[X1 ANNEX I

Editorial Information

X1 Substituted by Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials 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 (Official Journal of the European Union L 91 of 31 March 2007).

Annex I to Directive 2002/72/EC is amended as follows:

(1) The following points 2a and 2b are inserted:

2a. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF):

"Fat Reduction Factor" (FRF) is a factor between 1 and 5 by which measured migration of lipophilic substances into a fatty food or simulant D and its substitutes shall be divided before comparison with the specific migration limits.
General rules

Substances considered "lipophilic" for the application of the FRF are listed in Annex IVa. The specific migration of lipophilic substances in mg/kg (M) shall be corrected by the FRF variable between 1 and 5 (M_{FRF}). The following equations shall be applied before comparison with the legal limit:

$M_{FRF} = M/FRF$

and

FRF = (g fat in food/kg of food)/200 = (% fat × 5)/100

This correction by the FRF is not applicable in the following cases:

(a) when the material or article is or is intended to be brought in contact with food containing less than 20 % fat;

(b) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 91/321/EEC and 96/5/EC;

(c) for substances in the Community lists in Annexes II and III having a restriction in column (4) SML= ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg;

(d) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm^2/kg.

This correction by the FRF is applicable under certain conditions in the following case:

For containers and other fillable articles with a capacity of less than 500 millilitres or more than 10 litres and for sheets and films in contact with foods containing more

than 20 % fat, either the migration is calculated as concentration in the food or food simulant (mg/kg) and corrected by the FRF, or it is re-calculated as mg/dm^2 without applying the FRF. If one of the two values is below the SML, the material or article shall be considered in compliance.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

2b. Correction of specific migration in food simulant D:

The specific migration of lipophilic substances into simulant D and its substitutes shall be corrected by the following factors:

(a) the reduction factor referred to in point 3 of the Annex to Directive 85/572/EEC, hereinafter termed simulant D Reduction Factor (DRF).

The DRF may not be applicable when the specific migration into simulant D is higher than 80 % of the content of the substance in the finished material or article (for example thin films). Scientific or experimental evidence (for example testing with the most critical foods) is required to determine whether the DRF is applicable. It is also not applicable for substances in the Community lists having a restriction in column (4) SML = ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg.

(b) the FRF is applicable to migration into simulants, provided the fat content of the food to be packed is known and the requirements mentioned in point 2a are fulfilled.

(c) the Total Reduction Factor (TRF) is the factor, with a maximum value of 5, by which a measured specific migration into simulant D or a substitute shall be divided before comparison with the legal limit. It is obtained by multiplying the DRF by the FRF, when both factors are applicable.

(2) The following point 5a is inserted:

5a. Caps, lids, gaskets, stoppers and similar sealing articles:

(a) If the intended use is known, such articles shall be tested by applying them to the containers for which they are intended under conditions of closure corresponding to the normal or foreseeable use. It is assumed that these articles are in contact with a quantity of food filling the container. The results shall be expressed in mg/kg or mg/dm^2 in accordance to the rules of Articles 2 and 7 taking into account the whole contact surface of sealing article and container.

(b) If the intended use of these articles is unknown, such articles shall be tested in a separate test and the result be expressed in mg/article. The value obtained shall be added, if appropriate, to the quantity migrated from the container for which it is intended to be used.**]**