The Director General

Maisons-Alfort, 23 July 2013

OPINION
of the French Agency for Food, Environmental and Occupational Health & Safety

on the assessment of the safety of organic materials used in permanent facilities for the production, treatment and distribution of drinking water (PDWs) – Parameters to be analysed in the water used in migration tests and acceptance criteria

ANSES undertakes independent and pluralistic scientific expert assessments.
ANSES primarily ensures environmental, occupational and food safety as well as assessing the potential health risks they may entail.
It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.

It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).

Its opinions are made public.

At the European level, France, Germany, the United Kingdom and the Netherlands (referred to as the 4MSs[1]) are working together within the scope of the regulations on products coming into contact with drinking water (PDWs). The aim is to adopt common or directly comparable practices for (4MS, 2011):

- the acceptance of the constituents used in the manufacture of PDWs (eventual use of a common positive list (PL)),
- examining the formulation with regard to the positive reference lists and particularly defining a tolerable percentage of non-compliance of the formulation with the common PL,
- migration testing and the choice of parameters to be analysed in the water used in migration tests,
- the methods to be used (using European standards),
- the setting of acceptance criteria (using shared conversion factors).

As part of this work, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) received a formal request from the French Directorate General for Health (DGS) on 17 April 2012 to conduct the following expert appraisal: assessment of the safety of organic materials used in permanent facilities for the production, treatment and distribution of drinking water (PDWs):

- procedures for assessing the formulation (see Request no. 2012-SA-0113),
- parameters to be analysed in the migration water used in migration tests and acceptance criteria (the subject of this formal request).

[1] *4MSs = Four Member States. A declaration of intent was signed by the 4MS's respective competent authorities in December 2010: www.sante.gouv.fr/IMG/pdf/4MS_Declaration_of_Intent_signedVF-4MS.pdf.*

More specifically, ANSES was asked to answer the following questions:

- considering the French regulations currently in force, is it possible to stop analysing certain parameters in the water used in migration testing?
- do other parameters, such as the enhancement of microbial growth (EMG), need to be introduced in the regulations?

1. BACKGROUND AND PURPOSE OF THE REQUEST

Some materials and articles, when in contact with drinking water (PDWs), can degrade its organoleptic, physico-chemical or microbiological qualities, and cause it to fall below the quality standards set by the French Public Health Code (CSP) transposing Directive No. 98/83/EC of 3 November 1998 on the quality of drinking water (DW).

Although this Directive on the quality of DW (see Article 10) and Regulation no. 305/2011/EC of 9 March 2011 relating to construction products (see Requirement 3 of Annex I) define the requirements relating to the safety of PDWs, they are not sufficiently precise to enable a harmonised European regulatory system.

In France, the marketing of materials and articles intended to come into contact with DW (PDWs), and their use in facilities for the production, distribution and treatment of water, are currently subject to the regulatory provisions of Articles R. 1321-48 and 49 of the CSP.

The procedures for verifying the health compliance of organic materials, articles (possibly reinforced by fibres) and ancillaries are described in the texts adopted in application of the CSP: the Ministerial Order of 29 May 1997, as amended, Circulars DGS/VS4 No. 99/217 of 12 April 1999, DGS/VS4 No. 2000/232 of 27 April 2000, DGS/SD7A/2002/571 of 25 November 2002 and DGS/SD7A/2006/370 of 21 August 2006.

Obtaining a sanitary conformity certificate (French ACS) for organic[2] materials, articles and ancillaries[3], or obtaining a certificate of compliance with positive lists (French CLP) for joints with diameters of less than 63 mm, and also obtaining a certificate of health proficiency (French CAS) for fibres, all issued by a laboratory authorised by the Ministry of Health (see Ministerial Order of 18 August 2009), are evidence of compliance with the regulatory requirements.

The ACS is issued on condition that:

- the substances used to manufacture the material are included in the positive lists of substances authorised by the national regulations (see the specific case of ancillaries in the table in Annex 1 of Request 2012-SA-0113),

[2] *As a reminder, organic materials include:*
- *plastics (polyvinyl chloride (PVC), chlorinated polyvinyl chloride (CPVC), polyethylene (PE), cross-linked polyethylene (PEX), polypropylene (PP), polybutylene (PB), polytetrafluoroethylene (PTFE), polyamide (PA), polysulfone (PSU), polyvinylidene fluoride (PVDF), acrylonitrile butadiene styrene (ABS), polycarbonate (PC), etc.),*
- *coatings (epoxy resin, polyurethane resin, polyurea resin, composite resin, etc.),*
- *rubbers and elastomers (ethylene-propylene (EPDM), nitrile butadiene rubber (NBR), etc.).*

These materials are used for:
- *manufacturing pipes,*
- *the inner lining of tanks and pipes,*
- *manufacturing joints and fittings,*
- *manufacturing assembled products (ancillaries).*

[3] *Assembly of at least 2 different materials.*

- the results of the migration tests carried out on the material comply with the acceptance criteria defined in the regulations.

The CLP certifies that the substances used to manufacture the joint are included in the positive list of substances authorised by the regulations.

The CAS is issued on condition that:
- the substances contained in the fibre are included in the positive lists of authorised substances and those contained in the sizing agent are known to the authorised laboratory,
- the results of the migration tests carried out on the sized fibre (in the event that one or more of the constituent substances of the sizing agent are not included in the positive lists of authorised substances) are compliant with the acceptance criteria defined in the regulations.

The procedures for assessing the constituent organic materials of membranes and resins used for the treatment of DW, as well as adhesives and lubricants, have already been addressed by specific Opinions (AFSSA, 2009a; AFSSA, 2009b; ANSES, 2010a; ANSES, 2010b).

Obtaining an ACS or CAS in France is subject to migration testing in accordance with the French standards XP P 41-250-1, -2, -3 and XP P 41-280.

At European level, testing standards (the standards in the EN 12873 series in particular) have been published and are used by Germany, the United Kingdom and the Netherlands. The parameters analysed in the water used in migration tests and acceptance criteria are not currently harmonised between the 4MSs.

The DGS is looking to update its system for assessing PDWs and achieve harmonisation between the 4MSs, which will mean using European standards.

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with the French standard NF X 50-110 "Quality in Expertise – General Requirements of Competence for Expert Appraisals (May 2003)".

The collective expert appraisal was entrusted to the Working Group on Assessing the safety of materials and products used in permanent facilities for the production, treatment and distribution of water intended for human consumption (PDWs WG) that was set up on 21 December 2011 (see Annex 1).

Experts were consulted by the PDWs WG regarding the ability of materials to enhance microbial growth (EMG) and the relevance and feasibility of determining an LC-HRMS[4] screening in addition to a GC-MS[5] screening to test for unsuspected substances released by materials (see Annex 1).

