Food Packaging Safety

By Ronald Golden

The food processing industry is under increased regulatory pressure due to growing public concern about the safety of food products and their packaging. Awareness of potential exposure to chemicals has been raised by sensitive analytical tests capable of detecting chemicals at extremely low concentrations in the environment. Such sensitive techniques virtually assure finding minuscule traces of packaging chemicals in food, whether they are derived from UV&EB or conventional thermally cured formulations. Detection of trace amounts of bisphenol A, nonylphenol, lead and phthalates in food packaging materials has raised outcries about the risks of environmental toxins that may come into contact with food.

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Very aggressive campaigns[1] have been initiated to pursue claims that man-made chemicals interfere with the body's own hormones (so-called endocrine disruptors) and body functions, most importantly reproduction and fetal development. While present in only trace quantities in the environment, the body burden of toxic chemicals can accumulate over time. This has led to increased food safety legislation and particular concern for children's safety, since children frequently taste or ingest non-food materials, consume more food and water per pound of body weight, and can be exposed to trace chemicals *in utero* and in breast milk.

These concerns have been greatly intensified by a number of highly publicized food contamination incidents in the past few years. For example, in 1994 California authorities found that candy imported from Mexico was contaminated with lead that had migrated from ink used in the packaging. In 1999, animal feed contaminated with dioxin and polychlorinated biphenyls (PCBs) in Belgium caused a consumer panic, temporarily interrupting trade with more than 30 countries. Also in 1999, concerns about possible contamination of Coca-Cola products caused removal from commerce in parts of Europe until the company could guarantee that the problems had been corrected; public confidence was regained more slowly. Such food scares continue to agitate public reaction. In 2004, Coca-Cola recalled more than half a million bottles of bottled water in the UK, after finding samples that contained higher than permitted levels of bromate due to inadvertent use of an off-grade raw material. In 2005, the discovery of potentially carcinogenic Sudan 1 red dye in a wide range of foods resulted in massive recalls. Consumer outrage and reaction to such incidents have been broad in scope, but particularly strong in Japan and Europe, where member states issued 3,158 food and feed safety notifications in 2005.

Of particular interest to RadTech members are the finding in 1999 that certain cationic UV photoinitiators produced traces of benzene and the discovery in 2005 of traces of the photoinitiators isopropylthioxanthone (ITX) and 2-ethylhexyl-4-dimethyl-aminobenzoate (EHDAB) in some Nestlé milk products distributed in Italy.

Although potential workplace and consumer exposures to benzene from cationic photoinitiators were miniscule

and orders of magnitude less than encountered when refueling an automobile, many packaging companies demanded reformulation and some UV-ink suppliers discontinued their cationic UV-ink formulations.

From a scientific perspective, the European Food Safety Authority (EFSA) determined that the presence of ITX in packaged foods at the levels detected,[2] while undesirable, did not pose a health risk. It was further stated that no urgent measures were necessary with regard to ITX in baby milk and other products. Nevertheless, Italian authorities confiscated millions of liters of Nestlé baby milk and obtained a court order to force the company to recall the affected brands in Italy. The recall was further extended to France, Spain, Portugal and the Netherlands, and Tetra Pak immediately moved to phase out UV inks for the affected products. Consumer and food processor attitudes to potential food contamination are so sensitive that a recall or elimination of a processing technology is probable whenever there is any chance of consumer backlash. Moreover, the controversy surrounding the migration of ITX into packaged food will likely result in new EU regulation of food packaging.

Potential Financial Impact of a Recall

Why must food-packaging companies be so concerned about avoiding even the minutest traces of unwanted chemicals in their product? Even assuming that the detected levels of contamination are so low that there is little risk of altering the wholesomeness, taste, odor or texture of food, there still remains a very high likelihood of consumer reaction, including wholesale rejection of the questionable product. Consider the following example to put into perspective the potential financial impact of a food-packaging product recall.

Assume that a 20,000 kg truckload of a 19% solids water-borne acrylic epoxy beer and beverage can internal liner is contaminated, resulting in unacceptable toxic migration or an off-flavor or odor. These internal coatings typically are applied at about 100 mg per can. Assume that each finished can has a market value of about $0.08, and that if filled with beverage, the final beverage product has a market value of about $0.15 to $1.00 per can. Assuming that the original coating has a market value of about $0.90/kg, the matrix in Table 1 demonstrates the potential financial exposure of a recall at each stage of the value chain.

Preventing Adulteration

Under the Federal Food, Drug and Cosmetic Act, a food is adulterated if its container is composed, in whole or in part, of any toxic or deleterious substance, which may render the contents injurious to health. Moreover, any contamination that changes the odor, taste or texture of a packaged food or beverage can render that product unacceptable for consumption. There are a number of basic steps that a company can take to minimize the risk of inadvertent contamination and adulteration of a food packaging ink, coating or adhesive.

