A guide to FDA regulation of adhesives and coatings for flexible packaging

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A basic requirement dictated by these regulations is an adherence to good manufacturing practice.

In the United States, the responsibility for the protection of consumer health belongs to the Food and Drug Administration (FDA), Department of Health and Human Services. This agency undertakes its role by regulating various items, including food intended for human consumption. Food regulations cover the food item itself, additives to food, indirect food additives, and the processing of food.

The diversity of our lifestyles has inspired many food-packaging innovations. Technological developments have made it possible to package beverages in composite paperboard containers, sauce-covered vegetables frozen in boilable pouches, and condiments in unit packages for use at fast-food establishments. Indeed, the food-packaging industry has grown worldwide, and this growth is expected to continue.

In the United States, the FDA regulates packaging that comes into direct contact with food as an indirect food additive. Packaging is regulated in this way because of the migration that can occur between package and food. Any adhesive or coating that is used in the packaging of a food item for human consumption must conform to the applicable regulations of the FDA.

This article examines these regulations as they apply to the use of adhesives and coatings in the flexible-packaging industry. Adhesives and coatings are used to customize and combine one or more flexible webs to create a single composite web for use primarily in food packaging. The ability to combine different webs provides functional and synergistic benefits unattainable with a single, unmodified web. Although the emphasis of this article is on flexible packaging, most of the general statements and basic concepts apply to all areas of FDA regulation, such as coatings for cans.

Code of federal regulations

The *Federal Register*, a document published daily by the federal government, provides comprehensive coverage of all federal administrative and regulatory actions. The Office of the Federal Register also publishes a set of volumes as a special edition, the *Code of Federal Regulations*. This is a systematic classification of the general and permanent rules published in the *Federal Register*. The *Code of Federal Regulations* contains specific subject areas, and Title 21 concerns food and drugs, the areas where food-packaging adhesives and coatings are regulated. Anyone who is involved with determining the suitability of a material for use in food packaging should have a copy of the current year's Title 21 parts 170–199 available as a reference guide.

Title 21 is revised annually as of April 1. In the introductory pages, the "Explanation" section details the simple procedure to determine whether Title 21 of the *Code of Federal Regulations* has been amended since its April 1 publication date. To remain up-to-date with the regulations, it is necessary to use the *Code of Federal Regulations* in conjunction with the individual issues of the *Federal Register*. It is probably not necessary to subscribe to the *Federal Register* and read it every day, but it would be prudent to try to remain current on new rules and proposed regulations by reading periodicals or published abstracts.

Reading the *Federal Register* and the *Code of Federal Regulations* can be frustrating to the first-time user. These are legal documents written by people with legal training. They read accordingly. Rereading of any confusing area may sometimes clarify it. It is important to realize, however, that the regulations are legally binding. One must, therefore, defer to legal counsel for anything that is in question and follow counsel's opinion in any matter requiring interpretation.

Proper reference to a regulation in the *Code of Federal Regulations* cites the title, part, and section numbers followed by the name, e.g., 21 CFR 175.105, Adhesives. This designation translates into: Title 21 of the *Code of Federal Regulations*, Part 175, section 105, entitled Adhesives.

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Indirect food additives

Adhesives and coatings in food-packaging applications are regulated because they are considered to be indirect food additives. This designation acknowledges the possibility of migration between package components and food items. The *Code of Federal Regulations* addresses indirect food additives in the following parts of Title 21:

- Part 174—Indirect food additives: General provisions
- Part 175—Indirect food additives: Adhesives and components of coatings
- Part 176—Indirect food additives: Paper and paperboard components
- Part 177—Indirect food additives: Polymers
- Part 178—Indirect food additives: Adjuvants, production aids, and sanitizers

Regulation 21 CFR 174.5, General provisions applicable to indirect food additives, makes two important points that must always be considered in any application involving food packaging.

1. It is only permissible to use an indirect food additive under conditions of good manufacturing practice. In the case of adhesives and coatings, good manufacturing practice means that the amount of material used may not exceed the quantity needed to accomplish the packaging requirements, may not exceed any limits that might be prescribed, and may not have any physical or technical effect on the food itself. Furthermore, any substance used in the adhesive or coating must be of suitable purity.
2. One may not utilize a material indicated as safe by Title 21 for use as an indirect food additive if the material is prohibited by any other provision of the Federal Food, Drug, and Cosmetic Act.

Bearing in mind that the requirements of 21 CFR 174.5 apply in every case, a packager must consider several rather specific regulations governing the use of adhesives and coatings in flexible packaging. The most common of these regulations are listed in **Table I.**

The information in each of these regulations is organized in a shared format. A given regulation can contain some or all of the following parts:

- Introductory section
- List of allowable substances
- List of restrictions on the use of the allowable substances
- Testing protocols that must be satisfied.

