Partial Agreement in the Social and Public Health Field Accord Partiel dans le domaine social et de la santé publique



P-SG (2004) 8

PUBLIC HEALTH COMMITTEE

COMMITTEE OF EXPERTS ON MATERIALS COMING INTO CONTACT WITH FOOD

POLICY STATEMENT CONCERNING

COATINGS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

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NOTE TO THE READER

The following documents are part of the Policy statement concerning coatings intended to come into contact with foodstuffs:

- Frame Resolution AP (2004) ... on coatings intended to come into contact with foodstuffs
- Technical document N° 1 List of substances to be used in the manufacture of coatings intended to come into contact with foodstuffs
- Technical document N° 2 Scientific background for the elaboration of the Frame Resolution AP (2004) ... (under preparation)

The documents are available on the Internet website of the Partial Agreement Division in the Social and Public Health Field:

www.coe.int/soc-sp

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FRAME RESOLUTION AP (2004) .. ON COATINGS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

FRAME RESOLUTION AP (2004) ...ON COATINGS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

(Adopted by the Committee of Ministers on ...at the ... meeting of the Ministers' Deputies)
(Superseding Resolution AP (96) 5)

The Committee of Ministers, in its composition restricted to the Representatives of Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom, member states of the Partial Agreement in the Social and Public Health Field,

Recalling Resolution (59) 23 of 16 November 1959, concerning the extension of the activities of the Council of Europe in the social and cultural fields;

Having regard to Resolution (96) 35 of 2 October 1996, whereby it revised the structures of the Partial Agreement and resolved to continue, on the basis of revised rules replacing those set out in Resolution (59) 23, the activities hitherto carried out and developed by virtue of that resolution; these being aimed in particular at:

a. raising the level of health protection of consumers in its widest sense, including a constant contribution to harmonising – in the field of products having a direct or indirect impact on the human food chain as well as in the field of pesticides, pharmaceuticals and cosmetics – legislation, regulations and practices governing, on the one hand, quality, efficiency and safety controls for products and, on the other hand, the safe use of toxic or noxious products;

b. integrating people with disabilities into the community; defining – and contributing to its implementation at European level – of a model of coherent policy for people with disabilities, which takes account simultaneously of the principles of full citizenship and independent living; contributing to the elimination of barriers to integration, whatever their nature, whether psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to the action carried out for several years for the purposes of harmonising their legislation in the public health field and, in particular, with regard to materials and articles intended to come into contact with foodstuffs:

Considering that coatings intended to come into contact with foodstuffs may, by reason of migration of constituents to the foodstuffs, pose under certain conditions a risk to human health;

Noting that certain issues expressed in general terms in the Appendix to the present frame resolution need further reflection, the input from other scientific projects currently carried out and appropriate innovative solutions;

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 to the governments of the member states of the Partial Agreement in the Social and Public Health field to take into account in their national laws and regulations on coatings intended to come into contact with foodstuffs the principles set out hereafter.

APPENDIX TO FRAME RESOLUTION AP (2004) ...

1. Field of application

The Frame Resolution applies to coatings which in the finished state are intended to come into contact or which are brought into contact with foodstuffs and are intended for that purpose. The following types of coating are covered:

- a) Coatings for metal packaging;
- b) Flexible packaging coatings;
- c) Heavy-duty coatings.

2. Definition

For the purpose of the Frame Resolution, "coatings" mean the finished material prepared mainly from organic materials applied to form a layer/film on a substrate in such a way as to create a protective layer and/or to impart technical performance.

3. Specifications

Coatings used for food contact applications under normal or foreseeable conditions of use should meet the following conditions:

- 3.1. They should not transfer their constituents to foodstuffs in quantities, which could endanger human health, bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.
- 3.2. They should be manufactured in accordance with guidelines on good manufacturing practice for coatings intended to come into contact with foodstuffs and using substances of Technical document N° 1 List of substances to be used in the manufacture of coatings intended to come into contact with foodstuffs as well as aids to polymerisation as set out in Resolution AP (92) 2 on control of aids to polymerisation (technological coadjuvants) for plastics materials and articles intended to come into contact with foodstuffs or substances of relevant national regulations, and prepared, applied and cured in strict adherence to manufacturer's specifications, according to the conditions specified.
- 3.3. They should not transfer their constituents to foodstuffs in quantities exceeding 10 mg/dm² of surface area of material or article (mg/dm²) (overall migration limit). However, this limit should be 60 mg of the constituents released per kg of foodstuff (mg/kg) in the following cases:
 - a) Articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 l;
 - b) Articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;
 - c) Caps, gaskets, stoppers or other similar devices for sealing.

3.4. They should not transfer migrating components not listed in *Technical document N° 1* - List of substances to be used in the manufacture of coatings intended to come into contact with foodstuffs of MW < 1000 D in quantities, which could endanger human health. These non listed substances of MW < 1000 D should be subjected to appropriate risk assessment taking into account dietary exposure as well as toxicological and structure activity considerations.

TECHNICAL DOCUMENT N° 1

LIST OF SUBSTANCES TO BE USED IN THE MANUFACTURE OF COATINGS INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

1. CLASSIFICATION SYSTEM OF SUBSTANCES TO BE USED FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

General specifications

List 1 - Substances approved for the use of materials and articles intended to come into contact with food

- 1. Substances evaluated by SCF, classified in list 0-4, and used in compliance with specific migration limits or other restrictions, if any;
- 2. Substances evaluated and approved by the Committee of expert on materials coming into contact with food;
- 3. Substances approved in Partial agreement member states or by FDA, based on an evaluation of a toxicological dossier, which meets the present SCF criteria;
- 4. Substances authorised as direct food additives in compliance with specific migration limits or other restrictions:
- 5. The substances which have been approved by Partial agreement member states or by FDA applying scientific evaluation criteria of the time of their approval will be listed in a Temporary Appendix to List 1.

List 2 – Substances not approved for the use of materials and articles intended to come into contact with food

Substances which do not meet the criteria set for List 1 substances.

Complementary specifications

- 1. The substances of the Temporary Appendix should be integrated in List 1 or List 2 not later than five years after adoption of the List of substance.
- 2. List 1 and List 2 will be updated in principle once a year in order to take into account newly evaluated substances, new submissions by industry or substances to be deleted.