[4] *Liquid Chromatography-High Resolution Mass Spectrometry.*

[5] *Gas Chromatography-Mass Spectrometry.*

Bitumen will be evaluated separately in the context of the 4MS's work, and was excluded from the scope of this expert appraisal.

The analysis conducted and the conclusions reached by the WG were adopted by the Expert Committee (CES) on Water on 2 July 2013.

3. ANALYSIS AND CONCLUSIONS OF THE CES ON WATER

The legal foundations of the French system for verifying the health compliance of PDWs, which describe the requirements governing the parameters to be analysed in test water and acceptance criteria, have remained the same since 1999[6].

Section 3.1 of this Opinion lists the parameters currently analysed and their acceptance criteria. Section 3.2 specifies the parameters responsible for migration testing non-compliances observed by the authorised laboratories. Section 3.3 presents arguments for removing or adding certain parameters to be analysed in the migration water used in migration tests. Section 3.4 sets out acceptance criteria for the approved immersion conditions and Section 3.5 proposes points to be changed in the context of European harmonisation.

3.1. Current situation of the parameters analysed in migration water for organic materials in contact with drinking water and their acceptance criteria

The tests to be undertaken, parameters to be analysed in test water and acceptance criteria for organic materials were defined in 1999 (Circular of 12 April 1999; Hérault *et al.*, 2004):

The following tests for assessing the effects of organic materials on water quality are carried out successively:

- the rapid screening test which includes the measurement of organoleptic and physico-chemical parameters according to the method defined by the XP P 41-250-1 Standard;
- the analytical screening test which includes the measurement of metallic, mineral and organic micropollutants according to the method defined by the XP P 41-250-2 Standard;
- the final screening test which includes mass spectrometry analyses according to the method defined by the XP P 41-250-2 Standard and the measurement of cytotoxicity as defined in the XP P 41-250-3 and NF P 41-290 Standards;

noting that the analytical screening test is performed if the results of the rapid screening test are satisfactory; the final screening test is carried out if the results of the analytical screening test are satisfactory.

The parameters to be analysed to assess the effects of organic materials include:

- relevant parameters based on the quality limits of Decree no. 89-3 of 3 January 1989 as amended on drinking water, excluding natural mineral water, which was in force when the 1999 Circular was written. These parameters are:
  - organoleptic parameters: odour, flavour;
  - parameters concerning so-called 'toxic' substances[7] (arsenic, cadmium, chromium, mercury, nickel, lead, antimony, selenium, polycyclic aromatic hydrocarbons (PAHs));

[6] *Circular DGS/VS4 no. 99/217 of 12 April 1999.*

  - parameters concerning so-called 'undesirable' substances (oxidability by $KMnO_4$, ammonium, nitrites);
- polychlorinated biphenyls (PCBs) (included in the "pesticides and similar products" section);
- relevant parameters based on the quality limits of Directive 98-83, which was being transposed into French law when the Circular of 12 April 1999 was published (trihalomethanes (THMs) (chloroform, bromoform, dibromochloromethane and bromodichloromethane) and tri- and tetrachloroethylene);
- overall indicator parameters (pH, conductivity[8], chlorine demand, total organic carbon (TOC));
- volatile organic compounds (carbon tetrachloride (CCl_4) and analysis according to the GC-MS method);
- testing for organic compounds released by the material (unsuspected because not declared in the formulation or 'neoformed' substances) by GC-MS screening;
- and measurement of the material's cytotoxicity.

When assessing the effects of certain materials, the number of tests to be performed or parameters to be analysed may be reduced (case of variants, extruded PE tubes, etc.) (Circular of 27 April 2000).

The acceptance criteria set for migration water generally correspond to 20% of the regulatory quality limits for DW (Decree no. 89-3 of 3 January 1989 as amended or Directive 98/83/EC for lead, THM, tri- and tetrachloroethylene parameters, etc.). Specific PDW criteria have been set for other parameters that do not appear in the aforementioned Decree or Directive, particularly for analysing unsuspected compounds released by the material. Semi-volatile organic compounds detected by GC-MS screening must have a concentration lower than or equal to 1 µg/L, based on the response of the closest internal standard. This value was adopted at the time based on analytical considerations, particularly given the method's limit of detection (LD).

The procedure for assessing the health effects of ancillaries is set out in the Circular of 25 November 2002. Considering that the risks related to the use of ancillaries in a water production/distribution system are lower than those linked to contact between tubes, pipes or tank coatings and supply water (ancillaries have small surface areas in contact with water and are infrequently used in distribution systems), the procedure for them has been simplified compared to the one set out in the Circular of 12 April 1999. For example, the number of parameters to be analysed in the protocol for assessing ancillaries has been reduced (parameters to be analysed: pH, odour, flavour, conductivity, chlorine demand[9], TOC, non-halogenated solvents (benzene, toluene, xylene), organic halogen compounds and testing for unsuspected compounds through GC-MS). The acceptance criteria defined in the Circulars of 12 April 1999 and 27 April 2000 have stayed the same.

Annex 2 lists:
- the parameters to be analysed in migration water and their acceptance criteria as defined in the regulation,
- the parameters actually analysed by the authorised laboratories.

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[7] Although Decree no. 89-3 includes cyanides in toxic substances, this parameter was not adopted as a parameter to be analysed to assess the effects of organic materials.

[8] Quality reference in Decree no. 89-3.

[9] Parameter not analysed if the accessory contains at least one metallic component in contact with water.

3.2. Analysis of the results of the survey of authorised laboratories on the parameters that result in migration testing non-compliances

ANSES undertook a survey of the laboratories authorised by the Ministry of Health in order to record the results of analyses yielding migration testing non-compliances over the 2007-2011 period.

Annex 3 lists the parameters responsible for migration testing non-compliances.

An examination of the non-compliant analysis results by parameter, as recorded by the authorised laboratories to assess the safety of materials and accessories for the 2007-2011 period, shows that the primary non-compliances involve flavour and the GC-MS screening.

3.3. Relevance of the analysed parameters by type of organic material

3.3.1. Parameters to be dropped

The PDWs WG recommends no longer analysing the following parameters in test water, for the reasons given below:

Conductivity and pH: the potential impact of organic materials on these parameters is near zero. Experience shows that these parameters are not discriminating (see Annex 3).

Chlorine demand: chlorine may react with organic substances released by a material (also measured thanks to TOC and GC-MS) or present on its surface. High chlorine demand indicates that the material is not inert to chlorine in the testing conditions and that it may alter the effectiveness of the post-chlorination phase during the production of DW.
Some materials, such as metals and cements, have initial high chlorine consumption (oxidation of metals or consumption by the inorganic substances of cements) and are not subject to this test in France.
The analysis of this parameter was dropped in Germany because unsuspected organic substances released by materials are already detected through TOC and GC-MS analyses. This analysis is not required in the United Kingdom or the Netherlands.
Moreover, the test methods currently used and the European test method (NF EN 14718) cannot assess the long-term chlorine consumption of drinking water facilities.
Experience shows that this parameter is not discriminating (see Annex 3).

