Inks for Direct Food Contact

A review and update of US and European regulations.

by Fred E. Bichaylo

Although a number of articles have been published in the past several years on the subject of direct food contact inks, there still is a great deal of confusion and misunderstanding regarding the laws and regulations that apply to food packaging materials. This article will review the regulations and update some of the major changes that have occurred in the US and Europe with respect to packaging inks in general, and direct food contact inks in particular.

The FDA, CFR and Food Additives

The Code of Federal Regulations (CFR) is the embodiment and codification of all laws and regulations adopted by the various agencies and departments of the US Federal Government. It consists of 50 "Titles" that represent all the regulations related to a specific agency. All regulations under the jurisdiction of the US Food and Drug Administration (FDA) are found in Title 21, commonly referred to as 21CFR.

The FDA is empowered by Congress to adopt and enforce the regulations promulgated by the Federal Food, Drug and Cosmetic Act of 1938 and the Food Additives Amendment of 1958, which requires a user to obtain pre-market approval of any new food additive.

All food additives, except some colorants and diluents in color additive mixtures, are found in Parts 170-189 of 21CFR. These are the regulations that we need to be concerned about when we are formulating inks and coatings for food packaging.

Food additives may further be divided into direct and indirect additives. **Direct additives** are those substances that are not normally a part of the food itself, but are added to foods to perform some specific function. Examples of these include flavorants, thickeners, preservatives, anticaking agents, colorants and most of the other ingredients we usually see on a food label. They may have specific purity requirements or quantity restrictions.

Indirect additives are those substances used in processing, packaging, holding or transporting food that have no functional affect on the food, and are not intended to become part of the food, but may reasonably be expected to become a component of the food or otherwise affect the characteristics of the food, and are subject to regulation. This includes all packaging materials and additives, inks, coatings and anything else that would contact food and could migrate to it, affecting its taste, odor and color.

There are three other categories of substances that may contact food which we need to consider: Substances that are generally recognized as safe (GRAS); prior sanctioned ingredients, and substances not reasonably expected to migrate and become components of food. These substances are not considered to be food additives per se, based on the definition of a food additive in section 201(s) of the Federal Food, Drug and Cosmetic Act (FDCA), as amended, and are, therefore, exempt from the pre-marketing approval required of food additives.

Many substances have had a long history of safe use in foods prior to the 1958 Food Additives Amendment, and are, therefore, considered GRAS. A number of substances also have been added to the GRAS list after 1958, but these GRAS determinations must, by FDA regulation, be based on scientific studies to establish the safety of the ingredient, general availability of the studies to the scientific community and a consensus among qualified experts as to the safety of the substance, rather than on prior use. Packagers or others can make their own self-determinations that a substance used in connection with food is GRAS, and do not need to submit their data to the FDA before marketing or using the substance.

However, because of concerns over the safety of some GRAS ingredients in the 1970s, the FDA instituted a GRAS affirmation petition process (GRASP), wherein any interested party can petition the FDA to *affirm* the GRAS status of a substance. Unfortunately, this is a long and costly process, sometimes taking years. Because of this, the FDA recently proposed a new, less cumbersome "notification" process to replace the affirmation petition (GRASP), known as 62 FR 18938-18964, April 17, 1997). If adopted, FDA will acknowledge receipt of a notification within 30 days, and will respond within 90 to indicate whether it has any objections to the determination. If it does not, the response will be equivalent to an "accepted for filing" letter currently being issued. The FDA stresses that it is not the same as an "affirmation," but merely documentation that the Agency is aware of the determination.

The second category, "Prior Sanctioned," means that the substance was approved for a specific use by the FDA or US Dept. of Agriculture (USDA) prior to the 1958 Amendment. These substances are listed in 21 CFR Part 181.

The final category of substances not requiring food additive approval are those not reasonably expected to become part of the food. By definition in 21 CFR 170.3(e), *"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*

thus is not a food additive." It is important to remember that appropriate analytical methodology must be considered to support claims of no migration. All other substances that are added to food or migrate to food from food packaging were, until recently, subject to the premarket petition and approval process. In this process, complete chemical composition and toxicological data for the substance, as well as any contaminants or by-products, must be provided. In addition, it is necessary to indicate the conditions of use, including the concentration, time and temperature of contact, and type of food contacted; the quantity of the substance likely to become a component of food under the intended conditions, based on validated migration studies (otherwise the FDA assumes worst-case migration); an estimate of the concentration of the additive in the human diet, and information on the potential environmental impact involved in the manufacture, use and disposal of the material.

