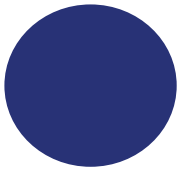


Recognizing and Avoiding Food Packaging Safety Related Risks



A Materials Safety Guide for Manufacturers, Converters, Vendors And End Users of Food Packaging





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About EHA Consulting Group Inc.

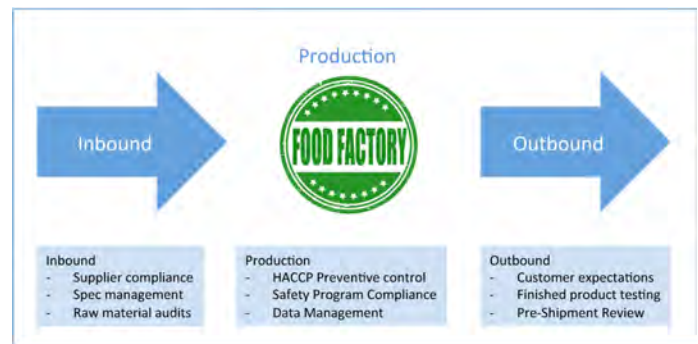
EHA Consulting Group, Inc. (EHA) offers comprehensive public health consulting, epidemiology and food packaging safety services before, during and after a crisis. EHA provide food and food packaging-related services to Retail Food, Food Service, Food Processing, and Contract Food Service Management companies.

Need our Services? Call us today at 800-969-1441.

C1

Introduction

“Supply chain partners are often ill-prepared to understand, identify, and mitigate risks relating to preparation, expectations, and application of basic food (packaging) safety programs.”



This food packaging safety guide is intended to assist suppliers, vendors, and manufacturers of packaging materials used in connection with comestibles. The guide will help readers identify, prepare for, and prevent contamination and unsuitability risks from packaging materials, manufacturing processes, handling, storage and other steps in the supply chain.

The implementation of the Food Safety Modernization Act (FSMA) has put all food and food materials manufacturers, processors, handlers and suppliers on notice that safety is of the utmost concern to Federal authorities and regulators. Before FSMA was signed into law, suppliers to the domestic food chain were “urged” to understand and implement programs intended to decrease the risk of food safety “events”. When that process was found to be insufficient due to a perceived increase in consumer harm due to physical, chemical and biological contamination or unsuitability, Congress legislated compliance by putting the responsibility for safe foods and food-related materials (including packaging and other non-comestibles) directly on the shoulders of those who place them into commerce. In doing so, they gave the FDA unprecedented authority to act swiftly and affirmatively to enforce requirements and stipulations within the FSMA and FFDCA.

Every year, money is spent to offset the impact of food packaging-related defects and insufficiencies. The best way to mitigate risk is through familiarity with the latest tools to prevent or find it. Planning can assist in the identification of risk and the mitigation of crises. Without experience, knowledge, and awareness of food packaging safety risks and best practices, supply chain partners are often ill-prepared to understand, identify and mitigate risks relating to preparation, expectations, and application of basic food (packaging) safety programs.

Successful mitigation begins with management commitment and flourishes via employee training and awareness. EHA Consulting Group, 30-year veterans of food safety and public health services, is best prepared to assess risk and recommend corrective actions in conjunction with the implementation of effective, targeted safety protocols.

Familiarizing oneself with the common causes of packaging safety defects (as described in the latter sections of this white paper) and following up with risk assessment exercises as well as food packaging safety program training are significant and important first steps towards helping your packaging company understand and attain compliance. Staying current on packaging safety rules and best practices will position your company to avoid crisis rather than struggling to deal with the consequences.

Avoiding Food Packaging Safety and Regulatory Issues with Understanding and Knowledge

“Food packaging material manufacturers and converters often underestimate the requirements and expectations to which they are held, both by regulators and by customers.”



