APPENDIX 9: **ALLERGEN CROSS-CONTACT PREVENTION**

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INTRODUCTION.

In addition to effective cleaning and sanitation controls, processors should also consider processing controls to prevent or minimize the likelihood of the allergen cross-contact.

Allergen cross-contact may result in the un-intentional introduction of allergens into foods that do not properly declare the allergens on the labels. Allergen cross-contact controls are intended to provide separation by time and space between allergen-containing products and non-allergen-containing products, or between products consisting of or containing different allergens. These controls should be considered at all points in processing where cross-contact or inaccurate allergen declarations can be prevented. Controls may be considered at specific processing steps and should include comprehensive procedures such as process scheduling, traffic control, physical segregation, and air filtration. Allergen cross-contact controls should also be considered and used when creating and processing new product samples for public consumption. Development of written procedures and posting appropriate allergen cross-contact control procedures will help ensure the consistency in the application of controls. Implementation of a recordkeeping system provides a method of tracing ingredients and labels and identifying their disposition. The development and oversight of processing cross-contact controls requires an understanding of the allergens and the health hazard they present in addition to effective methods for prevention of allergen cross-contact.

Seafood processors must meet the requirements of 21 CFR 117.4. This regulation requires that all individuals engaged in manufacturing, processing, packing and holding food (including temporary and seasonal personnel) and supervisors must have the education, training, or experience necessary to ensure the production of safe food as appropriate to their assigned duties and that supervisory staff have the knowledge necessary to supervise the production of safe food. Seafood processors must ensure that their employees have been trained in the controls necessary to prevent allergen cross-contact. Since this training is specific to food safety, records of the training must be maintained in accordance with 21 CFR 117.4. The training should, at a minimum:

- Identify allergens and the hazard they present to sensitive individuals;
- Cover the principles of allergen cross-contact prevention; and
- Specifically cover the processor's allergen cross-contact prevention protocols, including corrective actions, and the required recordkeeping.

The following recommendations may not apply to every type of facility and situation. FDA has identified these recommendations as a means of assisting facilities as foundational information for them to better understand and evaluate or create an allergen cross-contact control program based on the needs of their facility. These are recommendations and considerations only. FDA does not legally require firms to adopt any of the recommendations.

RECEIVING.

Preventing allergen cross-contact begins when labels and ingredients are received at a facility. Consider the following when receiving materials to control allergen cross-contact as appropriate for the facility needs:

- Compare the received preprinted labels and the labels of ingredients received against product specifications. Check for any changes in the list of declared allergenic ingredients. Segregate and hold ingredients and labels whose allergen declarations do not match the product specification in a defined area with restricted access. The segregated ingredients and labels should be tagged to indicate that they should not be used. Close attention should be paid to sub-ingredients.

- Inspect materials for damaged packaging and exposed/leaking materials. Damaged packages should be removed, sealed and segregated from the shipment for return to the supplier or destroyed. Handle damaged containers of allergens in a manner that prevents allergen cross-contact during receipt and storage, if they must be accepted with the shipment. Segregation areas should be clearly identified, and damaged packages should be marked as not to be used. Do not move damaged or leaking containers or packages into production areas unless allergen-containing ingredients or materials have been contained.

- Clearly identify the allergen content on packages (e.g., case, pallet, bag, or carton) of incoming ingredients immediately upon receipt to ensure that the allergen content of each can be clearly identified during storage and on the production floor when in use. A color-code system that is easily understood and preferably identifies the specific allergen hazard can be utilized.

  Note: Ensure color codes are clear, and not in conflict with other coding schemes in use at the facility.

- Establish and implement controls to ensure the integrity of ingredients received in bulk including those delivered by railcar or tanker. For example, verification of tanker and/or railcar cleaning for allergens (e.g. hopper, boxcar, tanker, etc. wash-tags), prior load information, clean transfer areas and equipment cleaning.
    - Reject the shipment if identified requirements have not been met.

STORAGE.

Storage of allergens and allergen-containing materials should be done to minimize the risk of allergen cross-contact in a facility. Consider the following when establishing and implementing procedures to control allergen cross-contact during storage that are appropriate for your facility:

- Segregate allergen-containing ingredients. Use of separate storage areas (e.g. dedicated allergen storage room, or shelving) provides a physical separation for allergen and non-allergen-containing ingredients. The physical separation should ensure that allergen-containing ingredients are stored in a warehouse, cooler, or storage areas where they do not come in contact with each other or any non-allergen containing ingredient. This dedicated area should only be used for allergen-containing ingredients and not used for non-allergen-containing ingredients or other products at any time.

