APPENDIX 10: CLEANING AND SANITATION FOR THE CONTROL OF ALLERGENS

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

INTRODUCTION.

Appropriate cleaning procedures are essential for preventing allergen cross-contact in a processing facility, particularly when allergen-containing and non-allergen-containing foods or foods with different allergen-containing components are manufactured on the same processing lines. Cleaning is also essential for preventing transfer of allergens from soiled containers, utensils, employee apparel (e.g., aprons and gloves), and tools into food products. The main purpose of an allergen cleaning program is the removal of the allergens from areas of the processor, including processing and packaging equipment, food-contact surfaces, storage, employee wardrobe, and in the processing and packaging environment. It is important to understand that cleaning procedures targeting microbial hazards may not be adequate for allergen removal and therefore a processor will need to assess the adequacy of their cleaning and sanitation program(s) to ensure it is effective to remove allergens and prevent allergen cross-contact. This appendix has been created to assist a processor in developing a sanitation program and/or assess their current program to determine its adequacy and efficacy. The development and oversight of cleaning and sanitation controls require an understanding of allergens and the health hazard they present in addition to effective methods for cleaning and sanitation.

An effective sanitation program includes procedures, practices, and processes to ensure a facility is maintained in a condition that significantly minimizes or prevents the hazard of allergen cross-contact. The sanitation program should implement procedures and monitoring for the following:

- Cleanliness of food-contact surfaces, including food-contact surfaces of utensils, staff wardrobe, and equipment; and
- Employees overseeing this program should possess an understanding of the allergen hazard and the principles for control of cross-contact that are required to execute the program.

The following recommendations do not apply to every type of processor and situation. FDA has identified these recommendations as a means of assisting processors as foundational information for them to better understand and evaluate or create a cleaning and sanitization program based on the needs of their facility. These recommendations and considerations will assist a processor create and implement an effective cleaning and sanitation program for the control of allergens. FDA does not legally require processors to adopt the following sanitation and cleaning recommendations for the control of allergens. However, these recommendations and considerations will assist the processor comply with the regulatory requirements of the seafood HACCP regulation.

CLEANING CONTROLS FOR ALLERGENS.

A processor that uses allergenic ingredients should evaluate the risk of allergen cross-contact and implement cleaning methods that effectively prevent or eliminate allergen cross-contact when necessary. The cleaning methods should be appropriate for the processing environment, the equipment, the type of product/ingredient, and the identified allergen. The development and oversight of the cleaning methods may also require technical expertise in the characteristics of food allergens, types of food contact surfaces, additional cleaning procedures, and/or specific cleaning chemicals, in addition to routine cleaning protocols.

Development of written sanitation standard operating procedures (SSOPs) for allergen management is a helpful tool that can ensure the desired results and a consistent application of controls. Written procedures to include:

- All instructions necessary to ensure that equipment and utensils are effectively cleaned and sanitized along with instructions for monitoring of cleaning procedures and verifying cleanliness, including:
    - Identify what is intended to be cleaned (e.g., processing and transport equipment, utensil, food contact surface);
    - Define a frequency of cleaning specific to the removal of targeted allergenic food residues. This frequency may vary dependent upon processing schedules, the type of equipment used, products produced, and the allergens involved. The frequency should consider risk of cross-contact and be consistent with cGMPs;
    - Provide detailed instructions on equipment breakdown for cleaning, if appropriate;
    - Define specific protocols, chemicals, concentrations, temperature set-points, solution flow rates, or any other factors that are critical to the effectiveness of the cleaning process. Cleaning treatments should be appropriate for their specific use and that directly apply to the products and processes in the facility. For example, cleaning treatments required for removing allergenic food pastes are different from cleaning treatments required for removing allergenic foods that are in a liquid form. The methods should be based on validation studies that are either conducted by the processor or by outside agents (e.g., chemical or equipment manufacturer, scientific study);
    - Require use of freshly prepared cleaning solutions rather than reuse of cleaning solutions whenever possible. Reused cleaning solutions may not be effective at removing allergenic food residues and may also cause recontamination of surfaces with allergenic food residues. Reuse of cleaning solutions should be limited, however, if re-used cleaning solutions are used, then their effectiveness in allergen removal should be verified;
    - Establish written verification procedures, when appropriate;
    - Conduct verification testing using analytical methods (e.g., allergen-specific enzyme-linked immunosorbent assay (ELISA) kits; lateral flow devices (LFD) or dipsticks; protein swabs; adenosine triphosphate (ATP) swabs (or general protein swabs); or polymerase chain reaction (PCR) methods). Examples of use included:
        - Consider using qualitative ELISA testing of cleaned surfaces in combination with quantitative ELISA testing of finished product to validate allergen cleaning procedures;
        - ATP swabs can be used during ongoing verification of cleaning when they have been documented to function adequately for this purpose during the validation process. It is not recommended to use ATP swabs alone for allergen cleaning verification since ATP is present in most foods and is not a specific indicator for allergens;
        - Consider using these analytical methods on both the equipment **and** the rinse water to verify the removal of allergens if the facility utilizes clean-in-place (CIP) protocols;
        - When a product contains two or more allergens, validation procedures using analytical techniques should focus on the highest percent allergen within the formula or other considerations, such as allergens that are the most difficult to remove from the food processing environment;
        - Validate the efficacy of the analytical method(s) using a competent or accredited laboratory or trained personnel.
    - Ensure that the cleaning practices and procedures do not result in transfer of allergens to other areas of the facility and prevent the dispersal of allergenic materials during the cleaning process:

- Describe protocols for segregating, isolating and holding dirty equipment awaiting cleaning;
- Protect the clean equipment and clean areas from recontamination from allergenic materials;
- Prevent cleaned equipment from contact with overspray during cleaning of floors, walls, ceiling or other equipment;
- Use vacuums equipped with filters designed to capture allergenic particles to remove loose, dry particles from surfaces. Other cleaning methods may be needed to remove residues not removed with a vacuum cleaning step;
- Avoid the use of compressed air and grit blasting for removing food residue from difficult-to-clean areas or protect other equipment or areas from allergenic materials during cleaning. Compressed air and grit blasting can disperse allergens from one area to another;
- When overspray from a high-pressure water hose affects nearby food contact surfaces procedures should be in place to ensure affected food contact surfaces are adequately cleaned to prevent allergen cross-contact. Another option would be to avoid using high pressure water hoses that could spread and aerosolize allergenic materials during cleaning or protect other equipment or areas from allergenic materials during cleaning.

