The Director General

Maisons-Alfort, 5 February 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 water intended for human consumption (PDW) – Procedures for assessing the formulation

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 4MS's[1]) are working together within the scope of the regulations on products coming into contact with drinking water (PDW). The aim is to adopt common or directly comparable practices for the acceptance of the constituents used in the manufacture of PDWs (eventual use of a common positive list (PL)), for examining the formulation (% of tolerable non-compliance of the formulation with the common PL), for migration testing and analysis of parameters in the water used in the migration tests (in accordance with European standards), and for the setting of acceptance criteria (using shared conversion factors) (4MS, 2011).

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 of 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 water intended for human consumption (PDW):

- procedures for assessing the formulation (the subject of this formal request),
- parameters to be analyzed in the migration waters after the migration tests and acceptance criteria (see Request no 2012-SA-0114).

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

- can a mass concentration value be defined for all organic materials (plastic, rubber, coatings, etc.) and articles (pipes, tanks, fittings, joints, etc.), below which the substances in the formulation are no longer required to comply with the positive

[1] *4MS = 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.

lists, as has already been proposed by the Agency for adhesives and lubricants (ANSES, 2010a; ANSES, 2010b)?
- if so, what would this threshold of compliance be and how is it defined?

The DGS also asked ANSES to analyse proposals made by a trade union.

1. BACKGROUND AND PURPOSE OF THE REQUEST

Some materials and products, when in contact with drinking water (PDW), 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 water intended for human consumption (WIHC).

Although this Directive on the quality of WIHC (see Article 10) and Regulation (EU) No 305/2011 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 placing on the market of materials and products intended to come into contact with WIHC, 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, products (possibly reinforced by fibres) and accessories 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, products and ancillaries, 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 regulatory requirements.

[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*).

The CAS is issued on condition that:

- substances used to manufacture the material are included in the positive lists of substances authorised by the regulations (see the specific case of accessories in the table in Annex 1),
- the results of the migration tests carried out on the material comply with the acceptance criteria defined in the regulation.

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

The CAS is issued on condition that:

- the substances contained in the fibre are included in the positive lists of authorised substances and those used in the composition of 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 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 WIHC, as well as adhesives and lubricants, have already been addressed by specific Opinions (AFSSA, 2009a; AFSSA, 2009b; ANSES, 2010a; ANSES, 2010b).

Currently, three of the 4MS have positive lists (France, Netherlands and Germany). In France, qualification for the ACS or CLP depends on the principle that all substances used in the formulation of PDW must be included in the reference positive lists (see Annex 2). However in the Agency's recent Opinions and in the regulations, for specific materials and products, it has been accepted that a small proportion of the formulation may not be taken into account (see Annex 1). Similar provisions exist in the Netherlands and Germany (UBA, 2011)[3].

In the context of the 4MS's work, it has been acknowledged that a substance not included in the positive list of authorised substances for the manufacture of PDW may be accepted provided it can be demonstrated that the concentration of the substance expected in the consumer's tap water is lower than a reference value (0.1 µg/L currently proposed).

2. ORGANISATION OF THE EXPERT APPRAISAL

The expert appraisal was carried out in accordance with French standard NF X 50-110 "Quality in Expert Appraisals – 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 (WG PDW) that was set up on 21 December 2011.

[3] *In Germany these provisions are only applicable to catalysts and initiators; spin finish of yarns and fabrics; sizing for filling materials, especially glass fibres; solvents for additives and other accessory agents.*

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 8 January 2013.

3. ANALYSIS AND CONCLUSIONS OF THE CES ON WATER

Substances used in the formulation of materials must be known in full and compared to substances included in the positive lists.

In principle, all substances used in the formulation of materials must be included in the positive lists. However, the use of substances not included in the positive lists may be tolerated, provided there is no risk of migration into water above an acceptable concentration at the consumer's tap.

The method used to define the acceptable percentage of non-compliance requires the definition of a maximum tolerable concentration at the consumer's tap (MTC_{tap}), and a calculation method for defining the maximum amount of the substance in the material corresponding to this MTC_{tap}.

3.1. Position on the maximum allowable concentration in the consumer's tap

Although the limit of 0.1 µg/L at the consumer's tap (MTC_{tap}) was selected as part of the 4MS's work, the need for better scientific justification for this value was emphasised, with regard to further discussions on the approach for the threshold of toxicological concern (TTC).

