COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

(PARTIAL AGREEMENT IN THE SOCIAL AND PUBLIC HEALTH FIELD)

RESOLUTION AP (92) 2

ON CONTROL OF AIDS TO POLYMERISATION (TECHNOLOGICAL COADJUVANTS) FOR PLASTICS MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS[1]

(Adopted by the Committee of Ministers on 19 October 1992 at the 482nd meeting of the Ministers' Deputies)

The Representatives on the Committee of Ministers of Belgium, France, Germany, Italy, Luxembourg, the Netherlands and the United Kingdom of Great Britain and Northern Ireland, these states being parties to the Partial Agreement in the social and public health field, and the Representatives of Austria, Denmark, Finland, Ireland, Norway, Spain, Sweden and Switzerland, states which have participated in the public health activities carried out within the above-mentioned Partial Agreement since 1 October 1974, 2 April 1968, 20 June 1991, 23 September 1969, 11 July 1979, 21 April 1988, 10 June 1975 and 5 May 1964 respectively,

Considering that the aim of the Council of Europe is to achieve a greater unity between its members and that this aim may be pursued, amongst others, by common action in the social and public health field;

Having regard to the provisions of the Brussels Treaty, signed on 17 March 1948, by virtue of which Belgium, France, Luxembourg, the Netherlands and the United Kingdom of Great Britain and Northern Ireland declared themselves resolved to strengthen the social ties by which they were already united;

Having regard to the protocol modifying and completing the Brussels Treaty, signed on 23 October 1954 by the signatory states of the Brussels Treaty, on the one hand, and the Federal Republic of Germany and Italy, on the other hand;

Observing that the seven states parties to the Partial Agreement which have continued within the Council of Europe, the social work hitherto undertaken by the Brussels Treaty Organisation and then by Western European Union, which derived from the Brussels Treaty as modified by the protocol mentioned in the fourth paragraph above, as well as Austria, Denmark, Finland, Ireland, Norway, Spain, Sweden and Switzerland, which participate in Partial Agreement activities in the field of public health, have always endeavoured to be in the forefront of progress in social matters and also in the associated field of public health, and have for many years undertaken action towards harmonisation of their legislation;

Having regard to the fact that aids to polymerisation (technological coadjuvants) are used in the manufacture of a wide variety of plastics intended to come into contact with foodstuffs;

Believing that, in order to ensure effective consumer protection, any control system adopted for food contact plastics should take into consideration all of the substances which may potentially migrate into food, and this includes aids to polymerisation;

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1. When this resolution was adopted, the Representative of Germany, in application of Article 10.2.*c* of the Rules of Procedure for the meetings of the Ministers' Deputies reserved the right of his government to comply with paragraph 2.7.

Taking the view that each member state faced with the need to introduce regulations governing this matter would find it beneficial to harmonise such regulations at European level,

Recommend that the governments of the states parties to the Partial Agreement as well as the governments of Austria, Denmark, Finland, Ireland, Norway, Spain, Sweden and Switzerland take into account, in their national laws and regulations on the control of aids to polymerisation for plastics intended to come into contact with foodstuffs, the principles and the positive lists and methods set out in the appendices hereafter.

Appendix 1 to Resolution AP (92) 2

General principles

1. *Definitions*

Aids to polymerisation (technological coadjuvants) are those substances which, together with additives (which are primarily intended to achieve a technical effect), as well as with monomers and starting materials, are necessary for the synthesis of plastic materials and articles.

Aids to polymerisation can be categorised into two groups:

- substances which directly influence the formation of polymers; and
- substances used to provide a suitable medium in which polymerisation occurs.

This resolution deals only with the former and examples are given in Table 1. However, it should be noted that none of the categories in the table is exhaustive.

Table 1 – *Examples of the primary functions and types of substances which directly influence the formation of polymers*

Primary function	Typical substances used
Initiators	Peroxides, azo compounds, imidazoles
Catalysts	Aluminium/metal/alkyl complexes
Catalyst supports	Calcium and magnesium carbonates, silicon dioxide, magnesium chloride
Catalyst modifiers	Aromatic esters, aromatic and aliphatic silanes and silanols
Catalyst deactivators	Alcohols, metal stearates
Chain transfer agents	Thiols, hydrocarbons, halogenated hydrocarbons
Chain stop reagents	Hydrocarbons, alkylated phenols
Chain scission reagents	Peroxides
Polymerisation inhibitors	Substituted phenols
Cross-linking agents/acccelerators	Peroxides, aliphatic amines, phenols, substituted ureas, waters
Cross-linking catalysts	Organotin compounds

It should be noted that although some aids to polymerisation may be bound to the polymer, they do not appear systematically in the repeating unit and therefore fall outside the definition of monomers and starting materials. Moreover, although some of these substances may have a small effect upon the properties of the final article this is not their primary function and they therefore fall outside the definition of additives.

