

Emerging Opportunities in Food-Contact Applications

By Martha Marrapese,
Colleen M. Evale and
Sebastien Louvion

Various options are available to establish a suitable regulatory status for use of UV/EB coatings, adhesives, and inks in food-contact applications in the U.S. and in Europe. This article provides the current regulatory lay of the land in these two jurisdictions so that individual company needs can be more readily assessed.

By way of general background, in the U.S. a "food additive" is defined in Section 201(s) of the Federal Food, Drug, and Cosmetic Act as a substance that is reasonably expected to become a component of food under the

Contact Notification (FCN), (b) the subject of a prior sanction or approval, or (c) deemed generally recognized as safe (GRAS) for the intended application. Both the Threshold of Regulation and food additive petition procedures have been largely replaced by FCN submissions.

Food Packaging Alliance

In May 2004, the Food Packaging Alliance was formed to make use of the FCN process with the objective of serving as a catalyst for expanding the use of UV/EB materials in food packaging. The Alliance is working to accomplish one or more successful FCNs for UV/EB workhorse materials. It is thought that the Alliance FCN can establish a public baseline for what the FDA will accept in designing UV/EB formulations for food packaging uses and provide possible options with respect to adding 21 C.F.R. § 175.300 sanctioned materials to the FCN formulation without additional clearance.

Currently, the Alliance is comprised of 33 supplier, formulator, equipment manufacturer, and converter members. Ron Golden is chairman of the Alliance and Bob Lieberman, of Cognis Corporation, is vice-chairman. Debbie Smith, of Sartomer Company Inc., is treasurer/secretary and Steve Lapin, of Northwest Coatings, is chairing the Alliance's Technical Committee.

The Alliance has selected a number of candidate formulations consisting of several fundamental

In May 2004, the Food Packaging Alliance was formed to make use of the FCN process with the objective of serving as a catalyst for expanding the use of UV/EB materials in food packaging.

intended conditions of use. If a company can document that a substance is not reasonably expected to become a component of food under the intended conditions of use, it is not a food additive by definition, and may be used without any prior action by, or consultation with, the Food and Drug Administration (FDA).

Consequently, a food-contact article, or component thereof, that is reasonably expected to become a component of food must be (a) the subject of an applicable food additive regulation, Threshold of Regulation exemption letter, or an effective Food

While the FCN will not cover specific commercial applications, which may include additional monomers, additives, and reactants, it is hoped that the FCN, once effective, will allow expansion of the clearance without substantial additional work.

monomers commonly used and one photoinitiator. In addition, use of new food-contact substances typically calls for conducting migration studies in advance, under the intended conditions of use, to determine if and to what extent the substance may migrate to food.

Alliance members have designed a test protocol to address some of the unique recovery issues associated with these formulations. Several Alliance members have volunteered their expertise and equipment to conduct preliminary migration studies using the Alliance protocol to determine the parameters that will minimize migration to food, such as different monomer combinations, different levels of monomers in the polymer, and different coating curing rates. This initial screening is intended to simulate rigorous conditions of use—direct contact with fatty foods at hot-fill temperatures. Based on the results, the Alliance will determine if these use conditions can be supported by existing data (described below), or whether to set additional specifications in the FCN submission, such as on fill temperature or the type of packaged food. Once the screening activities are completed, samples will be selected for the migration tests that will be submitted as part of the FCN, to provide the type and quality of chemistry data that the FDA needs to establish the safety of the intended use and to issue an effective FCN.

The associated toxicity data requirements in an FCN are determined by the level of dietary exposure to the food-contact substance, which in turn is derived from the level of migration of the food-contact substance to food. The Alliance has extensively reviewed the existing publicly available toxicity data on the monomers of interest and their structural analogs, with a special focus on identifying the oral toxicity and genotoxicity data that typically accompany FCN submissions.

As the same chemical reactive group functionality exists across the relevant analogs with the monomers of interest, the Alliance believes that the safety of any of the monomers of interest can be established by consideration of the toxicology data on the basic acrylates. The reason for this proposed approach is that, while there is a fairly large database of toxicology information on the basic acrylates, there is a much smaller database on the multifunctional acrylates; thus, the Alliance proposal is to rely in a significant way on the toxicology of the basic acrylates to establish safe dietary exposure levels for the multifunctional acrylates. Precedent for this approach in predicting human and environmental health effects is provided by the longstanding, cooperative interaction between industry and the U.S. Environmental Protection Agency (EPA) and regulatory agencies in Europe to develop a sound scientific approach to studying acrylates and

methacrylates as a class. The Alliance will be meeting with FDA soon to discuss this proposal. Currently, it is not clear whether additional toxicity testing will be necessary to support the FCN.