Formulate Products from Components Cleared under FDA and European Regulations during Product Design and Development

Volume 21 of the Code of Federal Regulations (CFR) provides detailed FDA requirements for the composition and conditions of use and quality control of

TABLE 1

Example potential financial impact of a recall at various stages of the value chain

The problem is identified before sale of the coating, and the product is scrapped.	The problem product is sold and finished cans are manufactured (assume 75% coating transfer efficiency).	The problem product is sold and finished cans are manufactured and filled with beverage.
$0.90/kg x 20,000 kg =	$18,000 Plus 20,000 kg x 0.19 x 0.75 x 10,000 cans/kg x $0.08/can =	$18,000 Plus 20,000 kg x 0.19 x 0.75 x 10,000 cans/kg x $0.15/can (or $1/can) =
$18,000	> $2.3 million	>> $4 million to $28 million
Scrap Coating Product	Bad Coating Product Credit/Plus Buy Back Scrap Cans Plus Any Lost Business Claims	Bad Coating Product Credit/Plus Buy Back Defective Beverage Product Plus Recall/Disposal Costs Plus Any Lost Business Claims Plus Any Consumer Claims

adhesives and coatings intended for use in food packaging applications. Moreover, there are extensive guidance documents and instructions available on the FDA Center for Food Safety & Applied Nutrition Web site.[3] The only current EU regulation that applies to surface coatings for food packaging is (EC 1935/2004), which establishes general requirements that must be met by all articles intended to come into contact directly or indirectly with food. Suppliers of inks, adhesives and coatings in the EU also must consider the "Plastics Directive" (2002/72/EC and its amendments) and various food packaging "positive lists" that exist for some of the member states. Laboratories formulating inks, coatings and adhesives for food packaging applications should assure that all of the components selected for the new or modified formulation comply with FDA (and if appropriate, EU) regulatory specifications from the very beginning of the product design process.

In some cases, a detailed legal interpretation is required before an opinion confirming suitability for intended food packaging use can be obtained. In all cases, whether a simple match with components listed in 21 CFR or chemistry requiring a sophisticated legal evaluation, supporting documentation of FDA compliance should be maintained for each product intended for use in food packaging applications.

Assure that Raw Materials are a Suitable Grade for Food Packaging Applications

It is not enough to use only substances that comply with the specified gross chemical compositions specified in the FDA and EU regulations; the grade of raw material also must be suitable for the intended use. For example, a solid powdered chemical may be treated with a flow or anti-caking agent that is not compatible with use in food contact applications, or it may be a "technical" grade that contains a significant amount of toxic impurities. It is essential to assure that the raw material being used in the formulation does not have unsuitable contaminants. This can be addressed by purchasing a certified food grade material, or by reviewing a detailed chemical analysis of the material. Whenever possible, obtain a certification of FDA compliance from the raw material supplier. Documentation supporting raw material quality should be maintained.

For some critically sensitive applications, such as tobacco or chocolate packaging, end users may demand that they conduct their own evaluation of the raw materials used in a formulation. Suppliers of basic chemicals normally have no problem to disclose the CAS numbers and detailed chemical composition of their products, but suppliers of specialty chemicals and formulated products may not be so forthcoming. In such cases, it often is possible to have the supplier submit their product information to a third-party expert or to the end-user safety department for review under a confidentiality agreement.

Conduct FDA Quality Control Tests

The FDA regulations may require quality control tests on the cured finished coatings. For example, 21 CFR Section 175.300(c) and 21 CFR Section 176.170(c) require that chloroform-soluble extractives do not exceed allowed levels for specified intended end-use applications. Formulators cannot assume that the selection of "FDA approved" components is sufficient to certify their product for use in food packaging under these sections of the FDA regulations. At the very least, the specified quality control test should be conducted on a number of representative cured coatings to confirm and document that they can reasonably be expected to meet the maximum allowed extractable specifications. That data should be kept on file as supporting documentation.

Pay Attention to Odor and Taste Considerations

Components of formulations must be selected to minimize any potential to add to or detract from the taste or odor (organoleptic properties) of the packaged product. Adverse effects can occur as a result of poor selection of the composition or grade of raw material, or from inadvertent contamination of the product. Some products may be suitable for packaging dry foods, for example, but they impart an undesirable taste when used to package sensitive foods, such as chocolates. Suppliers of finished formulations intended for use in food packaging applications may find it advisable to maintain an internal taste panel or contract with an external taste panel service to aid in product design. In some cases, for particularly sensitive or high-potential liability exposure applications, formulators may choose to pre-qualify every batch of finished product through a taste panel before it is released for sale.

Implement Change Management Controls

Formulated products intended for direct food contact typically are pre-qualified by the package manufacturer and subject to rigorous change controls, while chemicals and formulations used in external packaging applications may not be so tightly controlled. Constant efforts to improve product performance and manufacturing efficiency and to control costs generate strong pressures for product and process modification. Suppliers of raw materials and formulations intended for food packaging should implement effective change management controls to assure that approved raw materials, formulations and processes are not inadvertently modified without careful review and authorization. Food packaging customers often require that they must be notified in advance about any product or process

modifications, and these requests must be rigorously respected.

