Printing Ink Guidelines for Package Inserts

A primer for direct food contact, these guidelines cover a number of government regulations and their impact on ink selection.

by Michael F. Gettis

There is nothing new about couponing or packaging promotions among marketers in the food industry, a practice that turned 100 years old in 1996. We live in such a fast-paced world, you wonder when consumers find the time to sort through the many methods of distribution. Shoppers are bombarded with messages from every conceivable angle, but the only ones that are difficult to ignore are those attached to, or found inside, the products they buy. If flexographic printers decide to bid on a direct food contact promotion, they should be aware of certain guidelines that will help them to comply with US Food and Drug Administration (US FDA) regulations.

Promotion Overview

The phenomenal growth of coupon distribution during the past 20 years, and the sophistication with which marketers utilize that proven promotional tool today, is quite varied. The use of direct food contact printing inks for in-pack coupons has contributed to both the growth and advancement of present day couponing. Flexible packaging printers have seen package size reduction become one of the goals of the food industry due to environmental waste stream, source reduction pressures. Along with that goal, food marketers find themselves with less space to entice the consumer to purchase their product.

Over the years, the inside of the food wrapper has increasingly become a target for the enticement mechanism. In-pack marketing is a targeted promotional tool that can either encourage trial/repeat purchases, build brand loyalty or tempt the consumer to purchase another product offered by the company. More manufacturers are discovering how effective a package can be as a promotional delivery vehicle. Consumers are bombarded with enticements from every direction; freestanding inserts are the primary vehicle (such as the ones that fall out of the Sunday newspaper), but the redemption rate continues to decline. The in-pack approach can be the stimulus for consumers who are looking for high perceived value. Often it is that extra element that convinces people to switch brands. Sales can climb anywhere from 15% to 25% with a strong "free offer inside" message. Eighty percent of brand decisions are made in-store, so it stands to reason that a visible offer will generate interest and sales. Arguably, even though on-pack promotions have the highest redemption rate, in-pack promotions provide a cost effective method of getting the message across in a package that lacks the necessary space for an on-pack announcement.

Narrow Web In-Packs

Once a food marketer decides to promote a product with in-packs, there still is a very important choice to be made: How to produce the in-packs and assure compliance with strict US FDA regulations regarding direct food contact (see FLEXO, June 1995, pages 30-32, as well as an update in a future issue). Currently, there are three methods of manufacturing:

1. Utilize conventional printing ink and overwrap the in-pack with a functional barrier.
2. Print with conventional inks and

overprint with a US FDA-acceptable coating.

3. Utilize inks that, when dried, have a resultant ink film that is acceptable for direct food contact.

Whatever method is chosen, the over-riding concern is that the inks do not migrate to the food product. An examination of the pluses and minuses of each method reflects why the use of US FDA-acceptable ink is fast becoming the method of choice by marketers looking to get the most for their money while complying with the regulations.

Overwrapping with Plastic

This is a commonly used method of protection that can comply with the functional barrier concept as dictated by the US FDA. This method requires the use of food-approved plastics, those materials that have been found to resist both abrasion and bleed in wet and greasy foods. Because overwrapping adds another manufacturing step and requires additional material, it is by far the most expensive method, with production costs of about $12 per 1,000 coupons. Some food companies will not allow any printing ink or paper to come into direct contact with food products, and rely solely on plastic overwraps for in-pack work. Even then, there is a likelihood that, due to pouch failure rates, migration could occur if the overwrapped package were opened and the food product came into contact with the insert.

Overprinting Conventional Ink

Overprinting with a varnish or aqueous coating is the least expensive method of production for food contact coupons. At the same time, the possibility of pinholing or voids occurring due to press conditions poses cause for concern. The US FDA would consider the overprinting method suitable, provided the packager could prove that the overprint serves as a functional barrier that will prevent migration to food products. Varying conditions encountered with different applications also should be considered. Extremely abrasive foods could wear down the overprint and compromise the barrier. Some food packagers have elected to use the overprinted conventional ink method and insert the coupon between the food wrapper and the carton so that the wrapper acts as a functional barrier. However, consumers might miss the offering since it can not be easily seen or found.

