FDA Compliance Myths

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There are a number of misconceptions or myths prevalent in both the printing and printing ink industries regarding FDA-compliant inks and coatings. Some of the more common ones are shown at right.

A brief discussion of each of these myths should help to dispel them and give a better understanding of the regulations that apply to printing inks and what is needed to comply with them.

THE REGULATORS

As an introduction to printing inks and the "GRAS" (Generally Recognized As Safe) List, I would like to briefly explain the organization of the FDA and the CFR (Code of Federal Regulations). The FDA is the agency empowered by Congress to adopt and enforce the regulations promulgated by the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. It is the FDA's responsibility to make sure that any ingredients added to our foods or drugs, either purposely or inadvertently, are both safe and effective, and that all such products are properly and correctly labeled.

The CFR is the embodiment and codification of all the laws and regulations adopted by the agencies and departments of the Federal Government. It is divided into 50 so-called Titles, which represent broad areas of regulations related to a specific issuing agency. For example, all regulations under the jurisdiction of the EPA are found in Title 40; the DOT is Title 49; the IRS is Title 26; and the FDA is Title 21. Title 21 is further subdivided into Chapters, Parts, Sections, Paragraphs.

1. The "GRAS" List

All food additives, except for some colorants, are generally found in 21 CFR Parts 170 to 189. These are the parts we need to be most concerned with when attempting to formulate FDA-compliant inks and coatings. Food additives are further divided into direct additives and indirect additives.

Direct additives are those substances which are not naturally a part of the food itself, but are approved for direct addition to foods. Remember that they must not only be safe, but must perform some specific function; for example, colorants, thickening agents, flavorants, stabilizers, preservatives and many of the chemical ingredients we normally see on a food label. They may or may not have restrictions with regard to their purity or the quantity that may be used.

Indirect additives are those substances used in the processing, packaging, holding or transporting of food that have no functional effect in the food but which may reasonably be expected to become components of

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the food or otherwise affect the characteristics of the food. An example would be the colorants or slip agents in paper or plastic packaging, the adhesive on the package or the components of the ink or coating used on the package — anything that might possibly migrate to the food and thereby adulterate it or change its characteristics, including its taste, odor or color. Indirect additives are usually found in parts 170-179.

CLARIFICATION

Confusion often arises over direct and indirect food additives as opposed to direct and indirect food contact substances. A processing or packaging component which is intended to be in intimate or immediate contact with the food is a direct contact material.

An example would be the inside, or food contact, surface of a polyethylene bread bag or a cents-off coupon inserted directly into a box of cereal. Indirect contact is when there may be only occasional or minimal contact with a food product. The outside surface of a bread bag would be an example. If a material will be in direct contact with a food, it must be composed only of direct or indirect food additives as found in 21 CFR 170-189.

We've all heard of inks or coatings being referred to as safe because they were GRAS. What is the GRAS list?

THREE PARTS

GRAS consists of three distinct parts in the CFR.

Part 182 is entitled "Substances Generally Recognized as Safe." This section contains many common food ingredients which have been safely used for decades or centuries, such as salt, pepper, sugar, MSG, citric acid, and a large number of similar ingredients.

Part 184 is entitled "Direct Food Substances Affirmed as Generally Recognized as Safe." The difference between this and Part 182 is that all of these substances have been reviewed and/or tested by the FDA in order to "affirm" their safety.

The third list is Part 186, "Indirect Food Substances Affirmed as Generally Recognized as Safe." This list contains only a handful of substances that the FDA has reviewed and found to be safe as indirect

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additives where they become components of food by migration from immediate wrappers, containers, or other food-contact surfaces. They cannot be added directly.

Can an ink be made entirely from substances that are GRAS? Theoretically, no, since no pigments or colorants appear on the GRAS lists. Even food grade or certified colorants are regulated in other specific sections of the CFR and are not GRAS.

Although it might be possible to formulate an ink vehicle or clear coating from GRAS substances alone, such a vehicle would have very limited use or practicality.

Fred Bichaylo

How did the myth of inks being "GRAS" get started? Much of the misunderstanding apparently came about by package printers and others describing inks and their components in a very broad sense as "being safe for their intended usage." In the strict sense, however, as we have seen, only those substances listed in 21 CFR 182, 184, or 186 are GRAS. Because of the prevalence of the incorrect use of the GRAS term, NAPIM issued a bulletin in 1983 in an attempt to clarify this issue.

