Allergy Inspection Guide (4/01)

GUIDANCE ON INSPECTIONS OF FIRMS PRODUCING FOOD PRODUCTS SUSCEPTIBLE TO CONTAMINATION WITH ALLERGENIC INGREDIENTS

This guidance is reference material for investigators and other FDA personnel. The guidance does not bind FDA and does not confer any rights, privileges, benefits or immunities for or on any person(s). An alternative approach may be used if such an approach satisfies the applicable statutes, regulations or both.

August 2001 (Editorial Changes Only)

INTRODUCTION

Prior to conducting inspections involving any manufacturer using ingredients that are considered allergens, review the general inspectional instructions in the Investigations Operations Manual (IOM) Chapter 5 -Establishment Inspections, particularly those in IOM 530 -Food Inspections; and review Compliance Program 7321.005 -Domestic NLEA, Nutrient Sample Analysis and General Food Labeling Program and Compliance Policy Guide Section 555.250, titled “Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens”.

Each year the Food & Drug Administration (FDA) receives reports of consumers who experienced adverse reactions following exposure to an allergenic substance in foods. Food allergies are abnormal responses of the immune system, especially the production of allergen-specific IgE antibodies to naturally occurring proteins in certain foods that most individuals can eat safely. Frequently such reactions occur because the presence of the allergenic substance in the food is not declared on the food label. Current regulations require that all added ingredients be declared on the label, yet there are a number of issues that have arisen in connection with undeclared allergens that are not clearly covered by label regulations. This guidance covers the following problem areas:

1. Products that contain one or more allergenic ingredients, but the label does not declare the ingredient in the ingredient statement;
2. Products that become contaminated with an allergenic ingredient due to the firm's failure to exercise adequate control procedures, e.g. improper rework practices, allergen carry-over due to use of common equipment

and production sequencing, inadequate cleaning;

3. Products that are contaminated with an allergenic ingredient due to the nature of the product or the process; i.e., use of common equipment in chocolate manufacturing where interim wet cleaning is not practical and only dry cleaning and product flushing is used;
4. A product containing a flavor ingredient that has an allergenic component, but the label of the product only declares the flavor, e.g., natural flavor. Under current regulations, firms are not required to declare the individual components of flavors, certain colors, and spices. However, firms are encouraged to specifically label allergenic components/ingredients that are in spices, flavors, and colors;
5. Products that contain a processing aid that have an allergenic component, but the label does not declare it. Processing aids that contain allergenic ingredients are not exempt from ingredient declaration under the incidental additives regulation (21 CFR 101.100(a)(3)), and therefore, must be declared.

FDA believes there is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies:

Peanuts Soybeans Milk Eggs Fish Crustacea Tree nuts Wheat

If you are requested to do a follow-up investigation involving an allergic reaction which appears to be caused by an undeclared food other than the eight foods listed above, then contact the CFSAN / Office of Field Programs regulatory contact listed in the compliance program for guidance.

PRODUCT DEVELOPMENT

Determine whether the firm identifies potential sources of allergens starting in the product development stage. For example, do they identify for each product all ingredients, ingredient components, processing aids, rework, processing steps, environmental conditions, and product carry over due to use of common equipment? Are potential sources of allergen contamination identified at each step?

Determine whether the products contain allergenic ingredients. For the most frequently produced products, request formulas. If formula information is refused, construct formulations by observing production.

Determine if the firm has assessed whether the packaging material used in direct contact with the product contains an allergen; e.g., foil coated with wheat ingredient as releasing agent.

Does the firm use processing aids in the manufacture of the food? If so, do the processing aids contain allergenic ingredients? If so, what are the allergenic ingredients?

Does the firm use spices, flavors, or colors that contain allergenic components? If so, do these spices, flavors or colors contain allergenic ingredients? If so, what are the allergenic ingredients?

RECEIVING

Determine whether the firm uses allergenic ingredients.

Determine how these allergenic ingredients are handled at receiving and how they are identified and/or segregated in raw material storage.

Determine if the firm stores any of these allergenic ingredients in bulk tanks. If yes, how are the contents of the bulk tanks identified?

Determine what the firm’s procedure is for receiving ingredients into the bulk tank and what controls are in place to ensure proper product identity at all times.

Determine if the firm receives any raw materials that are labeled with a statement, such as "this product was processed on machinery that was used to process products containing (allergen)" or "may contain (allergen)". If so what ingredients? How are such statements reflected on the label of the firm’s finished product?

