



White Paper

Understanding FDA Food Packaging Regulations

Extensive food contact regulations put in place by the U.S. Food and Drug Administration (FDA) are critical for ensuring the safety of food that is packaged and consumed. As a result, compliance is a key consideration for companies converting and utilizing simple formats or complex multi-layer structures for food packaging. Choosing a supplier that follows and uses strong regulatory expertise and strict compliance protocols will help converters and brand owners make the best decisions about selecting and handling materials used in this demanding packaging area.

Food Contact Compliance Merits Careful Consideration

While FDA regulations are complex and achieving compliance can sometimes seem like a burden, proceeding without careful consideration can cause serious harm to converters, packaged goods companies, the food industry as a whole and, most importantly, consumers. Contamination can lead to widespread negative media, lawsuits, lasting public censure and permanent damage to brand reputations. Handling FDA regulatory matters improperly may require materials to be recalled, requalified or resubmitted for regulatory approval. This is a resource-intensive and time-consuming process that could result in millions of dollars lost due to added compliance costs, destroyed materials and lost sales while the final packaged product is off the shelves.

Putting a Priority on Compliance

The complexity of meeting FDA regulations often makes adherence a challenge. The flexible packaging industry has experienced rapid growth. Ongoing innovation across a wide range of application areas has led to more new materials being used, growth in complex multilayer packaging formats, extreme in-use conditions and increasingly more stringent FDA regulations. To remain competitive, converters and brand owners are challenged with commercializing advanced applications in much tighter timeframes and at reduced cost while still remaining compliant to the regulations.

Although FDA compliance is an extremely important issue for suppliers of food packaging components and consumer packaged goods, resources are often focused more on product development. In an effort to put the priorities on product development and to control costs, some companies choose to trust outside sources to read, understand, and give guidance for making safe, FDA compliant packaging. In such an environment, it can be difficult to push regulatory concerns to the top of a flexible packaging company's to-do list.

Understanding Compliance Claims

It can be increasingly difficult to fully understand supplier claims relative to the compliance of their products. While the converter or packaged food company has the best insight into the particular product's end-use needs, packaging design, manufacturing conditions and filling requirements, an experienced raw materials supplier can provide valuable information about its products that can help others involved in the manufacturing cycle make the best decisions about the food packaging products they specify.

Suppliers often claim that their materials are "suitable" for demanding food packaging applications, such as those requiring high temperatures in use, but a claim of general suitability is not the same as proof of FDA compliance for that specific application. In general, material "suitability" may only mean that the packaged product can meet the physical performance requirements of the package during manufacturing and in use without meeting FDA requirements.

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extraction and migration testing. It is the basis of this certification that provides the converter and food packaging companies assurance that the packaging meets the strict food safety requirements of the FDA regulations. If a supplier claims that a material is suitable for any application, it should be confirmed that the material also complies with the proper FDA regulations needed for the use requirements of that package. The supplier should be willing to provide certification or data to confirm that all compliance requirements are fully met.

The U.S. Food & Drug Administration (FDA) requires that plastics used in food packaging be of very high purity levels. This is commonly referred to as food contact grade plastic. Although not practiced by responsible material suppliers, disreputable suppliers may sell offgrade materials for use in food packaging applications. Offgrade materials of any type will not pass FDA regulations for food contact applications, even if the same prime material is approved for use.

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Understanding FDA Food Packaging Regulations

How do converters and packaged food companies evaluate which suppliers provide accurate information relative to FDA regulation compliance? It's good business for converters and food packagers to first determine which regulations apply to their applications and how they must comply. When working on demanding food packaging applications such as retort, steam-sterilization, microwave, hot fill and wet food, the food ingredients and processing temperatures involved may lead to a greater likelihood of chemical extraction and migration, making compliance even more difficult. This is why understanding the impact of manufacturing and use conditions is of the utmost importance, and why the FDA has established regulations, with even more rigorous requirements for high temperature applications.

The following is an overview of FDA regulations for food packaging involving the use of laminating adhesives and an initial checklist to use with prospective material suppliers.

FDA Requirements

Adhesives used in multilayer food packaging laminants can meet these FDA food contact safety requirements in three ways:

1. Compositional Compliance

This is compliance based on matching the chemical composition and quality of the packaging materials used, to the food chemistry and use environment of the packaged product(s) with the existing FDA regulations. Within the regulations are lists of cleared or 'approved' starting raw materials to fabricate the adhesive. Packaging structures that are compositionally compliant are subject to using raw materials made from the cleared list, and following strict handling recommendations and limits of use. For example, if the packaging structure's composition complies with FDA regulation 21 CFR 175.105, the package material including adhesives cannot rise above room temperature (up to 120°F or 49°C) during manufacturing, converting, storage or end use. Specifications to establish "food contact grade" standards are imposed on materials that comply based on their chemical composition.