Regulation 21 CFR 175.300, Resinous and polymeric coatings, is a good example of a regulation containing each of these parts. This regulation has a short introduction [paragraph (a)] that addresses the application and characterization of a coating. Following this, there is a long list [paragraph (b)] of the allowable ingredients for the coatings and their limitations. Next, there are tables in which types of food are identified and conditions of use are classified, with corresponding extraction tests and the allowable level of extracted material [paragraphs (c) and (d)]. Finally, there are analytical methods for performing the extraction tests [paragraphs (e) and (f)]. While this is perhaps an oversimplification of a complex regulation, it indicates what is covered and where it is located.

I. Regulations for flexible packaging

175.105	Adhesives
175.125	Pressure-sensitive adhesives
175.300	Resinous and polymeric coatings
175.320	Resinous and polymeric coatings for polyolefin films
176.170	Components of paper and paperboard in contact with aqueous and fatty foods
176.180	Components of paper and paperboard in contact with dry foods
177.1200	Cellophane
177.1390	High-temperature laminates
177.1630	Polyethylene phthalate polymers
178.1005	Hydrogen peroxide solution

Regulation 21 CFR 175.105, Adhesives, is an example of a regulation where some of the four general parts are missing because they are not relevant. This regulation contains introductory material regarding the use of adhesives [paragraphs (a) and (b)] followed by allowable ingredients [paragraph (c)].

Using the regulations

The best way of explaining how to use these regulations is by presenting examples of the procedure.

Example 1

The first example involves a typical laminate that might be used for a rice package. It is a composite of a reverse-printed polyethylene film laminated to an unprinted polyethylene film. Since the rice is an item intended for human consumption, it is obvious that the package must have approval under one or another of the various FDA regulations. We want to know which regulation is applicable. A basic but important concept in the use of any of these regulations is that the applicable regulation must be identified.

In tracing this rice bag lamination from its earliest inception to its final use, we find that there are a variety of different manufacturers involved. First are the suppliers of the raw materials to the manufacturers of the polyethylene films, the inks used for printing, and the adhesive. Next are these three manufacturers themselves. Also involved are the printer who applies the ink and the laminator who manufactures the composite. Following this is the food packager who assembles the package and places the contents inside. Finally, of course, there is a consumer who uses the food item.

For almost all instances, the logical choice of who should identify the proper FDA regulation in this chain of manufacturers is the food packager. The packager is generally the only one who knows exactly what the food item is and all of its conditions of use. Selection of the proper regulation by anyone else, such as the film supplier or the adhesive supplier, would really be nothing more than a well-educated guess that might be wrong.

In this case, the company supplying the rice might indicate that the lamination must meet FDA regulation 21 CFR 175.105, Adhesives. With this basic piece of

information, all of the other parties involved in the rice bag can now proceed with their investigation into the suitability of the products they intend to supply. Obviously, each supplier must first read the regulation to find those parts that apply specifically to him and then proceed accordingly. The laminator would learn that his composite must contain components that meet the composition requirements of 21 CFR 175.105, Adhesives, and must provide a functional barrier to separate the adhesive from the food as well as follow the good manufacturing practices outlined in 21 CFR 174.5, General provisions applicable to indirect food additives.

Functional barrier

Although the FDA has not provided a legal definition of a functional barrier, they will accept as a functional barrier any material that serves to prevent total migration of any component. The keyword here is total. The manufacturer of the finished product must determine whether the packaging is in fact a functional barrier to the packaged food. However, regulation 21 CFR 175.105, Adhesives, provides an alternative to providing a functional barrier. For dry-food applications, the amount of adhesive that contacts the packaged food may not exceed the limits of good manufacturing practice in the absence of a functional barrier. If the food item is aqueous or fatty, the amount of adhesive contacting the food may not exceed the trace amount at the seams and at the edge exposure of the laminate that falls within the limits of good manufacturing practice, and the laminate must remain firmly bonded together.

Another reference to functional barrier occurs in 21 CFR 177.1390, High-temperature laminates. In this case, a functional barrier is any material that can prevent the migration of extractable materials to a level below that actually specified in this regulation under the stated test conditions.

Since this article is concerned chiefly with adhesives and coatings for flexible packaging, we consider how the adhesive is affected by the requirement that the rice-bag lamination must comply with 21 CFR 175.105, Adhesives. The laminator communicates to the adhesive supplier the need for compliance with this regulation. The adhesive supplier, in turn, reads the regulation to learn that all of the ingredients in the adhesive must be listed in the regulation and that the shipped adhesive must be labeled as a "food-packaging adhesive." The adhesive supplier must also make certain that all the materials used to formulate the adhesive are listed in the regulation by their chemical name or are certified by his suppliers as being acceptable for the composition requirements of the regulation. The adhesive supplier then communicates this information to the laminator using a letter of certification.

