



## Understanding FDA Food Packaging Regulations

**Choosing a supplier with strong regulatory expertise helps converters and end-users make the best decisions about selecting and handling food contact materials.**

### **Protect the public *and* protect your brand**

Searching for light pleasure reading? The U.S. Food and Drug Administration food contact safety regulations don't qualify. A single example from one of the FDA's 21 CFR chapters illustrates why: "...polyester epoxy urethane adhesives formulated from the following: a) polyester resin formed by the reaction of polybasic acids and polyhydric alcohols listed in section 175.300 (b) (3) (viii) (a) of this chapter. Azelaic acid may also be used as a polybasic acid... ."

### **Food Contact Safety Regulations Merit Scrutiny**

Yet such regulations are critical for ensuring the safety of the food we eat and, therefore, for companies converting and utilizing multi-layer structures for food packaging. Yes, they're lengthy and complicated, but the FDA has convincing data to support their exhaustive recommendations. The agency's success record includes milestones like improving infant formula content, vanquishing botulism in canned foods and labeling products with possible food allergens. From its first industry guidance in 1949 on evaluating chemical toxicity in food, the FDA has clearly stated its position and underscored the food industry's challenge: that inappropriate food contact poses serious harm to food supplies and the public. Contamination also may unleash lasting public censure, principally for consumer products companies wherever they may do business: witness the recent furor in Italy when a printing ink affected baby formula.

#### ***Food Contact Safety Matters to Everyone***

*True, regulations are not light reading. But neither are lawsuit briefs and critical media coverage that threaten if customers let their responsibility fall by the wayside. This is an extremely important issue for suppliers of food packaging components and customers, as well as end-users, packaging engineers, and buyers. Handling the matter improperly can hurt people and businesses, incite consumer ire, cause bad press, and seriously harm brands. Indeed, food contact safety matters to everyone.*

## **Sifting Through Regulations**

Despite the risks, the complexity of regulations makes adherence a challenge. This is true for some converters and packagers who may find the minutiae mind numbing and who therefore trust outside sources to read, understand, and give instructions for making safe, compliant packaging. A glance at the business shows why this is tempting. The flexible packaging industry, 55 percent of whose products are primarily used for food packaging, is a good example. Spurred by innovations like standup pouches and breathable films, flexible packaging is a \$21.3 billion yearly business in the United States that expands at 3.5 percent yearly, a rapidly growing technology that is fast replacing rigid choices and challenging converters to bring forth the latest advances at breakneck speed. Furthermore, the typical converter serves a widely varied customer base on a very tight schedule. Converters often operate against stiff competition, both domestic and import, and on tight margins since they field frequent customer requests to reduce costs. In such an environment, it can be difficult to push regulatory concerns to the top of a flexible packaging company's to-do list.

Even with heavy workloads and short deadlines, avoiding the temptation to delegate regulatory responsibilities is essential; after all, it is the end-user who is responsible for a package's compliance. While the end-user has the best insight into his particular product, packaging design, manufacturing and filling, a well-informed and experienced supplier can provide valuable information about its own products that helps end-users make the best decisions about handling food packaging materials.

So how *do* converters and packagers evaluate which suppliers provide accurate information? Imported pouches or laminates may meet the regulations for the country of origin, but how do they comply with FDA guidance? For example, adhesives used in imported pouches may meet the rigorous performance requirements of retort packaging, but do they comply with FDA's regulation 177.1390 for retort packaging? Or can that flow wrap packaging sourced offshore truly be used to produce safe food packaging? Such questions are particularly critical for retort, steam-sterilization, hot fill and wet food applications, which due to the food and temperature processing involved may have more likelihood of chemical migration. This is why the FDA established regulations for more rigorous, higher temperature applications. Understanding a supplier's regulatory expertise, analytical capabilities and testing procedures lends useful perspective, as do supplier responses to probing questions. Safe food packaging, safe consumers and continued brand integrity literally depend upon gathering better information.

## **FDA Matters are a Full-time Job**

For suppliers, staying abreast of the issues and understanding how the regulatory landscape impacts their products is a full-time activity. In the area of adhesives, for example, state-of-the-art analytical and toxicology departments staffed with doctorate-

level chemists, toxicologists, and a full-time regulatory manager with many years of experience in food packaging regulatory compliance can be required for comprehensive testing and successful compliance. Indeed, assessing food contact parameters is often one of the biggest jobs an adhesive company's technical staff undertakes.

This level of effort is absolutely necessary because of the complexity of the regulations. It's also vital because customers can use many more materials than the regulations specifically identify – but only if they have extensive migration testing results that show that nothing migrates into food simulants.

Adhesives for multi-layer food packaging laminates can meet FDA food contact safety regulations in one of two ways: by compositional compliance or through migration testing. For instance, one representative compositionally compliant flow wrap for confectionary incorporates only eligible films named in CFR regulations elsewhere and specific adhesives listed in 21 CFR 175.105. Further, the structure is subject to strict handling limits: for example, it doesn't rise above room temperature during manufacture, converting or storage.

### **High Temperatures Turn Up the Heat on Compliance**

It's much more difficult to build a compositionally compliant package for a food that is fatty and will be packaged at elevated temperatures. Many materials and processes suited for such applications aren't addressed in FDA regulations. If they are listed under 21 CFR 177.1390, then converters must follow instructions to the letter; they must not “mix and match” adhesive components that are listed under separate subparagraphs. Further, elevated temperatures encourage migration due to thermodynamic principles. Hence, these higher-performance laminates must be carefully evaluated and generally must undergo migration testing. Adhesives suppliers vary widely in their ability to perform such tests and acquire reliable data. That's because a great deal of time coupled with a major financial investment is required to establish proper and reliable standards for exhaustive migration testing. In addition to equipment investments, the adhesives company has to assign highly knowledgeable technical specialists to spearhead the effort.

The process demands a knowing and well-equipped hand: structures must be built in-house and fully cured before testing. Once the testing period elapses, technical staff examines the food simulants used in order to determine if chemicals have migrated from the adhesive. For this task, state-of-the-art equipment capable of sophisticated tests such as liquid chromatography mass spectrometry and carbon 13 nuclear magnetic resonance are used. Such high-powered equipment is an absolute necessity, and such a significant investment demonstrates a supplier's strong commitment to the business. Without both, reliable data are impossible.

Even though testing yields a robust set of results that customers and end-users find extremely useful, converters' and packagers' jobs don't end after studying regulations and consulting supplier test results. The adhesive must be used under the same manufacturing conditions – cure time, film types and thicknesses, food types, and temperature — as those vetted during extraction testing. In sum, producing safe food packaging demands a complex combination of skills from those making and using food packaging: regulatory knowledge, smart design, informed materials purchasing, good manufacturing practices and, of course, strict handling procedures.

### **Asking Suppliers Probing Questions**

It's simply good business for converters and food packagers to determine which regulations apply to their applications and how they must comply with them. Outside resources such as legal firms that specialize in food contact law aid the process. It is wise for food packaging customers to supplement their knowledge by asking suppliers probing questions and assessing their replies critically. The following is an initial checklist to use with prospective suppliers:

- What specific regulation and subsection address the materials we will be purchasing from you?
- Have you performed migration testing on these materials?
- 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?

By coupling the right answers with an independent assessment of the regulations, customers become better equipped to select and use appropriate materials for safe food packaging. They may become more competitive on a global basis, too; for countries that haven't established their own policies, FDA regulations often constitute default guidance.

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100 Independence Mall West  
Philadelphia, PA 19106-2399  
Web: <http://www.rohmmaas.com>