

FDA HAZARD GUIDE APPENDIX 1 COMMON PROCESS-RELATED AND FACILITY-RELATED HAZARDS

BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment For example, a heat treatment that is not properly delivered (e.g., the temperature is too low, or the heating time is insufficient) could allow a pathogen to survive; in some cases, the surviving pathogens could subsequently grow and produce toxin.
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control For example, a cooling mechanism that does not function as intended could allow a small number of microbial pathogens to increase in number.
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control For example, if insufficient acid is added to reduce the pH sufficiently in an acidified food, pathogenic sporeformers could grow and produce toxin.
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging For example, reduced oxygen packaging that is used to increase shelf life could create an environment that supports the growth of C. botulinum.
	Bacterial pathogens – Presence due to ingredients added after process controls
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity For example, if a container is not properly sealed and it is cooled in water, water containing pathogens can be drawn into the container.
	Environmental pathogens – presence due to recontamination from the processing environment For example, equipment that is difficult to clean or is prone to damage could increase the risk for environmental pathogens to contaminate the product post-processing.
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label Examples include: a label printed incorrectly, labels are not changed after product formulation changes, and when a label is applied to the wrong product.
	Unintended food allergen presence – allergen cross-contact Shared equipment is not properly cleaned after running a product containing a food allergen, unintentional addition of the wrong ingredient [that contains a food allergen].
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5) Examples include: misformulation can occur when some products are manufactured/processed with added sulfites and other products without sulfites, and sulfites are unintentionally added to a product that does not include sulfites in the product recipe or when ingredients with a maximum use level for safety, e.g., preservatives, are added over the allowed maximum usage level.
	Process-contamination hazards in certain plant-based foods (e.g., acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils) For example, some chemical hazards (such as acrylamide in certain plant-based foods and 3-monochloropropane-1,2-diol esters (3-MCPDEs) and glycidyl esters (GEs) (developed in some refined oils)) have the potential to form during food production, particularly at high temperature.
PHYSICAL HAZARDS A1.7.3	Metal For example, a process that uses a metal chopping blade could introduce metal fragments if the blade breaks.
	Glass (when product packed in glass) For example, a product packaged in glass containers could introduce glass fragments if a container breaks.
	Hard Plastic For example, hard plastic can be introduced into food when tools and equipment such as scoops, paddles, buckets, or other containers develop fatigue, crack, and break as they wear, or when plastic sieves and screens deteriorate.