The following list may be used as a guide for food packaging manufacturers and auditors of food packaging manufacturers for potential food safety risks that may be associated with the various types of packaging materials. This list is not all inclusive and does not eliminate the need for a thorough food safety risk assessment. Evaluation of potential food safety risk must be done for the entire process and performed from the perspective of the consumer. Also, some hazards may not be true food safety but in some cases could be perceived as food safety issues (e.g., chemical odor migration). Many of these hazards may be controlled by strong prerequisite programs but some may require being considered Critical Control Points (CCPs) in a HACCP plan or equivalent food safety focused control plan.

Potential Food Safety Risks and Possible Controls for Food Packaging Materials

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
ALL PRINTED PACKAGING MATERIALS	
The following issues and controls may be applicable to most printed materials (labels, cartons, rigid plastic containers, lids, film, pouches, sleeves, …)	
Printing error—allergen ingredient left off of ingredient line *(potential for unlabeled allergen after food is packaged)*	▪ Controls at customer providing print proof copy to assure proof copy and file to make plates is accurate ▪ Controls at printing press to assure print from the line matches proof copy
Wrong printing plates used *(potential for unlabeled allergen after food is packaged)*	▪ Controls to archive or destroy old plates and old print files ▪ Controls in place at press to verify that print matches proof copy that is scheduled
Rework process allowed for materials to be mixed *(potential for unlabeled allergen after food is packaged)*	▪ Strict controls for rework procedures (only 1 material reworked at a time or no rework allowed) ▪ Controls to identify/label rework correctly ▪ Work procedures for in-process rework that assure that rework us used during the same production run if possible (vs. being set aside which allows potential to rework into the next run by mistake)

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
ALL PRINTED PACKAGING MATERIALS	
Returned goods mixed with non-like materials *(potential for unlabeled allergen after food is packaged)*	▪ Strict controls for identification and storage of returned goods. Strict rework controls utilized if material is to be reworked.
Incorrect label applied to identify finished goods (units, cases, rolls, and pallets) *(potential for unlabeled allergen after food is packaged)*	▪ Controls for pre-printing case labels, core tags (rolls), and pallet labels. ▪ Account for all labels printed, destroy or segregate any left-over printed unit labels ▪ Vision systems to verify that case label matches material within the case and matches the pallet label
Mixed materials within a case or on a pallet due to inadequate/incomplete line clearance procedures (cases, rolls, etc.) *(potential for unlabeled allergen after food is packaged)*	▪ Strict line clearance/changeover procedures throughout the process including all equipment areas, partial cases, partial pallets, cases on conveyors, quality check samples, rework, etc. ▪ A detailed checklist must be used and a second verification utilized to assure that no materials from the previous run are inadvertently left on the line
Mixed materials on a pallet—manual or automatic palletizing *(potential for unlabeled allergen after food is packaged)*	▪ Bar code scanners and sorting devices to separate cases on a common conveyor to divert to the correct palletizing area ▪ Color coded case labels to assist in correct palletizing for manual palletizing operations ▪ Full pallet scanners to scan the exterior labels on a pallet to assure all are correct

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
ALL PRINTED PACKAGING MATERIALS	
HUMAN ERROR— Note that human error is one of the main causes of many of the mixed material issues	▪ Adequate training of employees, management commitment to food safety, and reinforcement are essential to prevent potential for food safety issues ▪ Documented work procedures, employee accountability ▪ Implementation of multiple systems may be required to adequately control the risk in some processes (vision systems are good if applicable to the process) ▪ Some packaging manufacturers have found that positive reinforcement for employees identifying potential issues or preventing or reducing issues at the customers to be successful
Inks not approved for specific use *(potential chemical or odor migration into food)*	▪ Regulatory (FDA) approval letters for specific use (food contact, incidental contact, non-food contact)
Inks containing potentially allergenic materials (e.g., soy-based) *(potential for allergen contact to food after packaging if material is printed on food contact material)*	▪ Inks containing potential allergenic materials must be coated with an appropriate coating to prevent exposure of the allergen (for product contact surfaces)
Coating layer over printing not adequate or not suitable for use for food packaging *(potential chemical or odor migration into food—of particular concern if ink is touching product contact surface of packaging, e.g., nested printed rigid plastic cups, rolls of film, stacks of flat cartons, etc.)*	▪ Controls in place to assure coating layer over print is adequate and correct coatings (GRAS or FDA approved) are used for specific application

