

TECHNICAL ADVISOR'S REPORT
TO THE
FOOD, DRUG, AND COSMETIC PACKAGING
MATERIALS COMMITTEE

“The Fourth Amendment to the Plastics Directive”

June 18, 2007

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Technical Advisor's Report^{*}

to the

Food, Drug, and Cosmetic Packaging

Materials Committee

Ladies and Gentlemen:

It is a great pleasure for me to be with you once again in the role of the Committee's Technical Advisor. This report will describe one of the current technical issues we are dealing with in establishing satisfactory regulatory positions for plastic food-contact materials. Specifically, this report will provide a review of recent legislation by the European Union (EU) regarding the use of substances in contact with food.

Background

The EU has for some time now been engaged in the process of harmonizing legislation on food-contact substances, principally by adopting Directives that are designed to replace the existing national provisions of the Member States. The EU has adopted a "Framework Regulation" governing all food-contact materials (Regulation 1935/2004/EC), which is presently in force in all the Member States. Article 2 of the Framework Directive establishes the general principles that food-contact materials must be manufactured in accordance with good manufacturing practice (GMP) so as not to 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 has been adopting specific Directives and Regulations for certain classes of food-contact materials. The Directives generally are applied by the Commission's consulting body, the European Food Safety Authority (EFSA),¹ in the review of Technical Dossiers to clear new substances. The most comprehensive of these specific Directives is the Plastics Directive, which applies to materials consisting exclusively of plastics.² Article 2 of the Plastics Directive provides that all

^{*} Prepared by Dr. Lester Borodinsky, Keller and Heckman LLP, for the June 18-20, 2007 meeting of The Society of the Plastics Industry, Inc.'s (SPI) Food, Drug, and Cosmetic Packaging Materials Committee, Baltimore, Maryland, Sheraton Inner Harbor Hotel.

¹ EFSA provides independent scientific advice on all matters linked to food and feed safety (including food-contact materials).

² The "Plastics Directive" (2002/72/EC) replaced and consolidated the so-called "Monomers Directive" 90/128/EC and its seven amendments. Directive 2002/72/EC itself has now been amended four times, as discussed below.

plastic articles must meet an overall (total) migration limit (OML), which is designated as 10 milligrams per square decimeter of surface area of material or article (in most cases). Thus, plastic articles may not transfer their constituents to food in quantities exceeding this limit.

The Plastics Directive provides a complete positive list of permissible monomers or other starting materials for use in manufacturing polymers for use as components of food-contact plastic materials. Monomers intended for use in the production of food-contact plastics must, therefore, be included on the Plastics Directive unless a specific exemption applies. In the case of many of the monomers, finished articles that employ polymers that are manufactured using the monomers must meet a specific migration limit (SML) for the substances in addition to the overarching requirement of meeting the OML that is in place for all plastic articles.

In addition, the Plastics Directive contains an “incomplete” list of substances that may be used as additives to polymers used in the manufacture of plastic materials; these substances have been reviewed and considered safe by EFSA (or, prior to May 2003, the EU Scientific Committee on Food (SCF), the body formerly responsible for evaluating food-contact substances in the EU³); as is the case for monomers, in the case of many of the additives, finished articles that contain the additives also must meet an SML for the additive. However, as noted above, the additives list is not yet complete. At the present time, unlisted additives may still be used, provided that such use is demonstrated to be safe and meets any relevant Member State national requirements, subject to the Common Market principle of mutual recognition. In 2002, the European Commission confirmed its intention to transform the additives list of the Plastics Directive into a “positive list” of the additives that are permitted for use in the EU to the exclusion of all others. When this is realized, only additives listed on the Plastics Directive will be able to be used in food-contact materials made entirely of plastic (and possibly in multi-material articles, as well).

In addition to the Framework Directive and the Plastics Directive, other directives are important for administering the use of materials in contact with food. There are three directives relating to the use of vinyl chloride in the manufacture of food-contact materials (78/142/EEC, 80/766/EEC, and 81/432/EEC), a directive (and its amendments) relating the rules for performing migration tests (82/711/EEC and its two amendments, 93/8/EEC and 97/48/EC), and a directive relating the specific simulants to be used for migration testing for various “food types” (85/572/EEC).

As noted above, the migration testing parameters for clearing new substances in the EU are provided in the European Commission’s Directive 82/711/EEC, which was amended for the second time (the most recent amendment) on July 29, 1997, in the Official Journal of the European Communities.⁴ Directive 82/711 establishes “the basic rules for testing migration of constituents of plastics materials and articles intended to come into contact with foodstuffs;” the

³ EFSA was legally born from the European Parliament and Council regulation (EC) No 178/2002 of 28 January 2002, designed as a replacement for the SCF; EFSA became practically operational in May 2003 with the establishment of its Scientific Committee and Panels.

