

PACKAGING MATERIALS SAFETY

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Overview

- A broad range of substrates comprise the list of approved food contact (direct and indirect) packaging materials
- FDA considers, controls and regulates direct contact packaging materials in the same manner as food ingredients
 - Assumptions are that packaging substrates and all contacting substances can and may be consumed along with the food
- Manufacturers of packaging raw materials and finished, converted packages alike are expected to understand, apply and validate their processes for consistency, quality, safety and adherence to required methods and protocols

Contact Material Regulations

- Direct and indirect contact packaging materials, substances, processing aids, coatings, adhesives and adjunct substances controlled and conditionally approved for use are described and referenced in 21CFR sections 173-182.
- Additional information, directives, procedures and controls may be found in sections of 21CFR dedicated to the specific food type (i.e., package fill level control for certain food categories) Additional sections of 21CFR control and direct GMP (110-111), while others control the packaging of specific food categories and systems (e.g., 113, thermally-processed low acid foods and 129, bottled water)
- 21CFR may categorize foods, ingredients and materials by type, processing method, packaging methods and other qualifiers. Manufacturers and suppliers are strongly advised to consult 21CFR or experts to verify that materials and adjunct substances are approved for each and every intended use.



General Risks

- As with every substance and material connected with the processing and packaging of edibles and comestibles, packaging and related materials are no safer than their components and environments.
- The understanding and proper application of HACCP and related safety control processes represent the cornerstone of Good Manufacturing Practices

Biological Risks

- Although packaging materials are not typically connected with pathogenic outbreaks or biological contamination, manufacturers and converters ARE strongly advised to be vigilant and proactive
 - Implement and maintain a biological program which fingerprints and baselines your operation including:
 - Ambient facility atmosphere (air-flow in each section of the facility where packaging or components reside)
 - Outside air and soil quality (can contamination be coming from neighboring facilities, farms, etc.?)
 - Contact surfaces (not just the production equipment, but the floors, walls and ceilings; or all areas including warehouse and storage).

Biological Risks

- Implement and maintain a biological program which fingerprints and baselines your operation including:
 - Utilities (air handling, HVAC, water, sewer, and compressed gasses, including air)
 - Production equipment and adjunct processes
 - Raw materials (native materials, with special focus on recycle, regrind, rework and bulk storage facilities)
 - “Packaging” of the packaging (bio fingerprint of totes, rail cars, hoppers, FIBCs and other containment devices)

Biological Risks

- Implement and maintain a biological program which fingerprints and baselines your operation including:
 - Pre, in and post process sampling
 - General personnel health and sanitation practices (swab employee contact surfaces, especially high-risk areas.
 - Base your program on the assumption that consumers will ingest your packaging
- When the results return, you will have a comprehensive microbiological baseline to use as a reference going forward, factored by regulatory guidelines and established norms.

Risks of Reusable Support Packaging

- Although packaging materials are not typically connected with pathogenic outbreaks or biological contamination, re-use or improper handling and storage of packaging can and does promote contamination
- Reusable pallets, wooden or plastic, act as hosts for physical, chemical and biological contamination
 - These items may leave your plant uncontaminated, but do they return in the same condition?
 - Who knows what contaminants, trace and otherwise, reside on those items?

Risks of Reusable Support Packaging

- Reusable cartons, gaylords, totes and shippers may harbor pathogens and other contaminants
 - Reusable plastic dairy crates may harbor Salmonella and other pathogens; a recent incident in Oregon resulted in a positive finding of Salmonella, triggering a product recall. The cause – improperly sanitized reusable crates.
 - Reusable corrugated cases, totes or “gaylords” used for shipping bulk product are absorbent paper, which can inadvertently come in contact with contaminants (including pathogens) **anywhere and at any time** including during transportation or other handling within or outside of the manufacturers’ control.

Risks of Reusable Support Packaging

- Wooden or other absorbent reusable accessories are at risk of harboring pathogens and other contaminants
 - Packaging and most other raw materials are shipped on wooden pallets. Sanitary containers (cans and other) are often palletized and secured with wooden “frames”, saved, stacked, stored (by the customer) and returned to the can vendor.. **Wood is extremely absorbent!** Have the frames or pallets absorbed contaminants?
 - **Once returned, that contamination is now in your facility!**
 - The effectiveness of a sanitation or cleaning process for reusable packaging and accessories **must be validated by analysis!**

Reuse of packaging creates risk and requires special handling, testing and analysis to avoid being a source of inbound contamination

Reusable Support Packaging Safety: Best Practices

- Protect yourself against unknown contamination
 - Sequester reusable packaging
 - Assess and document the risks!
 - Customize handling and sanitation procedures for each reusable item
 - High risk (dairy, meat plants etc.) hygiene facilities need to take extra precautions.
 - Perform periodic, routine microbiological testing to validate program
 - Porous and intricate reuse packaging and peripherals are high-risk and may not fully sanitize due to porosity, design and geometry.

