

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

Resolution ResAP(2005)2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs

*(Adopted by the Committee of Ministers on 14 September 2005
at the 937th meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the Representatives of the states of the Council of Europe which are members of the Partial Agreement in the Social and Public Health Field,¹

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 application: 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 – 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 legislation in the public health field and, in particular, with regard to materials and articles intended to come into contact with foodstuffs;

Considering that packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs may, through migration of constituents to the foodstuffs, under certain conditions, pose a risk to human health;

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,

Recommends to the governments of the states members of the Partial Agreement in the Social and Public Health Field to take into account in their national laws and regulations on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs the principles set out hereafter.

¹ Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

1. SCOPE

1.1. This resolution applies to printing inks and varnishes (hereafter called “packaging inks”) and any layer of printing inks or varnishes, coloured or uncoloured, applied by an appropriate process to the non-food contact surface of any material or article intended to come into contact with foodstuffs.

1.2. Layers of packaging inks in direct contact with foodstuffs are excluded from the field of application of the present resolution.

1.3. When there is evidence that a substrate renders the migration of any substance in packaging inks substance impossible, and that the set-off or transfer via a gas phase can be excluded, the present resolution does not apply.

2. DEFINITIONS

In this resolution:

2.1. packaging inks are printing inks and varnishes intended to be printed on the non-food contact surface of materials and articles intended to come into contact with foodstuffs;

2.2. packaging inks means any mixture manufactured from colourants, binders, plasticisers, solvents, driers and other additives. They are solvent-based, water-borne, oleo-resinous or energy-curing (UV or electron beam) formulas. They are applied by a printing or varnishing process, such as flexography, gravure, letterpress, offset, screen printing (ink or varnish) and roller coating;

2.3. packaging inks, in their finished state, are thin films of dried or hardened printing ink or varnish on the non-food contact surface of substrates;

2.4. a substrate is any material or article intended to come into contact with food such as glass, metal, paper, board, plastic, textiles and laminates of these materials.

3. REQUIREMENTS

3.1. Printed materials and articles intended to come into contact with foodstuffs, should not, in their finished state and under normal and foreseeable conditions of use, transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof, in accordance with Article 3 of Regulation (EC) No. 1935/2004.

3.2. In order to achieve this aim, the following requirements should be met:

3.2.1. the substances in packaging inks should be selected in conformity with the requirements for the selection of packaging ink substances as set out in Technical Document No.1:

3.2.1.1 only substances which are listed in the inventory list can be used in the manufacture of packaging inks covered by this resolution;

3.2.1.2 substances which are listed in the inventory list but not evaluated can be used subject to the condition that it can be demonstrated that they will not migrate into the food.² The demonstration can be carried out by “worse case calculation” or by a practical test as set out in Technical Document No. 3;³

3.2.2. the packaging inks should be manufactured in accordance with the guides for good manufacturing practice set out in Technical Document No. 2, Part 1;

3.2.3. the packaging inks should be applied in accordance with converters’ good manufacturing practices as set out in Technical Document No. 2, Part 2;

3.2.4. the finished printed material or article intended to come into contact with foodstuffs should meet the following requirements:

3.2.4.1 the printed or overprinted varnished layer of finished printed material or article should not come into direct contact with food;

3.2.4.2 global and specific migration from the finished printed material or article should not exceed the relevant limits;

3.2.4.3 there should be no, or only negligible, visible set-off or migration from the printed or varnished non-food contact layer to the food contact surface.

4. CONFORMITY ASSESSMENT

4.1. Verification of the compliance of the substances in packaging inks with the quantitative restrictions laid down by the resolution should be carried out in conformity with the rules set out in Technical Document No. 3.²

4.2. The finished printed and/or varnished food contact material or article should be tested in accordance with the intended conditions of use (one side migration test on the side intended for food contact) and according to the rules set out in Technical Document No. 3.²

5. RESPONSIBILITY

The packaging ink suppliers are responsible for the composition of packaging inks in accordance with the requirements set out in this resolution. In line with Article 16 of Regulation (EC) No. 1935/2004, they should communicate without any unjustified delay to the concerned business operator, under appropriate confidentiality agreements, the relevant information necessary to manufacturing the finished materials or articles in compliance with the rules applicable to them.

6. TRACEABILITY

The packaging ink suppliers are responsible for the traceability of packaging inks. They should have in place systems and procedures to allow the identification of the businesses from which and to which the packaging inks are supplied.

² For the purposes of control, this means that they shall not be detectable at the lowest concentration at which a substance can be measured with statistical certainty by a validated method of analysis. It is agreed that the detection limit would depend on the nature of the raw materials. However, this limit expressed as concentration shall not exceed 0.01 mg/kg of food or food simulant. It shall apply to the sum of migration of a group of compounds if they are structurally and toxicologically related (e.g. isomers).

³ Technical Document No. 3 – Test conditions and methods of analysis for packaging inks: under preparation.