Oxidability by $KMnO_4$: the analysis of this parameter was removed from the XP P 41-250-1 Standard but is still included in the Circular of 12 April 1999. The Ministerial Order of 11 January 2007 as amended requests that either oxidability or TOC be analysed. Furthermore, oxidability analyses are subject to many interferences and replacing the measurement of oxidability with the measurement of TOC is recommended in the literature (Rosin *et al.*, 2009). Experience shows that this parameter is not discriminating (see Annex 3).

Ammonium and nitrites: the analysis of these parameters was removed from the XP P 41-250-1 Standard but is still included in the Circular of 12 April 1999. Experience shows that these parameters are not discriminating (see Annex 3).

Polychlorinated biphenyls (PCBs): the regulations and the XP P 41-250-2 Standard do not specifically mention which compounds are to be analysed. Organic materials do not affect this parameter. Experience shows that this parameter is not discriminating (see Annex 3).

Volatile organic compounds (VOCs): the regulation and the XP P 41-250-2 Standard do not specifically mention which compounds are to be analysed. The solvents used in the manufacture of materials are in principle eliminated during the production or implementation of coatings applied *in situ*. Experience shows that the measurement of VOCs is not discriminating (see Annex 3).

Polycyclic aromatic hydrocarbons (PAHs): the analysis of these compounds is relevant only if they are found in the formulation, for bitumen in particular which is excluded from the scope of this expert appraisal. Experience shows that the measurement of PAHs is not discriminating (see Annex 3).

Cytotoxicity: the loss of metabolic capacities over time in the cells used for this test ('HeLaS3' human cells) is problematic. 'HepG2' human liver cells are recommended in the recent standards (NF EN 15845 Standard, Bach Campa, 2011).
This overall test for assessing the behaviour of a material in contact with water was justified in the past for two reasons: the formulation study was weak and the GC-MS technique was undeveloped. Furthermore, the use of a radioactive product makes the method cumbersome. Experience shows that this test is not discriminating (see Annex 3) due to its low sensitivity (Moulin *et al.*, 2007a).
In the United Kingdom, an initial cytotoxicity test is carried out to rule out high-discharge materials (BS 6920-2.5). After 24 hrs of contact with the material, a check is undertaken to ensure that the migration water does not affect the morphology of mammal cells (monkey kidney cells). This low-sensitivity test is not suitable for use as a final test (CPDW, 2004).

However, chemical analyses cannot exhaustively identify all of the substances in the migration water and are not sufficient to assess the toxicity of migrant molecules. As a result, it is useful to supplement these analyses with methods measuring the biological effects of the migration water. That said, the use of one or more biological tests to estimate general toxicity (cytotoxicity, genotoxicity, endocrine or other disruption) has not been adopted in the current state of knowledge (technical difficulties, lack of validated tests for certain effects, lack of micro-methods for evaluating toxicity for certain effects, etc.) (AFSSA, 2006; Severin *et al.*, 2011a and 2011b; Chagnon, 2010; Störmer *et al.*, 2010; Bach Campa, 2011).

3.3.2.Parameters to be kept

The PDWs WG recommends continuing to analyse the following parameters in test water, for the reasons given below:

Odour and flavour: some materials may release compounds in drinking water at very low concentrations, which generally cannot be detected analytically, that can cause an unacceptable odour and flavour for consumers.

Total organic carbon (TOC): TOC analysis can estimate the overall migration of organic substances.

Metallic elements and minerals: these may be constituents (e.g. stabilisers) or impurities (found in colouring agents and pigments for example) contained in certain substances included in the positive lists. Advanced analytical techniques and particularly inductively

coupled plasma mass spectrometry (ICP-MS) can simultaneously test for 62 elements[10] at low concentrations whether they have been intentionally added or not. The PDWs WG suggests testing for the 62 elements by ICP-MS screening (NF EN ISO 17294-2 Standard) and testing for mercury even though acceptance criteria have only been set for some of them.

Trihalomethanes (THMs): if the material releases organic substances, they may react with chlorine and form THMs. The analysis of this parameter should be kept only for tests in chlorinated water. The following four compounds should be analysed: chloroform, bromoform, dibromochloromethane and bromodichloromethane.

Organic substances: GC-MS screening can be used to analyse (detection, semi-quantification and sometimes identification) organic substances, whether found in the formulation or unsuspected (not declared or 'neoformed'), released by materials. The WG recommends using the European method (DR NF EN 15768) which is more efficient considering extraction protocols and quality control (James, 2003; James, 2006; Löschner, 2011).

However, this technique cannot detect all substances likely to be found in migration water (non-extracted, non-volatile compounds, etc.).

Using new liquid chromatography-high resolution mass spectrometry (LC-HRMS) systems would be a more exhaustive option for analysing these compounds (semi-quantification and identification). These techniques are increasingly used to test for organic elements in the environment.

There are databases for their identification (pesticides, pharmaceuticals, drugs, etc.) but they depend on the apparatus and the operational conditions of the systems. In the case of compounds likely to be released by PDWs, these databases require improvement. LC-HRMS could currently be used only for the detection of unsuspected compounds and possibly their semi-quantification but identification would remain difficult.

Considering the expected link between LC and GC, the PDWs WG recommends undertaking studies using these LC-HRMS techniques in the migration water used in migration tests for various organic materials with the following aims:

- confirm the link between these two techniques in terms of detected substances,
- specify operational conditions (extraction or direct injection, type of column, etc.),
- assess the performance of the available techniques (limits of detection, quantification, etc.),
- define procedures for interpreting results,
- launch the development of specific databases on PDWs.

3.3.3.Parameters to be added

The PDWs WG recommends adding the analysis of the following parameters in test water, for the reasons given below:

[10] *The NF EN ISO 17294-2 Standard specifies a testing method for the following 62 elements: aluminium, antimony, arsenic, barium, beryllium, bismuth, boron, cadmium, caesium, calcium, cerium, chromium, cobalt, copper, dysprosium, erbium, europium, gadolinium, gallium, germanium, gold, hafnium, holmium, indium, iridium, lanthanum, lead, lithium, lutetium, magnesium, manganese, molybdenum, neodymium, nickel, palladium, phosphorus, platinum, potassium, praseodymium, rubidium, rhenium, rhodium, ruthenium, samarium, scandium, selenium, silver, sodium, strontium, terbium, tellurium, thorium, thallium, thulium, tin, tungsten, uranium, vanadium, yttrium, ytterbium, zinc and zirconium.*

Colour and turbidity: some materials may change the colour and increase the turbidity of DW. DW should have a satisfactory appearance for consumers.

