

## The safety of materials and products intended for contact with foodstuffs and meals

In the category of products intended for contact with foodstuffs are included all materials and objects that intentionally come into contact with foodstuffs, raw foodstuff material and meals in the course of the whole manufacturing process including their weighing and measuring, wrapping and packaging, storage, transport and serving. Further only as FCMA – food contact materials and articles.

### Thus, FCMA include:

- ❖ wrapping and packaging material of all kind (wrapper foil, cups and other vessels, lids and caps)
- ❖ parts of food industry machinery and other equipment that comes in contact with foodstuffs
- ❖ vessels, utensils and other aids of polymerized materials, paper, cork, glass, ceramics, porcelain, enamels, metals and alloys
- ❖ lacquers and surface finishes of metal or wooden racks and stands or other parts of furniture in which there are stored or transported unwrapped foodstuffs of all kind
- ❖ oven trays including their anti-adhesive finish
- ❖ equipment of catering facilities
- ❖ kitchen appliances (e.g. blenders, whippers, percolators), beverage dispensers, etc.

### FCMA do not include

casings and surface finishes of foodstuffs, that are consumed together with the foodstuffs, such as substances covering the surface of cheeses, of processed meat products (e.g. edible casings) or fruit.

In view of the worldwide trend towards the safeguarding of safety to health and hygiene of foodstuffs and thereby towards the maximal protection of the consumer, the most important requirement on

FCMA is their **safety to health**. Articles intended for contact with foodstuffs have to meet a number of concrete requirements so they could be used without any danger that they unfavorably affect the safety and quality of foodstuffs and thereby also the health of the consumer.

In the assessment of the health safety of FCMA attention is presently focused on problems of microbiology, sensory properties, and most of all, on the danger of food contamination with chemical substances present in the material the object is made of.

The follow-up and assessment of the safety to health of FCMA have a long-standing tradition in the Czech Republic. In the past the health safety of that category of products had been dealt with in Act No. 20/1966 Dig. on health care, and in the Decree of the Ministry of Health of the Czech Republic No. 45/1966 Dig. and subsequent directives and edicts of that Ministry.

Upon the decision on the opening of the Czech Republic's negotiations on accession to the EU and within the framework of harmonization of Czech legislation with that of the EU there came about changes in a number of laws. From January 1, 2001, FCMA intended for contact with foodstuffs and foods are covered by Act [No. 258/2000 Dig.](#), on the protection of public health, and its executive regulation – Decree of the Ministry of Health of the Czech Republic [No. 38/2001 Dig.](#), on the public health requirements regarding articles coming into contact with foodstuffs, in the wording of its amendment – decree [No. 186/2003 Dig.](#), which amends the previous decree No. 38/2001 Dig.



## Laws and executive regulations

Requirements regarding FCMA that can substantially influence the safety of raw foodstuff material, foodstuffs and foods have been set in the Decree of the Ministry of Health of the Czech Republic No. 38/2001 Dig. (further only **Decree**), on public health requirements regarding articles coming into contact with foodstuffs in the wording of amending decree No. 186/2003 Dig. (further only **Amendment**) that is one of the executive regulations to Act No. 258/2000 Dig. (further only **Act**) on the protection of public health.

Through the **Act** and consequent **Decree** there has been substantially narrowed the previous great scope of approvals regarding the hygienic requirements on articles preceding the commencement of their import or production. Thereby in the realm of healthcare there has been eliminated a superfluous bureaucracy in the approval procedure.

**For entrepreneurs there was eliminated the obligation of an approval procedure at the Ministry of Health of the Czech Republic.**

The approval procedure is now being carried out only when **allowing exceptions**, namely only in such cases when the article is made of material differing from those listed in the **Decree**.

The **Decree** consists of two basic parts and 15 supplements that contain vast positive listings of substances that can be used in the manufacture of FCMA, including specific public health criteria concerning the content or migration, i.e. elution limits for each substance or group of substances.

Legislation, through the **Decree**, has been approximated to the following EU directives:

❖ 78/142/EEC (limit for monomer vinyl chloride in

polyvinyl chloride)

- ❖ 80/590/EEC (graphic symbol to accompany articles intended to come into contact with foodstuffs)
- ❖ 80/766/EEC (analytical method for determining monomer vinyl chloride in articles)
- ❖ 81/432/EEC (analytical method for determining monomer vinyl chloride in articles)
- ❖ 82/711/EEC (plastics, basic rules for migration tests)
- ❖ 84/500/EEC (ceramics – limits and method for lead and cadmium determinations)
- ❖ 85/572/EEC (list of foodstuff simulants to be used in migration tests of plastics constituents)
- ❖ 89/109/EEC (skeleton directive on general requirements relating to all material and articles intended to come into contact with foodstuffs)
- ❖ 90/128/EEC (requirements relating to plastics, and listing of ingredients and monomers for production of plastics and articles intended to come into contact with foodstuffs)
- ❖ 92/39/EEC 1<sup>st</sup> amendment of directive 90/128/EEC (plastics, ingredients and monomers)
- ❖ 93/8/EEC 1<sup>st</sup> amendment of directive 82/711/EEC (plastics, migration tests)
- ❖ 93/9/EEC 2<sup>nd</sup> amendment of directive 90/128/EEC (plastics, ingredients and monomers)
- ❖ 93/11/EEC (N-nitrosamines and N-nitrosatable substances from rubber teats and soothers)
- ❖ 95/3/EC 3<sup>rd</sup> amendment of directive 90/128/EEC



