



AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

THE DIRECTOR GENERAL

**Afssa – Request no. 2008-SA-0292 (associated
requests 2006-SA-0334 and 2007-SA-0401)**

Maisons-Alfort, 30 March 2009

OPINION

of the French Food Safety Agency (Afssa) on the inclusion of tin coatings for copper pipes in Annex 1 of the Order of 29 May 1997 amended on materials and objects used in fixed installations for the production, treatment and supply of water intended for human consumption

Reminder of the request

On 23 September 2008, the Directorate General for Health (DGS) requested the French Food Safety Agency (Afssa) for an opinion on the inclusion of tin coatings for copper pipes in Annex 1 of the Order of 29 May 1997 amended on materials and objects used in fixed installations for the production, treatment and supply of water intended for human consumption.

Context

Whereas the conditions of adding a new substance to one of the positive lists appended to the Order of 29 May 1997 amended, stipulated in the practical guide¹ in accordance with article 6 of this order;

Whereas Afssa's opinion (request no. 2005-SA-0047) of 4 July 2006 on drawing up guidelines for assessing metals and alloys with a view to including them in Annex 1 of the Order of 29 May 1997 amended;

Whereas the guidelines of the Council of Europe (9 March 2001) on metals and alloys (particularly tin) intended to come into contact with food;

Whereas the report entitled "*Procedure for the acceptance of metallic materials used for products in contact with drinking water*" put forward by the working group of 4 Member States (4MS): France, United Kingdom, Germany and the Netherlands;

Whereas the stay of proceedings, pronounced by Afssa (request no. 2006-SA-0334) on 20 July 2007 on the request to include tin coatings in Annex 1 of the Order of 29 May 1997 amended on the conditions for authorising the use of materials and objects coming into contact with water intended for human consumption;

Whereas Afssa's opinion (request no. 2007-SA-0401) of 23 May 2008 on the application to include tin coatings for fittings in Annex 1 of the Order of 29 May 1997 amended on the conditions for using materials and objects coming into contact with water intended for human consumption.

Expert assessment method

The "Water" Scientific Panel was consulted about this request on 3 February and 10 March 2009.

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¹ Practical guide for compiling dossiers on the health conformity of materials put in contact with drinking water (Materials of fixed supply installations) – Directorate General for Health – March 1999.

Argument

Whereas the request concerns copper pipes that are tinned internally by chemical method;

Whereas the non-toxicity of metal tin (monographs and assessment of the Joint Expert Committee on Food Additives);

Whereas the test results supplied and existing scientific data show that the risks of metal migrating in water are low for tin coatings according to good practice;

Whereas some countries have authorised tin coatings, subject to an inspection and monitoring of tinning baths and the technical quality of finished products;

Whereas the aforementioned 4MS report provides for the authorisation, under certain conditions, of tinned copper pipes in water supply installations, but these conditions do not require verification that the organic substances used in tinning baths do not diffuse into the water;

Whereas the dossier stipulates the monitoring carried out in the factory to inspect the technical quality of the pipe coatings and tinning baths;

Whereas the assessment procedures and test results featured in the dossier do not totally rule out the risk of organic residues being present in tinning baths in the final coating and therefore the risk of certain substances migrating in the water, some of which can be included in the lists of substances that are carcinogenic, mutagenic or toxic to reproduction subject to harmonised European classification².

Conclusion and recommendations

The French Food Safety Agency (Afssa) issues a favourable opinion on the request to include tin coatings for copper pipes in Annex 1 of the Order of 29 May 1997 amended, provided that the tinned copper pipes produced by a specific manufacturer obtain a health conformity certificate (ACS) from one of the laboratories accredited by the French Ministry of Health in accordance with article R*. 1321-52 of the French Public Health Code (CSP). This ACS is issued for a maximum period of 5 years, provided that:

- 1°) the copper conforms to the criteria stipulated in Annex 1 of the Order of 29 May 1997 amended;
- 2°) the copper pipes conform to standard NF EN 1057³;
- 3°) the tin layer is applied by chemical process;
- 4°) the composition of the surface layer meets the requirement: Sn + Cu ≥ 99.90%;
- 5°) the thickness of the tin layer is at least 1 µm;
- 6°) the coating quality is checked on a regular basis according to an official quality assurance plan;
- 7°) checks are made on a sample of coated pipe taken immediately before the tinning bath is regenerated that no organic substances used in the tinning baths diffuse in the water. This should be analysed by:

² ND 2168-187-02 of the French National Research and Safety Institute (INRS): Chemical products that are carcinogenic, mutagenic or toxic for reproduction – Regulatory classification.

³ NF EN 1057 (August 2006): Copper and copper alloys – Round copper pipes without welding for water and gas in washing and heating applications.

- a. implementing a test using the method described for assessing migration in standard XP P 41-250-2⁴ by filling the pipes to obtain a surface/volume (S/V) ratio of 3,000 cm²/L;
 - b. testing for the following parameters in the migration water (after 24 hours in contact with the pipe):
 - total organic carbon (TOC),
 - organic substances in accordance with standard XP P 41-250-2 by coupling gas chromatography to mass spectrometry (GC/MS),
 - substances present in the tinning baths and featuring in the lists of substances that are carcinogenic, mutagenic or toxic to reproduction;
 - c. sending the laboratory accredited by the French Ministry of Health in charge of the tests:
 - the formulation (constitution and composition) of the pickling, tinning and rinsing baths with:
 - the chemical names of the substances,
 - the CAS (Chemical Abstracts) number of the substances,
 - the concentration of each substance,
 - the methods for analysing substances that are carcinogenic, mutagenic or toxic to reproduction in the water;
- 8°) the test results will be deemed satisfactory if:
- the increase in TOC in the migration water is less than 1 mg C/L,
 - no substance is detected in the migration water by GC/MS at a concentration exceeding 1 µg/L, the quantity expressed with regard to the closest internal standard response,
 - the concentration in the migration water of a substance that is carcinogenic, mutagenic or toxic to reproduction specifically checked is less than 0.1 µg/L.

Afssa also recommends:

- 1°) that research be conducted to eliminate any substances that are carcinogenic, mutagenic or toxic to reproduction in the tinning baths within 5 years;
- 2°) that each product be subject to regular audits of factory production by an independent organisation;
- 3°) that a sampling plan for tests be carried out by an independent organisation, by spot check of products sampled in the factory immediately before regenerating the tinning bath.

Key words

Drinking water, materials in contact with water, metals, alloys and metal coatings, tin coatings.

⁴ XP P 41-250-2 (December 2001): Effect of materials on the quality of water intended for human consumption – Organic materials – Part 2: method for measuring mineral and organic micropollutants.