In Germany, the Federal Environment Agency (UBA[4]) and the Federal Ministry of Health and Social Security (BMGS[5]) recommend a pragmatic "health-based parametric value (HPV)" of 0.1 µg/L based on a cancer potency factor of 10^{-6} for most non-threshold toxic substances. This maximum value is a precautionary value for substances for which an assessment based on toxicological data is not possible. For "highly" genotoxic substances (primary genotoxicity leading to guideline values which may be below 0.1 µg/L), the duration of exposure to this value should not exceed 10 years (UBA, 2003; Dieter, 2003).

ANSES used the TTC approach with a threshold of 1.5 µg per person and per day to determine the tolerable percentage by weight of non-compliance of formulation for adhesives and lubricants (ANSES, 2010a; ANSES, 2010b). This was established assuming that 10% of unidentified substances are carcinogenic and that one third of daily intake comes from solid foods (0.5 µg per person and per day) and the rest from drinks (1 µg per person and per day) (Kroes *et al.,* 2004; Rulis, 1986). It considered that for a daily consumption of 2 litres of water, the TTC approach led to a maximum value in WIHC of 0.5 µg/L. In addition, the acceptance criteria for the migration tests state that if CMR[6] substances are present, they should not exceed 0.1 µg/L in WIHC.

[4] *Umwelt Bundes Amt für mensch und umwelt.*

[5] *Bundesministerium für Gesundheit.*

[6] *Substances included on the lists of carcinogenic, mutagenic and reprotoxic substances (CMR) that have undergone harmonised European classification.*

Assuming that the unknown substance is a potential carcinogen, the threshold of the TTC approach of 0.15 µg per person and per day was applied. The above reasoning concerning daily intakes would lead to a maximum value in WIHC of 0.05 µg/L. The 4MS's proposal to set to 0.1 µg/L the maximum tolerable concentration at the consumer's tap (MTC_{tap}) for an unknown substance can be accepted given the small excess risk (2.10^{-6}).

3.2. Position on methods of predicting migration

The migration level of a substance in a material into the water it comes into contact with must be evaluated in order to compare it with the MTC_{tap} that was adopted (0.1 µg/L).

It can be estimated by calculation or modelling.

3.2.1. Calculation methods

Methods involving calculation only consider the dissolving of the material by the water penetrating it, whereas migration involves many other phenomena that can only be taken into account by modelling (Briand, 2007).

3.2.1.1. French approach (DGS, 1999; ANSES, 2010a; ANSES, 2010b)

The amount of substance that can migrate corresponds to the "wettable" part of the material, which depends on its chemical nature.

Therefore, if:
- **e** (in metres) is the thickness of the "wettable" material[7],
- **S** (in m^2) is the surface area of the material,
- **d** (in kg/m^3) is the density of the material,
- **p** (in %) is the percentage by weight of the substance in the material,

then the mass **m** (in kg) of this substance liable to migrate into the water is:

$$m = \frac{S.e.d.p}{100}$$

- If the substance migrated all at once, its concentration in the water would be:

$$C_1\,(kg/m^3) = \frac{S.e.d.p}{100.V} \qquad \text{or} \qquad C_1(\mu g/L) = \frac{S}{V}.e.d.p.10^4$$

where **S/V** (in m^{-1}) is the ratio of surface area of exposed material relative to the volume of water[8].

[7] *The term "wetted thickness" does not correspond to any identified property of the organic materials, in the remainder of the document it will be replaced by the term "water-material interaction zone".*

[8] *the S/V ratios defined in the DGS's Practical Guide are those recommended for conducting migration tests according to the XP P 41-250-2 Standard.*

- If the substance did not migrate massively and all at once, but gradually over 100 days (which is closer to reality), its concentration in the water would be:

$$C_2(\mu g / L) = \frac{S}{V}.e.d.p.10^2$$

Therefore the percentage by weight of a substance in a material corresponding to a given concentration C_2 in the water would be:

$$p(\%) = \frac{C_2.10^{-2}}{S/V.e.d}$$

This last equation is used by the authorised laboratories to verify compliance with the specific migration limits (SMLs) defined in the positive lists.

