

# U.S. and EU Requirements for Recycled Food Contact Materials



*Food manufacturers are responsible for ensuring that food packages comply with applicable regulatory requirements*

**G**reen is in. And although one must be concerned with the types of environmental claims made for recycled materials that may be used in food packaging, one should be just as concerned that such materials comply with the legal requirements pertaining to their safe use.

In this regard, the use of recycled materials in food packaging applications is governed by the same principles that apply to all food packaging. Namely, in the U.S., the packaging materials must comply with any applicable regulations and must meet the suitable purity requirements of the Food, Drug and Cosmetic Act (FD&C Act). In the European Union (EU), the materials must comply with any applicable EU or Member State legislation (depending on whether the recycled material is plastic or paper) and must meet the safety requirements outlined in the EU Framework Regulation. Safety requirements in this context generally mean the product is suitably pure so that it will not adulterate the food it contains.

Below is a summary of the regulatory systems governing recycled food contact materials in the U.S. and the EU.

## **U.S. Regulation of Recycled Food Contact Materials**

The U.S. Food and Drug Administration (FDA) generally regulates the use of materials in food packaging by

way of its food additive regulations (21 C.F.R. Sections 170 et seq.) or through the Food Contact Notification program. FDA does not, however, mandate special regulatory review or preclearance of recycled food contact materials. This is because FDA regulates food contact materials based on their composition, not on the specific process by which they are manufactured or the source of their raw materials. Accordingly, recycled food contact material must meet the same regulatory specifications that virgin material is required to meet (with the exception of paper, see below). Recycled food contact materials also must comply with the FDA Good Manufacturing Practices (GMP) requirements that apply to food contact materials (21 C.F.R. Section 174.5), which require, among other things, packaging materials to be of a purity suitable for their intended use.

Since recycled food contact materials don't require preclearance from FDA, a company can establish to its own satisfaction—using scientifically sound methods—that a recycled material complies with the existing regulations and is suitably pure for its intended use. Or a company can establish an acceptable regulatory status for a recycled food contact material by demonstrating through appropriately conducted extraction studies or calculations that it is not reasonably expected to become a component of food and therefore is not a food additive under the FD&C Act when used as intended (just as one may for a virgin material). Because FDA can challenge a determination of this sort postmarket (although that doesn't happen very often), and because some product end-users demand it, some companies that produce recycled food contact materials will also request FDA to review their determinations and issue a letter of no objection if the agency agrees with the determination.

*Recycled Plastic:* FDA provided guidance on the use of recycled plastics in its August 2006 document, “Guidance for Industry: Use of Recycled Plastics in Food Packaging: Chemistry Considerations.” In this guidance, FDA discusses some specific issues manufacturers should address in establishing the safety and regulatory compliance of recycled polymers for food packaging, including the need for recyclers to ensure that possible contaminants from prior use are removed sufficiently by the recycling process.

There are three types of plastics recycling operations: 1) primary recycling (e.g., industrial scrap); 2) secondary recycling (e.g., physical reprocessing, such as grinding, melting, reforming); and 3) tertiary recycling (or regenera-

tion of purified starting materials, such as by methanolysis or glycolysis). Recyclers can establish suitable purity for secondary and tertiary recycling operations by demonstrating the effectiveness of the cleanup and reprocessing steps in removing contaminants through surrogate contaminant testing and, if appropriate, additional migration testing.

In the guidance, FDA states that estimated daily intakes (EDIs) of contaminants from recycled food contact articles on the order of 1.5 µg/person/day (0.5 ppb dietary concentration) or less generally present no more than a negligible risk. An example is provided of how to calculate the maximum acceptable contaminant level in polyethylene terephthalate (PET) that would result in an EDI of no more than 1.5 µg/person/day. Based on a consumption factor of 0.05, a food-type distribution factor of 1.0, consumption of 3 kg of food per day, a surface-area-to-volume ratio of 10 g/in<sup>2</sup> and a container wall thickness of 2 mils (0.50 mm), the maximum residual

contaminant level equivalent to an EDI of 1.5 µg/day would be 220 µg/kg.

FDA’s guidance on surrogate contaminant testing recommends exposing virgin flake or bottles from feedstock that contain only food contact materials to surrogate cocktails of contaminants for 2 weeks at 40 °C. If the feedstock may include non-food contact materials, virgin flake, not bottles, should be exposed to higher concentrations of surrogates for 2 weeks at 40 °C. Surrogate concentrations must be equal to or greater than the sorption values provided by FDA in the guidance. Once surrogate exposure is completed and the flake or bottles are rinsed, the cleaning and recycling process is followed and then residual contaminant levels may be deter-

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mined.