Enhancement of microbial growth (EMG):
Materials can be a source of nutrients for micro-organisms and thus promote the formation of a biofilm on their surface. An increase in the number of planktonic or fixed micro-organisms may cause organoleptic problems (taste, odour) and risks to consumer health.

Various complementary approaches may be used to limit microbial growth during the storage and distribution of DW:

- reducing organic matter by implementing water treatment methods tailored to the quality of the resource;
- disinfecting the water before distributing it;
- maintaining a residual amount of disinfectant in the system to the consumer's tap;
- optimising the hydraulic operating conditions of systems;
- selecting materials that do not enhance microbial growth.

That said, it is acknowledged that all materials placed in contact with water for an extended amount of time are colonised by a biofilm. Since the intrinsic characteristics of a material (composition, surface condition, etc.) alone cannot determine whether a biofilm will form, it is important to have a test procedure that can distinguish between materials based on their ability to promote the development of a biofilm.

This aspect is not currently covered by the French regulations on materials in contact with DW (PDWs).

Three test methods have been developed in the past few years in the United Kingdom, the Netherlands and Germany. They rely on different test procedures and measurement principles and it is complicated to compare their results. Lacking consensus on a single appropriate method applicable to all materials and products, the European Committee for Standardization (CEN) decided to write a standard (DR NF EN 16421) including the three methods (4MS, 2013).

Of the three proposed methods, the WG considers that the one that uses ATP testing[11], which can measure both the free biomass (planktonic micro-organisms) and the fixed biomass (biofilm), is the most efficient in terms of its sensitivity (limit of detection < 1 ng ATP/L or even < 0.1 ng ATP/L in DW) and the range of concentration levels observed when distinguishing between materials (less than 50 to over 48,000 pg ATP/cm^2) (Mathieu, 1998; Veenendaal *et al.*, 1999; van der Kooij *et al.,* 2003*,* 2006 and 2007; Enkiri et al., 2006 and 2011; Moulin *et al.*, 2007b; Tsvetanova, 2008; Kiwa, 2008).

However, while the analysis of EMG may be a criterion for ranking materials and make it possible to identify a material whose EMG is far from the values in its category, it is difficult to establish a relationship between the result of the analysis and potential impact on the microbiological quality of water in real-life situations. For this reason and for want of experience, at least in France, with the use and interpretation of tests performed according to Section 1 of the DR NF EN 16421 Draft Standard, no acceptance criteria can be set over the short term.

[11] *ATP testing: indirect assessment of biomasses (or Biomass Production Potential, BPP) by analysing microbial adenosine triphosphate (ATP).*

As a result, the WG considers that it is premature to introduce the analysis of EMG as part of ACS until data have been acquired by undertaking tests according to the method using ATP testing as described in Section 1 of the European draft standard.

Other parameters:
Substances with a Specific Migration Limit (SML_{food}) or a Maximum Tolerable Concentration at the consumer's tap (MTC_{tap}) mentioned in the positive reference lists should be specifically analysed if their compliance ($MTC_{tap} = SML_{water} = SML_{food}/20$) cannot be validated by a calculation.

The analytical methods to be used are specified below (see Table I, page 14).

3.4. Immersion conditions and new acceptance criteria

The European standards offer several options for immersion conditions:

- the type of test water (chlorinated or chlorine-free),
- the number of tests for each type of test water,
- the number of migration periods.

For these options, choices may be made either through national regulations or product standards.

Since water is generally chlorinated in France, the WG considers it is necessary to undertake tests in chlorinated and chlorine-free water.

Since it is assumed that the product for testing is of constant quality and since migration testing is standardised and conducted under accreditation, the WG considers that repeated testing is not necessary and recommends conducting only one test for each type of water.

In light of the flushing stages prior to migration recommended in the European standards (pretreatment procedure of stagnation and prewashing), the WG considers that compliance with the acceptance criteria should be assessed after the third migration period, with no possibility of extending the number of migration periods. The analysis of water from the first, second and third stagnation periods, in accordance with the recommendations in the European standards, allows the laboratory to verify that testing went smoothly and the results are consistent. The requirement of having decreasing analysis results for the migration water across the three migration periods has not been adopted as an acceptance criterion.

Studies comparing the French (XP P 41-250) and European (NF EN 12873) approaches, financed by the Agency and the DGS, were undertaken by the laboratories authorised by the Ministry of Health to assess the safety of materials and accessories (CRECEP, 2002; CARSO, 2005, 2006 and 2009). The results of these studies and the acceptance criteria defined in the Netherlands, Germany and the United Kingdom were used as a basis for setting the new acceptance criteria.

3.4.1. Organoleptic parameters

The impact of materials on organoleptic parameters (odour, flavour, colour and turbidity) shall be assessed according to the NF EN 1420-1 (odour and flavour of water in piping

systems), NF EN 13052-1 (colour and turbidity of water in piping systems) and NF EN 14395-1 (organoleptic assessment of water in storage systems) Standards:

- for materials intended to be used in cold water, testing at the temperature of (23 ± 2)°C, with chlorinated water having a level of free chlorine equal to (1 ± 0.2) mg/L of Cl_2, and also with chlorine-free water,
- for materials intended to also be used in hot water, additional testing in chlorine-free water at a temperature ranging from 60 to 85°C depending on the intended use of the material.

The WG suggests that:

- threshold odour numbers (TONs) and threshold flavour numbers (TFNs) should be determined according to the NF EN 1622 Standard for the migration water from the first, second and third migration period and the acceptance criterion should be set at: TFN and TON ≤ 4 for the migration water from the third migration period irrespective of the temperature[12];
- colour should be determined according to the NF EN ISO 7887 Standard in the migration water from the first, second and third migration period and the following acceptance criterion should be set: ≤ 10 mg/L Pt/Co in the migration water from the third migration period irrespective of the temperature;
- turbidity should be determined according to the NF EN ISO 7027 Standard in the migration water from the first, second and third migration period and the following acceptance criterion should be set: ≤ 0.5 NFU in the migration water from the third migration period irrespective of the temperature.

3.4.2.Migration of organic and inorganic substances

For migration testing, the NF EN 12873-1 (factory-made products) and 12873-2 (site-applied materials) Standards should be applied with the following options:

- for materials intended to be used in cold water, testing at the temperature of (23 ± 2)°C, with chlorine-free water and with chlorinated water having a level of free chlorine equal to (1 ± 0.2) mg/L of Cl_2,
- for materials intended to also be used in hot water, additional testing in chlorine-free water at a temperature ranging from 60 to 85°C depending on the intended use of the material.