While the FCN will not cover specific commercial applications, which may include additional monomers, additives, and reactants, it is hoped that the FCN, once effective, will allow expansion of the clearance without substantial additional work—for example, in future formulations, it may be possible to build on existing clearances and conduct migration tests for only new monomers and oligomers that are not covered by the FCN listing. In that case, dietary exposure to the already-cleared monomers will be considered “replacement” exposure for the exposures already in place, if the intended use is the same.

Food Contact Framework in the European Union

The European Union (EU) currently is in the process of harmonizing legislation on food-contact substances, principally by adopting measures (*i.e.*, Regulations and Directives) that are designed to replace the existing national provisions of the Member States. The system may be summarized by classifying products as those that are subject to harmonized EU law and those that are not the subject of measures at the EU level. Products that are subject to harmonized EU Regulations or Directives are to comply with these measures. Regulations are directly applicable in all Member States, while Directives must be implemented in the Member States' national legislations before they are binding.

Products and applications that are not the subject of EU measures (or that are the subject of Directives that

have not yet been finalized or implemented) are to comply with the appropriate laws of each of the EU Member States, subject to the principle of mutual recognition in case of conflicts between different legal requirements in place in several EU Member States, as discussed further below.

The EU's "Framework Regulation," adopted in 2004, governs all food-contact materials. Article 3 of this Regulation establishes the general principles that food-contact materials must be manufactured in accordance with good manufacturing practice and must not transfer their constituents to food in quantities that could endanger human health or bring about an unacceptable change in the composition, taste, or odor of food.

To achieve these objectives, the Commission of the European Communities is proceeding to adopt specific measures for classes of food-contact materials identified in the Framework Regulation. The most comprehensive of these measures is the Plastics Directive, as amended, which applies to materials comprised exclusively of plastic. However, surface coatings are explicitly excluded from the scope of the Plastics Directive and are not the subject of any other specific measure at the EU level at this time. Nevertheless, we note that "varnishes and coatings" is one of the classes of materials identified in the Framework Regulation as subject to specific measures in the future. Indeed, we understand that EU authorities intend to adopt a specific measure on coatings in the near future, which may require components used in coatings to be included in a positive list of authorized substances in this forthcoming legislation. It is not known at this time whether such legislation will address the irradiation of coating materials.

The Council of Europe adopted on December 1, 2004 a Framework Resolution on coatings intended to come into contact with foodstuffs, Resolution AP (2004)1. However, the resolution is not binding and only provides overall migration requirements for the components of the coating without addressing the curing processes which may be employed in their manufacture. Therefore, under legislation in place at the EU level, surface coatings are only required to meet the general principles of Article 3 of the Framework Regulation. (*i.e.*, Components of the coatings and the potential decomposition products resulting from the irradiation of the material must be safe and cannot cause any unacceptable change to contacted food.)

However, to ensure compliance with EU law, one must also evaluate compliance with the additional requirements in place in individual EU Member States. Eight EU Member States (Austria, Belgium, France, Germany, Greece, Italy, The Netherlands and Spain) have some form of national "positive list" of permissible substances for use in manufacturing plastic food-contact materials, or other compositional requirements beyond the required implementation of the EU Directives, that cover surface coatings without addressing the process by which the coatings are cured. Only one Member State, France, currently has legislation in place regarding irradiation of food-contact materials. National Member State legislation applicable to coatings is briefly summarized below.

Austria has strict positive list requirements applicable to all food-contact materials, including coatings, pursuant to its Lebensmittelgesetz (LMG) of 1975; components that are not cleared in the LMG or the Plastics Directive are subject to premarket approval.

Belgium maintains positive lists under a Royal Arrêté of May 11, 1992, that is applicable to coatings. However, the lists are now considered incomplete due to legislation that passed in December 2002 and became effective in 2003.

France has a series of circulars establishing compositional requirements for coatings, which includes a positive list of additives. In addition, the French Arrêté of August 12, 1986, subjects food-contact materials that are exposed or intended to be exposed to gamma, electron beam or X-ray radiation to a prior notice procedure if the materials are intended to be irradiated at doses up to 10 kGy, and to a premarket authorization procedure for materials intended to be irradiated at doses exceeding 10 kGy.

