

# Food Allergen Controls Table:

## FSMA Revisions of Food Allergen cGMPs

**T**he proposed Preventive Controls rule of the Food Safety Modernization Act would revise several provisions of cGMP part 110 to address allergen cross-contact, make it clear that cGMPs require protection against such cross-contact, and ensure that they continue to address health concerns related to allergens.

Following is a summary table of that created by FDA to identify the cGMP to be revised, detail the proposed requirement, clarify the reasoning for the requirement, and explain the proposed revisions and associated action(s).

Although FDA notes that the table does not include all requirements for allergen controls, stating that readers should visit [www.federalregister.gov](http://www.federalregister.gov) for the complete rule, the details of the table do provide a great deal of information and a good starting point in preparing for implementation of the final FSMA rules related to allergens. Read the full story in the *Food Allergen Controls: A Top Priority of Risk Management* (QA November/December, pages 42-43).

	<b>Section # and Clarification of Reasoning</b>	<b>Requirement for Action</b>
<b>Cleanliness</b> § 110.10(b) & (b)(9)	XI.E.1. Poor hygiene may result in the transfer of food allergens from persons working in direct contact with food, food-contact surfaces, and food-packaging materials to food.	<ul style="list-style-type: none"> <li>• All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against cross-contact and contamination of food.</li> <li>• All such persons must take any other necessary precautions to protect against the cross-contact of food.</li> </ul>
<b>Cleanliness</b> § 110.10(b)(1)	XI.E.1. Appropriate use of outer garments protects against the transfer of food allergens from food to person to food.	<ul style="list-style-type: none"> <li>• The methods for maintaining cleanliness must include wearing outer garments suitable to the operation in a manner that protects against the cross-contact of food.</li> </ul>
<b>Plant construction and design</b> § 110.20(b)(2)	XI.F. Inadequate construction and design of a plant can result in the transfer of food allergens to food. Separation of operations is a key means of preventing cross-contact.	<ul style="list-style-type: none"> <li>• The plant buildings and structures must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing packing, and holding) and would require that specific construction and design requirements apply to the “plant” rather than the “plant and facilities”.</li> </ul>
<b>Plant construction and design</b> § 110.20(b)(6)	XI.F. Inadequate construction and design of a plant can result in the transfer of food allergens to food. Proper ventilation, e.g., over powder dumping operations, and proper operation of fans and other air-blowing equipment are essential to prevent the transfer of allergens via dust in air currents. Additionally, separation of operations is a key means of preventing cross-contact.	<ul style="list-style-type: none"> <li>• The plant must take proper precautions to reduce the potential for cross-contact of food, food-contact surfaces, or food-packaging materials through adequate food safety controls and operating practices or effective design, including the separation of operations in which cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.</li> <li>• The plant must provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may cross-contact food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for cross contact of food, food-packaging materials, and food-contact surfaces.</li> <li>• The plant must be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties</li> </ul>

