Food Packaging Low Migration Ink Technology+

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Abstract

The use of ink to both decorate packaging and relay information continues be become a more complex endeavor as various regulatory agencies respond to market demands, consumer concerns and scientific knowledge. The FDA is the responsible agency for United States regulations but with the continued globalization of businesses, other regulations such as the Swiss Ordinance are impacting packaging technology. The situation is also impacted by brand owners requirements beyond the regulatory landscape. This paper deals with the evolution of the FDA and the current European situation relative to inks and coatings for food packaging applications.

Printing inks have decorated packages from the inception of the first container, where the first use simply may have been to identify the product contained therein. Although many people realize the value that inks provide, a few decades ago a minimalist effort to reduce costs by packaging with very little printed color met with complete failure when consumers balked at purchasing a product that simply stated "corn flakes" or "cigarettes." Over the years, inks and coatings have taken on more complex roles to achieve decorative graphics and protective attributes that help sell the product, assist in packaging and shipping, pass on information both mandatory and market driven, and contribute to shelf life. Today's inks must comply with a wide array of substrates, demanded finished properties, and an ever-growing list of local, state, federal and international laws regulating our environment, health, safety, transportation, consumer advocacy and product use, as well as responding to the needs and demands of brand owners.

A Brief History of the FDA

The Food and Drug Administration is for the US the focal point of food packaging laws covering food safety, and the origins and evolution of this organization are both interesting and enlightening. This complicated organization and its volumes of regulations started in 1820 when eleven physicians met to produce the US Pharmacopeia, the first compendium of standard drugs for the United States.

However, the actual precursor to what we now know as the FDA was begun in 1862, when President Lincoln started the Bureau of Chemistry under the Department of Agriculture. While the first proposed food and drug law was defeated in 1890, it led to other regulations that began the march toward the modern FDA. It wasn't until 1906 that the original Food and Drugs Act was passed prohibiting interstate commerce of misbranded or adulterated foods, drinks, and drugs.

Package labeling took a step forward in 1913 with the Gould Amendment that required food package contents to be "plainly and conspicuously marked on the outside of the package in terms of weight, measure or numerical count." The Food, Drug and Insecticide Administration was created in 1927, and the name was shortened to the Food and Drug Administration in 1930. Expansion of the FDA's role came in 1938 with the passing of the Federal Food, Drug and Cosmetic act. The Delaney committee in 1950 laid the ground work for the Food Additives Amendment enacted in 1958 requiring that new additives must show proof that they do not induce cancer in humans or animals. It was at this time that the famous GRAS (generally regarded as safe) list was published in the Federal Register.

One of the most significant changes to FDA regulations came in 1997 with the Food and Drug Administration Modernization Act (FDAMA) which created a streamlined approval process for a new material (one not recognized as FDA compliant) without the typical petitioning of the FDA, which is time consuming and costly. The new methodology does not circumvent existing safety standards, but does allow a tacit nod from the FDA through a Food Contact Notification (FCN). Since the FCN process was implemented in 2000, over 1200 new materials have been approved through it.

Current Packaging Situation

For years, inks have decorated packages without significant issues relative to FDA regulations. Although the FDA does not specifically single out inks, there are several sections within the Code of Federal Regulations (CFR) that do impact inks' use. The parts of the regulations that impact inks are:

Part 175 — Adhesives and Coatings
Part 176 — Paper and Paperboard
Part 177 — Polymers
Part 178 — Adjuvants, Production Aids, Sanitizers
Part 181 — Prior Sanctions
Part 182 — GRAS Substances
Part 184 — Direct Additives Affirmed as GRAS
Part 186 — Indirect Additives Affirmed as GRAS

The FDA in section 201 states that, "any substance the intended use of which results, or may reasonably be expected to result …in its becoming a component or otherwise affecting the characteristics of any food," is a food additive. Since most inks are on the outside of packaging, the industry has relied on the concept that the printed substrate is a barrier to the ink components, and therefore they are not food additives, as they are not intended to become a component of the packaged food. While the FDA does state that it is the packagers' responsibility to verify that materials in the intended use do not become part of the food product, the reality is that very few converters test the finished package to ascertain that it does indeed meet FDA guidelines.

