European Copper Institute
Copper Alliance

Technical Information on Materials Intended for Use with Food

September 2017

Materials and Food

1. The framework legislation

Regulation (EC) No 1935/2004 provides a harmonised legal EU framework for materials and articles intended to come into contact with food. The principles it sets out require that materials do not:

- Release their constituents into food at levels harmful to human health.
- Change food composition, taste or odour in an unacceptable way.

Moreover, the framework provides:

- For special rules on active and intelligent materials.
- Powers to enact additional EU measures for specific materials (e.g. plastics).
- The procedure for performing safety assessments of substances used to manufacture Food Contact Materials (FCMs), involving the European Food Safety Authority (EFSA).
- Rules on labelling, including an indication of use or the appropriate symbol to add.
- For compliance documentation and traceability.

The Regulation defines FCMs as 'materials and articles, including active and intelligent food contact materials and articles, which in their finished state: (a) are intended to be brought into contact with food; or (b) are already in contact with food and were intended for that purpose; or (c) can reasonably be expected to be brought into contact with food, or to transfer their constituents to food under normal or foreseeable conditions of use.'

It does not apply to: '(a) materials and articles which are supplied as antiques; (b) covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food; (c) fixed public or private water supply equipment.'

In addition to the general legislation, certain FCMs—ceramic materials, regenerated cellulose film, plastics (including recycled plastic), as well as active and intelligent materials, etc., used to produce FCMs—are also covered by specific EU measures.

Despite the aforementioned European and derived national Member State regulations defining the boundary conditions, they do not rule on the material assessment, a point that proved broadly unsatisfactory in terms of providing a level playing field for marketing metallic products across Europe (see Appendix 1).

The Council of Europe (CoE) aimed to overcome this gap in the ruling by compiling a set of Technical Guidelines. Guidance is now provided for specific metals and alloys (see Section 2).

2. Migration studies and certification for metals and alloys

Substance migration tests, and compliance with limit values, are mandatory for granting certification. For this purpose, authorised and certified laboratories must be commissioned. Excerpts from the corresponding CoE Guidance Document are available online. The complete document needs to be purchased.

3. Specificities of copper and copper alloys

As for any material, when items made from copper and/or copper alloys are to be used for the processing, transport or storage of foodstuffs, their suitability for contact with specific foodstuffs must be verified with the supplier (see guidance in Section 2).

Copper surfaces in contact with foods and beverages can dissolve. The rate and amount of release is dependent on the time the food or beverage is in contact with the copper, as well as its pH. Generally, the lower the pH, the faster copper leaches. The longer the contact time, the higher the amount of copper leached. Corrosion processes may also play a role.

Contact with acidic foods (e.g. fruit juices, jams, salads and sour foods) can increase the ratio of migration-related copper and therefore requires a particularly intensive and targeted assessment.

The suitability of copper and copper alloys when in contact with food must be evaluated based on normal handling and use experience, and results obtained in the standardised tests previously discussed. If it is deemed necessary, testing conditions should be adapted on a case-by-case basis.

As with iron and zinc, copper is a natural component of many foods, and so copper concentrations in food analyses may not be due to migration from the material used. It is therefore necessary to estimate the respective concentration ratios (naturally-occurring versus migration-related) and ensure compliance with migration limit values. Adequate and tolerable uptake limits for copper by humans were reviewed by the EFSA in 2015 (see Appendix 2).

Many copper materials are suitable for use in the food sector. From the past and present, there are numerous examples of food in contact with copper-based materials.

Crockery and vessels made from pure copper are required for the production of certain types of cheese. Many types of cheese (e.g. Emmental and Appenzeller even require direct contact with copper during their aging process, allowing for the dissolved copper ions to control the metabolic processes that give them their distinctive tastes.

Phosphorus-deoxidised copper (Cu-DHP) is also used in the food sector:

- The successful use of various copper-based materials is described for seawater desalination and the production of cooking salt.
- Some copper-aluminium and copper-tin alloys are required for the manufacture of specific construction parts in the food industry.

4. Special case: drinking water

Materials and products that are in contact with drinking water are subject to a separate legislation—both at European and national level—and warrant special consideration.

EU policy ensures water intended for human consumption can be consumed safely on a lifelong basis, and this represents a high level of health protection.

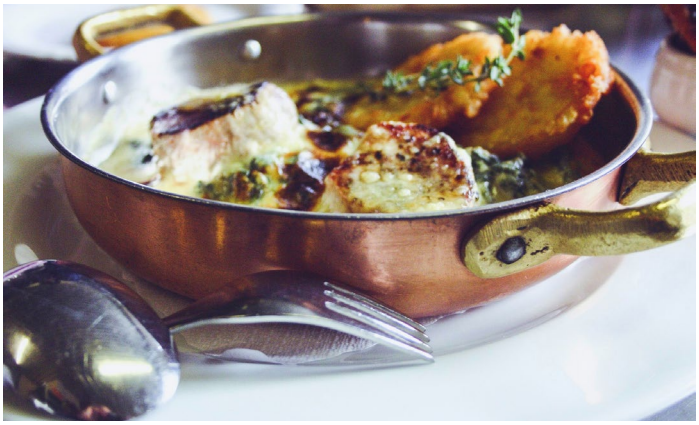
The European Drinking Water Directive 98/83/EC came into force in 1998 to set standards for safe levels of copper in drinking water at the point of use (i.e. the tap in domestic water distribution systems).