2. *Specifications*

The finished plastic materials and articles using aids to polymerisation and intended to come into contact with foodstuffs should meet the following conditions.

2.1. Under normal or foreseeable conditions of use plastic materials and articles should not, by reason of the use of aids to polymerisation in their manufacture, pose a risk to human health or bring about either a deterioration in the organoleptic characteristics or an unacceptable change in the nature, essential characteristic or quality of the food with which they come into contact.

2.2. May be used as aids to polymerisation:

– substances covered by the classes of substances quoted in Appendix 2, subject to their relevant restrictions;

– substances which are already listed as monomers in the EC directive on plastic materials coming into contact with foodstuffs[1], subject to the limitations mentioned in this document.

All substances which are used as aids to polymerisation should be of good technical quality.

2.3. Plastic materials and articles prepared using aids to polymerisation should not release their constituents to any of the simulants referred to in item 2.6 in excess of 60 mg/kg or 10 mg/dm^2 of total migrants (overall migration limit) (see Article 2 of reference 1).

2.4. The basic polymer should not contain any of the organic or inorganic functional groups given in Table 2.1 of Appendix 2 in quantities exceeding the limits given, if applicable. Under normal or foreseeable conditions of use, the specific migration of organic and inorganic functional groups from the finished plastic materials or articles should not exceed the limits specified in Table 2.2 of Appendix 2, if applicable.

2.5. Where a migration limit has been set for a category of functional group, there should be a mechanism whereby individual substances within that category can be reassessed. If toxicologically justified, the migration limit may be amended for that individual substance. This applies to all categories listed in Appendix 2.

2.6. Migration tests should be conducted according to EEC Directives 82/711/EEC[2] and 85/572/EEC[3]. Metals should be determined only in 3% aqueous acetic acid, which is the most vigorous extractant amongst the specified food simulants[2], and in which the metals can be determined at the required limits.

2.7. Where a limit of "not detectable" (n.d.) has been specified, "not detectable" means that the substance cannot be determined with reasonable statistical certainty by a validated analytical method. The method should have a specified determination limit.

When the validated method is used to test for the substance and the substance is below the limit of determination, the substance is considered to be "not detectable". If a validated analytical method does not exist, then the level of 0,01 mg/kg should be taken as a conventionally agreed and temporary value.

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All limits given below are based on existing European legislation or recommendations, or have been set to ensure an adequate margin of safety for even the most toxic known example of the category, or in a few cases represent good manufacturing practice. The limits are not intended to apply to oligomers, which are unavoidable components of the polymer. An oligomer is a polymeric species containing a limited number of repeat units (typically 2-10).

Analytical methods for the determination of limits given in this resolution are currently being collected and will be introduced when available. The limits for monomers and additives as laid down in the Council of the European Communities Directive No. 90/128/EEC and future directives stay valid and are not affected by this resolution.

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1. Directive No. 90/128/EEC of the Commission of the European Communities relating to plastic materials and articles intended to come into contact with foodstuffs. *Official Journal of the European Communities* L 075, p.19, 21 March 1990.
2. Directive No. 82/711/EEC of the Council of the European Communities laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs. *Official Journal of the European Communities* L 297, p. 26, 22 October 1982.
3. Directive No. 85/572/EEC of the Council of the European Communities 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 Communities* L 372, p. 14, 31 December 1985.

Table 2.1 – *The basic polymers should not contain the following in excess of the stated limits:*

- Epoxypropyl derivatives 5 mg/kg (as epoxy)
- Gallium compounds 20 mg/kg (as Ga)
- Germanium compounds 10 mg/kg (as Ge)
- Iridium compounds 20 mg/kg (as Ir) (80 mg/kg for silicone plastics only)
- Manganese compounds 60 mg/kg (as Mn)
- Morpholines n.d.
- Nitriles 1 mg/kg (as CN in the organic moiety)
- Osmium compounds 20 mg/kg (as Os)
- Palladium compounds 20 mg/kg (as Pd)
- Platinum compounds 20 mg/kg (as Pt) (120 mg/kg for silicone plastics only)
- Rhodium compounds 20 mg/kg (as Rh) (120 mg/kg for silicone plastics only)
- Selenium 10 mg/kg, (as Se)
- Thiols, sulphonic acids and other sulphur compounds 1 mg/kg (as S in the organic moiety)[1]

Table 2.2 – *The finished article(s) should not release to food or any of the food simulants referred to in item 2.6 the following, in excess of the stated limits:*