Packaging suppliers and manufacturers to the food industry often feel as though they should be held to lower standards for facility, process and infrastructure safety programs versus food ingredient manufacturers, simply because packaging is not consumed. In reality, food packaging benchmarked schemes as well as United States federal law (FSMA) considers food packaging materials certain or likely to contact food with the same diligence as food ingredients themselves! Even when inedible materials are not intended for food contact, you can be sure that no converter of food products knowingly wants to intake anything into the food supply chain that has not been thoroughly and safely investigated, manufactured, stored and transported.

If your company manufactures, wholesales, or provides packaging materials for the food industry, it likely falls under government laws, regulations, or guidelines. Regulations can be from Federal, State, or municipal agencies. Regardless of the agency, it is expected by your customers, consumers, and the regulatory communities that you are aware of and meet minimum food packaging requirements and regulations through the use of best practices and standards.

Are you unsure, unaware of, or uncomfortable with what it takes to properly protect yourself from supply, material integrity, regulatory, or other risks? Do you struggle with the quality of information in order to provide proof or support backing the regulatory letters or certificates of compliance signed and provided by your organization?

Creating an atmosphere of understanding, documentation, and compliance within your organization is not a simple task. Food packaging material manufacturers and converters often underestimate the requirements and expectations to which they are held, both by regulators and by customers. A professional evaluation of a packaging materials supply chain, process and infrastructure, provided by EHA Consulting Group, Inc. can greatly assist in assessing your facility and process for gaps and risks. This evaluation will need to be addressed in order to reduce the risk of unforeseen food packaging quality crises.

EHA's deep industry-specific experience and track record in support of food and food materials safety differentiates us from other consultants.

C3

Food Packaging Safety Programs and Training

“Practitioners - defined as persons or organizations that initiate and maintain a qualified food packaging safety program (e.g. SQF, ISO/TS 22002-4, BRC and others) - must create, document and execute “basic” food safety training programs for employees and contractors.”



Federal law considers food contact packaging to be an “indirect food ingredient”, which then subjects the contact packaging and all of its components to the requirements, limitations, and conditions for the respective material(s) as contained in Title 21 of the Code of Federal Regulations (21CFR) and the Federal Food Drug and Cosmetic Act.

21CFR is the “rule book” for those who are in the business of food packaging and materials. If your company: 1) sells packaging materials or components intended for direct or indirect food contact, or 2) if it is likely that the materials you sell or convert will be contacted by comestibles, your materials and/or your process and facility are governed under procedures, precepts, and guidelines documented in 21CFR.

Food Packaging Safety Programs and Training is critical at all levels of the organization. Practitioners - defined as persons or organizations that initiate and maintain a qualified food packaging safety program (e.g., SQF, ISO/TS 22002-4, BRC and others) - must create, document and execute “basic” food safety training programs for employees and contractors. Training can take a variety of forms which include personal hygiene practices, handling of sensitive materials and allergens, sanitation and other core best practices for safe food environments. Expectations and responsibilities must be clarified for all participants. Regular updates and refresher sessions are required as well in order to reinforce positive practices and procedures.

Supervisors and trainers must be cognizant that auditors expect to see written documented proof of understanding and expected practices and behaviors; thus, it is not enough to prove that employees and contractors have undergone training. Document management must include written proof of understanding and performance during evaluations and questioning by supervisors, trainers and related functions.

It is also incumbent upon upper management and quality organizations from each corporate link in the food packaging materials supply chain to understand and follow requirements and apply all processes necessary to ensure the safety of their food packaging materials. Executives and management should begin to educate themselves on food packaging safety by attending training sessions and leveraging online resources.

Compliance, HACCP (Hazard Analysis, Critical Control Points) and risk/mitigation committee members must be trained to inspect, observe and document non-conformances or lack of best practices and also be prepared to recommend practical corrective actions. We find through experience that use of employee inspection teams to rate and evaluate facilities for best practices and identify and apply non-compliance solutions helps your staff feel more aligned with business objectives.

Continuous training and calibration clarifies job responsibilities for individual employees and demonstrates the ongoing value of your employees to the organization. Whether working in the production area, laboratory, or quality, individual employees have the ability to make a meaningful difference within the organization.