- Establish procedures for staging and storage of food allergens and allergen-containing ingredients below non-allergens when dedicated areas are not available. This will help to prevent inadvertent cross-contact in the event that the packaging material used to store the allergen is damaged and subsequent leakage occurs.

- Use color coding, tagging, or other distinctive marks to identify containers of ingredients or foods that contain different food allergens when practical. This could include using colored shrink-wrap or colored placards, distinct pallets, and unique totes or bins. A dedicated color may be assigned to each of the major allergens defined by FALCPA. For example, prominently post a chart in key processing and ingredient storage areas that identifies the assignment of the major food allergen and its corresponding color.

  Note: Ensure the color codes are clear, and not in conflict with other color coding schemes being used in the facility.

- Use dedicated bins or containers that can be closed in a secure manner for storing allergen-containing ingredients and allergen-containing products.

- Establish procedures to ensure that non-allergen-containing ingredients or products are not mixed with allergen-containing materials, or that different allergens are not mixed when using bulk storage tanks or silos. Use visual identifiers (such as tags or labels), computerized verification checks, lockouts over valve openings, and requirements that inspections and sign-offs on a valve and tank set up before receiving or using material in a tank or silo as appropriate.

- Establish procedures to inspect warehouse handling equipment (dollies, forklifts, etc.) used to transport the ingredients containing allergens.

- Establish and implement procedures for damaged packaging or containers and the resulting spills or leaks of allergen-containing ingredients or products.

PROCESSING.

Allergen cross-contact can be prevented during food processing by providing separation in time and space between allergen-containing materials and non-allergen-containing materials, and between materials containing different allergens. The appropriate allergen control measures are facility and product dependent. When choosing which measures to take, the processor should consider the properties of the allergenic ingredients being used, the nature of the processing system and production facility, the product being produced, and the manufacturing processes.

A. Facility, equipment and process design

Allergen cross-contact of ingredients, in-process materials and final product can be minimized by utilizing dedicated facilities, processing and packaging lines, and equipment. The following considerations should be made when designing the facility, equipment and processes to prevent allergen cross-contact:

- Incorporate features in overall plant layout and process design that will minimize the potential for allergen cross-contact.

- Design traffic patterns (e.g., avoid crossovers of open production lines) in the facility to prevent allergen cross-contact. Develop a unidirectional traffic flow to avoid unrestricted movement of employees between allergen-containing and allergen-free zones in the plant. For example, designing in a buffer room or clean area between the two zones.

- Establish air flow controls in the facility, to prevent airborne allergen particulate matter from being brought into allergen-free zones (e.g. introduce a positive air pressure environment in the packaging area or use micro air filtration).

- Provide shielding, permanent and/or temporary partitions, covers, and catch pans to protect exposed unpacked product as necessary.

- Review facility and process design for new installations or upgrades to assess for the potential of allergen cross-contact.

- Configure processing lines with sufficient space or physical barriers between them to minimize any allergen cross-contact as a result of normal product spillage and splattering from processing or cleaning.

- Consider dedicating a section of the facility for processing of products containing specific allergens as appropriate and/or practical.

- Consider the configuration and use of your processing lines:

    - Use separate processing lines for products that contain different types of allergens, when possible.

    - Line crossovers should be avoided

    - Enclosing processing equipment

- Dedicate utensils, employee apparel (e.g., aprons and gloves), and tools to specific processing lines or products, when possible. The utensils, employee apparel, and tools should be subjected to an allergen cleaning and sanitation procedure after use and stored in a manner to prevent allergen cross-contact.

- Use dedicated color coded equipment, tools, employee apparel, and utensils for handling allergen-containing ingredients or finished products, when possible.

- Restrict employee movement in facilities to minimize the spread of allergen-containing residues to non-allergen-containing products. Visually identify employees that work on lines

containing different allergens (e.g., different color uniforms). In addition:

  - Restrict personnel from working between processing lines containing allergenic ingredients and non-allergenic ingredients during the same shift.

  - Implement procedures for requesting change of work clothing when employees move from an allergen to a non-allergen area, for example, in dusty environments. Likewise, gloves and hats can be unintended carriers of dust and seeds and should be changed as often as necessary to prevent allergen cross-contact.

  - Initiate controls of personnel movement and practices to prevent allergen cross-contact during breaks and meals.

- Utilize a valve system for closed processing lines to effectively move and clear allergenic and non-allergenic ingredients through the facility. Consider the following when valves are used:

  - Ensure that all valves are clearly marked.

  - Inspect valves routinely for potential leaks.

  - Ensure valves are secured into the appropriate position.

- Control the movement of materials to minimize the spread of allergenic materials throughout the facility.