Determine whether a label from each incoming lot of finished product labels is visually checked, either upon receipt or during production, to ensure the ingredient statement is correct for the intended product and that it is not a carton of mixed labels.

EQUIPMENT

Try to inspect the equipment before processing begins and document the adequacy of clean up. For example, is there a build up of residual materials or pockets of residue in corners that may contain an allergen from previous runs? What is the condition of the conveyor belts? Is there any product build-up above processing zones? Also observe whether the firm checks the processing lines for cleanliness prior to production and whether they maintain a record of the check. Is this simply a visual check or does the firm use another method?

Determine whether the firm uses a Clean-In-Place system for cleaning fixed lines, e.g. pipelines and tanks. If so, how do they ensure that the interior surfaces of the welds in the lines are smooth and will not entrap material during operation? Are the pipes free from dents?

Determine if equipment is cleanable, e.g. stainless steel, accessible for cleaning.

Determine if the firm has a written procedure for cleaning. Does the cleaning procedure include how to clean and at what frequency the equipment is cleaned? Describe procedure.

Determine if equipment and production lines are shared to process different products.

Determine if shared equipment is cleaned in between production of a product that contains allergens and one that does not, e.g. full clean-up with detergent and water.

PROCESSING

Determine what control measures, if any, are used by the firm to prevent the contamination of products that do not contain allergens? What control measures does the firm employ? At what steps in production are the control measures instituted?

Determine how the firm separates the production of those products that contain allergens from those that do not contain such ingredients. Is cross-contact likely to occur, e.g., airborne food particles, dust, allergen product residues from equipment, etc.?

Determine if unpackaged, exposed product on the processing line is handled in a way that protects it against contamination.

Determine if shared processing lines (equipment) are used. If yes, is allergen-containing product processed first or last?

Determine what is done with the portion of the product that is a mixture of the non-allergen product and allergen product, e.g., is it sent to waste or for animal feed or reworked?

Determine whether the firm reworks product, and if they only rework like products. How is rework controlled? Is rework inventory reconciled at the end of the day?

Determine how product to be reworked is stored and identified. Are rework containers clearly labeled?

Determine how such rework holding vessels and containers are cleaned and stored.

FINAL PRODUCT TESTING

Determine if the firm performs final product testing for the presence of allergens in products not intended to contain allergens. If so, for which allergens, and how is the testing documented?

Determine what method of analysis is used and the sensitivity of that method.

Determine if the testing is routine or periodic.

Note: You should use these questions solely for information gathering purposes. If the firm asks if FDA has methods for detecting allergens, your response should be that FDA has not yet designated any method of allergen testing for regulatory purposes. There are several commercial enzyme-linked immunosorbent assays (ELISA) kits for food allergens available in the marketplace. Currently, FDA is evaluating some of these kits and is also cooperating with kit manufacturers to conduct international collaborative studies to evaluate the performance of some

of the ELISA-based methods.

LABELING

Determine if finished product label controls are employed, e.g., how are labels delivered to the filling and/or packaging area?

Determine if product labels with similar appearances but different ingredients are controlled to ensure that the correct label is applied to correct product.

Determine if finished product packages are inspected prior to distribution to ensure that an allergen containing product is labeled properly, or that labels are inspected during production. Is that inspection documented?

Determine if secondary ingredients are incorporated in the final product ingredient statement, e.g. the raw material mayonnaise, which contains eggs, oil and vinegar.

Determine if the firm uses a statement such as "this product was processed on machinery that was used to process products containing (allergen)" or a statement such as "may contain (allergen)" if the firm uses shared equipment for products that contain and products that do not contain allergens. Any other such statement? Ask the firm why they believe they have to use the advisory statement.

Determine if the finished product label reflects any advisory statements that were on the raw material labels, e.g., "this product was processed on machinery that was used to process products containing (allergen)".

Determine if the firm has a system to identify finished products made with rework containing allergenic ingredients. Does the final product label identify the allergens that may have been in the reworked product?

INSPECTION/DOCUMENTATION/ESTABLISHMENT INSPECTION REPORT

It is extremely important that each Establishment Inspection Report (EIR) contain complete, precise, and detailed descriptions of the entire operation. The

investigator must attempt to fully identify or demonstrate the likely sources of and possible routes of contamination of the product with undeclared allergen ingredients.

The critical points in the food manufacturing operation should be identified and special attention given to these areas.