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Common Risks to Food Packaging Safety

“If not properly considered and mitigated, physical contamination risk may lead to defects, customer complaints and, in the worst case, product recall.”



A. Physical contamination

Physical contamination of packaging materials remains a high risk to food safety. If not properly considered and mitigated, physical contamination may lead to defects, customer complaints and, in the worst case, product recall. Metal particles, plastic shavings, and other physical contaminants are always lurking. They may be introduced to the food contact surface of the packaging components during conversion, secondary packaging, manufacturing (end use), warehousing, and transportation. Constant observation for physical contamination is a must.

All team members who handle packaging materials must be trained to understand types of physical contamination. Some forms of physical contamination are consistent in all environments, including:

- Unwanted material and components
- Metal, glass or plastic shards and shavings
- Mechanical parts (i.e., screws)

Other physical contaminants may be specific to a particular type of packaging material, component converter, or manufacturing location.

Best safety practices for consideration and mitigation include the creation of illustration boards with clear examples of physical hazards and contamination and a correction process, prominently posted in production areas.

Inspection teams should routinely inspect areas where packaging is stored, uncrated, and staged prior to use and filling/sealing or conversion. Inspection results and risk potential must be recorded, summarized, reported to management and mitigated in a timely manner.

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Common Risks to Food Packaging Safety

“Retail food product manufacturers and consumers alike are familiar with complaints regarding unusual tastes in food which likely occurred from product-package interaction.”



B. Chemical contamination

Chemical contamination is a high risk for packaging safety. Non-comestibles, including packaging materials or components, used in the production of food are not, by nature and composition, created to taste or smell pleasant. Under optimal conditions, a package component will smell neutral and add no “chemical” taste into the food it holds. However, in practice, once food is placed in contact with the package, the food likely takes on the characteristic sensory profile of the packaging.

Retail food product manufacturers and consumers alike are familiar with complaints regarding unusual tastes in food which likely occurred from product-package interaction. For example, metal cans have been said to impart a metallic or “tinny” taste and foods packaged in plastics or polymeric materials have been subject to complaints of “chemical”, “oily”, or other taste profiles not common to foods. Off-tastes in food are not always caused by taint from packaging materials, but quality professionals are trained to be suspicious of packaging materials as the culprit for off-tastes in food.

Chemical contaminations can originate from a variety of sources. Contamination sources include non-food approved substances and adulterants, unsuitable or unmerchantable materials or components sold as “food approved”, materials approved for general food use but not suitable for the intended application, intentional or unintentionally utilized functional additives, substances that impart unwanted and uncharacteristic taste and odor, lubricants and foreign materials.

Does your facility have the right programs in place to prevent chemical contamination? Could you identify contamination in the event it got around your prevention program? Chemical contaminants found in packaging conversion facilities typically include:

- Unexpected chemical sub-components in raw or intermediate materials (i.e., raw material contaminants)
- Unsuitable or non-conforming adulterants in or on incoming materials (i.e., contaminated converted components)

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Common Risks to Food Packaging Safety

“Know, with certainty, what components and substances your packaging materials contain. Insist upon certificates of suitability, compliance, and analysis supported by reports from a qualified laboratory in order to insure CFR compliance and food packaging safety.”



- Chemical cross-contamination from approved materials or substances used in your own facility (i.e., water additives, lubricants, solvents, cleaning aids, sweeping aids, sanitizers, slip agents, belt dressing)
- Contaminants from secondary packaging, warehousing and transportation (i.e., corrugated/paper dust/shreds)
- Uncontrolled or food-unsuitable lubricants or other chemical substances intended to support the manufacturing process (i.e., sanitation chemicals)
- Chemicals intended to be contained or confined and not approved for use in foods or food packaging (i.e., petroleum-based solvents, lubricants, adhesives, coatings)

Prevent chemical contaminants from getting into your supply chain. Know and assess risk from both internal and external sources. If you are using specifications, regulatory documents, certificates of compliance and other written evidence of analysis and suitability, be sure that you know what is being certified, analysis methods, suitability and the reliability (and location) of the analysis laboratories. Know, with certainty, what components and substances your packaging materials contain. A best practice is to insist upon certificates of suitability, compliance, and analysis supported by reports from a qualified laboratory in order to ensure CFR compliance and food packaging safety.