⁴ Unlike the United States Food and Drug Administration (FDA) system, the EU migration testing Directive is applicable to both acquiring the data to establish the clearance for a new food-contact material as well as performing compliance tests on food-contact articles composed of materials that are already permitted.

Second Amendment to this Directive is a total revision of the Directive, although most of the testing parameters were unchanged from the previous version. Additional guidance is provided in the EU's *Practical Guide*, which was amended most recently on 15 April 2003, as well as in the EU's *Note for Guidance*, which was amended most recently on 08 June 2006.

Recently, the Commission of European Communities enacted two new pieces of legislation – Directive 2007/19/EC “amending Directive 2002/72/EC relating to plastics and articles intended to come into contact with food and Council Directive 85/572/EEC “laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs,” and Regulation No 372/2007 “laying down transitional limits for plasticizers in gaskets in lids intended to come into contact with foods.” Each of these is discussed in turn below.

Commission Directive 2007/19/EC

Directive 2007/19/EC, the Fourth Amendment to the Plastics Directive, was published in the Official Journal of the European Union (OJ) on March 31, 2007. Member States have until April 1, 2008 to adopt the provisions of the directive into their national laws.

The Fourth Amendment incorporates the following notable modifications:

Sealing Gaskets

It makes clear that sealing gaskets for container lids now fall under the scope of the Plastics Directive. To allow sufficient time for lid manufacturers to comply with the provisions of the directive, however, the additives permitted for use in gaskets will not be restricted to those listed in Annex III at the time the additives list becomes a complete, positive list. If listed additives are used in gaskets, however, their use must comply with any established restrictions or specifications.⁵

Functional Barrier Concept

The Fourth Amendment introduces into EU legislation the concept of and definition of a “plastic functional barrier.” Under the amendment, a plastic layer separated from food by a “plastic functional barrier” may contain unlisted substances, or listed substances that do not comply with specified restrictions. The definition of a “plastic functional barrier” is carefully worded to avoid a numerical barrier description, stating only that the barrier must ensure compliance with the Framework Regulation and with the other provisions of the Plastics Directive. The Fourth Amendment makes clear, however, that migration of a non-authorized substance through a plastic functional barrier may not exceed a level of 0.01 mg/kg in food or a food simulant; thus, plastic functional barriers must, in effect, prevent the migration to food of unlisted materials at levels of 10 parts per billion (ppb). The Fourth Amendment also notes that

⁵ Because the authorities consider it necessary to enforce specific migration limit (SML) restrictions on plasticizers migrating from gaskets in lids sooner than the April 1, 2008 implementation deadline for the Fourth Amendment, the Commission also has promulgated a separate regulation laying down transitional migration limits for plasticizers from gaskets pending implementation of the Fourth Amendment to the Plastics Directive. The details of this Regulation are discussed below.

the 0.01 mg/kg (10 ppb) migration limit must always be expressed as concentration in the food or simulants (*e.g.*, mg/kg), rather than in units of mg/dm².

It is important to realize that the functional barrier concept is limited to plastic functional barriers, as opposed to barrier layers composed of other materials such as metal or glass. This restriction arises because Article 1, paragraph 4 of the directive maintains the exclusion (except for gaskets) of multi-layer, multi-material articles from the scope of the Plastics Directive. Another important detail is that the functional barrier exception does not apply to substances considered carcinogenic, mutagenic, or toxic to reproduction.

Non-Fatty Food

The Fourth Amendment introduces into EU legislation the definition of a “non-fatty food.” Under the amendment, a non-fatty food is defined as “foods for which in [sic] migration testing simulants other than simulant D are laid down in Directive 85/572/EEC.” This definition is not perfectly clear – if more than one simulant is required, *e.g.*, fresh meat, which requires the use of simulants A (water) and D (olive oil), and one of these is a simulant “other than simulant D,” as in the case of this example, would this be considered a non-fatty food? We do not think that this is the interpretation intended by this definition, rather, we believe that it was intended to cover foods that do not at all require simulant D.

Infants and Young Children

The Fourth Amendment also introduces special controls to guaranty infant safety. Specifically, to account for the fact that infants ingest more food in proportion to their body weight as compared to their adult counterparts, the Fourth Amendment requires that migration limits for plastic materials and articles used in contact with food intended for infants and young children always be applied in units of mg/kg, in other words, by concentration in the food (or food stimulant). For example, the overall migration limit (OML) for plastics in contact with food for infants and young children is always 60 mg/kg, whereas it is more broadly also 60 mg/kg (*i.e.*, for individuals other than infants and young children), except that the OML is 10 mg/dm² for containers that have a capacity of less than 500 mL or more than 10 L.