- Aldehydes 15 mg/kg
- Alkanes 6 mg/kg
- Alkenes 0,01 mg/kg
- Alkoxides and alcohols 1 mg/kg, (subject to any specific limit on the metal)
- Alkynes 0,01 mg/kg
- Aluminium compounds 60 mg/kg ***
- Amines, aromatic n.d.*
- Amines, primary aliphatic (including their ammonium salts) 2 mg/kg
- Amines, secondary and tertiary aliphatic (including their ammonium salts) and amides 0,05 mg/kg
- Ammonium salts, quaternary 0,5 mg/kg
- Antimony compounds 0,005 mg/kg (as Sb)
- Arsenic compounds 0,01 mg/kg (as As)
- Aryl urea derivatives (0,1 mg/kg)
- Azo compounds –- (determined as the equivalent amine)
- Barium compounds 0,2 mg/kg (as Ba)
- Bismuth compounds 1 mg/kg (as Bi)
- Boron compounds 12 mg/kg (as B)
- Bromides (inorganic) 0,5 mg/kg (as Br)
- Cadmium compounds 0,005 mg/kg (as Cd)
- Calcium compounds 60 mg/kg ***
- Carboxylic acids, aliphatic and aromatic (including salts, esters and anhydrides) 2 mg/kg
- Cerium compounds 1 mg/kg (as Ce)
- Chlorides (inorganic) 60 mg/kg ***
- Chromium (hexavalent) compounds n.d. (as Cr VI)
- Chromium (trivalent) compounds 60 mg/kg ***
- Cobalt compounds 0,1 mg/kg (as Co)
- Copper compounds 30 mg/kg (as Cu)
- Fluorides (inorganic) 0,5 mg/kg (as F)
- Hydrazines (n.d)
- Hydrocarbons halogenated 0,01 mg/kg
- Hydrocarbons, aromatic, non-substituted 0,01 mg/kg
- Hydroquinones 0,6 mg/kg
- Hydroxylamine derivatives 0,05 mg/kg
- Imidazoles 2 mg/kg *****
- Iodides 1 mg/kg (as I)
- Iron compounds 60 mg/kg ***

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1. This limit can be exceptionally exceeded for dodecanethiol when used as a chain-stopper in ABS co-polymers, if adequate supporting data on the technological need and toxicological safety are provided.

– Ketones 6 mg/kg
– Lead compounds 0,01 mg/kg (as Pb)
– Lithium compounds 0,6 mg/kg (as Li)
– Magnesium compounds 60 mg/kg ***
– Mercury compounds 0,005 mg/kg (as Hg)
– Nickel compounds 0,1 mg/kg (as Ni)
– Peroxides (including hydroperoxides and inorganic peroxyacids) 0,05 mg/kg (as O), when extracted into distilled water**
– Phenols (polychlorinated phenols should not be used as aids to polymerisation) 60 mg/kg ***
– Phosphonium compounds 1 mg/kg
– Phosphorus acids and oxides 60 mg/kg ***
– Piperidine derivatives 0,1 mg/kg
– Potassium compounds 60 mg/kg ***
– Quinones 0,01 mg/kg
– Rubidium compounds 1 mg/kg (as Rb)
– Silicon compounds 60 mg/kg ***
– Sodium compounds 60 mg/kg ***
– Terpenes 60 mg/kg ***
– Tin compounds (inorganic) 60 mg/kg ***
– Tin compounds (organic) 0,05 mg/kg (as Sn) (0,02 mg/kg for di-n-octyltin)
– Titanium compounds 60 mg/kg ***
– Triazine derivatives (unless otherwise specified) 0,25 mg/kg **** (6 mg/kg for melamine)
– Urea 60 mg/kg ***
– Vanadium compounds 0,1 mg/kg (as V)
– Zinc compounds 60 mg/kg ***
– Zirconium compounds 0,1 mg/kg (as Zr)

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* Benzidine, B-napthylamine and 4-aminobiphenyl should not be used as aids to polymerisation.

** No peroxide compounds should be extracted from the final article after immersion in distilled water for 24 hours at 23°C ± 3°C, using an analytical method with a limit of detection of 0,05 mg/kg of active oxygen. Where no volume to surface area ratio is specified, the test should be at the ratio of 1 dm^3 to 6 dm^2 of surface area. For H_20_2 the maximum permitted migration is 0,5 mg/kg as active oxygen.

*** See Appendix 1, item 2.3

**** 2,4,6-tris(ethylenimino)-1,3,5-triazine should not be used as an aid to polymerisation.

***** Imidazole compounds with nitrogen and/or sulphur containing substituents should not be used as aids to polymerisation.