This Directive harmonised the quality of drinking water across the European Union, with a transition period of 15 years during which the limit values of metals—such as copper alloys—are to be implemented into national legislation.

To ensure the hygienic safety of the water we drink, four EU Member States (France, Germany, the Netherlands and the United Kingdom)—known as 4MS—formalised arrangements in 2011 to work together on this important aspect of the regulatory frameworks.

Today, about 20 copper alloys are commonly used to carry safe and healthy tap water via copper pipes to our homes and businesses. The copper industry has continuously tested different alloys for their health effects and compatibility with the new EU requirements, and adapted the chemical composition of existing alloys.

New alloys are currently being tested and submitted for approval and publication by 4MS, which committed to making the information and documents public once fully agreed.



Appendix 1

Food Contact Materials – Regulatory Frameworks in the European Union

Member States legislation is based on different principles, as can still be observed in those areas that are not yet covered by EU legislation.

Three main legal systems exist, based on measures in operation at national level:

- A system of authorised substances and migration limits comparable to the Union System, which has been applied, for example, in the Netherlands (Warenwet).
- A system of recommendations for substances to be used in the final material or article, as applied in Germany (Bedarfsgegen Regulations).
- A system of no specific legislation, with an industry code of practice defining due diligence of business operators, applied, for example, in the United Kingdom.

An overview of the regulatory frameworks in the EU is provided in the 2016 JRC report Non-harmonised food contact materials in the EU: Regulatory and market situation.

Appendix 2

Recommended daily intake and upper limit values for copper, and copper content in food and drinking water

The adequate intakes (AI) confirmed by the European Food Safety Authority (EFSA) 2015: (DOI: 10.2903/j.efsa.2015.4253).

For adults, AIs of 1.6 mg/day are recommended for men and 1.3 mg/day for women.

For children, AIs are 0.7 mg/day for children aged 1 to <3 years. 1 mg/day for children aged 3 to <10 years. 1.3 and 1.1 mg/day for boys and girls aged 10 to <18 years, respectively.

For infants aged 7–11 months, based on mean observed intakes in four EU countries, the AI is 0.4 mg/day, which is supported by upwards extrapolation of estimated copper intake in exclusively breast-fed infants.

For pregnant women, an increment of 0.2 mg/day is estimated to cover the amount of copper deposited in the foetus and the placenta over the course of pregnancy and in anticipation of the needs for lactation. For lactating women, the same increment is estimated to cover the amount of copper secreted with breast milk. Thus, for pregnant and lactating women, the Panel derived an AI of 1.5 mg/day.

Tolerable upper intake level is based on the following references:

Tolerable Upper Intake Levels for Vitamins and Minerals by the Scientific Panel on Dietetic products, nutrition and allergies (NDA) and Scientific Committee on Food (SCF) 2006 Copper Voluntary Risk Assessment Report, EU/European Copper Institute 2008

Regarding chronic toxicity, the No Observed Adverse Effect Level (NOAEL) has been set at 10 mg/day, judged with the most sensitive organ, the liver.

Acute toxicity is infrequent in humans and is usually a consequence of contamination of food stuffs or beverages by copper-containing vessels or dispensers.

Two studies (Pizarro et al, 1999; Donohue, 1997) have identified the threshold for acute gastrointestinal effects from copper in water at about 4.8 mg/day (based on a level of 3 mg copper/L in the water and a mean intake of 1.6 L of water/day).

A recent combined international trial determined a NOAEL and LOAEL (Lowest Observed Adverse Effect Level) for effects of nausea in healthy individuals who drank distilled water containing copper as the sulphate salt. An acute NOAEL and LOAEL of 4 mg and 6 mg copper/L, respectively were determined (Araya et al, 2001).

Preliminary unpublished data from the same research groups indicate that, in a further study, as volume increased, the effect of copper-induced nausea decreased. As copper dose increased, the incidence of nausea increased. An acute NOAEL for nausea in females (more sensitive than males) was confirmed at 4 mg copper/L of bottled water (Araya et al, 2003).

Copper content of food and drinking water

References:

The Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe 2013: Metals and alloys used in food contact materials and articles. A practical guide for manufacturers and regulators.

WHO 2004. Guidelines for Drinking-water Quality, 3rd ed., Volume 1: Recommendations, World Health Organization, Geneva.

WHO 2006. Guidelines for Drinking-water Quality, 1st Addendum to the 3rd ed.; Volume 1: Recommendations, World Health Organization, Geneva.

Based on the above tolerable upper intake values Copper-Specific Release Level (SRL) of 4 mg/kg food has been approved by the EDQM of CoE.

The European Drinking Water Directive 98/83/EC limit value and WHO recommendation for copper concentration in drinking water is 2 mg/litre.

For further information on copper, visit the European Copper Institute website: www.copperalliance.eu.