In addition, the Fourth Amendment also restates that, more generally, specific migration limits (SML) are set forth in the Plastics Directive in units of mg/kg (again, concentration in the food), but that such limits are expressed in units of mg/dm² for articles with a capacity of less than 500 mL or more than 10 L.

It is not clear to me why the 60 mg/kg OML (or individual SMLs) should not be applicable for all people (not just infants and young children), rather than being expressed in terms of surface area (*i.e.*, in mg/dm²). The relationship between the two ways in which the OML is expressed (60 mg/kg and 10 mg/dm²) is the EU default of 6 dm²/kg, *i.e.*, (60 mg/kg) x (1 kg/6 dm²) = 10 mg/dm². However, small containers have a larger surface area-to-food mass ratio than the default (6 dm²/kg). For example, a cylinder that has a diameter of 7 cm and a height of 26 cm is calculated to have a total internal surface area of 649 cm² (6.49 dm²) and capacity of 1 L (or 1 kg, assuming a density of 1 g/cm³); its surface area-to-mass ratio is 6.5 dm²/kg, only slightly larger than the default value. Because of its size (*i.e.*, its capacity is between 500 mL

and 10 L), its OML requirement is 60 mg/kg. On the other hand, smaller containers generally have a larger surface area-to-food mass ratio, *e.g.*, a cylinder that has a diameter of 7 cm and a height of 6 cm is calculated to have a total internal surface area of 209 cm² (2.09 dm²) and capacity of 0.23 L (or 0.23 kg, again assuming a density of 1 g/cm³); its surface area-to-mass ratio is 9.0 dm²/kg. Because of its size (*i.e.*, its capacity is below 500 mL (0.5 L)), its OML requirement is 10 mg/dm²; this would appear to permit a much higher concentration limit, as (10 mg/dm²) x (9.0 dm²/kg) = 90 mg/kg. Similar apparent permissible higher concentrations could be obtained when dealing with SMLs as well.

In addition, the Fourth Amendment states that the fat reduction factor (FRF) (discussed below) is not applicable to food contact articles intended for infants and young children.

Polymerisation Production Aids (PPA)

Polymerisation production aids (PPA) are “defined” as “substances used to provide a suitable medium in which polymerisation occurs (*e.g.*, emulsifiers, surfactants, and buffering agents) they are referred to as “Polymer production aids” in the *Practical Guide*. The amendment makes clear that the (currently “incomplete”) additives list in Annex III to the Plastics Directive does not cover additives exclusively acting as PPAs that are not intended to remain in the finished article. Thus, unlisted PPAs may continue to be used in the European Union (EU) subject to applicable national laws and the principle of mutual recognition. Nevertheless, for PPAs appearing in Annex III, any corresponding restrictions or specifications on their use continue to apply and must be met.

Azodicarbonamide

In the first amendment to the Plastics Directive (Directive 2004/1/EC), the use of azodicarbonamide as a blowing agent in the production of food-contact materials was suspended while the risks posed by semicarbazide (SEM), the decomposition product of azodicarbonamide, could be more fully assessed. EFSA has now completed its assessment and has indicated that, if exposure to SEM, as a decomposition product of azodicarbonamide, is eliminated, the carcinogenicity of SEM does not pose a human health risk at the concentrations found in food. Thus, the Fourth Amendment includes a new Article (Article 4e) that permanently prohibits the use of azodicarbonamide in the manufacture of plastic food-contact articles.

Written Declaration of Compliance

Finally, the Fourth Amendment identifies the information that needs to be included in the written declaration of compliance that must accompany finished plastic materials and articles as well as the substances used to manufacture plastic materials and articles. In particular, the declaration of compliance must include the following: (1) the name of the product and the manufacturer or importer; (2) confirmation that the product complies with the Plastics Directive and the Framework Regulation (EC No. 1935/2004); (3) specifications on use (*e.g.*, food types, temperature conditions, ratio of food-contact surface area to volume); (4) if a functional barrier is used, confirmation that the material complies with applicable requirements; (5) information on any restrictions in place under the Directive; and (6) information on any restrictions in food based on experimental data or theoretical calculations. To substantiate the declaration of

compliance, the Fourth Amendment specifies that business operators, including the downstream finished article manufacturer and the upstream materials supplier, must keep documentation regarding the conditions and results of testing, calculations, or other analysis demonstrating compliance with applicable requirements.