Beware of, anticipate and effectively address these risks!

Controlling Biological Risk

- Implement, control and maintain a reliable pest control plan
 - Understand it and challenge the provider for explanations
 - Read, understand and react to the reports. Demand detail.
- Choose qualified and certified providers (labs, microbiologists, pest control, etc.), not the least-cost or the well-known franchise.
- Fully understand where and how microbial and pathogenic contaminations occur. Implement practical preventative measures
- Monitor all areas and processes within your facility for microbiological contamination
- Training is a valuable tool against risky practices. Develop and execute best practices and risk-control employee training

Chemical Hazards

- Chemical risks can occur from multiple sources
 - Defective or mislabeled incoming substrate
 - Allergen contact (even trace amounts may cause illness)
 - Misuse of proper ingredient or processing aid
 - Contact with sanitizers, cleaners, solvents, lubricants, additives etc.
 - Uncured process chemicals (inks, coatings, adhesives etc.)
 - Unexpected adulteration or use of non-food approved components in raw materials
- Suppliers rarely perform surface chemistry or composition tests. Quality and compliance are controlled by quality programs, GMPs, prerequisites and CCPs



Controlling Chemical Hazards

- Verify quality of incoming chemical and polymeric materials through visual, sensory and analytical testing.
- Reduce reliance on CsOA and CsOC
- Consider a random audit program for direct contact materials, especially those sourced from increased risk supply chains
- Implement and validate an effective plan based on internal and external risk analyses.
- Perform frequent internal audits of the plan and processes. Perform mock incidents to evaluate responses and corrective actions.

Physical Hazards

- Physical materials can inadvertently enter the production process
 - Metal (nuts, bolts, random small parts and filings)
 - Wood/Paper (discards, pallet fragments, dust, punchouts etc.)
 - Polymers, rigid and flexible (nylon/Delrin chips, Teflon (slip agents) etc.)
 - Manufacturing defects (flash, burrs, sharp hot melt, mold defects)
 - Laser burn-through (weaknesses, leaks)
 - Glass dust or shards

Controlling Physical Hazards

- Corrective actions
 - Risk awareness
 - Preventative maintenance (schedule and perform)
 - Quality control
 - Sanitation and housekeeping
 - Inspection (visual, x-ray, metal detection)
 - Audits

Controlling Hazards: Paper Packaging

- Microbiological
 - Microbiological laboratory analysis of incoming, in-process and finished goods
 - Never assume that the conversion process is a kill step
 - High % recycle products are high-risk and require aggressive inspections vs. virgin stock
 - Verify cleanliness of equipment, materials and utilities (water, compressed air, etc.)
 - Maintain a practical, reliable, facility-specific internal micro sampling plan
- Chemical
 - Carefully control additives
 - Use reliable vendors
 - Spot audit/analysis of additives and chemicals
 - Execute risk analysis to yield an effective HACCP plan
- Physical
 - Metal detection
 - Audits and inspections
 - Protective packaging

Controlling Hazards: Rigid Containers

- Microbiological
 - Microbiological laboratory analysis of incoming resins, coils, preforms and bodystock
 - Do not assume that conversion is an absolute kill step
 - Maintain a practical, reliable, facility-specific internal micro sampling plan
- Chemical
 - Verify composition of chemicals, additives, adhesives, coatings and inks
 - Implement and verify strict control, storage, usage and testing of contact chemical-based materials
 - Audit raw materials and finished products including laboratory analysis
 - Control and audit supply chain
- Physical
 - Proper inspection and maintenance of conversion equipment
 - Audit finished packages for sharp seams/seals and surface protrusions
 - Maintain and inspect extruders, molds and nozzles
 - Metal detection or high-speed camera inspection where possible
 - Implement safety procedures and appropriate process control for glass

Controlling Hazards: Flexible Films

- Microbiological
 - Maintain a practical, risk-based micro-evaluation program for facility, process and materials
- Chemical
 - Carefully control and analyze adhesives, inks and other liquid chemical-based conversion materials
 - Carefully monitor ink and coating application and curing with strict adherence to manufacturer instructions and guidelines
 - Strict control of PMs, sanitation and process control
 - Audits, sampling plans, sensory and laboratory analysis of films and resins
 - Analysis of embedded active compounds for adherence to spec limits
- Physical
 - Frequent inspection of finished rolls and process equipment
 - Timely PMs and wear-part changeouts at required intervals

More on Packaging Safety

For more information about packaging safety, please visit:
<http://www.ehagroup.com/food-packaging-safety/>