Threshold of Regulation

Because the food additive petition process is so expensive and time-consuming, manufacturers and users of food packaging materials have for years asked the FDA if they could come up with a faster and easier process to clear substances whose migration limits were so low they would present a negligible risk to human health. The Agency also saw the need for such a "Threshold of Regulation" for a trio of reasons. First, analytical methodologies have improved to such an extent over the years, many of the food contact uses for which migration into food was not detectable using older methods may now be shown to result in measurable levels of migration. A second problem is that scientific laws of diffusion predict that any two substances that are in contact with each other for some period of time will migrate or diffuse into each other. Therefore, all food contact materials will ultimately migrate into food, even if it is at such a low level that it is below the analytical detection limit. Finally, the criteria for data needed to evaluate requests for exemption from the food additive petition process by the FDA from manufacturers was never formalized and the quality of the requests varied widely.

Consequently, the FDA formalized and published a proposed rule creating a "Threshold of Regulation for Substances Used in Food Contact Articles" (58 FR 52719-52729, October 12, 1993). The final rule was eventually adopted and published on July 17, 1995 (60 FR 34582-36596) and amends 21 CFR 170.39. Essentially, it sets the Threshold of Regulation for food contact substances at that which results, or may be expected to result, in a dietary concentration at or below 0.5 parts per billion, corresponding to dietary exposure levels of 1.5 micrograms/person/ day. If the substance currently is regulated for direct addition to food, the dietary exposure from the proposed use must be at or below 1% of the acceptable daily intake previously established. Known or suspected carcinogens are ineligible for threshold consideration.

Under this amendment, substances still are considered to be "food additives," but are exempt from regulation and are not listed in the CFR. As of March 31, 1997, 13 threshold of regulation exemptions have been issued since the final rule was published.

Functional Barriers

Another concept related to migration of packaging inks, coatings and other packaging materials is that of functional barriers. The FDA has defined a functional barrier as a resinous coating, protective film or transparent cover separating the printed matter from the food. If such a barrier is formed, then the Agency would not consider such use of a printing ink to be a food additive situation, and the printing ink ingredients would not need to be FDA approved.

However, in an opinion letter from the Indirect Additives Branch on the use of resinous coatings or overprint varnishes as functional barriers, the Agency states: *"Even though a resinous coating is acceptable on the basis of its containing components approved under the food additive regulations for their use, 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 that it prevents the ink from passing through the coating and migrating to food. The manufacturer must employ good manufacturing practices to ensure that the coating has formed a continuous coating over the ink and substrate so that no 'pinholing' is present and/or the coating is of sufficient thickness to prevent migration of ink through it. When these conditions of application of a coating are met, a functional barrier is formed."*

From these comments it is fairly obvious that a conventional ink overprinted with an FDA acceptable, press-applied varnish or coating would probably not meet the definition of a functional barrier in most instances. Most printers and converters will agree that it would be extremely difficult to monitor and guarantee a continuous coating free of voids and/or pinholes. For this reason the ink also must be made from food contact components approved for the intended use.

Requirements for Direct Contact Inks and Coatings

What materials can be used to make an ink or coating that is acceptable for direct contact with food? Strictly speaking, the only formal regulations the FDA has regarding inks are those ingredients used as "Diluents in Color Additive Mixtures for Food Use Exempt from Certification," contained in 21 CFR 73.1. In general, substances listed in this section for a specific use in inks, additives listed for direct use in food, and substances that are generally recognized as safe for use in food are acceptable for use in inks for food packaging or for printing directly on foods. In addition, the FDA indicates that substances currently regulated for use in food contact materials also may be acceptable to be used in printing inks and coatings for food contact if the use in the ink or coating is encompassed by the permitted use in the regulation.

In general, the following parts and/or sections of 21 CFR are most applicable to direct contact inks and coatings:

- Section 175.300 - Resinous and polymeric coatings.
- Section 175.320 - Resinous and polymeric coatings for polyolefin films.
- Section 176.170 - Components for paper and paperboard in contact with aqueous and fatty foods.
- Section 176.180 - Components for paper and paperboard in contact with dry food.
- Part 181 - Prior-Sanctioned Food Ingredients.
- Part 182 - Substances Generally Recognized as Safe.
- Part 184 - Direct Food Substances Affirmed as Generally Recognized as Safe.

Colorants

To this point, this article has focused primarily on "non-colored" direct and indirect food additives (polymers, resins, waxes and other materials) used

in food contact inks and packaging. How do colorants fit into this picture?

In general, the same rules and regulations apply to colorants as to any other food additive. If not already approved and allowed by a previous regulation, any new colorants (dyes, pigments or lakes) are subject to the same standard food additive petition process, or to the Threshold of Regulation rule if their migration is so trivial (0.5 ppb or less in the diet) that they do not require regulation as a food additive.