Suitable purity of the resin is established if the data show that these residual levels are below those noted in the guidance. If the maximum residual levels are exceeded, several alternatives are available, including conducting migration studies that simulate actual use conditions for the recycled materials to determine whether the surrogate contaminants are likely to transfer to food; blending the recycled material with virgin polymers to dilute out the level of the contaminants; limiting end-uses to those in which migration of the contaminants to food is unlikely; and using the recycled materials with a functional barrier that prevents migration of the recycled material to the food.

*Recycled Paper:* FDA permits the use of pulp from reclaimed (recycled) fiber if certain conditions are met (see 21 C.F.R. Section 176.260). In particular, the pulp may not contain “poisonous or deleterious substances” that migrate to food, and the source may not have

been used to hold or ship poisonous or deleterious substances. This regulation does not, however, require that additives found in the recycled pulp must comply with the regulations applicable to paper (21 C.F.R. Sections 176.170 et seq.). Food contact pulp, including recycled pulp, must be suitably pure for its intended use. There are currently three approaches used to establish the suitable purity of recycled pulp, namely, batch testing, surrogate testing or no-discernible-difference testing.

Batch testing involves baseline sampling with an initial test to establish that a mill produces suitably pure recycled paper. It focuses on a comprehensive list of unintentional chemical contaminants, including heavy metals, pesticides and polychlorinated biphenyls (PCBs), volatile and semivolatile organics and dioxins. Pass/fail criteria—based on demonstrating potential exposure below thresholds of concern for a specific chemical—are used. Periodic, focused sampling, or follow-up testing of common and mill-specific contaminants, is also required to confirm that contaminants of high concern remain within required limits. The trick here, of course, is determining the list of substances that should be examined.

With surrogate testing, selected chemicals, which model classes of contaminants, are spiked into the source material. The surrogates are selected to address incidental contaminants and intentional additives. The contaminated source material is then sent through the recycling process and the recycled paper is analyzed to confirm that the process removed the spiked surrogates. Functional-barrier testing also may be necessary. FDA issued a draft guidance document several years ago that lends credence to this determination method.

No-discernible-difference testing involves comparing paper samples produced from virgin fiber with ones produced from recycled fiber. The samples are analyzed for contaminants and substances of concern—such as polyaromatic hydrocarbons, heavy metals, dioxins, PCBs—to demonstrate “no

discernible difference” in potential contaminants between them. The analysis also can include comparison of total chloroform-soluble, nonvolatile (TNV) extractives between virgin and recycled samples. This can be accomplished by exhaustively extracting the samples with food simulants and measuring TNVs, then comparing the analytical “fingerprints” with gas-liquid chromatography, high-pressure liquid chromatography, ultraviolet-visible spectroscopy and/or infrared spectroscopy to identify and quantify differences. The problem here, of course, is that the method assumes that the virgin paper used for the baseline comparison is itself of suitable purity.

In addition to any of the above, microbiological loading analysis should be done using a swab or disintegration test. And, of course, ongoing quality assurance testing should be conducted to ensure that the recycling process continues to produce suitably pure products.

### EU Regulation of Recycled Food Contact Materials

As mentioned above, in the EU, all food contact materials must comply with the Framework Regulation (EC) 1935/2004. It requires that food contact materials and articles be manufactured in accordance with GMPs, and that materials and articles not transfer constituents to food that would endanger public health, bring about unacceptable change in composition of food or deteriorate its organoleptic characteristics.

*Recycled Plastic:* The European Commission (EC) published a regulation on recycled plastic materials and articles intended to come into contact with foods, EC 282/2008, on March 27, 2008. Under this regulation, only food contact materials and articles that contain recycled plastic obtained from an authorized recycling process may be marketed in the EU after petitions for recycling processes received by December 31, 2009 are evaluated. Applications for recycling process must first be submitted to a Member State authority, which will then forward them to the Eu-

ropean Food Safety Authority (EFSA). After EFSA issues an opinion, the EC will adopt a decision either granting or refusing authorization of the recycling process.

EC 282/2008 requires that the plastic input originates from plastic materials and articles that have been manufactured in accordance with EU legislation on plastic food contact materials and articles, and that the recycling process eliminates contamination or reduces it to a concentration that does not pose a risk to human health. Monomers and oligomers resulting from chemical depolymerization are subject to the same requirements as monomers manufactured by chemical synthesis and, therefore, are not covered by this regulation. In addition, recycled material used behind a functional barrier is not covered by the authorization procedure in this regulation.