Example 2

The second example involves the use of a printed paper that is coated on the reverse side with a polyvinylidene chloride copolymer, which functions as a heat-seal and barrier layer in the packaging of dry cereal products. In this instance, the cereal manufacturer might provide the information that the package must meet 21 CFR 176.180, Components of paper and paperboard in contact with dry food. As in the previous example, the coating applicator would read this regulation to learn that he must use a coating made of ingredients listed in the regulation and that he may only use a quantity of coating such that it will perform the intended physical or technical effect without affecting the food. Likewise, the coating manufacturer, after notification of the applicable regulation from the user of the coating, would read the regulation to learn that all of the ingredients in the coating must be listed in the regulation by their chemical name or be certified by his suppliers as being acceptable for the composition requirements of the coating. The coating manufacturer provides a letter of certification that communicates this information to the coating applicator.

Letters of certification

All of the manufacturers involved in the chain of package preparation will ask their respective suppliers for a letter certifying that a material meets a certain FDA regulation. In the case of an adhesive or coating, this is a letter signed by a responsible individual of the supplier company certifying that the product conforms to the composition requirements of the particular regulation in question. This wording is important. Manufacturers of adhesives or coatings lose all control over their product when it leaves the factory. The manufacturer can only certify that the product meets the composition requirements and not the regulation itself with respect to any other considerations of functional barrier, extraction requirements, good manufacturing practice, etc.

In addition, a well-written letter of certification will call the adhesive or coating user's attention to other provisions in the regulation that may govern the actual use of the product. It is, therefore, imperative that the user recognize the letter as a certification of composition and not in any way as a further guarantee of compliance with a regulation. The important distinction is that the letter of certification indicates conformation, not approval. In all instances, a user of an adhesive or coating must read the regulation to ensure that the final product complies with any and all of the other requirements that may be necessary.

Miscellaneous considerations

A discussion of FDA regulations would not be complete without mentioning the use of adhesives and coatings in three other applications:

- Boilable applications
- Microwave applications
- Packaging of meat and poultry products under inspection by the United States Department of Agriculture (USDA).

Boilable applications involve the use of adhesives and coatings in the manufacture of food pouches that will be immersed in boiling water. There are no specific FDA regulations for this particular food application. Instead, the FDA has adopted the position that 21 CFR 177.1390,

High-temperature laminates, should apply on the basis that the boilable pouch is simply a somewhat less-stringent application of a high-temperature laminate. Thus for an adhesive or coating to be acceptable for use in a boilable pouch, it must conform to the composition requirements of regulation 21 CFR 177.1390, High-temperature laminates, and meet the extraction requirements of that regulation.

Microwavable food-packaging applications are similar to the boilable pouches in that there are no specific FDA regulations. Obviously, however, one must follow good manufacturing practices for high-temperature applications. Furthermore, the FDA has taken the position that the microwave heating of food in a container does not constitute "holding food during cooking."* This means that polymeric materials that are cleared for use in all food-contact applications may be used to package food for heating in a microwave oven. Thus a precooked food that will only be reheated in a microwave oven can utilize any material that is cleared for a food-contact use provided there are not limitations as to food types, temperatures, or any other restrictions.

The USDA requires that all food-contact materials used to package meat and poultry products inspected by the Food Safety and Inspection Service must be backed by a guarantee stating that the material complies with USDA food laws and regulations. Since July 1984, the inspectors of the USDA have used such guarantees to establish that a packaging material can be legally used for meat and poultry products. This guarantee is a statement that the packaging material complies with the applicable FDA regulations. In other words, the USDA will generally accept the regulations of the FDA. Thus, for example, a boilable pouch containing meat must meet 21 CFR 177.1390, High-temperature laminates.

A plant under USDA inspection must obtain written guarantees from its suppliers stating that each material used in packaging complies with the FDA food laws and regulations. The guarantee will state that the packaging material meets the Federal Food, Drug, and Cosmetic Act and all applicable regulations governing food additives. A supplier of an adhesive or coating must, therefore, provide a letter of certification indicating that his product conforms to the composition requirements of the regulation in question.

The old procedure in which suppliers obtained from the Food Ingredient Assessment Division a letter confirming that the material meets the appropriate regulatory criteria is no longer necessary, nor will it substitute for the new required guarantee. Such letters are still available from the Food Ingredient Assessment Division, however, and they can still be sent to meat and poultry plants.

*Food Chemical News 29(2): 21(1987).

Conclusion

The use of adhesives and coatings in flexible packaging is regulated by the FDA. These materials are indirect food additives and, as such, are covered in Title 21 of the *Code of Federal Regulations* parts 174–178.

A basic requirement dictated by these regulations is an adherence to good manufacturing practice. Someone—usually the food packager—must decide which specific regulation is applicable for the particular food item and package in question. After this determination is made and communicated to each of the suppliers in the chain of manufacture of the packaging material, it is then possible to consult that regulation to ascertain the allowable substances, the restrictions on use, and the test protocols.

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