2. Low Heavy Metals = FDA Approval

Another misconception is that low heavy metal content is equal to FDA approval. In a number of instances inks were used for direct food contact applications based solely on the results of testing showing low heavy metal content.

First of all, inks or coatings are not really "approved" by the FDA. They are only considered to be "acceptable" for a specific food contact application if they are formulated solely from FDA-"approved" substances or ingredients. These are the direct or indirect additives listed in 21 CFR.

Certainly, low heavy metal content is one of the criteria used by the FDA to assess the safety of a substance as a direct or indirect additive. Chemical purity, carcinogenicity, other toxicity data, degree of migration, potential dietary exposure, etc. are just a few of the other requirements.

How did this myth come about? Apparently because inks that pass certain heavy metal requirements are deemed to be acceptable or approved for use on furniture, toys or other materials used by children — the so-called "toy inks." It is important to note that toy safety does not come under the jurisdiction of the FDA, but rather under Title 16 of the CFR — The Federal Trade Commission and The Consumer Product Safety Commission, which sets a voluntary standard for the safety of toys and other products used by children. It also sets a limit of 0.06% for lead. Specifications for lead and some of the other heavy metals were later adopted by toy manufacturers from ANSI Specification Z66.1 and ASTM's F963-86.

Remember, just because an ink passes the "toy specs" does not mean it meets FDA requirements. To comply with FDA regulations the substance or substances must be listed in Title 21. It is not enough that they are approved or safe for other uses.

END USE FACTORS

While still on the subject of heavy metals, I would like to take a few moments to discuss an issue that has currently been receiving widespread attention and adverse publicity: the use of leaded pigments in inks for polyolefin bread wrappers.

Even though the FDA was aware of this use, it held that the food additive laws do not apply since the ink is on the outside of the package and is separated from the food by a functional barrier — the polyolefin film. And most critics do not fault the FDA for this position; it is legally correct. What they do fault is that the FDA did not anticipate or consider all the potential uses for the package.

A recent survey indicates that a very high percentage of consumers not only re-use bread bags for storing foods, but that they turn them inside out to do so, which was very surprising. Thus, the ink could migrate to the food by being dissolved in some of the oil or other food ingredients or flake off due to abrasion or "crinkling." In either case, it does pose a potential health hazard.

My entire point here is to show that all potential end uses need to be considered when selecting ink or coating components in food packaging applications. What may be considered safe for one application may not be so for another.

3. Inks Don't Migrate To Dry Foods

Until recently it was assumed by many people, and wrongly so, that components of printing inks did not migrate to dry foods and, thus, the food additive regulations did not apply. This myth was perpetuated, I believe, by the misinterpretation of a paragraph in an opinion letter on inks from the FDA to NAPIM in 1980, and a reaffirmation of that letter in May of this year. Paragraph 3 of that letter states:

"We are of the opinion that printing inks used in accordance with the principles of good manufacturing practices for coupon inserts in packages of ordinary dry granular foods are not food additives within the meaning of Section 201(s) of the Act if there is no reasonable expectation of migration of any of their components to the foods."

It does not say, "if there is a reasonable expectation;" it says "there is" a reasonable expectation of migration.

The crux of this statement lies in the last 16 words: "...if there is no reasonable expectation of migration...". Unfortunately, the tone of the paragraph implies that migration to dry foods is unlikely.

To the contrary, not only does the possibility of migration exist, recent tests and migration studies, by both industry and the FDA, show it is a very real probability.

In fact, in a proposed ruling involving colorants for polymers, published in the Federal Register of April 6, 1988, the FDA argues that existing theory and experimental data demonstrate that essentially everything will migrate to food under normal conditions of use. Fick's first and second laws of diffusivity are cited as proof of their position.

In addition, I recently asked the FDA to clarify the issue of migration of printing inks to dry foods. Their response is quoted, in part, as follows:

"Because the printing ink on a paper coupon inserted into a package of dry food (e.g., cereal, rice, pasta, bread, etc.) will have direct contact with the food, there is a reasonable expectation that the ingredients of the printing ink will become components of the packaged food, and they are, therefore, subject to the provisions and requirements of the FD&C Act."