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
CUT AND STACK LABELS	
Cut and Stack Labels are printed on large sheets and could be printed on sheet-fed or roll-fed printing presses. Printing more than 1 SKU on a sheet is discouraged (or may not be allowed by the customer), however, with some products may not be able to be avoided. After printing the sheets, the stacks of sheets are typically cut into rows and then rows are die-cut into desired shape of labels. The stacks of labels may be shrink wrapped and ultimately placed into cases and palletized.	
Mixed labels within a stack or a mislabeled stack due to the top label being incorrect *(potential for unlabeled allergen after food is packaged)*	▪ Prohibit combo printing (multiple SKUs on each sheet)—design layout with only 1 SKU printed on a sheet at a time <u>If combo printing must be used</u>: ▪ Design print layout so that print faces with like allergens or duplicate faces are side by side ▪ Design print layout so that print faces have different die cut shapes that are side by side (so if they were mixed it would be obvious that it was the wrong label when applied to the finished food package) ▪ Print tick marks on labels to differentiate between SKUs (utilize different colors, location on labels, size and appearance of mark (e.g., single vs. double line) ▪ Train operators to watch for and correct issues if sheets move after slitting and slide onto the adjacent row ▪ Train operators at die cut operation to check dies between SKUs to make sure that labels are not stuck in die (and could cause next stack to have the wrong label on top)

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
CUT AND STACK LABELS	
Mixed stacks of labels within a case *(potential for unlabeled allergen after food is packaged)*	▪ Train operators to be diligent when sorting and packing stacks into cases ▪ Utilize vision systems to sort stacks ▪ Utilize vision systems to read the top labels of stacks in a case and compare to case label to assure all stacks within a case are the same and match the case label (scanners can not be utilized to check all labels within a stack as labels are not handled individually) ▪ Assure reject or alarm mechanism for mixed cases is working properly and can not be by-passed by human error (putting a case back on the line that was rejected without checking it) ▪ Complete material inventory reconciliation (if all materials are accounted for inventory reconciliation could identify if labels were mixed due to one SKU being short and another with excess when comparing material printed and final quantities)
Mixed materials or mixed cases on a pallet *(potential for unlabeled allergen after food is packaged)*	▪ Complete and thorough line clearance procedures to assure all material from the previous run is cleared from line—utilize a detailed checksheet and have a second person verify that line is cleared of all materials (2nd person visually check line not just the paperwork) ▪ Removal of all partial cases and partial pallets ▪ Removal of any Quality check samples remaining in the area ▪ Removal of rework from the area (identify and store properly or destroy per procedures) ▪ Removal of all cases or bundles on conveyors

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
PRESSURE SENSITIVE LABELS	
Pressure sensitive labels are typically printed on roll-stock through a printing press and excess material is cut out and pulled off with labels remaining on roll-stock. Rolls may go through re-winding/finishing process after printing process to verify print quality and make rolls with label quantities and sizes per customer specifications.	
Roll contains mixed labels due to splice *(potential for unlabeled allergen after food is packaged)*	▪ Strict controls for splice procedures to prevent inadvertent splicing of unlike materials ▪ Utilize vision system (e.g., bar code reader) at rewinder to assure all labels are alike on a roll
Roll contains mixed labels due to tail from previous run attached to new roll (typical process is to leave tail of material inside press rollers to prevent need to re-thread rollers at changeover) *(potential for unlabeled allergen after food is packaged)*	▪ Strict controls at printing press to assure tail of prior run printed material is not allowed to be attached to new roll for next run-- ◦ Run tail from previous run out onto floor and cut off when new material comes through, then attach new material to roll and proceed ▪ Alternatively material left inside press rollers without printing on it-- ◦ Raise printing rollers at press but still leave material inside threaded through rollers at the end of a run—this will result in blank material that could be run directly onto the new roll and cut off at rewinding (easier to identify blank material vs. printed material)