Previously regulated colorants that are permitted for use in direct food contact packaging inks are those that are permitted for use in foods, and those that are found in the final rule for Colorants for Polymers (56 FR 42927-42935, August 30, 1991) and the amendment and responses to objections to the final rule published December 21, 1993 (58 FR 67318-67323). This rule transferred various scattered listings for colorants in polymeric food contact materials to a single regulation. The pertinent 21 CFR references are:

- Part 73 - Listing of Color Additives Exempt from Certification, Subpart A - Foods.
- Part 74 - Listing of Color Additives Subject to Certification, Subpart A - Foods.
- Section 81.1(a) - Provisional lists of color additives — Color additives previously and presently subject to certification and provisionally listed for food, drug and cosmetic use.
- Part 82 - Listing of Certified Provisionally Listed Colors and Specifications, Subpart B - Foods, Drugs and Cosmetics.
- Section 178.3297 - Colorants for Polymers.

On March 4, 1996, the FDA issued a proposed rule (61 FR 8372 - 8417) amending the regulations to list certain color additive lakes permanently as suitable for foods, drugs and cosmetics. A number of issues remain to be resolved before the ruling is finalized.

Other US Legislation

Several FDA reform bills that affect the way food additives are approved currently are being debated in Congress. One provision mandates that the FDA meet existing statutory requirements that it review and act on all new petitions and applications within 180 days, or hire third party, non-government private contractors to complete any pending reviews, although FDA still would have the responsibility of making safety determinations. Another provision would alter the Delaney Clause's "zero-risk" standard for carcinogens and replace it with a "negligible risk" standard. The Delaney Amendment prohibits the approval of any food additive that is known to cause cancer in humans or animals, regardless of the risk. Because of the controversial nature of both these issues, it does not appear that Congress will pass this legislation in the near future.

European Regulations

While European Community (EC) legislation on food contact materials began in 1976, there still are currently no specific laws, directives or regulations in the United Kingdom, the EC or any of the non-EC nations that govern the use of either indirect or direct contact food packaging inks. As in the US, there basically are three categories of food packaging inks where contact with foods may occur: external packaging; "immediate wrappers" and direct food contact applications.

External packaging generally understood to mean that another, more "immediate" packaging medium is present. For example, a box or bag that holds a number of individually wrapped food items, such as candy bars, or a box of cereal that contains a plastic bag inside. Although the inks in this case are rather remote from the food product and migration normally would not be expected, it would be prudent to use inks that are suitable for at least immediate wrappers since various components still could migrate through the packaging material and affect taste and odor properties of the food product.

Immediate food wrappers or containers are those which hold, or are next to, the food itself, such as the individual candy bar wrappers previously mentioned. The ink would be applied to the outside of the wrapper and the wrapper should act as a functional barrier between the ink and the food. Although not intended to contact food, the ink still may migrate through the wrapper, or it could transfer to the food contact side while the printed wrapper is stored in a roll or stack.

Direct contact inks are, obviously, those intended to come in contact with the food product and are used to print coupons, inserts and similar promotional material that is included within the immediate wrapper itself.

The original 1976 EC *Framework Directive*, 76/893/EEC, replaced in 1989 by 89/109/EEC, set out some general requirements that all food contact materials must meet; namely, that all *"materials and articles should be manufactured in accordance with good manufacturing practice so that they do not transfer their constituents into food in such a way that they endanger human health or bring about organoleptic or other acceptable changes in the food's nature, substance or quality."*

Most EC directives and proposals to date have dealt with plastics, the monomers and polymers that may be used, and other additives in plastics. These are found in 90/128/EEC as amended by 92/39/EEC, 93/9/EEC and 95/3/EEC, and recently further amended by 96/11/EC (Plastic Materials and Articles in Contact with Food Regulations). There also are some Directives on coatings, as well as colorants and other ingredients for use in foodstuffs.

In addition to the EC Council, another organization that deals with food contact substances is the Council of Europe (CoE) Committee of Experts on Materials and Articles Coming into Contact with Food, whose membership includes both EC and non-EC countries. Although they prepare resolutions and guidelines on food contact materials, these resolutions are merely recommendations that have no legal standing. However, they are sometimes adopted as legislation by the non-EC countries and form the basis for many official EC directives, as well.

Two organizations that also have no legal standing, but are influential in the area of standards and guidelines for the printing ink industry, are the British Coatings Federation (BCF), formerly the Society of British Printing Ink Manufacturers (SBPIM), and the European Confederation of Paint, Printing Inks and Artists Colors Manufacturers Association (CEPE). These are essentially counterparts to the National Association of Printing Ink Manufacturers (NAPIM), the Flexographic Technical Association (FTA) and the National Printing Ink Research Institute (NPIRI) in the US.

