

UV&EB Inks for Food Packaging Materials: Going the Extra Mile

By Tom Dunn

With the increased consideration of ultraviolet (UV)- and electron beam (EB)-cured inks and coatings for food-packaging materials, suppliers of such energy-cured chemicals have focused much of their attention on compliance with U.S. Food and Drug Administration (FDA) regulations for food-packaging materials. Although the FDA currently does not regulate inks used for food-packaging materials, other laws and many consumer packaged goods companies (CPGCs) limit or prohibit the deliberate addition of specific chemicals in packaging materials. This paper reviews the nature of such limitations and the compliance expectations that CPGCs have of packaging material suppliers. UV and EB inks for direct food contact packaging materials must satisfy the same expectations. Suggestions for anticipating and complying with such expectations are provided.

Introduction

Presentations at recent TAPPI (Technical Association of the Pulp and Paper Industry) PLACE (Polymers, Laminations, Adhesives, Coating and Extrusions) Conferences have anticipated future expanded use of UV- and EB-cured inks and coatings from labels and periodicals to food-packaging materials.¹⁻⁹ Much of this discussion focuses on the chemical identities and quantities of whatever materials can be extracted from the materials using

laboratory analyses. This paper seeks to broaden the perspectives on such considerations to include other chemical restrictions, customer expectations, and general public attitudes towards “chemicals.”

Certainly FDA compliance is necessary, but such compliance is not sufficient to satisfy the CPGCs who would package their products in material made with these coatings. Many of these products carry with them valuable brand equity and their brand managers dare not expose that equity to avoidable market place risks. One significant category of such risk is public perceptions of a product's safety. If the public perceives a risk, science and logic are hard pressed to change those perceptions faster than buying decisions change the value of a brand's equity. In commenting on Source Perrier's 1990 crisis with the finding of benzene in its bottled water (and its 21% drop in operating profits as a result!) management consultants point out one key reason that “managers tend to be wrong-footed by corporate crises [is] because they are used to shaping events, not to having events grasp control and shape them. Once it had regained control of the affair—a week-long struggle—Perrier did most things right.”¹⁰

The Clear Expectations

U.S. Food and Drug Administration

The FDA rules for food-packaging materials indicate very simply

(21 CFR 174.5) that the materials cannot (1) adulterate food or (2) cause taste or odor in food and (3) must be suitably pure for their intended use. From these three requirements flow hundreds of pages of regulations officially codified in the Code of Federal Regulations, and many times more “informal written opinions,” technical guidance documents, and food contact notifications, all of which have the force of law (21 CFR 170.6).

Through one such series of such “informal written opinions,” RadTech sought and received letters from the FDA with general guidance to the effect that if nothing from the inks or coatings migrates into the packaged foods, there is no “food additive” for the agency to regulate. Such is the basic rationale for the use of various printing inks separated from the packaged food by a functional barrier.¹¹ See Figure 1.

Act of 1986,” was enacted as a ballot initiative in November 1986. The proposition was intended by its authors to protect California citizens and the state’s drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals. A regular scientific and legal process maintains a list of such chemicals, listing and de-listing chemicals as evidence indicates (http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html). The primary obligation of those using listed chemicals is to provide a clear and reasonable warning to those exposed to the chemical as a consequence of such use. In particular, if the chemical is used in a product or its packaging, the package must warn any user. As a consequence, many CPGCs require that the packaging material they buy from us be free of any listed chemicals.

of cadmium, lead, mercury and chromium IV in packaging materials based on model legislation developed by the Council of Northeast Governors (CONEG). For more information visit <http://www.coneg.org/programs/other.htm#TPCH>. As with Prop 65 listed chemicals, many CPGCs require that the packaging material they buy from us be free of these CONEG heavy metals.

The net result of these two state-level initiatives is *de facto* national policy eliminating the use of these substances. Unlike Figure 1, the requirement is simply that none of the objectionable chemicals be present in the *packaging material*, regardless of whether or not they migrate into the packaged product.

California Proposition 65

California Proposition 65, the “Safe Drinking Water and Toxic Enforcement

CONEG Heavy Metals

As of April 2004, nineteen states had adopted legislation limiting the amount

The Surprising Expectations

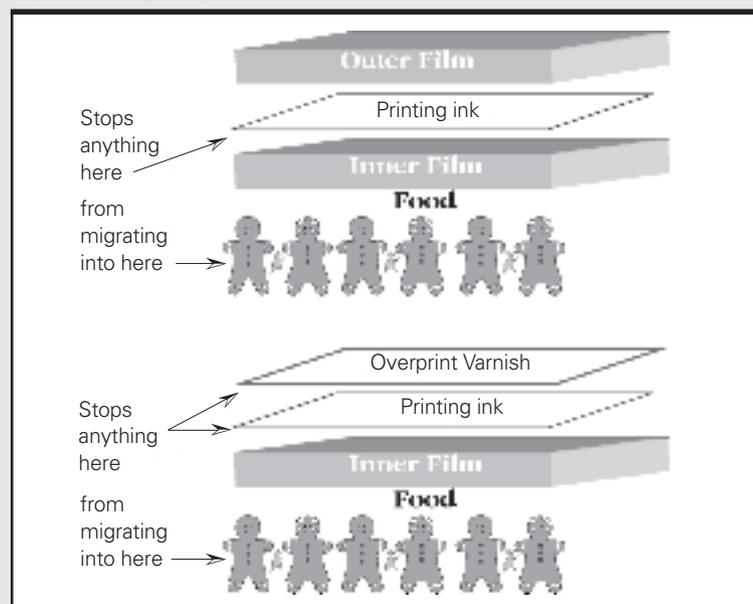
Safe Chemistry Under a Cloud

Compliance with the “clear expectations” of FDA, Prop 65, and CONEG is still no guarantee of merchantability of packaging materials! These examples illustrate the point:

- Some customers require rabbinical certification for manufacturing plants and that they are operated according to Jewish dietary law. As a result, some animal-derived slip additives for coatings, inks, and films are prohibited even though they are allowed by 21 CFR 178.
- Allergen labeling requirements have prompted CPGCs. to prohibit the use of any of the common allergens (those accounting for over 90% of all food allergies, peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat) in our converting operations. As a result, we must now insure that we do not use wheat-based dusting powders even though they are allowed under 21 CFR 176.
- Certain grease-resistant coatings and additives are specifically allowed in paper used for packaging under

FIGURE 1

Printing inks separated from packaged food by a functional barrier



21 CFR 176, but in the fall of 2005, when *USA Today* carried a story with allegations by a former employee of the supplier that the allowance was based on incomplete data, requests were received from 16 customers—even those buying only all plastic structures—within 120 days asking for certification that the material not be used.

Suspect Chemistry Under Fire

With CPGCs prohibiting the use of chemicals clearly allowed by U.S. FDA, it should be no surprise that they are quick to ban others when suspicions arise in the press or public opinion. One clear example is urethane-based adhesives, both those in solvent solution and the 100% solids ones. These are explicitly allowed by detailed component listings of 21 CFR 175.105. However when an August 2001 issue of a Danish magazine published an article alleging excessive amounts of primary aromatic amine (PAAs) by-products of these adhesives in food-packaging laminations, the packaging world was embroiled in testing and retesting commercial samples to understand the true state of affairs.

In fact, improper converting practices do leave PAAs in packaging laminates if proper curing conditions are not provided. In particular, the FDA obligation to insure “good manufacturing practice” (GMP) in the manufacture of food-packaging requires proper curing! In spite of the FDA listings, GMP compliance, and confirming laboratory data, we still have a major CPG customer who will not allow the use of urethane-cured adhesives in its packaging materials.

In the summer of 2005, Italian authorities found isopropylthioxanone (ITX) from foil packaging laminates in the baby formula they packaged. ITX was soon deemed by European Food Safety Authority to pose no identified danger to human health. In spite of

this, the producer recalled millions of liters of formula from several European countries. Again, the residuals were linked to inadequate GMP controls by the converter, allowing ITX, not crosslinked into the UV-cured ink, to migrate into the sealant while in roll form.

Packaging suppliers experience recurrent customer requests to advise about any use of Bisphenol A (BPA) in packaging materials. The chemical, a critical component of polycarbonate containers (reusable water bottles and baby bottles) and epoxy-based coatings for various packaging materials, has FDA approval, but exists in a limbo of charge and counter-charge about alleged effects on human and animal reproductive health. BPA is a starting compound in the production of its diglycidyl ether (BADGE), a workhorse component of energy-curable inks and coatings.

Managing Expectations

Stay Informed

In the “information age,” the best strategy for a supplier of flexible packaging materials is an affirmative knowledge plan. They must know what is contained in the raw materials purchased from their direct suppliers and in turn from others further up the supply chain. Technical data, patents and, material safety data sheet (MSDS) forms from suppliers are essential, but so is your network of industry contacts. Bookmark the Web sites of suppliers, the chemical industry groups, and government agencies! And remember to glance at special interest group Web sites in order to “see which way the wind is blowing.”

Specify Exclusions

It is recommended that your company establish standard purchasing specifications that specify maximum allowable levels of chemicals of

concern. If suppliers advise that the maximums are or may be exceeded, manage exceptions by restricting those materials to non-critical uses, or establishing sampling and testing protocols.

When reactive chemistry is involved, as in the case of polyurethane adhesives and certainly any energy-cured inks and coating, communicate to manufacturing management about the legal as well as functional responsibilities of a converter to provide minimum levels of cure. Even better, provide sampling plans, test methods and process controls for practice in the plant that will confirm those minimum levels of cure.

Provide Responses

Most importantly, the converter must be able to provide CPGCs with the documentation as required by law and internal risk management. Doing so in a responsive, accurate and auditable manner dictates that information be trusted and available. It is recommended that they respond as able: “None intentionally added?” or “None detectable at (indicated) level?” ■

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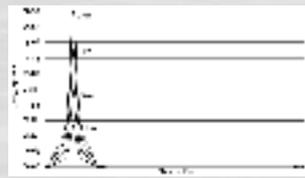
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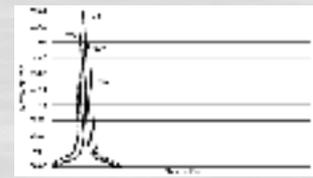


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