The US FDA states that if there is a food-contact-approved functional barrier (resinous coating, protective film or transparent cover) separating the printed material from the food, such a use of printing ink would not be considered a food additive situation, and the printing ink ingredients would not need to be approved for that particular package. However, even though a resinous coating is acceptable on the basis that it contains components approved for use under the food additive regulations, it must be applied in such a manner that it forms an effective functional barrier; that is, it must be of sufficient thickness and continuity to prevent the ink from passing through the coating and migrating to the food. The manufacturer must employ good manufacturing practices to ensure that the coating has formed a *continuous layer* over the ink and substrate. There should be no pinholing, and/or the coating should be thick enough to prevent migration of ink. When these coating application conditions are met, a functional barrier is formed. Most printers and converters will agree that a continuous coating (free of voids and pinholes) would be a difficult task to monitor — and ultimately guarantee — to an end-user company.

Direct Food Contact

This type of ink usage is a safe and cost-effective method of manufacturing in-pack coupons. All of the ingredients used in these inks, as well as the paper on which the inks will be printed, should be guaranteed compliant with US FDA regulations. Production costs reportedly are about $4.50 per 1,000 coupons. The savings are significant versus the overwrapped method, and an informed printer can consult with the marketer to show him or her the savings. Some printers have purchased their own overwrapping equipment or have an agreement with an overwrapping specialist, and the message may never reach the marketer.

Most food companies supply packaging specifications to their printing vendors so they are assured of regulatory compliance. Many people involved in the process are concerned and confused about the terminology, let alone the specifications.

A "food additive," as defined in the Federal Food, Drug and Cosmetic Act, is "*. . . any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food;. . .), if such substance is not generally recognized, among experts qualified by scientific training or experience to evaluate its safety, as having been adequately shown through scientific procedures... to be safe under the conditions of its intended use . . .*"

A strict interpretation of the definition of "food additive" would make all substances that migrate, or may be expected to migrate, from food-contact materials into food, subject to premarket approval as food additives. US FDA personnel, in response to inquiries from manufacturers of food-contact articles, have stated that certain specific uses of substances in food-contact materials did not require regulation under the food additive provisions. The US FDA felt it necessary to formalize the system of pre-market approval since historically, a number of companies have made their own determination that a particular substance effectively does not migrate to food and thus is not a food additive under its conditions of use; they have marketed these products without recourse to the regulatory process.

Nothing in the regulatory scheme of the 1993 proposed rule would prevent a company from making its own determination that a particular use of a substance does not meet the definition of a food additive. However, as always, the company makes such a determination at its own risk. If, for example, the US FDA learns of the use of a substance from a competitor and reaches a different conclusion than the company, the US FDA may take regulatory action against the substance as an unsafe food additive, or against the company that makes the substance, for introducing an adulterated food into interstate commerce.

INK GUIDELINES

Recently, the US FDA agreed to simplify approval for substances used in food contact packaging by doing away with the time consuming pre-market approval process that requires explicit US FDA consent. Instead, a streamlined pre-market notification (PMN) process takes its place. Such a change, however, requires a modification to the law, and it appears increasingly unlikely that Congress and the President will enact and sign pending US FDA reform legislation that is expected to include the PMN provision.

The change means food manufacturers or packaging suppliers would notify the Dept. of Health and Human Services of their intent to introduce an additive into the market. Instead of waiting for US FDA approval, companies could proceed with the new additive if they did not receive an explicit rejection from US FDA within 120 days. In the notification, the company would submit the same type of safety information that currently is in a food additive petition. US FDA insists on a provision that allows it to issue a regulation stating that certain additives still would require a food additive petition, and would not be permissible under the new PMN process. However, this agreement does not affect US FDA's environmental impact requirements, and an environmental assessment is likely to be part of any petition.