- ❖ 96/11/EC 4<sup>th</sup> amendment of directive 90/128/EEC (plastics, ingredients and monomers)
- ❖ 97/48/EC 2<sup>nd</sup> amendment of directive 82/711/EEC (plastics, migration tests)
- ❖ 93/10/EEC (regenerated cellulose – cellophane). The **Amendment** by which the **Decree had been amended**, came into force June 24, 2003. That **Amendment** integrated into Czech legislation regarding public health requirements relating to FCMA the following EU directives:
  - ❖ 1999/91/EC
  - ❖ 2001/62/EC
  - ❖ 2002/17/EC
  - ❖ 2002/72/EC,
 (i.e. 4 amendments of 90/128/EEC)
  - ❖ 2001/61/EC
  - ❖ 2002/16/EC.

All the named directives came into force following the issuing of the **Decree**. The **Amendment** ensured full compatibility with EC legislation relating to the problems of FCMA.

**The legislation of the Czech Republic relating to that of the EU has been fully harmonized.** In the case of FCMA for which there have not yet been issued specific EC directives, procedures follow Art 6 sub 5 of directive 89/109/EEC. In such cases there **remain in force present national requirements (rubber, metals and alloys)** or for the purpose public health protection there have been adopted new measures, often taken over from the national legislation of other member countries (**paper and paste-board** according to BRD – BGVV regulations, Empfehlung XXXVI) or there have been taken over into the national legislation of the Czech Republic recommendations issued by the Council of Europe (**purity of colors and pigments** in AP Resolution 89).

**National health supervision** over articles intended to come into contact with foodstuffs is **by Decree executed** by organs of public health protection – **Regional Centers of Public Health**.

### Review of relevant EU directives

- ❖ 78/142/EEC Council Directive of 30 January 1973 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs
- ❖ 80/590/EEC Commission Directive of 9 June 1980 determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs
- ❖ 80/766/EEC Commission Directive of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles

which are intended to come into contact with foodstuffs

- ❖ 81/432/EEC Commission Directive of 29 April 1981 laying down the Community method of analysis for the official control of the vinyl chloride released by materials and articles into foodstuffs
- ❖ 82/711/EEC Council 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



- ❖ [84/500/EEC](#) Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramics intended to come into contact with foodstuffs
- ❖ [85/572/EEC](#) Council Directive of 19 December 1985 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
- ❖ [89/109/EEC](#) 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
- ❖ [90/128/EEC](#) Commission Directive of 23 February 1990 relating to plastics materials and articles intended to come into contact with foodstuffs
- ❖ [92/39/EEC](#) Commission Directive of 14 May 1992 amending Directive [90/128/EEC](#) concerning plastics materials and articles intended to come into contact with foodstuffs
- ❖ [93/8/EEC](#) Commission Directive of 15 March 1993 amending Council Directive [82/711/EEC](#) laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs
- ❖ [93/9/EEC](#) Commission Directive of 15 March 1993 amending for the second time Directive [90/128/EEC](#) concerning plastics materials and articles intended to come into contact with foodstuffs
- ❖ [93/11/EEC](#) Commission Directive of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from rubber teaths and soothhers
- ❖ [95/3/EC](#) Commission Directive of 14 February 1995 amending for the third time Directive [90/128/EEC](#) concerning plastics materials and articles intended to come into contact with foodstuffs
- ❖ [96/11/EC](#) Commission Directive of 5 March 1996 amending for the forth time Directive [90/128/EEC](#) concerning plastics materials and articles intended to come into contact with foodstuffs
- ❖ [97/48/EC](#) Commission Directive of 15 March 1993 amending for the second time Council Directive [82/711/EEC](#) laying down the basic rules necessary for testing migration of the constituents of plastics materials and articles intended to come into contact with foodstuffs
- ❖ [1999/91/EC](#) Commission Directive of 23 November 1999 amending for the fifth time Directive [90/128/EEC](#) concerning plastics materials and articles intended to come into contact with foodstuffs
- ❖ [2001/61/EC](#) Commission Directive of 8 August 2001 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs
- ❖ [2001/62/EC](#) Commission Directive of 9 August 2001 amending for the sixth time Directive [90/128/EEC](#) concerning plastics materials and



articles intended to come into contact with foodstuffs

- ❖ [2002/16/EC](#) Commission Directive of 20 February 2002 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs
- ❖ [2002/17/EC](#) Commission Directive of 21 February 2002 amending for the seventh time Direc-

tive [90/128/EEC](#) concerning plastics materials and articles intended to come into contact with foodstuffs

- ❖ [2002/72/EC](#) Commission Directive of 6 August 2002 concerning plastics materials and articles intended to come into contact with foodstuffs – codification of directive [90/128/EEC](#) + 7 amendments

**For more information:**

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