Fat Reduction Factors (FRF)

As expected, the Fourth Amendment also introduces the concept of fat reduction factors (FRF), which are intended to correct the specific migration levels of “lipophilic substances” to foods that contain more than 20% fat. The FRF, when applicable, has a value between 1 and 5. Substances considered to be lipophilic for the application of the FRF are listed in Annex IVa. The FRF is not applicable (1) for foods that contain less than 20% fat, (2) for food intended for infants or young children, (3) for substances for which the SML is ND (non-detected), (4) for the non-listed substances in association with a functional barrier (*i.e.*, migration limit of 0.01 mg/kg), and (5) for materials and articles for which it is impractical to estimate the relationship between the surface area and the quantity of food and for which the migration employs the conventional surface area-to-mass ratio of 6 dm²/kg. The FRF is determined by the following equation:

$$\text{FRF} = (\% \text{ fat in food} \times 5) / 100$$

In addition, the amendment provides for the correction of the specific migration of lipophilic substances into food simulant D and its substitutes by application of a simulant D reduction factor (DRF). The DRF has been in place since the inception of Council Directive 85/572/EEC “laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs,” *i.e.*, since 1985. The Fourth Amendment renames it the “DRF”⁶ and further indicates that it is not applicable (1) when the specific migration into simulant D is higher than 80% of the content of the substance in the finished material or article (*e.g.*, thin films), (2) for substances for which the SML is ND (non-detected), and (3) for the non-listed substances in association with a functional barrier (*i.e.*, migration limit of 0.01 mg/kg). The maximum DRF value listed in Directive 85/572/EEC is 5, and varies from food to food (*i.e.*, applicable to specific foods).

When a DRF and a FRF both apply, the total reduction factor (TRF), obtained by multiplying the DRF by the FRF, cannot exceed a value of 5.

50% Ethanol Simulant

The Fourth Amendment also amends Directive 85/572/EEC to make 50% ethanol (instead of distilled water) the appropriate simulant for milk products, which includes whole milk, partly dried milk, skimmed or partly skinned milk, fermented milk (such as yogurt and buttermilk), cream, sour cream. The use of 50% ethanol does not apply to dried milk, cheeses, or rennet (wet or dry).

⁶ In the original text of Directive 85/572/EEC, it was referred to merely as the “reduction factor” applicable to certain fatty foodstuffs.

Certain Plasticizers

The Fourth Amendment introduces restrictions on the use of phthalate plasticizers and epoxidized soybean oil (ESBO). For example, di(2-ethylhexyl)phthalate (DEHA) is limited to (1) use as a plasticizer in repeated use materials and articles contacting non-fatty foods, (2) use as technical support agent in concentrations up to 0.1% in the final product, and (3) an SML of 1.5 mg/kg (for the above uses). Similarly, ESBO is limited to an SML of 60 mg/kg, except that it is 30 mg/kg for certain foods intended for infants and young children when used in PVC gaskets to seal glass jars; there were no such SMLs prior to the adoption of the Fourth Amendment. The issue of plasticizers and their SMLs is the subject of Commission Regulation (EC) No 372/2007, discussed below.

Commission Regulation (EC) No 372/2007

Regulation (EC) No. 372/2007, “laying down transitional migration limits for plasticizers in gaskets in lids intended to come into contact with foods,” which was published in the Official Journal of the European Union on April 3, 2007, entered into force and is binding on all EU Member States as of April 23, 2007.⁷ This Directive is intended to apply to lids containing plastic layers or plastic coatings, forming gaskets in these lids that, together, are composed of two or more layers of different types of materials.

This Regulation fixes “transitional SMLs” for seven (7) specific plasticizers, in effect until June 30, 2008, for the gasket applications specifically. In the case of six of the seven substances, the SMLs are (1) 300 mg/kg food or food simulant (or 50 mg/dm² of the total food contact surface of the lid and sealed container) for foods requiring the use of simulant D and (2) 60 mg/kg food or food simulant (or 10 mg/dm² of the total food contact surface of the lid and sealed container) for other types of food (*i.e.*, those not requiring the use of simulant D). These limits apply to the total migration of all six substances. One of the six is ESBO, which imposes an additional SML of 30 mg/kg for certain foods intended for infants and young children, as discussed above. The seventh plasticizer listed in the Regulation is not encompassed by the above limits, but, rather, is subject to a lower SML of 30 mg/kg (or 5 mg/dm² of the total food contact surface of the lid and sealed container) for all types of food.

⁷ As noted above, because the authorities consider it necessary to enforce specific migration limit (SML) restrictions on plasticizers migrating from gaskets in lids sooner than the April 1, 2008 implementation deadline for the Fourth Amendment, the Commission also has promulgated this separate regulation.