In accordance with the NF EN 12873 Standard:

1) the concentrations (C^T_n) measured in the migration water for each of the analysed parameters will be converted into migration rates (M^T_n):

$$\mathbf{M^T_n\ [\mu g/dm^2/day] = C^T_n\ [\mu g/L] / t\ [day] / (S/V)\ [dm^{-1}]}$$

where:

- C^T_n is the concentration of the measured substance in µg/L or mg/L, for the following conditions:
  - T is the test temperature [(23 ± 2)°C or another temperature set in the NF EN 12873-1 & 2 Standards],
  - n is the sequence number of the migration period (3 for the third stagnation period);

[12] *The chosen threshold is higher than in the current regulations on DW (no odour detected for a dilution rate of 3 at 25°C) because:*

- *given the dilution rates recommended in the NF EN 1420-1 Standard, only values in a geometric series with a factor of 2 can actually be assessed (2, 4, 6, etc.);*
- *migration is exacerbated when using this standard (72 hours of contact instead of 24 and higher S/V ratios than in the XP P 41-250-1 Standard).*

- ✓ t is the duration of the migration period in days (3 days in cold water, 1 day in hot water);
- ✓ S/V is the surface area-to-volume ratio in dm^{-1} used for the test (may range from 5 to 40 dm^{-1} according to the NF EN 12873-1 & 2 Standards);

2) a conversion factor (CF) will then be applied to the migration rate (M^T_n) to calculate a concentration at the consumer's tap ($C_{tap, n}$):

$$\mathbf{C_{tap, n}\ [\mu g/L] = M^T_n\ [\mu g/dm^2/day] \times CF\ [day/dm]}$$

Conversion factors (CFs) have been defined for each product and area of application. The values adopted by the 4MSs are given in Annex 4.

In the common approach, the 4MSs recommend, for parameters having a parametric value (PV) set in Directive 98/83/EC, that the quantities supplied by the materials should not exceed 10% of the quality requirements. The 4MSs therefore recommend setting Maximum Tolerable Concentrations at the consumer's tap (MTC_{tap}) as follows as acceptance thresholds for materials: MTC_{tap} = 0.1 x PV (4MS, 2011). It should be noted that the French system for assessing materials has until now considered that these quantities should not exceed 20% of the regulatory quality limits and references.

In light of these points and for harmonisation purposes, the WG is proposing that:

- the parameters should be analysed for the migration water from the first, second and third migration periods and the following acceptance criteria should be set: $C_{tap,3} \leq MTC_{tap}$ for the migration water from the third migration period irrespective of the temperature,
- the quantities supplied by the materials should not exceed 10% of the quality requirements for DW, which means that tolerance is lower for the substances contained in materials than in the current regulations, and this principle should be applied to parameters with a quality limit (QL) set in the Ministerial Order of 11 January 2007[13]. Thus, the WG recommends:
  - ✓ for mineral elements analysed according to the NF EN ISO 17294-2 Standard and mercury analysed according to the NF EN 1483 or NF EN ISO 17852 or NF EN 12338 Standards, the following MTC_{tap} values:
    - o antimony: 0.5 µg/L (Sb),
    - o arsenic: 1 µg/L (As),
    - o barium: 0.07 mg/L (Ba),
    - o boron: 0.1 mg/L (B),
    - o cadmium: 0.5 µg/L (Cd),
    - o chromium: 5 µg/L (Cr)[14],
    - o copper: 0.2 mg/L (Cu),
    - o mercury: 0.1 µg/L (Hg),
    - o nickel: 2 µg/L (Ni),
    - o lead: 1 µg/L (Pb),
    - o selenium: 1 µg/L (Se);
  - ✓ for THMs (chloroform, bromoform, dibromochloromethane and bromodichloromethane) analysed according to the NF EN ISO 10301 or NF

[13] *Chemical parameters having a minimum quality requirement specified in Annex I, Section A of Directive 98/83/EC as well as barium.*

[14] *The value may be lowered if the quality limit in DW is revised, particularly due to effects potentially induced by chromium VI (ANSES, 2012).*

EN ISO 15680 Standards, the following MTC_{tap} for the sum of the four compounds: 10 µg/L.

The WG is also proposing:

- that for TOC with a quality reference (indicator parameter, analysed according to the NF EN 1484 Standard), the MTC_{tap} should be set at 0.5 mg/L, the most stringent value adopted by one of the 4MSs (Schlosser, 2002);
- to conduct GC-MS screening according to the DR NF EN 15768 Draft Standard and to set the MTC_{tap} at 1 µg/L, based on the response of the closest internal standard. The S/V ratio used should be large enough to be able to verify, for the relevant threshold in the method[15], the value corresponding to the MTC_{tap} in the migration water (see Annex 5). The MTC_{tap} established bearing in mind analytical constraints remains compatible with a threshold of toxicological concern (TTC) set at 1.5 µg/day for substances whose toxicity is not known[16];
- that substances with an MTC_{tap} or an SML_{food} mentioned in the PLs should be analysed (if the maximum concentration expected in the migration water cannot be determined by a calculation) and that the MTC_{tap} or the $SML_{food}/20$ should be respected. Regarding the specific case of bisphenol A (BPA), the WG proposes that it should be analysed according to a method that can reach a detection limit (DL) of 10 ng/L and that BPA should not be detected (ND)[17] in migration waters.

The acceptance criteria are summarised in Table I on page 14.

[15] *The threshold value of 2 µg/L is the concentration below which detection and/or identification is not guaranteed (DR NF EN 15768).*

[16] *The analytical method should be optimised to be able to measure an MTC_{tap} of 0.1 µg/L as recommended by the 4MSs and ANSES, considering that an unknown substance is potentially carcinogenic (4MS, 2011; ANSES, 2013).*

[17] *The use of BPA is authorised, except for the manufacture of polycarbonate baby bottles, in materials in contact with food in the European Union in accordance with Regulation (EU) no. 10/2011 as amended on plastic materials and articles intended to come into contact with food with an SML of 0.6 mg/kg. As for acrylamide, vinyl chloride and epichlorohydrin, the WG proposes that the BPA concentration should be lower than the DL.*

Table I: Summary of parameters and acceptance criteria used

	Parameters	Immersion methods		Analytical methods	Acceptance criteria	Units
		Pipes	Tanks			
Series 1	Odour and flavour	NF EN 1420-1	NF EN 14395-1	NF EN 1622	≤ 4	Threshold
	Colour	NF EN 13052-1	NF EN 14395-1	NF EN ISO 7887	≤ 10	mg/L Pt/Co
	Turbidity	NF EN 13052-1	NF EN 14395-1	NF EN ISO 7027	≤ 0.5	NFU
Series 2	TOC	NF EN 12873-1 NF EN 12873-2	NF EN 12873-1 NF EN 12873-2	NF EN 1484	≤ 0.5	mg/L
	Substances with an MTC_{tap} or SML_{food} mentioned in the PLs	NF EN 12873-1 NF EN 12873-2	NF EN 12873-1 NF EN 12873-2	Analysis or calculation	≤ MTC_{tap} or $SML_{food}/20$ (BPA: ND)	µg/L
	GC-MS screening	NF EN 12873-1 NF EN 12873-2	NF EN 12873-1 NF EN 12873-2	DR NF EN 15768	≤ 1	µg/L
	Test for the 62 metallic elements and minerals by ICP-MS screening + Mercury	NF EN 12873-1 NF EN 12873-2	NF EN 12873-1 NF EN 12873-2	NF EN ISO 17294-2 + NF EN 1483 or NF EN ISO 17852 or NF EN 12338	≤ 0.1 x QL (Parameters with an QL set in the Ministerial Order of 11 January 2007)	µg/L
	Total THMs for tests in chlorinated water only	NF EN 12873-1 NF EN 12873-2	NF EN 12873-1 NF EN 12873-2	NF EN ISO 10301 or NF EN ISO 15680	≤ 10	µg/L