External analysis by EHA can assist in setting up the correct risk assessment and compliance program. Complement external and vendor analysis with internally-sponsored and controlled random checks, audits, and independent analysis. Provide copies of results to vendors in order to notify them of your diligence.

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Common Risks to Food Packaging Safety

“One microbiological contamination event can ruin an entire facility or business.”



C. Microbiological Contamination

Packaging materials manufacturers typically believe that they are at low or no risk of microbiological contamination in their facility, supply chain, or on their products because they insist one or more steps in the conversion process somehow sanitizes the end products, freeing any microbiological contaminants. The facts suggest otherwise.

Complete elimination of all microorganisms in any non-sterile environment is extremely difficult, if not impossible. Location, flow of human and other traffic, pest activity, air quality, and other difficult-to-control factors influence microbiological quality of all surfaces in any type of facility. Microbiological contaminants can reside in a myriad of places, including on people, pests, vehicles, materials, or equipment entering from outside sources. Without a sampling and analysis plan created by trained experts, it is impossible to determine if microbiological contaminants are present in a facility.

Trained experts examine and inspect all potential sources, surfaces, and areas of a facility (storage, manufacturing, conversion etc.) for microbiological breeding and hosting. Spoilage organisms are harmful to product quality and shelf life, whereas pathogenic organisms can be deadly to humans and animals. Exposure of humans and pets, the foods they eat, the equipment converting those foods and the packaging materials containing them to pathogens must be diligently considered, evaluated, and controlled through continuous validated programs based on training, prevention, sanitation, and inspection. One microbiological contamination event can ruin an entire facility or business.

Microbiological risk is not one-size-fits-all. Without an in-person, on-site evaluation of a facility, supply chain, and process, it is all but impossible to assess microbiological risk and its extent to product and process. Each facility and location is unique and must undergo evaluations and assessments in order to understand and characterize microbiological risk type. Trained EHA microbiologists and scientists develop a microbiological evaluation plan at each individual facility using a comprehensive set of risk assessment criteria, procedures, and methods.

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Common Risks to Food Packaging Safety

“Without clear, precise, and accurate documents and specifications, lines of responsibility, cause, and fault, become and may remain permanently blurred.”



D. Missing, Incomplete, or Vague Written Documents and Specifications

There is no language strong enough to emphasize the need for creating and maintaining comprehensive, accurate, and detailed document estates. Whether these documents represent policies and procedures, analysis records, quality evaluations, specifications, test methods, training or any other aspect of your food safety/quality programs and operational principles, they must exist, be consistent, filed and located in ways they can be accessed in event of an emergency, audit, or inspection and be a complementary part of a broad process and plan (i.e., PLM, ERP, food safety scheme).

Documentation acts as proof that specific details exist and have been required by or agreed to by multiple parties. It is evidence of requirements, analysis, test results, training, understanding, policies, procedures and corrective actions. Without clear, precise, and accurate documents and specifications, lines of responsibility, cause, and fault become and may remain permanently blurred.

Documents must exist to prove a host of activities, such as tables of organization, food-safety committees, meeting objectives and results, training courses, proof of understanding and application, safety and quality analysis, findings of non-compliance, root cause analysis, corrective actions, process and policy changes, evidence of validation.

Time and again, EHA has observed clients become the victims of inadequate documentation, work instructions, written validation, inspection results, training logs, test results, product and process specifications, and meeting notes and follow-ups. In virtually every case, these errors or omissions lead directly to failures in the supply chain, which were costly to everyone. The most critical takeaway from these experiences is that they could have been prevented or limited in scope through the application of comprehensive and executed documents and communications.

To reiterate, an accurate, consistent and complete volume of documents, validations, specification and results is invaluable to any company. The lack of possessing these represents incalculable risk.