  - Ensure allergen-containing materials are covered, contained, and identified when in transit in the facility.

  - Move collection bins, totes, and containers with allergen-containing materials, ingredients, and wastes in a manner that prevents allergen cross-contact with other processing lines.

  - Collect and contain waste materials (e.g., spills, defective and unusable products, used ingredient packaging) on a continuous basis, especially those containing allergens, during production. Contain the waste materials in sealable containers such as covered collection bins, totes, and containers. These bins, totes, and containers should be labeled and/or color coded to identify which allergens they contain.

- Develop and implement procedures to minimize aerosolized allergenic material. For example, dust generation and accumulation on equipment can be minimized by adding liquid ingredients to mixers before or at the same time as powders, using dust collection systems (i.e., local exhaust, ventilation systems and/or vacuum systems), controlling surrounding dust sources, and covering equipment.

- Stage allergen-containing materials in designated areas before opening, weighing or transferring them to the processing line. Care should be taken to prevent the allergen-containing materials from spreading outside the staging area(s). Position the staging area(s) so that potential exposure to allergens is minimized, such as locating the staging area immediately near point of entry into the product. The staging location should facilitate the transport of materials to the line without the need to cross other lines where non-allergen-containing products are produced.

- Control of allergen-containing and non-allergen containing oils for fryers. Control can be managed through product scheduling or use of dedicated fryers to minimize the risk of allergen cross-contact.

B. Production scheduling

Controlling the scheduling of production runs can be an effective method for preventing allergen cross-contact. Considerations that should be made are as follows:

- Implement production scheduling to separate the manufacture of allergen-containing products from non-allergen-containing products by time. A separation between allergen-containing products and non-allergen-containing products can be achieved by establishing a production order; that is, producing the foods in a sequence whereby the food with the fewest allergens or no allergen is produced first and the food with the most allergens is produced last, combined with effective allergen cleaning and sanitation procedures between changeover of productions containing different allergens.

- Add the allergenic ingredient as late in the production process as possible to minimize the amount of equipment and the time that the processor's production area comes in contact with the allergen.

- Cluster allergen-containing runs to reduce the number of required changeovers and to reduce the risk of allergen cross-contact.

REWORK AND WORK-IN-PROGRESS (WIP).

The term rework refers to finished or partially finished products that are reincorporated into the manufacturing process. Work-in-Progress (WIP) consists of partially finished products that are between different production stages/ steps. Both rework and WIP can increase the risk of introducing allergens, either by erroneous addition of allergen-containing rework/WIP into a product that does not contain the specific allergen(s) as ingredients, or by cross-contact of allergen-containing materials with non-allergen-containing materials through shared containers or utensils during holding or storage. Since rework/WIP containing an allergen is inherently risky to handle, processors should assess their rework and WIP processes, identify opportunities for cross-contact or accidental inclusion of unintentional allergens, and develop written procedures to prevent their occurrence.

Controls can include:

- Storage of rework and WIP materials in labelled closed containers indicating the contents. The labeling should be consistent with the coding used in your allergenic ingredients controls and identify the product (e.g., intended finished product, batch code, and REWORK, or WIP). Rework/WIP materials collected online and in the processing area should be collected in similarly marked containers. Assume that rework/WIP materials obtained from any step of the production process include all allergens identified in the intended finished product specification.

- Storage of rework and WIP materials in designated areas that are clearly marked.

- Implementation of measures, whenever practical, that require adding rework back into the production of only identical finished product, rather than another product with the same/ similar allergen components. If this is not feasible or practical, predetermine and identify what specific product to which rework materials may be added to and develop a system that tracks and ensures that rework materials are only incorporated into items on that predetermined list. The product specification for each of the predetermined products should identify all the allergens incorporated within the rework materials.

- Implementation of and maintaining a record-keeping system for monitoring allergens for the rework/ WIP material for comparison against the label of the new finished product to ensure the allergens from the rework/WIP material match.

- Attaching information sheet(s) to each container of rework/WIP that identifies the allergen-containing ingredient, name of product, the specific production line the materials will be added to, the date the rework/WIP was produced, and the batch and/or lot number to which the rework/WIP was added.

- Using a recordkeeping system to control, track, reconcile, and inventory rework/WIP. Certain information should be considered as necessary to track the movement of rework and WIP and be identified accordingly.

- Conducting mock internal ingredient traceability drills to assure the facility has the capability of tracing the path and final destination and/ or disposition of all rework, whether or not it was incorporated into finished food products or disposed of due to the lack of a suitable finished product match.

BIBLIOGRAPHY

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The documents are available at that location between 9 a.m. and 4 p.m., Monday through Friday. As of July 2018, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after July 2018.

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