- Establish written **validation** procedures when necessary to ensure that cleaning methods are effective at removing allergenic food residue. They may include how to conduct visual examinations, identify testing methods, and frequency of verification. Visual monitoring should be conducted when equipment is still disassembled after cleaning. This applies to products where single or multiple allergens are utilized on the same processing equipment (e.g., fish, milk, wheat, eggs, tree nuts, peanuts, and/or soy in hot filled (soups), shrimp and French fries cooked in same oil fryolators; and batter/breading equipment of fish or non-fish products):
    - Conduct validation studies of the effectiveness of using "push-through" methods to clean food-contact surfaces to establish the critical factors for the process. Push-through methods are used when the processor pushes finished product (e.g., specific quantity of finished product from the following product cycle), salt, flour or other material through the processing line as a method to remove the allergens. Determine the amount of time or volume of material needed to purge all allergenic food from each piece of equipment cleaned with a "push-though" treatment to ensure that all equipment surfaces are "allergen clean";
    - Use CIP systems to clean processing equipment with validated protocols that have been examined for their effectiveness. CIP systems are beneficial because cleaning is automated and can be applied consistently once procedures are validated and monitored accordingly;
    - Validation of cleaning procedures should occur: at least annually; when introducing a new product(s) or allergenic ingredient(s); when introducing or implementing new cleaning procedures, equipment, or chemicals; or when modifying (reducing) cleaning frequencies.

SAMPLING PLAN IN SUPPORT OF VERIFICATION AND/OR VALIDATION ACTIVITIES.

Obtaining and analyzing samples from hand-held tools, employee apparel (e.g., aprons and gloves), equipment surfaces, rinse water, push-through material, ingredients and final product for the presence of allergenic food residue can help support and verify processor's sanitation control program.

Consider the following:

- Establish sampling procedures, which includes the identity of the allergen, the type of sample (e.g. ingredient, equipment surface, push-through material and/or rinse water), the amount of sample to take at each location, and the collection method (e.g. swab or container).
- Predetermine the locations for sampling on equipment surfaces taking into consideration areas that can be considered potentially food contact or directly impact food contact surfaces and are difficult to clean.

- Develop a valid sampling plan to accurately represent the condition of what is being sampled and the outcome of the cleaning and sanitation procedures for all pieces of equipment.

- Ensure that the sampling plan includes all the equipment where allergen build-up could occur, or residual allergenic proteins could be trapped [e.g., pneumatic lines (product contact) conveyor belts, fillers, mixers, silos, bulk tanks, packaging equipment, hand utensils, shovels, scrapers, aprons, and gloves]. The identification of equipment should be based on the processor's practices and allergenic ingredients.

- Obtain equipment pre- and post-cleaning swabs at multiple locations on each processing line. Swabs obtained pre-cleaning serve as positive control samples. When multiple lines are used, sample all lines for presence of allergenic food residue pre- and post-cleaning.

- Obtain push-through samples at multiple locations in the processing line. When multiple lines are used, obtain push-through samples for all processing lines.

- Use validated analytical testing procedures that are specific to the targeted allergen(s) and the type or matrix of sample(s) to be tested. Monitor analytical test kits to ensure they have not expired.

- Ensure that the proper control samples are used in all analyses and that the analytical method demonstrates an acceptable sensitivity, specificity, and reproducibility for detection of the targeted allergen.

- Define the final criteria for acceptance of analytical results.

- Establish and implement a training program for personnel who will collect samples and perform the analyses.

- Periodically, verify in-house testing by using an independent laboratory.

- Establish and implement corrective actions that address finished products that were affected by potential cross-contact conditions and correct the condition to prevent recurrences of the deviation (e.g., evaluating cleaning methods, conducting validation studies, re-training staff, and/or modifying operating procedures.)

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.

- Deibel, K., T. Trautman, T. DeBoom, W. Sveum, G. Dunaif, V. Scott, and D.Bernard. 1997. A Comprehensive Approach to Reducing the Risk of Allergens in Foods. *Journal of Food Protection*, 60: 436-441.
- Food Allergy Research and Resource Program, and University of Nebraska. 2009. Components of an effective allergen control plan: A framework for food processors.
- Fu, T., L. Jackson, K. Krishnamurthy, and W. Bedale. *Food Allergens: Best Practices for Assessing, Managing and Communicating the Risks*. Food Microbiology and Food Safety. Springer
- Jackson, L., R. Al-Taher, M. Moorman, J. DeVries, R. Tippett, K. Swanson, T. Fu, R. Salter, G. Nunaif, S. Estes, S. Albillos and S. Gendel. 2008. Cleaning and Other Control and Validation Strategies to Prevent Allergen Cross-Contact in Food-Processing Operations. *Journal of Food Protection*. 71: 445-458.
- Stone, W., and K. Stevenson. 2009. Managing Allergens in Food Processing Establishments 4th Edition. Grocery Manufacturers Association.

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