Note that it does not say "if there is a reasonable expectation;" it says "there is" a reasonable expectation of migration.

There are two other issues that need to be considered with regard to migration of food contact components to dry food. What is the definition of a "dry" food? Many of the foods we normally think of as dry actually contain significant quantities of oil and/or moisture which can contribute to bleed or migration of ink components. In addition, the abrasive nature of most dry, granular food products can cause particles of ink to flake off the food contact surface into or onto the food.

The conclusion is that migration to dry food can occur in greater than insignificant quantities and must be considered when formulating inks for dry food contact.

4. Overprint Varnishes Are Functional Barriers

Another related myth is that overprint varnishes are functional barriers to migration. On numerous occasions printers have used conventional or non-FDA compliant inks with an FDA-acceptable overprint varnish for direct food contact applications and assumed they conformed to the law because they had placed a chemically acceptable barrier between the ink and the food. Can overprint varnishes be effective functional barriers? That depends; they may or may not be. The key word is "functional."

The opinion letter received by NAPIM that was mentioned earlier and a position letter I recently received from the FDA's Division of Food and Color Additives are both essentially identical in their definition of what constitutes a functional barrier. It is not enough that the varnish be chemically acceptable under the food additive regulations. In addition, it must (1) be applied in such a manner that it forms a continuous coating over the ink or substrate so that there are no voids or "pinholes" present; (2) be of sufficient thickness to prevent migration through it; and (3) be of such chemical composition that it is insoluble in the food or ink to such an extent that the ink or food ingredients are incapable of passing through it.

Would a normally applied sheetfed or web offset overprint varnish meet all of these criteria? You be the judge. I would certainly be hesitant to guarantee "no migration" without running extensive and sophisticated extraction and analytical studies. In fact, migration of ink components has even been substantiated through plastic films such as polyesters and polyethylene, even though these are normally considered to be functional barriers.

5. Environmentally Safe Inks Are Food Safe

Earth Day, and the great amount of interest and publicity surrounding "green" packaging and other environmental concerns in the printing and converting industries in recent months have contributed greatly to the next myth: the belief that environmentally safe inks are also food safe or FDA acceptable.

Many of the same or similar synthetic resins and polymers used in conventional inks are also acceptable for use in FDA-compliant inks.

Actually, in the majority of instances, it has been presented in the opposite way — that because an ink is FDA acceptable for direct food contact, it must also be environmentally safe. Neither statement is necessarily true.

Before discussing the biodegradeability, recyclability and emission aspects of FDA-compliant inks, we need to examine another term which is commonly used in conjunction with these inks and which may have had something to do with the mistaken impression that FDA-compliant inks are environmentally safe. This is the term "vegetable" ink.

Seldom does a day go by that we don't hear someone requesting a "vegetable" ink for a direct-food-contact application. Obviously, this is a misnomer, and I can only speculate on how the term originated. Perhaps people think that the only way to make an oil ink good enough for food contact is by using vegetable oils. Certainly vegetable oils are safe and FDA acceptable, but rarely could they be used as the sole, or even the major, vehicle component of a printing ink, just as soybean oil is not the primary component of most of the current soybean inks which are generating so much interest. Actually, many of the same or similar synthetic resins and polymers used in conventional inks are also acceptable for use in FDA-compliant inks.

Possibly the term referred to the colorants that are permitted, or which people think need to be used, in food-grade or food contact inks. I've often heard these colorants referred to as "vegetable dyes," probably because some of the known safe colorants many years ago were those of vegetable origin. Beet powder, annatto, turmeric, carrot oil, the caretenoids, grape extract, and many other natural colorants are still permitted, but they rarely have any practical applications in FDA-compliant inks because of their poor tinctorial and lightfastness properties.

The FD&C-certified colorants and some of the other colorants currently permitted not only for foods but for drug and cosmetic use are synthetic inorganic compounds or organic dyes, lakes or pigments, and many are derivatives of coal tar dyes.

WHAT IS BIODEGRADABLE?

Are FDA-compliant inks biodegradable? Are conventional or non-FDA-compliant inks biodegradable? Both questions are difficult to answer unless, and until, we have a good definition of biodegradability.

Just as with some of the FDA issues, there are numerous misconceptions involved with biodegradability. In fact, ASTM has formed a committee to come up with a definition and a standard testing protocol for biodegradability.