Implement Good Manufacturing Practices

FDA regulations require not only compliance with the specified chemical composition of coatings and appropriate quality control, but also *Good Manufacturing Practices* in production facilities to prevent contamination and assure product consistency (21 CFR Section 110). Production facilities that manufacture food contact products must follow appropriate sanitation procedures and should be isolated from general production lines. If this is not possible, products that are co-manufactured in the same equipment should be selected to avoid potential toxicity or organoleptic problems. Common manifolds for charging raw materials and discharging products should be designed to eliminate any chance of possible cross-contamination with potentially problematic materials. When appropriate, equipment used to manufacture food contact products should be cleaned thoroughly before processing products for that intended use.

Good Manufacturing Practice also includes strict traceability of raw materials by source and lot number and strict traceability of finished products. This is particularly critical if a batch is potentially contaminated. Good traceability procedures can enable rapid segregation of questionable product before release, or if it is shipped, can enable effective and efficient recall at the lowest possible eventual liability cost.

Consider Applicability of Hazard Analysis and Critical Control Point (HACCP) Guidelines[4]

The National Advisory Committee on Microbiological Criteria for Foods developed the HACCP management system to help assure that potential biological, chemical, and physical food safety hazards can be identified and controlled in raw material production, procurement, processing and distribution. While HACCP is targeted principally at preventing microbial contamination in food processing plants, retail food stores and food service operations, the basic principles are broadly applicable.

- Analyze hazards
- Identify critical control points
- Preventive measures with critical limits for each control point
- Procedures to monitor the critical control points
- Corrective actions to be taken when a critical limit has not been met
- Procedures to verify that the system is working properly
- Effective record keeping

Moreover, certain potential hazards considered in HACCP, such as unintended allergens, contaminated compressed air, rodent and pest control, potential contamination from other materials in an uncontrolled environment, etc. require attention in any production facility for food packaging materials.

Track Regulatory and News Developments Related to Food Packaging

Suppliers of food packaging materials should keep track of regulatory developments to assure continuing compliance and to take advantage of new developments that might allow the use of new materials. Historically, UV curing has been severely constrained by lack of FDA recognition and concerns about migration in certain applications, such as wide web printing, mainly because wide web's primary use is in food packaging. On the positive side, the RadTech Food Contact Notification Alliance is working to obtain FDA clearance for a number of basic UV&EB-curing acrylates. If successful, this development should greatly expand the flexibility of formulators to offer UV&EB-curing products for food packaging.

Outlook For ITX

From a purely technical perspective, it may be possible to replace ITX with chemical substitutes or variants, or formulations or packaging can be redesigned to reduce or substantially eliminate migration. For example, ITX with a polymerizable substituent or an improved functional barrier in a redesigned package[5] should be capable of reducing the migration of ITX, even for containers of milk products. Eventually, the improved chemistry or package design must be tested to confirm that the level of ITX migration is either undetectable or below any threshold of concern. However, the marketplace does not base its decisions on purely technical considerations. Even if it can be demonstrated that there is no toxicologically significant migration of ITX, and even if such changes are practical and cost effective, consumer emotional reaction and/or food marketer sensitivity to consumer concerns may prevent the reintroduction of this photoinitiator for food packaging in some regions.

Conclusions

Concerns about environmental toxins and a number of highly publicized food contamination incidents have raised consumer, food processor and regulatory sensitivity to the possibility of migration of chemicals from packaging into food. Careful attention to applicable regulations and good manufacturing practices can help suppliers of food packaging and inks, coatings and adhesives intended for use in food packaging to minimize the risks and consequent liabilities of unintended contamination and migration of harmful chemicals from their products into food.

Any future use of ITX in UV formulations intended for use in food packaging will depend not only on formulation and package design modifications to reduce migration, but also on market acceptance of the improved packaging. ◗

References

1. See, for example Our Stolen Future at *www.ourstolenfuture.org/index.htm.*
2. Levels of ITX found in all milk products ranged from about 25 ppb to a maximum of about 600 ppb; levels of EHDAB ranged from less than 5 ppb to 125 ppb.
3. *www.cfsan.fda.gov/list.html.*
4. *http://vm.cfsan.fda.gov/~lrd/haccp.html.*
5. A study (UK Food Standards Agency report number A03027 (FS2255): *Determination of the potential for transfer from secondary packaging to foods and development of guidelines to reduce transfer to levels of no concern* (September, 2004)) confirmed that migration of packaging components into foods is dependent on the volatility and concentration of the migrating substance, storage temperature, humidity and time, and on the structure of the packaging. The relative effectiveness of packaging substrates in terms of reducing migration into food was poly(ethylene) terephthalate (PET) > nylon > poly(vinylidene chloride)-coated poly(propylene) (PP) > metalized PP/PP laminate > PP > paper.

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