3.5 Conclusion and recommendations

The PDWs WG is issuing the following recommendations:

<u>1) regarding the parameters to be analysed in the migration water used in migration tests:</u>

- the following parameters no longer need to be analysed: conductivity, pH, chlorine demand, oxidability by $KMnO_4$, ammonium, nitrites, polychlorinated biphenyls (PCBs), volatile organic compounds (VOCs), polycyclic aromatic hydrocarbons (PAHs)[18] and cytotoxicity;

- the following parameters should continue to be analysed: odour and flavour, total organic carbon (TOC), metallic elements and minerals, trihalomethanes (THMs) in chlorinated water only and organic substances (GC-MS screening);

- the following parameters measurement should be added: colour, turbidity, substances with an SML_{food} or an MTC_{tap} mentioned in the positive lists;

<u>2) regarding immersion conditions and acceptance criteria:</u>

- migration testing should be undertaken in accordance with the European standards in force:
  - ✓ NF EN 1420-1, NF EN 13052-1 and NF EN 14395-1 Standards for the analysis of organoleptic parameters,

[18] *PAHs should however be analysed when they are found in the formulation, for asphalt paving in particular which is excluded from the scope of this expert appraisal.*

- ✓ NF EN 12873-1 and -2 Standards for the analysis of organic and inorganic substances;

- for materials intended to be used in cold water, migration testing should be performed at the temperature of (23 ± 2)°C, with chlorinated water having a level of free chlorine equal to (1 ± 0.2) mg/L of Cl_2, and also with chlorine-free water;

- for materials intended to also be used in hot water, additional migration testing should be carried out in chlorine-free water at a temperature ranging from 60 to 85°C depending on the intended use of the material;

- the relevant parameters adopted should be analysed in the migration water from the first, second and third migration periods and the acceptance criterion should be set for the migration water from the third migration period irrespective of the temperature;

- the parameters used should be analysed according to the standards mentioned in Table I, page 14, which also lists the proposed acceptance criteria;

3) regarding research needs:

- studies should be undertaken implementing liquid chromatography-high resolution mass spectrometry (LC-HRMS) techniques in the water used in migration tests for various organic materials with the following aims:
  - ✓ confirm the link between liquid and gas chromatography techniques in terms of detected compounds,
  - ✓ specify operational conditions (extraction or direct injection, type of column, etc.),
  - ✓ assess the performance of the available techniques (limits of detection, quantification, etc.),
  - ✓ define procedures for interpreting results,
  - ✓ launch the development of specific databases on PDWs;

- the enhancement of microbial growth (EMG) should be analysed for a large number of materials that already have a ACS according to the method using ATP as described in Section 1 of the DR NF EN 16421 Draft Standard in order to define acceptance criteria.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety adopts the conclusions and recommendations of the CES on Water.

The Director General

Marc Mortureux

KEYWORDS

Drinking water, materials in contact with water, organic materials, migration tests, acceptance criteria.

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DR NF EN 16421: Influence of materials on water for human consumption - Enhancement of microbial growth (EMG) – Method 1: measured by ATP – Method 2: measured by biomass volume – Method 3: measured by mean dissolved oxygen depletion.

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XP P 41-250-2: Effect of materials on the quality of water intended for human consumption – Organic materials – Part 2: Measurement method for the organic and mineral micropollutants.

XP P 41-250-3: Effect of materials on the quality of water intended for human consumption – Organic materials – Part 3: Measurement method of the cytotoxicity.

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NF T90-008: Water quality – Determination of pH.

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ANNEX 1: PRESENTATION OF THE PARTICIPANTS

Working Group

Chairperson
Mr Jean BARON - Materials in contact with water, chemistry of water, ageing and corrosion of materials

Members
Ms Christelle AUTUGELLE - Migration testing, positive lists, formulations, EU standards and regulations
Mr Olivier CORREC - Chemistry of water, indoor systems modelling, corrosion
Mr Xavier DAUCHY - Chemistry of water, water analyses
Ms Sophie HÉRAULT - PDW regulations, EAS
Mr Michel JOYEUX - Toxicology, HRA, PDWs
Ms Maud LANÇON - Migration testing, positive lists, formulations, EU standards and regulations
Mr Pierre LEROY - Corrosion and scaling of indoor systems, calcium-carbon balance

ANSES participation

Scientific coordination
Ms Anne NOVELLI - Water Risk Assessment Unit (UERE) – Risk Assessment Department

Scientific contribution
Ms Pascale PANETIER - Head of the Water Risk Assessment Unit (UERE) – Risk Assessment Department

Administrative secretariat
Ms Christine LECAREUX - Risk Assessment Department

External parties consulted

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Ms Françoise ENKIRI and Mr Fabien SQUINAZI - Hygiene Laboratory of the City of Paris (LHVP)
Ms Laurence MATHIEU - UMR 7564 CNRS / Nancy-University - Laboratory for Environmental Physical Chemistry and Microbiology (LCPME)
Mr Laurent MOULIN - Eau de Paris
Ms Aurélie THOUET - Directorate General for Health (DGS) – Bureau of water quality

Liquid Chromatography-High Resolution Mass Spectrometry (LC-HRMS)
Mr Auguste BRUCHET - SUEZ Environnement – PAS – CIRSEE
Ms Valérie INGRAND and Ms Gaëla LEROY - VEOLIA Environnement Research & Innovation - Innovation in Chemistry Analysis Unit
Ms Isabelle VECCHIOLI - CARSO - LSEHL

ANNEX 2: LIST OF PARAMETERS ANALYSED IN MIGRATION WATER AND ACCEPTANCE CRITERIA

The table below lists the parameters to be analysed in migration water and their acceptance criteria set in the regulations in addition to those actually analysed by the laboratories authorised by the Ministry of Health to assess the safety of materials and ancillaries.

