

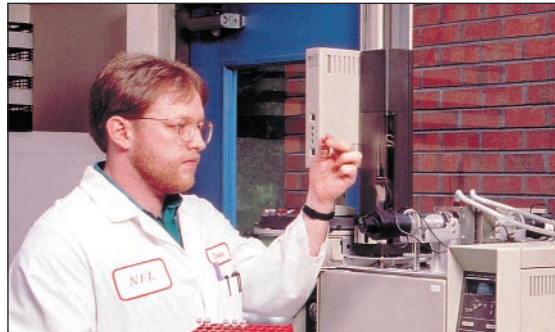
Product Safety and Consumer Acceptance in Food-Packaging Applications

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Ever since the word “plastic” was spoken in the 1960s film *The Graduate*, a revolution has been occurring in the food-packaging industry. New technology has resulted in improved materials, ranging from plastic films to modified atmosphere packaging. Brighter colors, improved adhesives, and reformulated inks have all reached the marketplace. Even the old standbys, paper and paperboard, have improved coatings and additives, such as plastic laminates, silicones, and processing aids.

However, this revolution has raised new issues that must be resolved. For example, possible paperboard contaminants, such as polychlorinated biphenyls (PCBs), which were difficult to detect in the past, have heightened concerns now that analytical technology is available to detect them. There are also concerns about the presence of commonly used toxic solvents, such as benzene and methylene chloride.

Another major concern is whether packaging components will migrate into the food product. In addition to concerns about the safety of a packaged food, packagers must also address concerns about whether the packaging will affect appearance, flavor, odor, and other factors affecting consumer acceptance. Will packaging ingredients migrate into the product, resulting in complaints about flavor, odor, or color? Or will the package actually remove desirable sensory attributes (known as flavor scalping)?



While consumer acceptance issues will determine the success or failure of a given product, unsafe packaging is a public health issue and will affect the future of the food and packaging manufacturers. Package component migration can result in food adulteration, which violates federal laws, and food safety professionals must be aware of regulations governing this area.

Staving-off problems with product packaging requires an integrated product strategy. Most companies, however, do not have the resources or expertise to deal with unexpected problems with product packaging, nor do they want to add permanent fixed costs by staffing new departments, because their core business is selling branded products. There are still risks and expenses even in coordinating separate consulting services, however, because any one service may have a limited view of and ability to react to the entire picture. Another strategy that is finding rapid acceptance within the

industry is the use of an external contract laboratory to manage the product-package relationship. This strategy may make the difference between getting a product package to market first and losing market share while trying to solve problems in-house with more limited resources.

For example, recently a packaging company was introducing a new plastic film; a colorant producer had a new market for printed packaging; and a major silicone producer was targeting the paper coating market. All were counting on launching and selling their products quickly but were unable to proceed because of changes in FDA rules. The delays cost them sales and market share and gave their rivals a competitive opening.

Testing performed at an independent contract laboratory helped these companies comply with the FDA's new Food Contact Notification (FCN) rules, which have been designed so the FDA can review data and make a decision within 120 days.

Under the new rules, migration studies with a food-simulating solvent, such as ethanol, introduced to the packaging material for a specific length of time are needed.

Complying with FDA Regulations

Any packaging material that comes in contact with food must receive FDA clearance before it can be used. Figure 1 shows a flow chart for obtaining FDA clearance. In the examples given earlier, the components were so new that FDA clearance was not available, and the clearance process had to be initiated through the FCN process. In many cases, however, a new food package will be made with previously cleared components. As a result, food safety professionals must first determine whether the desired packaging material already has FDA clearance. If it has, the regulatory issues are much simpler. Clearance applies to any packaging component that may affect food quality, not just the container, but also printing inks,

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labels, and seals. Packagers should insist that their packaging material suppliers demonstrate compliance by letter or other documentation. Some testing is also advisable as a quality check.

Title 21 (Food and Drugs) of the Code of Federal Regulations (CFR) contains the regulations for previously cleared materials as they apply to food safety. This is the first source you should check to find materials that have been cleared by the FDA for food contact use. Parts 170 to 199 of 21 CFR contain lists of materials grouped into parts (chapters) according to material type, such as adhesives and coatings (Part 175), paper and paperboard components (Part 176), and polymers (Part 177). In each part, material specifications are tabulated, making it easy to determine whether the desired packaging material is listed. If it is, the material can be used under the use conditions summarized in the regulations.

One or more extraction or solubility tests are described in detail in the regulations. These tests are conducted to ensure that a supplier is delivering materials that are in compliance with the regulations. Depending on the food product to be packaged and the temperature at which it will be used, the packaging material is heated in a solvent for a specified time and temperature. The solvent is then analyzed for extracted components. The test simulates the most extreme conditions to which the packaging will be subjected. The goal is to ensure that harmful compounds are not extracted into the food during normal handling and preparation.