2. Compliance based on Extraction Testing

Even though the materials may be compositionally compliant, elevated temperature use may require verification of acceptability of the regulated food contact surface by extraction testing and determination of whether the surface complies with its specific regulation. In this case, there are testing protocols to determine the total extractable material from the structure using intended use temperatures and appropriate food simulants. There are limits to the quantity of material extracted from the food contact surface of the structure that may not be exceeded. Materials may be extracted from the film(s), extrusion layers, adhesives, inks and other coatings of the structure that come to the food contact surface and could adulterate the food (become a food additive).

3. Compliance based on Migration Testing

It is more restrictive to design packaging structures that are compositionally compliant when they will be manufactured for use at elevated temperatures and contain fatty foods. The list of cleared materials for this scenario is short. Many structures may contain new materials that have no status in the regulations, or are using materials not cleared for use at elevated temperatures. In addition, many materials and processes suited for such demanding applications aren't fully addressed in FDA regulations. If materials and processes are listed under FDA regulation 21 CFR 177.1390, the regulation used for the most demanding retort package under the highest temperatures, converters must follow the manufacturing instructions to the letter: They must not "mix and match" adhesive (or other) components that are listed in separate subparagraphs of the specific regulation. Additionally, elevated temperatures create the added risk of migration of components due to thermodynamic principles. As a result, if the components of the structure are not on the cleared list (Compositionally Approved), higher performance packaging structures that are laminated with an adhesive, and the adhesives used within them, must be carefully evaluated and generally must undergo migration testing by the appropriate FDA protocol. This is especially required when new materials are used that are not listed in the approved substances of the FDA regulations, for retort applications or elevated temperature use, or when materials from other regulations are used. Migration studies are used for

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uncleared substances that are intended for food contact use, and are conducted to determine if, and to what extent, an uncleared substance may migrate to food when used as intended in the application (for example, a retort pouch).

The FDA regulations offer specific testing protocols and acceptable limits for potentially harmful extractable and migratable materials. These tests require expertise in the methods and high precision, since some limits for migratable materials are in the parts per trillion (PPT) range. Additionally, these migratable materials must be identified and quantified if they are suspected or known to be harmful. Migration testing of food packaging materials is used to confirm that the food contact substance (for example, the polymer components of the film or the adhesive components used in the packaging) has not migrated into the food itself and thus does not require classification as a food additive under FDA jurisdiction. Conditions used in migration testing are intended to simulate end use conditions of the packaged food product. Migration testing is generally far more complex than compositional compliance testing and extraction testing. Typically requiring 10 days or more for testing, the analysis involves the use of advanced computer-controlled instrumentation and analytical expertise in chemical analysis.

Importance of Materials Testing for Adhesives

The material evaluation process is aided considerably by understanding a supplier’s Environmental Health & Safety (EH&S) expertise, their regulatory practices and testing protocols and their analytical expertise.

In the area of adhesives, state-of-the-art material science, analytical, toxicology and risk assessment capabilities are a necessity. Assessing food contact parameters and assuring compliance is often one of the most important functions that the technical and EH&S staffs undertake. Extensive effort and expertise is needed due to the complexity of food contact and safety regulations and the need for precision. It is this materials expertise and evaluation that allows the use of many more materials in multilayer packaging structures than the regulations specifically identify as cleared for use.

Adhesives suppliers vary widely in their ability to perform the detailed analyses necessary for extraction, migration, toxicology, and risk assessment to support and affirm the food packaging uses for their products. Dedicated resources and extensive financial investments are required to maintain internal expertise and secure the necessary state-of-the-art equipment required for exhaustive extraction and migration testing. Proper testing protocols must be established, confirmed as appropriate and accurate, reproduced, enforced and upgraded as necessary.

The process of assuring food packaging compliance to the various regulations requires that packaging structures be manufactured either in-house or at the converter, using representative converting machines and processes. The packages must be fully cured before testing. Once the testing period concludes, technical, toxicology, risk assessment and regulatory experts must evaluate the food simulant results to determine the level of extraction and/or migration materials, identify and quantify each material as necessary and evaluate overall food contact safety and compliance.

This work is always supported by sophisticated analytical tests such as liquid chromatography, mass spectrometry and carbon 13 nuclear magnetic resonance. Without the internal expertise and equipment required, suppliers cannot conduct the needed tests or provide their customers with reliable data.