3.2.1.2. German approach (UBA, 2011)

The amount of substance liable to migrate is calculated on the assumption that all of the substance in the material, i.e. 100%, can migrate:

$$M = Q.O/V.L_p.D$$

where:

- **M** (in mg/L) is the maximum possible migration of the substance,
- **Q** (in mg/kg of polymer) is the quantity of substance in the finished product,
- **O/V** (in dm^{-1}) is the ratio of surface area of the material/volume of water,
- **Lp** (in dm) is the thickness of the product,
- **D** (in g/cm^3) is the density of the product.

This then determines the maximum amount of substance in the finished product corresponding to maximum migration (M) of 0.1 µg/L.

Three differences are worth noting compared to the French approach:

- the total thickness of the material is taken into account (Lp),
- the calculation is performed using the residual amount of the substance in the finished product (Q), whereas in the French approach, the percentage by weight of the substance in the formulation (p) is used without taking the manufacturing process into account,
- all of the migration takes place during the first period of contact with the water, whereas the French approach assumes migration over a period of 100 days.

3.2.1.3. Proposal

It is difficult to compare the two approaches because of a lack of data on the relationship between the initial concentration of a substance in a formulation and its residual level in the finished material.

It is more relevant to take the residual concentration of the substance in the material into account in the calculation, however this may lead to difficulties in determining extraction yield, detection limit, etc..

Moreover, the assumption that a substance migrates all at once and for the whole thickness, leads to migration being overestimated.

The results obtained by the two approaches on actual cases should be compared, in order to determine which is the most relevant.

In the meantime, the French approach, which can be applied to all cases, should be favoured.

However, the values associated with certain parameters should be changed (see Annex 3):

- the DGS's Practical Guide of 1999 sets values for the water-material interaction zone (t) of 0.05 or 0.1 mm depending on the material. The experts propose retaining the 0.1 mm value for this parameter and for all organic materials. In the event that a thickness is less than 0.1 mm, the entire thickness should be taken into account;
- the S/V ratios to be used are those adopted by the 4MS that correspond to real situations (4MS, 2011);
- the density of the materials will be as specified by the manufacturer.

3.2.2. Modelling (pr CEN/TR 16364; UBA, 2008)

The pr CEN TR 16364 draft technical report and the UBA guidelines (UBA, 2008) describe predictive diffusion models that seek to estimate the migration of substances contained in materials placed in contact with water.

Use of these models requires detailed knowledge of the diffusion behaviour of the materials and substances being investigated.

The basic assumption is that the process of migration of the substance contained in the organic materials obeys the laws of diffusion (Fick's second law).

Application of these models requires an understanding of the diffusion coefficient of the studied substance in the material, and the partition coefficients between the material and the water.

When the basic assumptions have been verified and the constants are known or can be estimated, these models estimate the substance's migration into the water as a function of time, which is closer to reality than with the methods described in Sections 3.2.1.1. and 3.2.1.2.

Unlike the formulas described in Sections 3.2.1.1. and 3.2.1.2, which can be generalised to all substances and materials, the diffusion models can only be applied to specific cases.

3.3. Analysis of proposals made by a trade union

A trade union proposed a health risk assessment methodology based on the TTC approach and a threshold of investigation of the material's formulation below which compliance with the positive lists would no longer be required (see Annex 4).

The MTC_{tap} should not be determined on a case-by-case basis depending on the TTC defined according to the Cramer Tree (Cramer *et al.,* 1978; AFSSA, 2005a) or the tolerable daily intake (TDI) of the substance, because it also needs to be applicable to

commercial mixtures for which the detail of the specific formulation would not be required (see Annex 1).

The choice of TDI and software used to establish the structure-activity relationships ((Q)SAR: Quantitative Structure-Activity Relationship), and its adaptation to the substance[9] should not fall under the responsibility of the authorised laboratories in charge of issuing the ACSs.

The calculation method proposed complies with that described in Section 3.2.1.1., but it must be applied using the MTC_{tap} of 0.1 µg/L and the S/V ratios defined by the 4MS (4MS, 2011).