If, however, a substance is shown to become a part of the food product, it is therefore an indirect additive, and can be deemed acceptable if it meets one of the following criteria:

- The substance is on the GRAS (generally regarded as safe) list
- The substance has been approved through a food additive petition
- The substance is below the TOR (threshold of regulation)
- The substance has been approved through an FCN

The increasing ability of analytical methodologies to detect exceedingly small quantities of chemicals and substances leads to the identification of potentially insignificant contaminants being able to be identified in food products and packaging. This situation led to the Ramsey proposal in 1968 to exempt some substances in paper packaging of dry food, and suggested that migration of up to 50 ppb into food-simulating solvents be exempt from filing a food additive petition. The latter case of Monsanto v. Kennedy, which ruled that a substance must migrate into food in more than insignificant amounts to consider it a food additive, supported this position and has served as a basis for "self-determination" for the last forty years. Under this situation, the substance that becomes an indirect additive cannot be a carcinogen, reproductive toxin, a poison or a substance proven to be toxic at a level of 40 ppm or less. If the substance is shown to be non-toxic, testing is required to determine that the level of migration into the food product is <50 ppb. Since those original determinations, this approach has been supported by other recognized scientific experts in the published literature:

- Munro, "Safety Assessment Procedures for Indirect Food Additives: An Overview," 12 *Regulatory Toxicology and Pharmacology* 2 (August 1990).
- M.A. Cheeseman, *et al*., A Tiered Approach to Threshold of Regulation, 37 Food & Chemical Toxicology 387 (1999)
- R. Kroes, *et al*., Structure-Based Thresholds of Toxicological Concern (TTC): Guidance for Application to Substances Present at Low Levels in the Diet," 42 Food & Chemical Toxicology 65 (2004)
- European Food Safety Authority (EFSA) July 12, 2011 "Draft scientific opinion on exploring options for providing preliminary advice about possible human health risks based on the concept of threshold of toxicological concern (TTC)"

European Situation

Over the last decade, several high-profile food recalls due to ink materials migrating into a food product have led to a changing regulatory scene. Partially due to the fact that governments and agencies do not move quickly, the first to respond were specific brand owners impacted by the recalls. Many took the situation in hand and developed their own set of rules beyond what regulatory groups had in position. Food product leaders like Nestle and Tetrapak developed lists of both positive and negative materials, either acceptable or not to be used. These lists were based on their knowledge about their products, and materials they regarded as unsafe due to potential for migration or other food packaging issues such as odor or off-flavor. Similar to FDA regulations, if a material is safe but alters the sensory aspect of the food product, it is deemed unacceptable.

The document that has come to be known as the "Swiss Ordinance" arose from the belief that the EU community was moving too slowly in response to the various recalls. In 2005, the Swiss Federal Department of Home Affairs published an Ordinance on Foodstuffs & Utility Articles and, in 2008, an amendment was adopted that dealt with packaging inks and materials used in their manufacture. Two Annexes in this ordinance list permitted substances: Annex I deals with monomers and additives used in making food contact plastics, and Annex VI deals with all other packaging ink raw materials. Within Annex VI, List A contains substances with evaluated and verified toxicological data and List B for those materials lacking sufficient toxicological data.

For List A, there are proposed appropriate migration limits based on the data supplied for the materials. These specific migration limits (SML) are the maximum allowable limit of a material that can migrate to a food product. Any material contained in List B automatically has a 10 ppb limit placed on it until more data warrants a higher allowable level. Note that this is very similar to the FDA stance but more specific as to materials and allowed levels. Also similar to the FDA, even if a substance is listed in either A or B, if the substance impacts the flavor, taste, or other organoleptic property, it is unacceptable.

As a Swiss regulation, the Ordinance is only binding for substances being manufactured in or imported into Switzerland, yet despite its having no legal status in any other country, its impact has been significant, since many major multi-national companies have adopted it in place of their own guidance documents. Moreover, Scandinavian countries, Belgium, and Germany have also started their own legislation, which will have a more far-reaching effect for the European Union. At this time, it is believed that the German effort, delayed until sometime in 2013, will become the EU standard.

Current Situation

The two approaches, US and Europe, are very similar in many respects. Both clearly state in their documentation that it is up to the converter to perform tests showing the end product does not lead to levels of contaminants that can cause issues. Even if the substance is not a health or safety concern, if it causes organoleptic or any product quality changes it is unacceptable. It is the responsibility of the ink supplier to formulate with materials that will not cause issues when the ink is properly applied according to its' purpose for use, and to be sure that the ink and resulting food packaging is manufactured in accordance with GMP (good manufacturing procedure) guidelines. The significant difference with the European approach is that they are assembling a list of "all" materials and evaluating each item. The FDA has put forth guidelines but leaves the responsibility of the substance assessment to the suppliers of the package materials. Each approach has advantages and disadvantages.