	Parameters	Standards	Regulatory parameters set between 1999 (materials) and 2002 (accessories)	Parameters analysed by the laboratories in 2012	Acceptance criteria (Units)
Organoleptic and rapid screening analyses (XP P 41-250-1 and XP P 41-280 Standards)	Odour & Flavour	NF EN 1622	Yes (materials and ancillaries)	Yes	Increase ≤ 2 (threshold)
	Conductivity	NF EN 27888	Yes (ancillaries)	Yes	< 1000 µS/cm at 20 ± 2°C
	pH	NF T90-008	Yes ancillaries)	Yes	Between 6.5 and 9 (pH unit)
	Total organic carbon (TOC)	NF EN 1484	Yes (materials and ancillaries)	Yes	Increase ≤1 mg/L (C)
	Chlorine demand	NF EN ISO 7393-1 and NF EN ISO 7393-2	Yes (materials and ancillaries)	Yes (consumption of free chlorine and total chlorine)	Increase ≤ 25% for free chlorine
	Oxidability by $KMnO_4$	NF EN ISO 8467	Yes (materials)	Yes until it is removed from the standard	Increase ≤ 1 mg/L (O_2)
	Ammonium	NF T90-015-2	Yes (materials)	Yes until it is removed from the standard	Increase ≤ 0.1 mg/L (NH_4)
	Nitrites	NF EN 26777	Yes (materials)	Yes until it is removed from the standard	Increase ≤ 0.02 mg/L (NO_2)
Fine screening analyses (XP P 41-250-2 and XP P 41-280 Standards)	Mercury	NF EN 1483 or NF EN ISO 17852 or NF EN 12338	Yes (materials)	Yes	Increase ≤ 0.2 µg/L (Hg)
	Cadmium	NF EN ISO 5961 or NF EN ISO 15586 or NF EN ISO 11885 or NF EN ISO 17294-2	Yes (materials)	Yes	Increase ≤ 1 µg/L (Cd)
	Chromium	NF EN 1233 or NF EN ISO 15586 or NF EN ISO 11885, or NF EN ISO 17294-2	Yes (materials)	Yes	Increase ≤ 10 µg/L (Cr)
	Selenium	NF EN ISO 15586 or NF EN ISO 11885 or NF EN ISO 17294-2	Yes (materials)	Yes	Increase ≤ 2 µg/L (Se)
	Antimony	NF EN ISO 15586 or NF EN ISO 11885 or NF EN ISO 17294-2	Yes (materials)	Yes	Increase ≤ 2 µg/L (Sb)
	Arsenic	NF EN ISO 11969 or NF EN ISO 15586 or NF EN ISO 11885 or NF EN ISO 17294-2	Yes (materials)	Yes	Increase ≤ 2 µg/L (As)
	Lead	NF EN ISO 15586 or NF EN ISO 11885 or NF EN ISO 17294-2	Yes (materials)	Yes	Increase ≤ 2 µg/L (Pb)
	Nickel	NF EN ISO 15586 or NF EN ISO 11885 or NF EN ISO 17294-2	Yes (materials)	Yes	Increase ≤ 4 µg/L (Ni)
	Polychlorinated biphenyls (PCBs): PCB no 28 PCB no 52 PCB no 101 PCB no 118 PCB no 138 PCB no 153 PCB no 180	NF EN ISO 6468	Yes (materials)	Yes	Increase ≤ 0.1 µg/L

	Parameters	Standards	Regulatory parameters set between 1999 (materials) and 2002 (accessories)	Parameters analysed by the laboratories in 2012	Acceptance criteria (Units)
Fine screening analyses (XP P 41-250-2 and XP P 41-280 Standards)	Volatile organic compounds (VOCs): Carbon tetrachloride Trichloroethylene Tetrachloroethylene Other analysed VOCs e.g. Benzene Toluene Xylene Bromochloromethane 1,1-dichloroethylene 1,2-dichloroethylene cis 1,2-dichloroethylene trans 1,1-dichloroethane 1,2-dichloroethane Dichloromethane 1,1,1-trichloroethane 1,1,2-trichloroethane Monochlorobenzene 1,2-dichlorobenzene 1,3-dichlorobenzene 1,4-dichlorobenzene Ethylbenzene Isopropylbenzene 1,3,5-trimethylbenzene 1,2,4-trimethylbenzene 1,2,3-trimethylbenzene Acetone Butanone Ethyl acetate Methyl isobutyl ketone Methyl ethyl ketone	NF EN ISO 10301 or NF EN ISO 15680 or NF ISO 11423-1	Yes (materials and ancillaries)	Yes	Increase ≤ 3 µg/L for carbon tetrachloride Increase ≤ 2 µg/L for trichloroethylene and tetrachloroethylene Increase ≤ 1 (µg/L) for other volatile compounds extracted by the dynamic headspace technique or by liquid/liquid extraction analysed by GC-MS
	Trihalomethanes (THMs): Bromoform Chloroform Dibromochloromethane Bromodichloromethane	NF EN ISO 10301 or NF EN ISO 15680	Yes (materials and ancillaries)	Yes	Increase ≤ 20 (µg/L)
	Polycyclic aromatic hydrocarbons (PAHs) e.g. Naphthalene Acenaphthene Fluorene Phenanthrene Anthracene Fluoranthene Pyrene Benzo(a)anthracene Chrysene Benzo(b)fluoranthene Benzo(k)fluoranthene Benzo(a)pyrene Dibenzo(ah)anthracene Benzo(3,4)pyrene Benzo(ghi)perylene Indeno(1,2,3cd)pyrene	NF T90-115 or NF EN ISO 17993 or NF ISO 28540	Yes (materials)	Yes	Increase ≤ 0.2 (µg/L) for the sum of the following 6 compounds: fluoranthene, benzo(3,4)fluoranthene, benzo(11,12)fluoranthene, benzo(3,4)pyrene, benzo(1,12)perylene and indeno(1,2,3-cd)pyrene
	GC-MS profile	XP P 41-250-2	Yes (materials and ancillaries)	Yes	≤ 1 µg/L for each detected and quantified compound based on the closest alkane

	Parameters	Standards	Regulatory parameters set between 1999 (materials) and 2002 (accessories)	Parameters analysed by the laboratories in 2012	Acceptance criteria (Units)
XP P 41-250-3	**Cytotoxicity analyses**	NF P 41-290	Yes (materials and ancillaries)	Yes	≥ 70% (% RNA synthesis)

The maximum residual quantities (MQs)[19] mentioned in the positive reference lists are verified when examining the formulation or analytically after extraction. However, the specific migration limits mentioned in the positive reference lists, established for materials intended to come into contact with food (SML_{food}) and adapted for materials intended to come into contact with DW (SML_{water})[20], are not systematically verified.

Certain compounds such as acrylamide, epichlorhydrin and BPA are specifically analysed if contained in the formulation. Acrylamide and epichlorhydrin should not be detected in the migration water and the BPA concentration should be ≤ 1 µg/L.