3.4. Conclusion and recommendations

The CES on Water:

- recalls that the substances used in the formulation of materials must be known in full and compared to the substances included in the positive lists of authorised substances for the manufacture of PDW;

- considers that the value of 0.1 µg/L in water supplied to the consumer's tap, proposed by the 4MS group for an unknown substance, can be used as the maximum tolerated concentration;

- considers that a substance not included in the positive lists may be accepted, provided it has been demonstrated that its migration is less than 0.1 µg/L;

- notes that the assessing of migration by modelling cannot be generalised for all substances;

- recommends comparing the results of the calculation approaches developed in France and Germany, using practical examples;

- advocates, in the meantime, using the French calculation method (DGS, 1999) that can be applied to all cases;

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[9] *In its Opinion No 2011-SA-0081 (ANSES, 2011), ANSES states that:*
"For a theoretical level of exposure (TLE) of less than 0.5 µg/person/day: The applicant may request a waiver from the genotoxicity tests, subject to the lack of genotoxic potential being demonstrated in silico. The applicant shall develop its arguments in a specific dossier. A structure-activity relationship ((Q)SAR) method may only be used if:

- *It is scientifically recognised (e.g. DEREK, MultiCASE);*
- *The substance falls within the scope of the method;*
- *Adequate and reliable documentation on the method is provided.*

The applicant shall be asked to present the results from two different software packages. Any available genotoxicity assessment studies should still be provided. In the event that genotoxic potential cannot be ruled out, the situation described for a TLE of more than 0.5 µg/person/day should be followed. In the light of the data provided by the applicant, the standard dossier may, however, be required."

In addition, the different existing software packages and their scope are listed in the report by the JRC - European Commission and the IHCP (EFSA, 2010).

- recommends setting the water-material interaction zone to 0.1 mm for this calculation, regardless of the material. If the thickness is less than 0.1 mm, the entire thickness shall be taken into account;

- recommends using the S/V ratios adopted by the 4MS (4MS, 2011).

4. ANSES CONCLUSIONS AND RECOMMENDATIONS

The French Agency for Food, Environmental and Occupational Health & Safety hereby endorses the conclusion and recommendations of the CES on Water.

The Director General

Marc Mortureux

KEY WORDS

Water intended for human consumption, materials in contact with water, organic materials, percentage of non-compliance of the formulation.

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accessories, made of organic materials coming into contact with water intended for human consumption (published in the Official Bulletin of the Ministry of Health No. 2002/52).

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ANNEX 1: PERCENTAGES OF NON-COMPLIANCE (%NC) TOLERATED IN RECENT AGENCY OPINIONS AND REGULATIONS FOR SPECIFIC MATERIALS AND PRODUCTS

Material	%NC	Rationale
Adhesives (ANSES Report from 2010)	0.5 %	The TTC[10] approach with a threshold of 1.5 µg per person and per day was used. This threshold was established assuming that 1/3 of daily intake comes from solid foods (0.5 µg per person and per day) and 2/3 from drinks (1 µg per person and per day). Thus, for a daily consumption of 2 litres of water the TTC approach leads to a maximum value in WIHC of 0.5 µg/L. The equation in the DGS's Practical Guide of 1999 was used to calculate the maximum percentage by weight of a substance (p) in an adhesive so that its migration (C_2) is below the acceptance criterion (gradual migration over 100 days): $p(\%) = \frac{C_2 . 10^{-2}}{S/V . e . d}$ Conversion factors (CF) were established according to the assumptions of the 4MS. Considering that assembly by bonding primarily takes place in indoor systems and that, in the worst case, over 1 linear metre of pipes there are 3 fittings corresponding to 6 bonding points, the actual S/V ratio was estimated at 14 and 17 cm^2/L for a residence time of 0.5 day (CF = 0.05): $C_{2(\text{in the test water})} = C_{2(\text{at the tap})} / CF$
Lubricants (ANSES Report from 2010)	0.5 %	The TTC approach with a threshold of 1.5 µg per person and per day was used. This threshold was established assuming that 1/3 of daily intake comes from solid foods (0.5 µg per person and per day) and 2/3 from drinks (1 µg per person and per day). Thus, for a daily consumption of 2 litres of water the TTC approach leads to a maximum value in WIHC of 0.5 µg/L. The equation in the DGS's Practical Guide of 1999 was used to calculate the maximum percentage by weight of a substance (p) in a lubricant so that its migration (C_2) is below the acceptance criterion (gradual migration over 100 days): $p(\%) = \frac{C_2 . 10^{-2}}{S/V . e . d}$ Conversion factors (CF) were established according to the assumptions of the 4MS. In view of the possible uses of lubricants, the selected use was help in assembling pipes in an indoor system, and as in the worst case, over 1 linear metre of pipes there are 3 fittings corresponding to 6 bonding points, the actual S/V ratio was estimated at 14 cm^2/L and the residence time 0.5 day. (CF = 0.1): $C_{2(\text{in the test water})} = C_{2(\text{at the tap})} / CF$
Resins (AFSSA Report from 2009)	< 0.1 % Between 0.1 % and 1 %	If the concentration of the substance is <0.1% of the dry weight of the resin (finished product), it is authorised for inclusion in the formulation. If the concentration of the substance is between 0.1% and 1% of the dry weight of the resin (finished product), it must undergo specific monitoring according to a validated method during migration testing (screened for in each of the four sample collections provided for in the test protocol).
Membranes (AFSSA Report from 2009 and Ministerial Order of 22 June 2012)	Depends on the percentage of the total wetted organic surface area of the module's component parts	Case 1: % of the total wetted organic surface area < 0.1 % → Verification of the formulation not required. Case 2: % of the total wetted organic surface area between 0.1 and 1 % → 90 % minimum compliance of the formulation. Case 3: % of the total wetted organic surface area > 1 % → 100 % compliance of the formulation. The sum of the parts taken into account in cases 1 and 2 should not exceed 5% of the total wetted organic surface area.

