

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

Resolution ResAP(2004)4 on rubber products intended to come into contact with foodstuffs

*(Adopted by the Committee of Ministers on 1 December 2004
at the 907th meeting of the Ministers' Deputies)*

The Committee of Ministers, in its composition restricted to the Representatives of the States members of the Partial Agreement in the Social and Public Health Field,¹

Recalling Resolution No R 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 No. R (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 No. R (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 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 rubber products intended to come into contact with foodstuffs may, by reason of migration of rubber constituents to the foodstuffs, pose under certain conditions 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 rubber products intended to come into contact with foodstuffs the principles set out hereafter.

*Appendix to Resolution ResAP(2004)4
on rubber products intended to come into contact with foodstuffs*

1. Field of application

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

The Resolution ResAP(2004)4 applies to finished materials and articles made of rubber including thermoplastic rubber and blend of rubber with plastics and other materials, which are intended to come into contact with or are placed in contact with foodstuffs, hereafter called "rubber products".

1.2 It also applies to rubber products which are in contact with water intended for human consumption.

1.3 It does not apply to fixed public or private supply equipment.²

1.4 It does not affect the national regulations concerning the quality of drinking water, and therefore the limits laid down in the national regulations for drinking water should be met.

1.5 It does not apply to soothers which are primarily not considered as products intended to come into contact with foodstuffs.

1.6. A non-exhaustive list of common application of rubber products is:

- food transportation (conveyer belts, hoses and tubing);
- handling food (gloves);
- food netting;
- pipe-work components (seals, gaskets, flexible connectors and diaphragm/butterfly valves);
- pumping systems (progressive cavity pumps stators, diaphragm pumps);
- plate heat exchangers (gaskets);
- general seals and gaskets (used in machinery and storage vessels);
- can sealants;
- bottle seals and closures;
- feeding teats and breast caps (nipple shields).

2. Definitions

Within the Resolution:

2.1. rubber designates a family of materials having property of high elasticity. In an unaged state, rubber can be substantially deformed under stress, but recovers almost to its original stage when the stress is removed. Rubber is usually made from a mixture of (solid and/or liquid) materials and can be subjected to a curing process, which changes its nature;

2.2. thermoplastic rubber is a polymer or blend of polymers that does not require vulcanisation or cross-linking during processing, yet has properties, at its service temperature, similar to those of vulcanised rubber. These properties disappear at processing temperature, so that further processing is possible, but return when the material is returned to its service temperature.

3. Specifications

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

3.1. they should not 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;

3.2. they should be manufactured in accordance with the following requirements:

3.2.1. they should comply with guidelines on good manufacturing practice for rubber products intended to come into contact with foodstuffs;

² See Directive 89/109/EEC, Article 1.

3.2.2. they should be manufactured using the substances of “*Technical document No. 1 – List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs*” and according to the conditions therein specified for each of the categories as set out in Article 5 of the Resolution. However, they can contain other decomposition and reaction products as well as impurities originating from authorised substances provided their migration complies with Article 3.1. of the Resolution;

3.2.3. rubber products belonging to Categories I and II should not transfer their constituents to foodstuffs or food simulants in total quantities > 60mg/kg of food or food simulant (overall migration limit);

3.2.4. rubber products of Categories I and II should comply with the restrictions laid down in “*Technical document No. 1 - List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs*”. In addition these rubber products should comply with the requirements set out in Table 1 of the Resolution (see below), with the exception of rubber teats which should comply with Directive 93/11/EEC;

Table 1: Restriction for N-nitrosamines, N-nitrosatable substances, aromatic amines

Substance/substance group	Restrictions
– N-nitrosamines	ND ¹ (DL ² = 0.01 mg/kg food or food stimulant)
– N-nitrosatable substances	ND (DL = 0.1 mg/kg food or food simulant)
Aromatic amines	ND unless an specific migration limit (SML) is set in Technical document N° 1

¹ ND = not detectable ² DL = the required detection limit of the analytical method at the indicated value

3.3. substances should be used only in amounts strictly needed for the manufacturing and performance of the rubber product;

3.4. where rubber is blended with plastics and/or other materials, the composition of these materials used in the blends should comply with relevant Council of Europe resolutions or European Union directives, or, in their absence, with relevant national regulations. In addition, the rubber products should comply with the overall migration limit as well as with the relevant specific migration limits;

3.5. rubber teats should also comply with Directive 93/11/EEC.