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
PRINTED PAPERBOARD CARTONS (Cut and Stack— Flat, and Glued)	
Note: Paperboard cartons are typically considered secondary packaging but could be considered primary due to foreseeable use (e.g., cereal or crackers falling out of the inside liner and into carton itself). Also, some cartons are primary packaging and used without a liner (e.g., pasta, some cereals, rice, …). Blank paperboard is typically is made at a separate facility than the carton manufacturing facility (or may be purchased externally). Paperboard is printed by sheet-fed or roll-fed printing presses depending on the operation. Printed paperboard is then die cut to the desired carton shape per the customer specs. Flat cartons are shipped in stacks and are folded and glued by the customer. Glued cartons require a separate operation after die-cutting and are fed through equipment where the cartons are folded and the side seams glued prior to stacking/casing/palletizing and shipment to the customer.	
Mixed cartons within a stack or a mislabeled stack due to the top carton being incorrect *(potential for unlabeled allergen after food is packaged)*	▪ Prohibit combo printing (multiple SKUs on each sheet)—design layout with only 1 SKU printed on a sheet at a time <u>If combo printing must be used</u>: ▪ Design print layout so that print faces with like allergens or duplicate faces are side by side ▪ Design print layout so that print faces have different die cut shapes that are side by side (so if they were mixed it would be obvious that it was the wrong label when applied to the finished food package) ▪ Print collation or tick marks on cartons (typically on flaps) to differentiate between SKUs (utilize different colors, location on flaps, size and appearance of mark (e.g., single vs. double line) ▪ Train operators at die cut operation to check dies between SKUs to make sure that labels are not stuck in die (and could cause next stack to have the wrong label on top)
Mixed cartons due to handling errors at casing or palletizing operation *(potential for unlabeled allergen after food is packaged)*	▪ Strict employee training and procedures to prevent mixing of cartons within a case or on a pallet ▪ Utilize vision systems (e.g., bar code reader or collation mark reader) after carton gluing operation to assure cartons are not mixed (can only be used for glued cartons, flat cartons are not handled individually)

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
PRINTED PAPERBOARD CARTONS (Cut and Stack— Flat, and Glued)	
Ink used for interior carton printing *(potential chemical or odor migration into food)*	▪ Ink used for interior carton printing (e.g., coupons or special offers) must be approved for food contact or incidental food contact
Paperboard quality—potential for micro, chemical, or extraneous contaminants	▪ Recycle material utilized by specific type into appropriate board products ▪ Biocide added to pulp slurry to prevent micro growth during process ▪ Chemicals used in process are GRAS or approved for specific use ▪ Foreign material removal systems to eliminate foreign material in recycle pulp ▪ Metal detectors on finished board lines to detect metal