Following extraction or migration testing, converters and packaged food companies must assure that adhesives (and other materials) are used under the same manufacturing conditions as those that were used and cleared during extraction or migration testing –film types and thicknesses, adhesive weights and component ratios, cure times and conditions, food types and temperatures during processing and end use.

Safe food packaging, safe consumers and continued brand integrity literally depend upon gathering better information about FDA compliance and having the expertise to evaluate this information.

FDA regulations include the following requirements for adhesives, including those used in packaging laminates.	
21 CFR 175.105:	Adhesives. Covers use of optional substances used to create adhesives behind a functional barrier at temperatures of 120°F (49°C) and below. Primary applications: indirect contact – dry snacks (trail mixes), dry foods, non-frozen fresh cut produce. Also appropriate for aqueous and fatty foods.
21 CFR 177.1395:	Laminate structures for use at temperatures from 120°F - 250°F (49°C - 121°C) Primary applications: hot fill, microwave; microwaveable fresh frozen or fresh cut produce; hot filled condiments, jams and jellies, sauces; boil-in bag products like rice or frozen vegetables
21 CFR 177.1390:	Laminate structures for use at temperatures of 250°F (121°C) and above Primary applications: retort; microwave heating/cooking of foods containing oil or fatty components, certain medical and pharmaceutical applications

Suggested Questions to Ask Material Suppliers

Safe food packaging, safe consumers and continued brand integrity literally depend upon gathering better information about FDA compliance and having the expertise to evaluate this information. Following are questions to ask suppliers that will aid this process:

- What specific regulations and subsections address the materials we will be purchasing?
- Have you performed migration or extraction testing on these materials in the intended structures?
- If migration testing has been performed, are you aware of any restrictions we should consider regarding cure times, food contact film types, food types, or temperature?
- What types of data can you provide about the food contact safety profile of the materials we will be purchasing from you?
- Have your toxicologists evaluated these materials?
- Do you have a formal risk assessment for these materials in this specific application?
- Do you have FDA experts on staff?
- Are you relying only on compositional compliance, or has further testing for safety been done?
- What do you mean by 'suitable for use' as listed on your documentation?

By coupling the right answers with a knowledgeable assessment of the regulations, converters and brand owners become better equipped to select and use appropriate materials for safe food packaging. This often becomes more important on a global basis, too, as countries that haven't established their own policies often defer to the FDA clearances.

Dow Testing Protocols for Packaging Materials

Dow's thorough testing protocols for adhesives supplied into food packaging applications are based on a long and strong history of industry leadership on EH&S performance. To back up our claims of material compliance to FDA regulations, or suitability for use, Dow performs the following tests:

- Extraction testing/gravimetric analysis, etc.
- Migration testing/gravimetric analysis, etc.
- Liquid chromatography to measure and identify extracted and migrated materials
- Mass spectrometry to identify extracted and migrated materials
- Carbon 13 NMR to measure specific composition of the materials under test
- Toxicology studies on new materials when appropriate
- Exposure assessment for the new material at the consumer level using sophisticated modeling
- State-of-the-art risk assessment methodologies to assure lack of risk to consumers in the final packaged product
- Global regulatory knowledge and experience going beyond FDA for customers needing EU or Asian regulatory compliance, or other regional food law requirements
- Global regulation monitoring to help customers respond quickly to rapidly changing regulatory environments

To further aid compliance testing, Dow manufactures laminated pouches. These are filled with the appropriate food simulant product per FDA protocols, and the filled pouches are subjected to certain temperatures and times. Then the food simulant used in the pouch undergoes detailed testing for any substance that could have potentially extracted or migrated into the food simulant from the adhesive used in laminating the pouch. These data are then reviewed by analytical, toxicology, risk assessment and regulatory experts to help ensure safety and compliance.

FDA Compliance: A Source of Confidence and Competitive Advantage

Overall, producing safe food demands a complex combination of skills from all who contribute to the final packaged product – those supplying materials, making the packaging, selling the final packaged products and enjoying what’s inside. Key factors to assuring food safety and FDA compliance include:

- strong product safety and regulatory knowledge
- an informed and thorough materials evaluation process
- smart packaging design
- good manufacturing practices
- rigorous material and packaging testing protocols
- strict handling and use requirements

Taking the right measures upfront helps assure that food packaging will meet in-use demands and regulatory requirements, and that the food contents can be enjoyed safely. Making well-informed material choices is necessary to help qualify and commercialize new food packaging concepts quickly. The bottom line (literally) is that a collective concentration on safety and compliance will result in competitive advantage and confidence throughout the value chain.

Food safety compliance standards for packaging materials are not the same in the United States as in the European Union.

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