The BCF has published guidelines for printing ink ingredients in *Printing Inks for Use on Food Packages* (1996) and the *Guide to Materials and Substances for Exclusion from Printing Inks and Varnishes* (1996). CEPE also has published a list of excluded raw materials to which all member associations in Europe have agreed. This list excludes any substances classified as "toxic" or "very

toxic" according to Directive 67/546/EEC (Dangerous Substances Directive). It also automatically excludes any recognized carcinogen, mutagen or reproductive toxin, as well as compounds based on heavy metals (antimony, arsenic, cadmium, chromium (VI), lead mercury and selenium). Various colorants, dyes, solvents and plasticizers are affected, and are on the list.

CoE Meeting

The CoE Committee of Experts on Materials Coming into Contact with Food currently is in the process of drafting a resolution on printing inks for food packaging. At the most recent meeting of the CoE, April 21-25, 1997, CEPE submitted a list of dyes used by its members to manufacture printing inks for the non-food surface of materials and articles intended to come into contact with foodstuffs (RD 8/1-31), as well as a list of generic groups of additives used by CEPE members for the manufacture of printing inks, primers and overprint varnishes for food packaging (RD 8/3-31). Lists of pigments, solvents, plasticizers and driers were supplied at earlier meetings of the CoE.

While this resolution will apply strictly to food packaging inks not intended to come into contact with food, the UK delegation, at this same meeting, noted that some printing does take place where the ink is in direct contact with food, and that the UK printing ink industry would welcome regulations to cover this application. The Committee welcomed the UK's offer to present a paper on the subject, and other delegations agreed to report on the use of direct contact printing inks and the associated regulations and controls in their respective countries. The EC, on the other hand, has no plans to introduce specific legislation on printing inks for food contact applications until the work on plastics, coatings and other categories of food contact materials set out in the framework directive are completed. Overall, however, some progress is being made in the area of legislation for food packaging inks. It is expected that this legislation will be modeled after, and harmonized with, the US FDA regulations.

Due Diligence

Since there are no specific laws, what currently is guiding the use of direct food contact inks in Europe? Generally, companies wanting to print direct contact coupons and promotions are exercising what is known as "due diligence" to ensure they have done everything possible to show that the ink, coatings and stock are as safe as possible for their intended use. The usual protocol that is followed consists of a literature review of the individual ink ingredients to determine their toxicology, regulatory status, purity and safety specifications in the country or countries of intended use; migration studies in contact with the actual product or using acceptable simulants under expected end-use conditions, and a review by the EC or CoA to render an opinion as to the safety of use. Regardless of the opinion of the EC or CoA, the company can choose to use the ink if it feels confident that it has followed "due diligence" and the components of the ink are not otherwise banned from use.

Most countries have organizations, government agencies or private laboratories that provide a complete service to industry by performing migration studies and regulatory assessments of substances intended for use in packaging materials and other food contact articles, including printing inks and coatings. In the UK, organizations such as Pira International and the British Industrial Biological Research Association (BIBRA) can be of great help. The Central Science Laboratory (CSL), an executive agency of the Ministry of Agriculture, Fisheries and Food (MAFF) also can provide guidance. A 1995 alliance between BIBRA and the CSL should result in many useful collaborative research and testing programs.

One final item that needs to be considered for direct food contact inks is Current Good Manufacturing Practice (CGMP). Both the FDA regulations and the EC framework directive require food contact materials be manufactured in accordance with good manufacturing practice, yet the term is misunderstood and confusing to most ink manufacturers. The rules for GMP for foods are found in 21CFR, part 110. Similar regulations apply to drugs (Part 210-211), medical devices and in vitro diagnostic products (Part 820). Basically, they require that adequate safeguards be used to ensure that a food product (in this case) is manufactured, prepared, packed or held under such conditions that it is not adulterated or contaminated whereby it would be injurious to health. This includes personnel, buildings and facilities, equipment and utensils, production and process controls, warehousing and distribution involved with the product.

Prudence dictates that inks for direct food contact be made under appropriate sanitary conditions, using dedicated equipment and utensils and employing appropriate cleaning procedures to prevent contamination from other products and non-conforming raw materials. Ideally, they should be manufactured, packaged and stored not only in a dedicated *area*, but in a dedicated *facility*, where only food or food contact ingredients are used. Unfortunately, it is doubtful that most ink manufacturers currently operate in a manner that would meet CGMP directives.

Printing inks that conform to all applicable regulations, including CGMP, for direct and indirect food contact packaging can, and are, being formulated and used today. Although FDA regulations are legally binding only in the US, existing regulations and proposed directives in most countries, including Canada and Europe, usually are modeled and harmonized along similar lines as those in the US. Therefore, the manufacture and use of these inks requires a thorough understanding of the US and/or global regulations that apply, not only by the ink supplier and end-user, but by the package designer, printer and converter as well. A cooperative relationship must exist among all these parties if a food contact printing application is to be a success and conform to all necessary regulations.

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It is with deepest regret we inform you Mr. Bichaylo passed away in July 1998.