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
PRINTED FILM	
Film may be made with various processes and the finished printed film may be multiple layers of films extruded or laminated together to form a film with the desired properties for the customer. During this process the film may be handled multiple times including re-winding, printing, and various finishing processes to meet customer requirements and roll sizes.	
Roll contains mixed SKUs due to splicing unlike materials together at rewinding or finishing operation *(potential for unlabeled allergen after food is packaged)*	▪ Strict controls for splice procedures to prevent inadvertent splicing of unlike materials ▪ Utilize vision system (e.g., bar code reader) at rewinder to assure all SKUs are alike on a roll
Roll contains mixed SKUs due to tail from previous run attached to new roll (typical process is to leave tail of material inside press rollers to prevent need to re-thread rollers at changeover) *(potential for unlabeled allergen after food is packaged)*	▪ Strict controls at printing press to assure tail of prior run printed material is not allowed to be attached to new roll for next run-- ◦ Run tail from previous run out onto floor and cut off when new material comes through, then attach new material to roll and proceed ▪ Alternatively material left inside press rollers without printing on it-- ◦ Raise printing rollers at press but still leave material inside threaded through rollers at the end of a run—this will result in blank material that could be run directly onto the new roll and cut off at rewinding (easier to identify blank material vs. printed material)
Functional barrier or odor migration issues due to incorrect resin used *(barrier issues could lead to spoilage or micro issues, incorrect resin could cause odor or chemical issues)*	▪ Controls in place to assure only correct resins are used. ▪ Resins for film for food products must be approved by regulatory (FDA) for specific food use ▪ Controls in place to prevent non-food approved resins from mixing with resins to be used for food packaging film

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
PRINTED FILM	
Film quality issues make functional barrier inadequate—package leakage *(barrier issues could lead to spoilage or micro issues dependant on type of food product)*	▪ Process parameters monitored at a frequency to assure material is produced per specification ▪ Quality check procedures verify film is within specifications ▪ Material that is out-of-spec is identified and segregated for disposition or rework
Potential for extraneous material, chemical, or microbiological contamination from raw materials, equipment, or environment	▪ Controls in place during manufacturing and finishing processes to prevent contamination from equipment or the environment (e.g., film not allowed to touch floor between rollers or other processes, building and equipment maintained so as not to be a source of contamination (e.g., no roof leaks), lubricants with potential for product contact food grade, lights in process area shielded, etc.) ▪ Rare earth magnets may be needed for bulk ingredients (unloading or later in process prior to melting resin pellets) ▪ Metal detection is not typically used for film, but may be used in some applications
Compressed air used on product contact surfaces *(could post potential for micro or chemical contamination)*	▪ Air used on product contact surfaces must be of acceptable micro quality (filtered) for the type of material being made (e.g., air used for film for dairy products needs filtration to prevent micro contamination) ▪ Compressors for food contact air must be oil-free or use food approved oil and filtered to remove oil prior to use
Cooling Water used in contact with film *(potential for micro or chemical contamination)*	▪ Cooling water may be used for film in some specific applications—if recirculated it must be treated to prevent microbiological growth and tested at a designated frequency to verify potability. Alternatively single pass potable water could be used
Processing aids approved for specific use *(potential chemical contamination if not approved for specific use)*	▪ Process aid materials must be approved for incidental food contact if appropriate

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
Rigid Plastic Containers and Lids	
Rigid plastic containers and lids are typically produced from injection molding (hot melted resin injected under pressure into a mold, then excess cut away) or from thermoforming (a sheet of plastic material is heated and pressed into the desired shape, cut out, etc..). Printing (decorating) typically occurs in a separate process following the molding/forming processes.	
Potential for extraneous pieces of plastic inside containers *(potential for physical hazard)*	▪ Vacuums, air blows, or other removal/cleaning devices in place and functional in thermoform and molding processes to remove excess material after forming and cutting (as applicable for specific process)
Potential for metal contamination from materials, equipment, or process *(potential for physical hazard)*	▪ Typically screens are in the process to prevent extraneous from entering the equipment. Screens must be on a routine inspection schedule to prevent the screen from becoming a source of the contamination itself ▪ Metal detection or x-ray may be needed based on the type of material, the process, and history of issues ▪ Incoming bulk materials may need rare earth magnets at the unloading area or in the process prior to melting the resin pellets
Compressed air used on product contact surfaces *(potential for micro or chemical contamination)*	▪ Air used on product contact surfaces must be of acceptable micro quality (filtered) for the type of container being made (e.g., cups for cold fill dairy products need filtration to prevent micro contamination) ▪ Compressors for food contact air must be oil-free or use food approved oil and filtered prior to use
Processing aids approved for specific use *(potential chemical contamination if not approved for specific use)*	▪ Mold release agents must be approved for incidental food contact if appropriate (e.g., cups will be nested after forming and outside of cup will touch inside of the next cup