Because solvents present fewer problems in the laboratory, they are generally used in food-packaging extraction testing instead of foods. The term "food-simulating solvent" is used because the solvents simulate the action of foods on packaging. For example, dilute aqueous ethanol simulates the action of aqueous, acid, or low-alcohol foods.

To select the most appropriate test conditions, you must know the food type to be packaged and the most extreme heat conditions to which it will be subjected. The FDA classifies foods into nine types (I-IX), depending on the amount of acid, alcohol, or fat they contain. The types are fully defined in 21 CFR Part 176.170. Temperature conditions are divided into Condition of Use groups, also defined in 21 CFR, including high temperature, heat sterilized (higher than 212°F); hot filled or pasteurized (above or below 150°F); and room temperature, refrigerated, or frozen uses. Understanding the food type and condition of use enables the manufacturer to choose the proper extraction test conditions.

What does the laboratory do with the extracts? Because many specifications are based on the amount of nonvolatile residue extracted by the food-simulating solvent, the solvent may simply be evaporated, and the residue weighed. Results generally are

expressed in milligrams of residue extracted per square inch of packaging surface area. Some specifications require that the ultraviolet absorption spectrum of the extract remain below a given value, while others detail the solubility in dilute hydrochloric acid or the maximum extractable fraction in solvents such as benzene, ethyl acetate, and chloroform.

FCN Clearance

What if a component of a packaging material isn't listed in 21 CFR? When the silicone manufacturer mentioned earlier wanted to market its product as a paper coating, they checked 21 CFR 176.170 and 176.180. The coating was not listed, indicating it had not been approved, and it could not be used until it was approved. To obtain approval, the producer had to initiate the FCN process.

Prior to January 2000, FDA clearance of a new food-contact material required the preparation of a Food Additive petition or a Threshold of Regulation request. These are expensive procedures that can take years to be cleared through the FDA. Since early 2000, however, the new FCN procedure has streamlined the clearance process considerably. Among other things, the notifier presents data to the FDA on the potential migration of the component into foods. If the FDA does not object within 120 days to the use of the substance, based on food safety concerns, it may be marketed immediately.

Migration data related to the food type and the condition of use are needed. Again, for ease of analysis, food-simulating solvents are generally used instead of actual foods. For example, migration into fatty foods usually requires evaluation with a food oil. Miglyol, a fractionated coconut oil, is often used to satisfy FDA requirements, while European regulations require olive oil. Testing for packaging migrants in food oil can present analytical difficulties,

so 50 or 95% aqueous ethanol sometimes can be substituted.

Tests must also be performed in triplicate. The test material is immersed in the solvent and heated to a specified temperature, depending on the condition of use. For example, the most extreme condition requires heating at 250°F for 2 hr, followed by 10 days at 104°F. Because these temperatures are higher than the boiling point for most food-simulating solvents, special cells designed to withstand the extremes of temperature and pressure encountered are used. Some cells are constructed so only glass and Teflon contact the solvent, while others may be all stainless steel. The cells are also configured so all surfaces of the test material can contact the solvent, or, in the case of a coating, only one side of a test sample is extracted.

For safety, cells are then placed in a high-pressure vessel, such as a steam retort, for heating. In this manner, cells can be over-pressurized, which prevents leaking. At various intervals during the testing period, the solvent is sampled, and the migrating components analyzed. If migration is found, the safety of the migrant must be evaluated, taking into consideration the amount found, probable consumer exposure, and toxicology of the migrant.

Analytical chemists trained in the use of gas chromatography, high-performance liquid chromatography, and mass spectrometry often apply these and other techniques to the analysis of extracts. For example, when the packaging material contains a new colorant with a metal that may migrate, the laboratory needs to use atomic absorption spectrometry or inductively coupled plasma spectrometry to analyze the materials. Each analytical method must be capable of reaching the required detection limit, typically 50 parts per billion or less. A well-equipped laboratory can choose the proper analytical technique to solve any analytical