Germany does not have binding positive list requirements for food contact materials, but its Federal Institute for Risk Assessment (BfR) issues recommendations that contain positive lists that are widely respected in Germany and throughout the EU. Recommendation XL specifically addressed surface coatings, but was withdrawn several years ago. The BfR now refers to the Dutch Warenwet and the Council of Europe Resolution on coatings for compositional requirements for coatings.

Greece has national provisions concerning dyes and pigments for food-contact plastics that cover coatings.

Italy regulates food contact materials under a Decree of March 21, 1973, and has positive list requirements for categories of materials: the positive list for plastics covers coatings.

The Netherlands regulates food-packaging materials under a Decree of October 1, 1979, known as “Warenwet,” which is a compilation of positive lists for different types of substances. Chapter X of the Warenwet is dedicated to coatings.

Spain has implemented the Plastics Directive into its own national law to cover coatings. Spain has also issued a resolution of November 4, 1982, that contains a positive list of additives that may be used in polymeric food-contact materials, including coatings. We understand that Spanish authorities consider the national positive list of monomers to be exhaustive, while the list of additives of the 1982 Resolution is currently considered incomplete. Therefore, monomers in coatings must be listed, but additives that are not listed may still be used in Spain provided they are shown to be safe.

Finally, with respect to the ten new Member States that joined the EU on May 1, 2004 (Poland, Hungary, the Czech Republic, Slovakia, Slovenia, Estonia, Lithuania, Latvia, Malta and Cyprus), some of the new Member States have maintained some national provisions in areas that are not fully harmonized. In the meantime, from a legal standpoint, food-contact materials that are lawfully marketed in any EU Member State, can be marketed in any new EU Member State on the basis of the principle of mutual recognition.

Specifically with respect to potential conflicts or inconsistencies in the food packaging rules in these countries, the principle of mutual recognition allows, in the absence of harmonized legislation and in the presence of differing legal requirements among EU Member States, for the legal importation and sale into one Member State of products that are legally

As an increasing number of UV/EB formulators produce food-packaging materials and seek to identify new markets for their products, the countries of the Pacific Rim are a frequent focus.

produced or marketed in another Member State even if the products do not comply with the specific regulatory requirements of the country of import.

“Mutual recognition” is grounded in the fundamental principle of the free movement of goods between EU Member States, set forth in Articles 28 and 30 of the Treaty of the European Union, and supported by EU case law. Mutual recognition is based on the principle that, once a product has been lawfully manufactured and/or placed on the market of a Member State, it is presumed as guaranteeing an adequate level of protection of health, consumers, and the environment, meaning that all other Member States must accept its placement on their market, unless the Member State of destination can demonstrate, following an appropriate procedure, that the product presents a danger to the public health.

Expanding Markets

Appropriate U.S. and EU status allowing use in food-contact applications may facilitate entry into other markets in the global arena. As an increasing number of UV/EB formulators produce food-packaging materials and seek to identify new markets for their products, the countries of the Pacific Rim are a frequent focus. In Asia and Australia, there is no “common market” system, like the EU. The regulatory system of each country must be evaluated individually before introducing a packaging component or finished package into commerce in the region. In many of the countries in the Pacific Rim, it is sufficient to demon-

strate that food packaging does not transfer any substance to food that could render the food injurious to health or otherwise unfit for human consumption. An appropriate FDA or EU status allowing use in food-contact applications in the United States or Europe may be a suitable demonstration that the material may be used for similar applications in the foreign jurisdiction in question. A source of information on the specific regulatory programs governing food-packaging materials in the Pacific Rim and other parts of the globe, including South America, is Keller and Heckman LLP’s dedicated Web site for food packaging, www.packaginglaw.com.

We predict that, as suppliers, formulators, converters, and end-users become more familiar with how to assess UV/EB in relation to food packaging rules in various parts of the globe, the confidence of the market in the use of these materials in food packaging applications will continue to grow. ▀

—Martha Marrapese is a partner, and Colleen M. Evale and Sebastien Louvion are associates in the law firm of Keller and Heckman. K&H is RadTech International NA’s legal counsel and is located in Washington, D.C.; Brussels, Belgium; San Francisco, Calif. and Shanghai, China.