

IN CONTACT WITH FOOD AND DRINKING WATER

No harmonised rules, No internal market!

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Rubber materials entering into contact with food and Drinking Water (Rubber DW-FCM) have been used in food contact applications worldwide for over 100 years. Rubber DW-FCM are mainly used in food processing industries and components in drinking water infrastructures, including: **food transportation** (conveyer belts, hoses, tubing, rotating transport rollers and rolling mills), **food handling** (gloves), **machinery components** (seals, gaskets, pipes, flexible connectors and diaphragm/butterfly valves), **pumping systems** (progressive cavity pumps stators, diaphragm pumps), **plate heat exchangers and general seals** (used in machinery and storage vessels), **sealants** (can and bottle seals/closures), **baby feeding** (teats and breast caps), **household appliances** (including seals in pressure cookers), **pipelines** conveying potable water, seals gaskets, joints, hoses, **lining** for water containers.



Rubber articles are flexible, resilient, mechanically strong and durable. They are designed along two parameters: mechanical strength and physiological inertness. The processes used to produce synthetic

rubber materials is in constant evolution. Given the variety of applications and specific technical requirements (for instance seals and hoses need elasticity, softness, flexibility and wide range of temperatures resistance) a large number of formulations and related raw materials is necessary: **more than 900 substances** are currently registered in Europe for uses associated to the rubber manufacturing industry. **New substances, compounds and materials** are constantly identified to improve the performances of the final products, as well as to switch towards safer alternatives.

Food Contact Materials are regulated in EU by the **Framework Regulation (1935/2004/EC)** on materials and articles intended to come into contact with food. The Framework Regulation stipulates that all kinds of materials and articles intended to come into contact with food must be **manufactured in compliance with good manufacturing practices (GMP)** so that, under foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could endanger human health or cause an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics (Article 3). Additionally, Annex I of the Framework Regulation lists ‘Rubbers’ and ‘Silicones’ among the groups of materials and articles, which may be covered by **specific measures**.

Compliance to article 3 of the Framework Regulation has been differently transposed across Europe. **Non homogenous individual national approval schemes**, containing a list of safety requirements and related tests to be applied to the final article, exist in various Member States. Additionally, some countries (such as France, Germany, Italy, The Netherlands, Spain) have adopted specific **positive lists** of chemicals that are permitted to be used in rubber food contact applications. The content of the positive lists varies from country to country (for instance the German BfR Recommendation on rubber lists elastomers, vulcanization aids and additives whereas, the French “Arrêté du 9 Novembre 1994” comprises monomers, vulcanization aids and additives) and chemicals could be differentiated by categories related to food, contact time, contact area and/or specific shapes.

On the 1st of December 2004 the Council of Europe (Committee of Ministers) adopted two resolutions respectively on rubber products¹ and silicones², comprising an inventory of existing “positive lists” of monomers and other compounding ingredients for rubber articles intended to come into contact with food. However, most European Member States have not taken up these resolutions.

Country	Food contact	Water contact	Positive list
France	Arrêté du 9/11/94 (in revision – new version submitted to ANSES)		Yes
Germany	BfR Recommendation XXI	UBA Recommendation (2012)	Yes
Italy	Decreto Ministeriale del 21/3/73 (in revision)	Decree 174/2004	Yes (list outdated)
Spain	Royal Decree 847/2011	Royal Decree 140/2003	Yes
Council of Europe	Rubber Resolution ResAP (2004)		Yes

The same level of protection is needed across Europe. From a consumer safety perspective, it is not acceptable that test method requirements, as well as the lists of substances authorized to be used in rubber DW-FCM are not aligned among Member States.

¹ **Resolution AP (2004) 4 on rubber products** intended to come into contact with foodstuffs.

² **Resolution AP (2004) 5 on silicones** used for food contact applications.

Substance	CAS Number	Authorised by
Acrylic acid	79-10-7	DE, F, I
zinc di(benzothiazol-2-yl) disulphide	155-04-4	DE, I, NL, F
Benzothiazole-2-thiol	149-30-4	DE, NL, F
5-vinylnorborn-2-ene	3048-64-4	NL, F
Dibenzylthiocarbamic acid, zinc salt	14726-36-4	NL, F
Dibenzoyl peroxide	94-36-0	NL, F
Diphenylamine, styrenated	68442-68-2	DE, NL, F
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Table 2 – Some of examples of substances authorized for rubber FCM

The lack of homogeneous approval scheme and positive lists, in combination with the absence of mutual recognition across Member States, is also creating an unjustified burden for companies, most of which SMEs. Costs for certifying product conformity³ or to authorize the use of new substances⁴ are now multiplied for each country where products are commercialized.

Industry needs an internal market for rubber materials in contact with food.

- **Work towards a horizontal European legislation to regulate rubber components (raw materials and finished goods) in contact with foodstuff and drinking water should be initiated**
- Criteria for including new substances in (a possible single harmonized) positive list should be based on the same risk assessment methodologies defined at European level, taking into account the **specific characteristics of the different materials and applications.**
- **Ad-hoc legislation on rubber materials is needed in order to address the unique properties of such materials in terms of chemical composition and physical properties.**

³ The costs for certifying a single product is at least 5.000 €. Depending on the number of countries in which the product has to be certified, costs to demonstrate compliance can be up to 2% of the turnover.

⁴ The costs for authorizing a single substance can vary from few k€ to several 100k€.