The regulation of plastics used in food contact materials is harmonized in the EU under the Plastics Regulation, EU No. 10/2011. This regulation includes an overall migration limit and a list of authorized substances for the manufacture of plastic food contact materials with corresponding specific migration limits.

EFSA issued its first opinion on the safety of a process for manufacturing recycled plastics to be used as food contact materials on December 20, 2010 and adopted its first three scientific opinions on the safety of processes to recycle PET for use in food contact materials on August 2, 2012. Once the EC adopts decisions on the authorization of the recycling processes for which a valid application was submitted—expected in 2014—the initial phase will be completed. EFSA is currently reviewing applications for both existing

and new processes for recycled plastics for use in food contact materials. New recycling processes are those that began operation after April 17, 2008 and for which an application was submitted after December 31, 2009.

*Recycled Paper:* The EU does not have harmonized legislation governing the use of food contact paper and board materials. Therefore, in addition to being governed by the Framework Regulation, these materials must comply with the appropriate laws of each EU

Member State, subject to the principle of mutual recognition, and this includes recycled paper as well. Some Member States have specific legislation or recommendations on food contact paper, which are described below.

The German Federal Institute for Risk Assessment or Bundesinstitut für Risikobewertung (BfR) Recommendation 36 covers the use of paper and board for

food contact applications. While the German BfR Recommendations are not legally binding, they are respected by industry throughout the EU. The annex to Recommendation 36 specifically addresses the use of recycled fibers as raw materials for the production of paper. Pointing out that care must be used in selecting fiber sources with respect to potential migration of substances into food, the annex specifies migration limits for: primary aromatic amines, 4,4'-bis(dimethylamino)-benzophenone, phthalates (di-2-ethylhexyl phthalate, di-n-butyl phthalate, diisobutyl phthalate), benzophenone, bisphenol A and diisopropyl naphthalene.

In Italy, recycled paper is permitted for use only in contact with foods that are not subject to migration testing (i.e., dry, nonfatty foods). In the Netherlands, recycled fibers are ex-

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licitly allowed; however, they are not permitted for use in paper for cooking applications or filtering drinks above 80 °C. In the Czech Republic, reuse of paper packages in direct contact with food is not allowed, whereas the use of reclaimed fibers from specific paper classes is permitted in the production of paper if there are no safety concerns. In Slovakia, recycled fibers are currently permitted, with some limitations, although this legislation may be revised in the near future.

## Mineral Oil Migration from Recycled Packaging

The detection of “mineral oil” compounds in food packaged in recycled cardboard by Swiss researchers and others led to further investigations on the extent of these compounds in food and their safety. Sources of mineral oils in food from food contact materials are thought to include recycled paper and board (especially from the ink used on newspapers), printing inks applied to paper and board and additives used in the manufacture of plastics. The main compounds of interest in recycled paper

are mineral oil saturated hydrocarbons (MOSHs) and mineral oil aromatic hydrocarbons (MOAHs).

EFSA published a scientific opinion on the potential presence of mineral oil hydrocarbons (MOHs) in food in June 2012. Although EFSA stressed that there are several uncertainties regarding the chemical composition of MOH mixtures to which humans are exposed, EFSA added, “on the basis of new information on the lack of toxicological relevance for humans of previous animal studies, the temporary acceptable daily intakes of some ‘saturated’ MOH present in specific food products warrant revision.”

Currently, there are no migration limits for mineral oils to food in the EU. However, the German Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) is currently drafting an ordinance that would prohibit the transfer of MOAHs to food from recycled board. The draft ordinance does not specify a level of detection, but BMELV has indicated that the confirmation of “no” transfer of MOAHs to food will be determined by

a test method that BfR will make available. An earlier version of the ordinance also addressed the transfer of MOSHs to food, but since MOSHs and MOAHs exist in recycled board at a fairly constant ratio, it is thought that controlling the MOAHs in the board will also control the MOSHs.

## Conclusion

Heightened interest in environmental issues is pressuring food manufacturers to consider using more recycled materials in food packaging. While regulations exist in some jurisdictions specifically addressing the safety of recycling processes and materials, ultimately food and food packaging manufacturers are responsible for ensuring that food packages comply with applicable regulatory requirements and are of a suitable purity for their intended use. ■

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