The only formal regulations that the US FDA has regarding printing inks are those for color additive diluents contained in Title 21 of the Code of Federal Regulations, Part 73. In general, substances listed in Section 73.1 for a specific use in inks are color additives listed for direct use in food, and substances that are generally recognized as safe for use in food are acceptable in ink formulations used on food or food packaging. In addition, substances regulated for use in food-contact material also may be acceptable if the use in inks is encompassed by the permitted use in food-contact materials. In cases where food packaging is a functional barrier to migration, the components of an ink on the exterior of food packaging are not considered food additives, and do not need to be regulated by the US FDA for their intended use. The category into which food packaging inks and coatings typically fit is "indirect food additives." Inks and coatings may have direct, indirect (commonly referred to as minimal), or incidental contact with the food. This means that they are not intended to become a part of food, but they inadvertently may do so through some type of food contact.

A Glossary of Terms Related to Food Package Printing

Definition of Food Additives

Direct Additives: Edible materials intended to become part of a food product, including such items as preservatives, flavors, gums and colorants.

Indirect Additives: Materials in the packaging, processing, holding or transporting of food that have no functional effect on the food but that may reasonably be expected to become components of food or to affect its characteristics. Items in which food may be packaged or wrapped and come into contact with the food, may become part of the food, and be subject to regulation.

Food Additive Note: Direct and indirect additives do not include materials that do not migrate to food. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and is not a food additive.

Definition of Food Contact

Direct Contact: Materials in intimate contact with, or touching, the food.

Indirect Contact: Materials that might come in contact with food, such as the outside of bags, boxes or cartons.

Incidental Contact: Contact not on purpose or not intended, such as on a part of a food processing machine.

Guidelines for the Printer

The printing of materials that come into contact with food is a specialized business. The US FDA has rigid guidelines concerning what types of substances (inks, varnishes and other coatings) may or may not come into direct contact with foods, and under what circumstances. Food manufacturers, meanwhile, also are sensitive to the US FDA's safety guidelines, as well as their own quality standards. After all, they do not want ink odors to affect the taste of their products.

A key to avoiding costly complications from direct food contact inserts is for the food company and the printer to provide the most complete information regarding the job. The printing process and all available press parameters are of great importance in enabling a food contact ink supplier to provide the best ink formula to produce a quality printing job. With direct food contact insert printing, it is vital that all parties have a thorough knowledge of the food product, packaging conditions and end-use requirements to which the insert will be subjected. The following should help in providing the necessary information to enable the ink supplier to anticipate any potential problems or interactions that might occur between the food product and the printed insert.

Type of Product

Is the product dry, wet or greasy? If wet or greasy, what is the approximate moisture, grease, fat or oil content? Be careful. Some so-called "dry" products — cookies, bread, tea, coffee and soft pet foods — may contain high levels of moisture or grease. Also, specify the product by brand name, since there can be big differences in moisture content between brands, such as white Wonder bread and Arnold's rye bread.

Coupon Insertion Storage Conditions

Temperature is a critical factor in determining whether an ink pigment will react with the product with which it comes into contact. Since various temperature conditions can affect pigments differently, it is important to inform the ink supplier about the condition of the product at the time of insertion. Will the pack be inserted while the product is hot, or cooled to room temperature? Provide actual temperatures if possible. Will it be inserted while the product is hot and then flash-frozen, or inserted and stored at room temperature?

End-Use Conditions

Product characteristics such as abrasiveness (salted potato chips) and shelf life also come to bear on the production of the insert. Products with heavy salt coverage, for example, can in some cases actually scrape ink off the

stock, while prolonged shelf life (a few days for bread vs. a few months for dry cereal) also could raise issues that can be dealt with up front by using waxes, varnishes or coatings.

Colors' Bleed Resistance

Historically, the color red, or colors containing considerable amounts of some red pigments (oranges, deep blues, reflex blue, and so on) were most likely to bleed or run when the insert came in contact with wet or greasy food. It may be necessary to limit usage of certain spot color shades. However, breakthroughs in food contact red pigment now allow for acceptable four-color process work. Yellows also may bleed, but usually only under more extreme conditions.