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Common Risks to Food Packaging Safety

“Use of a qualified and recognized or certified food safety scheme or program is the recommended process of choice for identifying and controlling risks in and to the food packaging supply chain.”



E. Failure to Develop, Validate, and Maintain an Effective, Current, Qualified and Recognized Food Packaging Safety Program

FDA guidelines require food processors and packaging manufacturers to understand procedures that represent “current good manufacturing processes” (cGMPs). The Food Safety Modernization Act (FSMA) puts the onus of responsibility on each member in the supply chain to be aware of and apply best practices necessary to maintain safety within their respective supply chain organizations.

There is commonality in any food-related material, as well as in the various segments of the industry (agriculture and harvesting, animal production and slaughter, meat handling, ingredient production, packaging materials, packaged convenience, foods, food service and more). Understanding this, members of food-related industries and the organizations which represent and support them (including packaging), have a mandate to develop common positions on key safety and suitability issues affecting consumer foods and packaging. The ultimate focus is on continuous improvement of food and food packaging safety and quality through a collaborative process of knowledge and communication led and supported by a network of industry leaders.

The Food Safety Modernization Act (FSMA), a key topic link of interest on the “Food” home page of the FDA website, provides guidance for the application of current best practices for every food-related business from grower to end user, including packaging components and materials. Use of a suitable, qualified and recognized food safety scheme or program is the recommended process of choice for identifying and controlling risks in and to the food packaging supply chain.

Industry quality and safety program professionals have spent years developing unified competencies, criteria, and best practices by which food processors, packaging manufacturers, and related suppliers are expected to operate in order to consistently assess risk and ensure food safety. An important objective in the food safety community is to combine best practices with consistency so that, in relation to food safety programs and schemes, commonality is linked with compliance. The intent is to avoid the need for redundant 3rd party inspections by multiple providers/programs, when in fact any and all suitable and recognized programs are satisfactorily and competently able to evaluate each auditee against unified, consistent and measurable goals and requirements.

Packaging-related corporations have the benefit of selecting one of any number of programs, or “schemes”, which incorporate the latest safety standards and practices. Suitable schemes are those which target or specifically include packaging components and materials. Examples include BRC, ISO/TS 22002-4, SQF and PACsecure. Regardless of the scheme used or applied, both supplier and end user can collaborate with the confidence that true best practices and latest guidelines are understood, incorporated and rated continuously for application, conformance and effectiveness. It is incumbent upon the business to remain updated and vigilant on its food packaging safety program.

C5

Conclusion

“Continuously evaluate your packaging safety programs, and retain EHA as your food packaging safety consulting advisor and advocate.”



This white paper discussed the most common causes of food packaging contamination and safety risks. As risk types vary in scope and produce unique challenges from facility to facility, it is critical that trained experts are included throughout the risk management process. Even the most responsible, well-run facilities are at risk for food packaging safety non-conformances or violations.

Clients and customers are likely to require annual 3rd party inspections of your facilities. Downgrades, major violations, and even minor non-conformances threaten to negatively affect your hard-earned reputation and customer contracts; therefore, it is critical that you put emphasis and priority on understanding, applying, and validating food packaging safety principles and best practices. Reevaluate your packaging safety programs and retain EHA as your food packaging safety consulting advisor and advocate.

C6

The EHA Advantage

“Over 100 years of cumulative experience in the food industry.”



The professionals at EHA carefully evaluate the needs of each client, facility and circumstance individually and then use that information intake to create a custom plan which considers unique client challenges and limitations as well as industry best practices and government regulations. EHA effectively works with the client to create, implement, validate and stress-test the plan or program. In the event of an audit or change, we are well positioned to represent your interests and provide additional guidance and support.

EHA's food safety experts have been providing valuable "farm to fork" food safety guidance to members of the food and packaging industry for decades. Our combined education, training and industry experiences are among the many reasons that make us the best-equipped resources to support your food packaging safety needs.

We are available to assist you BEFORE, DURING and AFTER any inspection, audit, or crisis.

Call us today at 800-969-1441 for more information.