In many instances, where the application has been around for a lengthy period of time, the assumption is made that there is not an issue and everything is acceptable. Without some data to back that optimism, the industry could be treading on thin ice. The recall of baby food in Italy was precipitated by an examination of what actually is present in the food product. Although the level of the UV photoinitiator was not a health concern, the discovery of its presence caused a small panic, a costly recall, damage to the brand owners' and converters' reputations, and led to new legislation.

Industry approach to food packaging has been to ask for "low odor" or "food safe" inks. The problem with this is that these terms are not well defined. What is "low odor" for one person or application may be a disaster elsewhere. The newer approach is to use the term "low migration" documented with real data such as the SML. With today's analytical techniques, it is close to impossible to achieve a non-detect level but it is possible for an ink to meet the low ppb migration level. Even in the world of very sensitive food packaging such as chocolates, the low migration approach has been shown to correspond with the standard Robinson test. Simply put, if the migration of substances is small enough (not necessarily zero), there is not a concern about changing the organoleptic characteristics of the food product.

The packaging industry has operated under the concept of using a "functional barrier" to prevent contamination or product quality issues resulting from the effect of the packaging structure or outside environment. Some substrates are better functional barriers than others, and in some cases migration through the substrate is a real concern and the substrate is not as good a barrier as was thought. The functional barrier properties of a food contact substance are directly related to the composition, processing, environmental conditions and conditions of consumer use. Even when

dealing with plastic film or heavy board, it is still possible to have migration contamination. There is also migration or offsetting of the materials onto the back food-contact side of the substrate after printing, while the printed product sits in a rewound roll or while stacked in sheets after printing. Conditions of time, temperature, pressure and the mobility of the substances will impact migration.

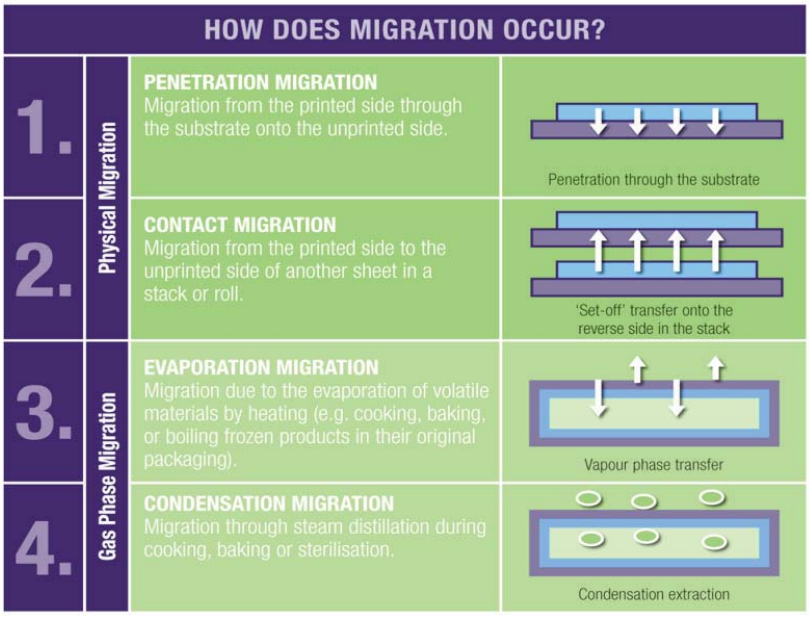

Figure #1

It should not be assumed that only the ink substances are responsible for potential issues. Recent concerns have been raised about the mineral oil that migrates from recycled board used in food packaging. Substrate can be an issue in some special applications, especially when ultraviolet light or electron beam energy is used for the curing of the ink/coating. There have been several well documented instances where the interaction of the curing energy will cause unwanted changes to the substrate. These changes can be simple physical alterations such as a PVDC sealing coating being cross-linked and the required sealing temperatures having to be increased or the film actually taking on a color. In some cases the substrate interaction can result in significant odiferous products. Other substances can interact with post print processes to cause unwanted issues as well.

If the decision is made to move to low migration inks, the control of the entire printing, converting and food packaging processes are critical to ensure that the intended end result is achieved. Care must be taken with the entire printing and post print processes. When the level of concern is usually very low (parts per billion), it does not take a significant amount of substance to destroy the end result. Press preparation, wash solvents, cleaning solutions and compounds, press room additives, fountain solutions (offset printing) and even where the substrate or printed product is stored can have an impact on the finished results. With offset presses, the roller train can be a significant source of material leaching out into the low migration ink.

In such a case, it is recommended that the press be dedicated to low migration applications once the rollers are replaced or cleaned properly. Storing or shipping a low migration job in the presence of volatile or odiferous materials will lead to failures even if the original printed material was acceptable.