4. Compliance testing

4.1. Verification of compliance with the quantitative restrictions should be carried out according to the requirements laid down in “*Technical document No. 2 - Practical guide for users of Resolution ResAP(2004) ... on rubber products intended to come into contact with foodstuffs*”;

4.2. the verification of compliance with the specific migration limits provided for in Article 3.2. of the Resolution does not apply, if it can be established that compliance with the overall migration limit laid down in Article 3.2.3. of the Resolution implies that the specific migration limits are not exceeded;

4.3. the verification of compliance with the specific migration limits provided for in Article 3.2. of the Resolution does not apply, if it can be established that, by assuming complete migration of the residual substance in the rubber product, it cannot exceed the specific limit of migration;

4.4. the verification of compliance with the specific migration limits provided for in Article 3.2.3. of the Resolution may be ensured by the determination of the quantity of a substance in the finished rubber product provided that a relationship between that quantity and the value of the specific migration of the substance has been established either appropriate experiments or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a rubber product, confirmation of the estimated migration value by experimental testing is obligatory;

4.5. rubber products intended for repeated use should be subjected to tests according to Directive 2002/72/EC, Appendix I;

4.6. the overall migration and specific limits per feeding teats are one-fifth of the values³ set out in “*Technical document No. 1 – List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs*”;

4.7. rubber products belonging to Category III do not require migration testing, unless otherwise specified.

5. Classification and migration requirements for rubber products

Rubber products are classified in three categories:⁴

5.1. Category I comprising the following rubber products for which migration testing is required:

- feeding teats;
- rubber products intended to come in contact with baby food, for which the R-total is equal to or greater than 0.001;

5.2. Category II, comprising other rubber products for which the R-total is equal to or greater than 0.001 and for which migration testing is required;

5.3. Category III comprising rubber products for which the R-total is smaller than 0.001 and for which migration testing is not required, except for rubber products containing substances listed in Table 1 and Category III substances with an SML in “*Technical document No. 1 – List of substances to be used in the manufacture of rubber products intended to come into contact with foodstuffs*”.

³ Concerning single-use teats, for practical reasons it is assumed that five bottle teats are used per child per day.

⁴ In view of the great variety of the applications for rubber products the migration may vary according to the application. Therefore rubber products are classified in different categories. The level of migration for rubber products may be estimated by taking into account four factors, R₁, R₂, R₃ and R₄ referring respectively to the relative contact area, contact temperature, contact time and number of times that the article is used. Categories are based on the intended use or on the result of the multiplication of the four factors (R₁ × R₂ × R₃ × R₄ = R_{total}).

The factors R₁, R₂, R₃ and R₄ are defined and determined as follows:

– R₁ refers to the relative contact area (A_R) between rubber products and the food or beverage, expressed in cm² of rubber surface per kg of food or beverage. For a relative area smaller than or equal to 100 cm²/kg foodstuffs, R₁ has a value calculated according to the formula: R₁ = A_R : 100. For a relative surface larger than 100 cm²/kg, R₁ always has the value 1.00.

– R₂ refers to the temperature during the contact period of the rubber product with the food or beverage. At a temperature lower than or equal to 130°C, R₂ has a value calculated according to the formula: R₂ = 0.05 e^{0.023T}. Where "e" is the base of the natural or Napierian logarithms and "T" is the contact temperature, expressed in °C. For temperatures higher than 130 °C, R₂ always has the value 1.00.

– R₃ refers to the time t, expressed in hours, during which a rubber product is in contact with the food or beverage. For a contact time shorter than or equal to 10 hours, R₃ has a value calculated according to the formula: R₃ = t : 10. For a contact time of more than 10 hours, R₃ has the value 1.00.

– R₄ refers to the number of times (N) that one and the same rubber product, or part of that rubber product comes into recurrent contact with a quantity of food or beverage. If the number of contact times is greater than 1000, then R₄ is calculated according to the formula: ¹⁰log R₄ = 6 - 2¹⁰log N. If the number of contact times is smaller than or equal to 1000, then R₄ always has the value 1.00.

(For detailed information see “*Technical document No. 2 - Practical guide for users of Resolution ResAP(2004)4 on rubber products intended to come into contact with foodstuffs*”).

References:

Council Directive of 21 December 1988 on the approximation of the laws of the member states relating to materials and articles intended to come into contact with foodstuffs (89/109/EEC) (Official Journal of the European Communities L40, 11.2.89).

Commission Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (82/711/EEC) (Official Journal of the European Communities L297, 23.10.82).

Commission Directive of 29 July 1997 amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs (97/48/EC) (Official Journal of the European Communities L222, 18.02.97).

Commission Directive of 15 March 1993 concerning the release of N-nitrosamines and N-nitrosatable substances from elastomers or rubber teats and soothers 93/11/EEC) (Official Journal of the European Communities L93, 17.04.93).

Methods for determining the release of N-nitrosamines and N-nitrosatable substances from elastomers or rubber teats and soothers of the European Committee for Standardisation (CEN) (EN 12868, September 1999).

Council of Europe Resolution AP (89) 1 on the use of colourants in plastic materials.

Council of Europe Resolution AP (99) 3 on the use of silicones for food contact applications.