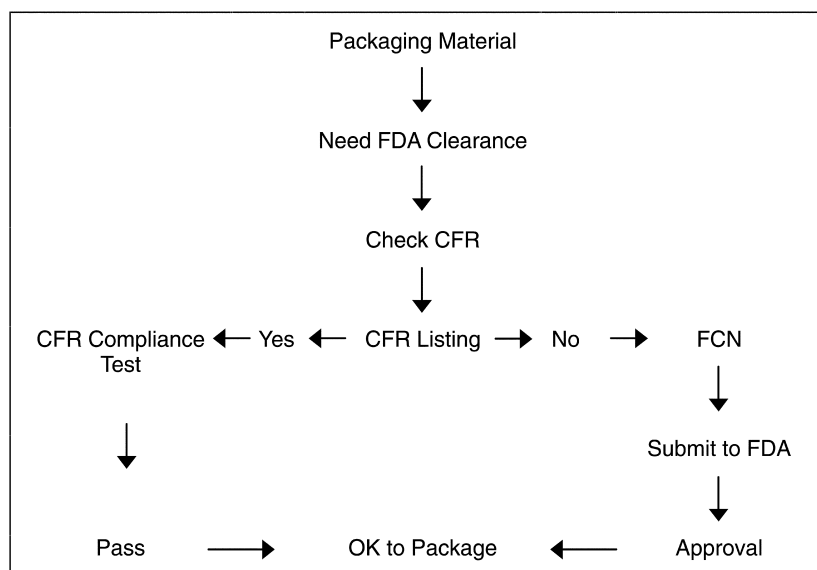


Fig. 1. Flow chart for obtaining FDA clearance.

problem that may arise during migration testing.

To show that the methodology used is suitable and capable of delivering the correct result, FCN regulations require that each analytical method be validated. Extracts of samples or controls must be spiked with the potential migrant at known levels, then analyzed using the same method used for the sample extracts. Adequate recovery of the spiked material shows that the method works as reported.

FCN can be a time-consuming process. What if a producer goes through the process only to find the migration rate is too great? If the migration rate is too great, the packaging material will have to be reformulated and retested, requiring more time and money. Exploratory tests can be designed to point the packaging developer in the right direction and lessen the risk that a costly migration study will have to be repeated.

Consumer Acceptance

FDA clearance of food-packaging materials is a food safety issue that is critical to the success of the product. Success in the marketplace, however, also requires consumer acceptance. Acceptance usually boils down to fine distinctions in flavors and odors. When expert flavor and odor evaluation is needed, a contract laboratory with specialists in this area can convene a trained panel with extensive experience. These sensory panelists are highly trained in evaluating packaging-related flavors, odors, and intensities, which can be used to help in quality control audits, product differentiation, and deciding whether to reformulate materials.

Manufacturers of packaging materials use the same types of lab facilities used by food manufacturers. For example, random analytical and sensory testing of paperboard and custom-printed folding cartons for the food industry can help a packaging manufacturer's customers and end users match products and packaging to meet federal regulations, which can help minimize any liability associated with the packaging.

One packaging material producer has begun working with several of its ink and coating suppliers to develop a new generation of ultra low-odor inks for high-risk packaging. These inks were intended for products such as tea, rice, and chocolate, which are extremely odor sensitive. Various grain and cereal products also fall within this category. When placed in contact with various odors, these products absorb and impart changes to the flavor characteristics of the food group.

A gas chromatograph with a mass spectrometer was used to test the headspace above the printed material for volatile compounds. Based on the chemical analysis of the printed

samples, the type and amount of different odor compounds were ranked. Sensory analysis was used to rank odor intensities. The two sets of results were ranked independently.

Analysis showed that some of the samples contained only a small quantity of a given compound, yet their impact on flavor or odor was large compared with other compounds with higher measurable quantities. The results were compared with an internal sensory panel to select the best option. Using a contract laboratory saved the manufacturer hundreds of thousands of dollars on specialized testing equipment that it didn't have to purchase. In addition, the manufacturer avoided the significant expense of recruiting and maintaining qualified in-house sensory panelists.

Before products reach consumers, a variety of factors may affect flavor and odor in packaging—from coatings, adhesives, and residual solvents to processing and sealing temperatures. To minimize this problem, systems can be developed that provide food processors, converters, and resin suppliers with common ground for comparing package flavors and odors.

For example, a list of standardized terms can be developed to represent particular odors and flavors picked up from packaging, because it can be very difficult to describe or characterize the flavor or odor of packaging materials with consistency. In many

cases, these terms, e.g., acetone-like or metallic, and their intensities are the result of the calibration of the panelists' noses and tongues (when safe!) using standard chemical solutions of known concentrations. These standardized terms, used with an intensity scale, are particularly useful in vendor certification, or when evaluating packaging changes, process variations, and new sources of raw materials. Packagers and product managers are always trying to develop a new twist for established applications, either to win market share or to lower costs. In so doing, they may change the chemistry, flavor, odor, or migration profile of the packaging material or product. As a result, food and beverage manufacturers need to continually monitor the packaging and product.

Conclusions

As consumers search for better tasting, easy to prepare foods, the food industry will continue to develop new packaging, ingredient, and processing options to meet consumer needs. With this proliferation of options comes the challenge of keeping up with factors affecting the safety and consumer acceptance of products. Identifying and establishing relationships with packaging experts is one method that can help guide manufacturers through ever-changing regulations and testing technology, so they can stay competitive with safe, novel products.

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