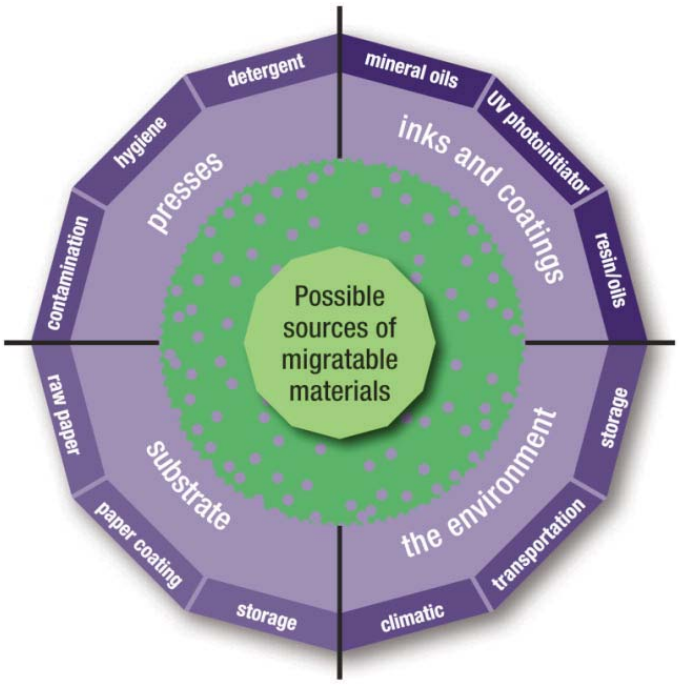

Figure #2

For food packaging, the question of low migration depends on the commitment to the entire process. This may become less of an issue as brand owners begin to demand this approach to eliminate the potential for recalls and bad press. There are certainly costs associated with both the ink technology and the implementation and, in the current market environment, there is pushback at all levels due to this. From the ink side of the picture, the there are several possible scenarios, in order of increasing risk:

- Ideal is no migration: no exposure = no risk
- Migration < 0.5 ppb safe under all circumstances (Threshold of Regulation – TOR). Must not be a carcinogen, reproductive toxin or poison.
- Migration < 10 ppb preferred, but < 20ppb unlikely to be of concern (analytical error +/- 10ppb)
- Migration < 50 ppb with favourable mutagenicity data (FDA recognized acceptable)
- Migration > 50 ppb need toxicity data and risk assessment evaluation

Again, these conditions assume that the substance in question is not a cancer causing agent, reproductive toxin or highly toxic. Also, if the material is on the GRAS list, has been sanctioned under a food additive petition or has received an FCN, levels higher than the 50 ppb may be allowed as long as the material does not impact the organoleptic or physical properties of the food.

For the FDA, the 50 ppb-or-less level should be sufficient, but for customers demanding Swiss Ordinance compliance, the level should be less than 10 ppb, as well as:

- Observe the limits set by experts (SMLs, TDIs, etc)
- Comply with industry Exclusion Lists

Testing of the finished product can be done by an outside certified/recognized facility an internal analytic laboratory. The FDA specifies various solvents depending on the food product and has recognized protocols for the work. An extraction cell would look something like Figure #3 showing the different spacer thicknesses that allow for varying the amount of extraction solvent relative to the printed sample.

Figure #3: *Photo courtesy of Dr. Thomas Hartman, Food Science Lab, Rutgers University*

Summary

While not widespread at this time, the use of inks for low migration packaging is beginning to gain traction due to many brand owners recognizing its' need and demanding the use of these technologies. However, simple use of "low migration" inks does not ensure that problems will not arise unless the entire process is set up to deliver the properties that the inks are capable of delivering. Testing must also be done to provide data to support any claims of meeting Swiss Ordinance or low migration results. Beware of claims such as "low odor" or "food safe" since these are marketing terms and not defined. The FDA and European approach may seem different on first sight but the principles are very similar:

- packaging materials should not become part of the food,

- if they unintentionally become part of the food, they must be benign and

in a small enough concentration to be inconsequential and

- the substances must not alter the food properties even if the first two criteria are met.

It is obvious that the consumer does not want to have to be concerned about food contamination. The brand owner does not want to suffer a product recall or the costs involved with this from either a monetary or a reputation standpoint. The correct way to meet these needs is to follow FDA guidelines in the United States and one part of that may be to utilize low migration ink technology.

Literature

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www.bag.admin.ch/themen/lebensmittel/04867/10015/index.html?lang=en