[19] *For substances that are unstable in water or for which there is no appropriate analytical method, compliance is checked by verifying the residual level in the final product expressed in mg/kg.*

[20] *SML_{water} = SML_{food}/20: the World Health Organization (WHO) conventionally assigns 10% (before 2008) of the tolerable daily intake (TDI) to water contaminants for daily water consumption of 2 litres.*

ANNEX 3: PARAMETERS RESPONSIBLE FOR MIGRATION TESTING NON-COMPLIANCES FROM 2007 TO 2011

The table below lists non-compliant (NC) analysis results by parameter as recorded from 2007 to 2011 by the laboratories authorised by the Ministry of Health to assess the safety of materials and ancillaries. In some cases there is no numeric value. This means there were no non-compliant analysis results.

Parameters	Laboratory no. 1				Laboratory no. 2							
	Materials		Ancillaries		Plastics		Coatings		Rubbers and elastomers		Ancillaries	
	No. of NC[1]	Total no.[2]	No. of NC[1]	Total no.[2]	No. of NC[1]	Total no.[2]	No. of NC[1]	Total no.[2]	No. of NC[1]	Total no.[2]	No. of NC[1]	Total no.[2]
Odour and flavour	< 10	260	< 10	750	5	397	1	111	2	107	6	783
Conductivity												
pH												
TOC					1	397	2	111				
Chlorine demand												
Oxidability by $KMnO_4$												
Ammonium												
Nitrites												
Mineral micropollutants												
PCBs												
VOCs					Acetone: 4*	397	Xylene: 4*	111				
THMs												
PAHs												
GC-MS	< 20	260	20	750	21	397	8	111	11	107	58	783
Cytotoxicity					2*	397	1*	111				

[1] Number of non-compliances
[2] Number of materials tested
* GC-MS results also non-compliant

ANNEX 4: CONVERSION FACTORS (CFS) USED TO DEFINE ACCEPTANCE CRITERIA FOR MIGRATION TESTING

The surface/volume ratio and the stagnation times used for migration testing in accordance with the NF EN 12873-1, -2 Standards do not reflect the reality of a water supply system. Conversion factors (CFs) are used to determine the actual impact of materials on the quality of DW based on the concentrations found in migration tests (4MS, 2011).

CFs are established based on the following assumption:

$$CF = F_g \times F_o \text{ [day/dm]}$$

where:

- Fg (geographic factor) is the S/V ratio representative of reality (dimension: dm^{-1}),
- Fo (operational factor) is water's assumed residence time in the system (dimension: day).

The conversion factors (CFs) used to pass between reality and migration testing as defined in this report correspond to:

Product categories		F_g = S/V in dm^{-1}	F_o = t in days	CF = Fg x Fo in day/dm
Group A Pipes and their linings	Domestic installations, buildings (Ø < 80 mm)	40	0.5	**20**
	Service piping (80 mm ≤ Ø < 300 mm)	5	2	**10**
	Mains piping (Ø ≥ 300 mm)	1.33	4	**5**
Group B Fittings and ancillaries	Domestic installations, buildings (Ø < 80 mm)	8	0.5	**4** ($CF_{group\ B} = CF_{group\ A}$ x 0.2)
	Service piping (80 mm ≤ Ø < 300 mm)	1	2	**2** ($CF_{group\ B} = CF_{group\ A}$ x 0.2)
	Mains piping (Ø ≥ 300 mm)	0.25	4	**1** ($CF_{group\ B} = CF_{group\ A}$ x 0.2)
Group C Components of fittings and ancillaries	Domestic installations, buildings (Ø < 80 mm)	0.8	0.5	**0.4** ($CF_{group\ C} = CF_{group\ B}$ x 0.1)
	Service piping (80 mm ≤ Ø < 300 mm)	0.1	2	**0.2** ($CF_{group\ C} = CF_{group\ B}$ x 0.1)
	Mains piping (Ø ≥ 300 mm)	0.025	4	**0.1** ($CF_{group\ C} = CF_{group\ B}$ x 0.1)
Group D Storage systems	In domestic installations, buildings	4	1	**4**
	In water supply	0.25	4	**1**
Group E Repair products for storage systems	In domestic installations, buildings – Products covering the total surface or a substantial part of that	4	1	**4**
	In domestic installations, buildings – Products covering less than 1 % of the total surface	0.04	1	**0.04**
	In water supply – Products covering the total surface or a substantial part of that	0.25	4	**1**
	In water supply – Products covering less than 1 % of the total surface	0.0025	4	**0.01**

ANNEX 5: GC-MS SCREENING – CONCENTRATIONS (C_n^T) MEASURED IN MIGRATION WATER CORRESPONDING TO AN MTC_{tap} OF 1 µg/L BASED ON THE S/V RATIOS (5 TO 40 dm^{-1}) RECOMMENDED IN THE NF EN 12873 STANDARDS

The C_n^T values measured in migration waters should be greater than the threshold value of 2 µg/L.

Product categories		Acceptance criterion (µg/L)	CF	M_n^T (µg/dm^2/day)	S/V (dm^{-1})	C_n^T (µg/L)	Dr NF EN 15768 Threshold value (µg/L)
Group A Pipes and their linings	Domestic installations, buildings (Ø < 80 mm)	1	20	0.05	5* 14 40	0.75 2.1 6	2
	Service piping (80 mm ≤ Ø < 300 mm)	1	10	0.1	5* 7 40	1.5 2.1 12	2
	Mains piping (Ø ≥ 300 mm)	1	5	0.2	5 40	3 24	2
Group B Fittings and ancillaries	Domestic installations, buildings (Ø < 80 mm)	1	4	0.25	5 40	3.75 30	2
	Service piping (80 mm ≤ Ø < 300 mm)	1	2	0.5	5 40	7.5 60	2
	Mains piping (Ø ≥ 300 mm)	1	1	1	5 40	15 120	2
Group C Components of fittings and ancillaries	Domestic installations, buildings (Ø < 80 mm)	1	0.4	2.5	5 40	37.5 300	2
	Service piping (80 mm ≤ Ø < 300 mm)	1	0.2	5	5 40	75 600	2
	Mains piping (Ø ≥ 300 mm)	1	0.1	10	5 40	150 1200	2
Group D Storage systems	In domestic installations, buildings	1	4	0.25	5 40	3.75 30	2
	In water supply	1	1	1	5 40	15 120	2
Group E Repair products for storage systems	In domestic installations, buildings – Products covering the total surface or a substantial part of that	1	4	0.25	5 40	3.75 30	2
	In domestic installations, buildings – Products covering less than 1 % of the total surface	1	0.04	25	5 40	375 3000	2
	In water supply – Products covering the total surface or a substantial part of that	1	1	1	5 40	15 120	2
	In water supply – Products covering less than 1 % of the total surface	1	0.01	100	5 40	1500 12000	2

***** S/V ratio values where the MTC_{tap} of 1 µg/L cannot be verified due to analytical constraints.