Theoretically, most things are biodegradable. The extent to which a material degrades and the time that it takes, however, depend on numerous factors, the most important of which are the presence of the right type of micro-organisms or aerobic bacteria, oxygen, moisture and temperature. A backyard compost pile makes a pretty good medium for biodegradability. But recent studies indicate that conditions in sanitary landfills, by their very nature, are not very conducive to biodegradation, and, in fact, inhibit degradation.

To answer the original question: both FDA-compliant and conventional inks for the same substrate, printing process, and conditions are somewhat similar in their basic compositions except, perhaps, for the purity of the vehicle or additive components, and the chemical composition of the pigments or colorants. Thus, under similar conditions, their biodegradability would be somewhat similar.

AND WHAT IS RECYCLABLE?

What about recyclability? Again, there would be a little difference between FDA-compliant and convention-

al inks or coatings in most instances. The only difference might be where one might want to recycle a food package back to a food packaging use. For example, a polystyrene clamshell such as those commonly used in the fast food industry, which is printed on the non-food contact surface with a conventional ink or coating, could not be recycled back to the same use, since the non-compliant components would now become part of the food contact surface.

On the other hand, if only food contact-acceptable inks, coatings or adhesives were used, the package might be acceptable for re-use as a food container, providing the components were not chemically changed during the recycling process in such a way that they would no longer conform to the food additive regulations, or if the components were not permitted for the new use, e.g., an aqueous or fatty food versus a dry food. The FDA will examine each recycling use on an individual basis.

Many food grade or "edible" inks or coatings are solvent systems and would be considered hazardous.

Turning to the emissions issue, we again find that there may be no significant differences between FDA-compliant and noncompliant inks. Just as with the "vegetable" ink myth, there are those who believe that FDA-compliant inks, coatings or adhesives must be waterbased. Obviously, this is not true. In fact, even many food grade or "edible" inks or coatings, such as those used to print or coat confectionery products or pharmaceutical dosage forms, are solvent systems and would be considered hazardous from a flammability, health or emissions standpoint. Remember, that, with some exceptions, the FDA is not concerned about the solvents or volatile components of a wet ink or coating. Of more importance are the residual solvents or volatile components remaining in the "dried" film that could contaminate the food with which it is in contact.

THE CONEG CONNECTION

Finally, are FDA-compliant inks safer with respect to CONEG legislation, or the EPA's new regulations with respect to leaching of toxic materials from landfills into surrounding ground water? On an individual basis they probably are safer, since they generally contain lower levels of heavy metals or other toxic contaminants to begin with. For example, CONEG's current maximum levels for the regulated elements (lead, mercury, cadmium, and hexavalent chromium) is 600 ppm, with eventual reduction to 100 ppm. With the exception of leaded pigments, most conventional pigments probably already comply with the 100 ppm level. However, the specification for lead in the FD&C certified colorants that are normally required in direct food contact applications is 10 ppm. So from a solid waste perspective, FDA-compliant inks are safer because they contain only FDA-approved direct and indirect contact food additives.

6. Guarantees

Just a brief word about guarantees of FDA compliance. The FDA regulations for food additives and their use are very specific. Therefore, any guarantees you might require from your raw material supplier or that you need to provide to a printer or a food packager should also be specific. All applicable parts, sections or paragraphs of the CFR should be cited and referenced for each component.

The difference between food additives "approved" by the FDA and the "acceptability" of inks or coatings based upon their use of "approved" ingredients has already been discussed at length.

All too often I've seen guarantees that are so vague, or general, or even so completely incorrect, that they are worthless, such as the GRAS list statement we've already discussed. Other common statements are: "all components of this product are food safe," or "this product was manufactured under GMP (Good Manufacturing Practice) conditions." There are very specific regulations governing what the FDA defines as Good Manufacturing Practice. It is doubtful that any ink or coating manufacturers currently operate in a manner that would meet the strict GMP conditions described in appropriate sections of 21 CFR.

In most cases, guarantees of FDA compliance can be very specific without compromising trade secrets or other confidential information.

I hope that this discussion has helped to dispel some of the common myths associated with FDA-compliant inks, and taken some of the mystery out of the workings of the FDA and the FDA regulations.