firm does so varies and depends on the control measure or activity assessed, and for each aspect of food manufacturing evaluated, FDA's inspections found that a certain percentage of facilities did not apply control measures in the handling and use of allergens. The degree to which these gaps may contribute to the unintended presence of allergens in food, and the degree to which those allergens are associated with adverse health effects, is not known. However, these gaps do suggest areas for improvement in food manufacturing to protect against cross-contact.

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[51] FDA also conducted allergen-focused inspections of 372 facilities in FY2003/2004. Data from the FY2002 and FY2003/2004 inspections were analyzed separately, and, despite the difference in the number of facilities inspected in the two time periods, the findings are remarkably similar. Accordingly, the discussion that follows uses percentage values from the FY2002 inspections because this set of inspections represents a sample nearly four times the size of the FY2003/2004 sample.

The inspection data show that firm size is an important factor in terms of processes, procedures, and practices relating to the use and control of food allergens in the food manufacturing environment. Larger (Category 3) firms were more likely to employ practices and procedures to reduce the potential for cross-contact. This trend is seen in the areas of product development, materials receiving, equipment use, and food processing. Importantly, however, although larger facilities are more likely to take measures to address concerns associated with use of food allergens, this percentage did not approach 100 percent for any factor evaluated during FDA's inspections and was about 50 percent or below for a number of factors. This suggests that increased awareness of the potential for cross-contact in food manufacturing should continue to be a goal for all facilities, including larger ones. Findings on the factor of firm size also suggest that encouraging smaller (Category 1) and mid-size (Category 2) firms to recognize and address potential allergen cross-contact during food production is an important and valuable goal.