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
Rigid Plastic Containers and Lids	
Plastic quality issues make functional barrier inadequate—package leakage *(barrier issues could lead to spoilage or micro issues dependant on type of food product)*	▪ Process parameters monitored at a frequency to assure material is produced per specification ▪ Quality check procedures verify containers and/or lids are within specifications ▪ Material that is out-of-spec is identified and segregated for disposition or rework
Functional barrier or odor migration issues due to incorrect resin used *(barrier issues could lead to spoilage or micro issues, incorrect resin could cause odor or chemical issues)*	▪ Controls in place to assure only correct resins are used. ▪ Resins for containers for food products must be approved by regulatory for specific food use. ▪ Controls in place to prevent non-food approved resins from mixing with resins to be used for food packaging containers

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
Glass Jars and Containers	
Glass container production involves a continuous process where molten glass is formed, typically in 2 stages, then cooled, inspected electronically, cased or bulk palletized, then shipped to the consumer. Defects that are culled out either by defective mold number or by inspection devices are reworked back into the process, as with recycle glass received as a raw component of the glass manufacturing process.	
Potential for extraneous pieces of glass in jars or containers due to breakage in manufacturing process *(potential risk of injury to consumer)*	Glass breakage prevention and controls: ▪ Line layout to minimize potential for contamination when breakage occurs—lines covered past cleaning devices (if present) ▪ Surface coatings adequately applied to minimize friction in container to container contact ▪ Electronic vision systems in place to detect: glass defects, extraneous glass in jars, seal defects, other… ▪ Vision systems must be set up with actual glass defects from jars/bottles being run ▪ Reject devices must be set-up to accurately reject the identified defective container ▪ Mold reader reject devices must be set up accurately to reject the specific mold number identified as defective ▪ Process parameters monitored to assure containers are made per specification ▪ Quality check programs in place and followed by operators
Glass defects made during manufacturing process *(potential risk of extraneous glass or injury, leakage due to seal surface not sealable, potential for breakage at food manufacturer or consumer level)*	Above controls applicable to this as well

Potential Issue (Food Safety Implications)	*Possible Controls (This list is not all inclusive, alternative controls are possible)*
Glass Jars and Containers	
Damage to glass during post-manufacture handling procedures ▪ Bulk palletizing procedures (e.g., forklift squeezes jars and cause potential damage) ▪ Casing procedures (e.g., internal case dividers not inserted properly allowing jar finishes to touch during shipping allowing cracking and breaking of jars) *(potential risk of extraneous glass or injury at food manufacturer or consumer level)*	▪ Procedures must be in place to prevent damage at the palletizing and casing processes. ▪ Periodic inspections of post-manufacture cases or bulk palletized glass to assure that damage has not occurred. ▪ Employees must be aware of potential hazards and prevention measures for glass containers post-manufacture
Glass containers used for hot-fill products susceptible to breakage *(potential risk of extraneous glass or injury at food manufacturer or consumer level)*	▪ Glass containers to be used for hot-fill products must be tested for thermo-shock during manufacturing process to assure containers will withstand the process at the food manufacturer and consumer level
Coatings applied to glass prior to cooling and post-cooling are appropriate and approved for specific use *(potential for chemical contamination if coating not approved for food contact or if hot end does not eliminate the coating)*	▪ Hot end coatings are typically not an issue because they will be burned off in the Lehr—but need to be sure that the coating used is applicable (GRAS for this use) ▪ Cold end coatings must be approved for use for food contact containers (GRAS or other approval)
Compressed air used on product contact surfaces *(potential for micro or chemical contamination)*	▪ Air used on product contact surfaces must be of acceptable micro quality (filtered) for the type of container being made (e.g., jars for cold fill products need filtration to prevent micro contamination) ▪ Compressors for food contact air must be oil-free or use food approved oil and filtered prior to use