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		and to protect from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.
<b>General maintenance</b> § 110.35(a)	XI.G.1. Improper cleaning and sanitizing that leaves food residues on utensils or equipment may result in the transfer of food allergens from utensils or equipment to food, food-contact surfaces, or food packaging materials that come in contact with the improperly cleaned and sanitized surfaces.	<ul style="list-style-type: none"> <li>• Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials.</li> </ul>
<b>Sanitation of food-contact surfaces</b> § 110.35(d) & (d)(2)()	XI.G.4. Inadequate sanitation of food-contact surfaces may leave residues of food containing allergens on the surfaces and result in the transfer of food allergens from food-contact surfaces to food.	<ul style="list-style-type: none"> <li>• Food-contact surfaces used for manufacturing/processing or holding low-moisture food must be in a clean condition at the time of use.</li> <li>• All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against cross-contact and contamination of food.</li> <li>• In wet processing, when cleaning is necessary to protect against cross-contact and the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated.</li> </ul>
§ 110.35(d)(3) (Sanitation of non-food-contact surfaces)	XI.G.5. Inadequate sanitation of non-food contact surfaces may leave residues of food containing allergens on the surfaces and result in the transfer of food allergens from such surfaces to food-contact surfaces or food. As such cleaning of non-food contact surfaces protect against cross-contact	<ul style="list-style-type: none"> <li>• Non-food-contact surfaces of equipment used in the operation of a food plant should be cleaned in a manner and as frequently as necessary to protect against cross-contact and contamination of food, food-contact surfaces, and food-packaging materials.</li> </ul>
§ 110.35(d)(4) (Sanitation of food-contact surfaces)	XI.G.4. Failure to properly store single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) could lead to cross-contact.	<ul style="list-style-type: none"> <li>• Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and must be handled, dispensed, used, and disposed of in a manner that protects against cross-contact and contamination of food, food-contact surfaces, or food-packaging materials.</li> </ul>
§ 110.35(e) (Storage and handling of cleaned portable equipment and utensils)	XI.G.6. Failure to properly store and handle cleaned portable equipment and utensils could lead to cross-contact of the equipment and utensils and then to cross-contact of food if the equipment and utensils come in contact with food.	<ul style="list-style-type: none"> <li>• Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from cross-contact and contamination</li> </ul>
§ 110.40(a) & (b) (Equipment and utensils)	XI.J.1. Inadequate processes and controls practices may result in the transfer of food allergens to food.	<ul style="list-style-type: none"> <li>• Reasonable precautions must be taken to ensure that production procedures do not contribute to cross-contact and contamination from any source.</li> <li>• Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible cross-contact and food contamination.</li> </ul>
§ 110.80(a)(1) (Processes and controls—raw materials and ingredients.)	XI.J.2. Raw materials and ingredients subject to cross-contact due to improper segregation prior to receipt or during storage may result in undeclared allergens in food.	<ul style="list-style-type: none"> <li>• Raw materials and ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and be stored under conditions that will protect against cross-contact and contamination, and minimize deterioration.</li> <li>• Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food or cause cross-contact.</li> </ul>

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§ 110.80(a)(5) & (7) (Processes and controls—raw materials and ingredients.)	XI.J.2. Improper handling of raw materials and ingredients may result in the transfer of food allergens to food.	<ul style="list-style-type: none"> <li>• Raw materials, ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against cross-contact as well as against contamination.</li> <li>• Liquid or dry raw materials and ingredients received and stored in bulk form must be held in a manner that protects against cross-contact and contamination.</li> </ul>
N/A	XI.J.2. Cross-contact may be associated with improper identification and holding of raw materials and ingredients that are food allergens, and rework that contains food allergens. Improper identification of an allergen-containing raw material, such as a seasoning mix that is not identified as containing soy protein, can result in the unintended incorporation of an allergen into a food (i.e., cross-contact). Improper holding, e.g., storing open-containers of raw materials or ingredients, including those containing allergens, in the same location can result in cross-contact.	<ul style="list-style-type: none"> <li>• Raw materials and ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents cross-contact.</li> </ul>
§ 110.80(b)(5-7, 10-13) (Processes and controls—manufacturing operations)	XI.J.3. Manufacturing operations may result in the transfer of food allergens to food. “Rework” is defined to mean clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. As with work-in-process, improper handling of rework could result in cross-contact, contamination, or growth of undesirable microorganisms.	<ul style="list-style-type: none"> <li>• Work-in-process and rework must be handled in a manner that protects against cross-contact.</li> <li>• Effective measures be taken to protect finished food from cross-contact and contamination by raw materials, ingredients, or refuse.</li> <li>• When raw materials, ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in cross-contact or contaminated food.</li> <li>• Food transported by conveyor must be protected against cross-contact and contamination as necessary.</li> <li>• Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food be constructed, handled, and maintained during manufacturing, processing, packing and holding in a manner that protects against cross-contact and contamination.</li> <li>• Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against cross-contact.</li> <li>• Food should be protected from contaminants that may drip, drain, or be drawn into the food batters, breading, sauces, gravies, dressings, and other similar preparations be treated or maintained in such a manner that they are protected against cross-contact and contamination.</li> <li>• Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against cross-contact.</li> </ul>
§ 110.93 (Warehousing and distribution)	XI.K. Inadequate storage and transportation conditions may result in the transfer of food allergens to food.	<ul style="list-style-type: none"> <li>• Storage and transportation of food must be under conditions that will protect against cross-contact of food in addition to protecting against contamination.</li> </ul>

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