Bleed vs. Product Resistance

Bleed occurs when the pigment itself is being attacked or solubilized by the product or the moisture/grease in the product. Product resistance occurs when some component of the product attacks the entire ink film itself and redissolves it. Generally, the easiest way to differentiate between color bleed and product resistance is whether only one or two colors smear and the others do not (color bleed) or whether they all smear (product resistance), which indicates the ink system itself has poor resistance to the product. In both cases, specialized coatings or varnishes can reduce or eliminate the problem. However, the only sure way to determine this is by product testing under actual end-use conditions.

Product Testing

Except for dry, non-abrasive products, testing is recommended in all cases. All of the colors to be used on the job should be tested with the food product under actual insertion and storage conditions. Lab testing is helpful in providing preliminary data, but actual conditions cannot always be exactly duplicated. The easiest way to product test is to utilize proofs (both with or without barrier varnishes or coating), leaving an unprinted border around each. Insert them with the product under conditions identical to the way it would be done on the actual job, and store the product as it normally would be for its anticipated shelf life, if it is short (a week or less). If the product shelf life or storage is longer, it can usually be checked after two weeks, since color bleed or poor resistance to the product usually occurs rather quickly. If no bleed or smearing is observed, it is unlikely it will occur if stored for longer periods.

Odor and Taste

Because many foods can pick up stray odors that can affect their taste, it is important that the inks be thoroughly dried before insertion. Although certain printing processes and the inks they use generally provide much less residual odor than others, it still is important to consider how and if stray ink and/or paper odors affect the taste of the product. This is particularly true of foods containing butter, chocolate, margarine or cocoa. It is not usually as much of a problem with dry cereals, pet foods, meats or poultry products.

The following list provides a general guide to the relative residual odor intensity of the various printing processes and the ink systems, from highest odor level to lowest.

1. Sheetfed Letterpress/Offset (Oil-based)
2. Non-Heat Web Letterpress/Offset
3. Silk Screen*
4. Heatset Web Offset
5. Glycol Based Letterpress/Dry Offset
6. Flexographic/Gravure (Water or Solvent)*

*These can rank higher or lower, depending on the resin or solvent systems used and the completeness of drying (residual solvent).

Although analytical tests can be used to detect residual solvents, odor and taste effects are subjective, and are generally tested using taste and odor panels. Odor and taste effects generally can be tested at the same time bleed and product resistance is tested, but because of differences in printing, drying and processing conditions, it is best to test from an actual production run. Most large food companies will do both.

Wide Web Flexible Packaging

Printers of wide web flexible packaging for the food and confectionery industries often have been presented with opportunities to print a game promotion or coupon on the inside surface of a packaging film. Some of them have taken the necessary steps to comply with EPA emission regulations and installed incineration or solvent recovery systems. For them, solvent-based direct food contact inks can be formulated for a variety of applications and substrates. Specialized water-based inks also can be used for the same purpose. Since flexographic and gravure inks provide the lowest odor characteristics of all traditional printing systems, flexible packaging printers have an advantage over other printers in that respect. But flexible packaging printers have to be concerned about product resistance as much as narrow web printers.

There are only a limited number of acceptable resin systems for direct food contact. Some resins can provide superior heat and product resistance, but at the expense of slightly poorer tape test adhesion. Information on the exact type of substrate, treatment level and product to be packaged should be communicated to the ink supplier. Open dialogue among the printer, ink supplier and food packager will avoid any misunderstandings when the project comes to fruition. The checklist should be used; product testing also should be paramount before any job goes to production.

In conclusion, the relationship among the printer, food contact printing ink supplier and the food packager is critical. Downsizing in the food industry has affected the amount of time packaging engineers can devote to these kinds of issues; as a result, some food marketers rely on printing brokers and advertising agencies to fulfill their needs. It is just as important to bring them into the loop, in the event their knowledge on the subject is limited.

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