[10] *Threshold of Toxicological Concern.*

Organic materials reinforced by fibres (AFSSA Opinion of 2005b and Circular of 21 August 2006)	Between 0 % and 100 % for the sizing agent	To obtain a CAS, 100% of the fibre's formulation must be compliant with the positive lists and the substances in the sizing agent's composition must be known but not necessarily included in the positive list.
Ancillaries (Circular of 25 November 2002)	Between 0 and 50 % of the wetted organic surface area	Case A: 100 % of the wetted surface area complies with the regulations → no migration testing required. Case B: 95 % of the wetted surface area complies with the regulations and the remaining 5 % are authorised in Germany, Netherlands, the United Kingdom or Belgium → no migration testing required. Case C1: More than 80 % of the wetted organic surface area has a compliant formulation → Class 1 migration tests. Case C2: More than 50 % of the wetted organic surface area has a compliant formulation and the remainder has an ACS → Class 1 migration tests. Case C3: Between 50 and 80 % of the wetted organic surface area has a compliant formulation → Class 2 migration tests. Case D: The wetted organic surface area of unknown formulation accounts for less than 5 % of the total wetted surface area and the remainder is metallic in nature → Class 2 migration tests.

In addition, Article 11 of Regulation (EC) No 1272/2008 of 16 December 2008 (the CLP Regulation) sets at 0.1% the generic cut-off value requiring a substance to be taken into account, whether it is in the form of an impurity, additive or individual constituent identified, for classification of a substance or a mixture[11].

The mass concentration, below which substances in the formulation may no longer be required to comply with the positive lists, corresponds to:

- known substances not included in the positive reference lists,
- commercial mixtures for which the detail of the specific formulation is not required due to the low percentage included in the formulation of the finished product.

[11] *However, some substances may have much lower thresholds.*

ANNEX 2: POSITIVE REFERENCE LISTS

The substances should be included in the following lists:

- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

- The "4MS Combined Positive List"[12], provided that they are authorised in France[13].

- Council of Europe Resolution AP (92)2 on control of aids to polymerisation that introduce and influence directly the formation of polymers, provided that the maximum amounts of starting materials used remain below 1% by mass[13].

- Consolidated Circular no 176 of 2 December 1959 as amended, relating to pigments and dyes for plastic materials and packaging, provided that they comply with the purity criteria mentioned in the draft Ministerial Order notified to the European Commission under the reference 2004/328/F[14].

[12] *www.umweltbundesamt.de/wasser-e/themen/downloads/trinkwasser/4ms_combined_positive_list.pdf*

[13] *Only usable during the transitional period until publication of the "4MS Core List".*

[14] *Draft Ministerial Order on the colouring of plastic materials and articles, varnishes and coatings intended to come into contact with foodstuffs, products and beverages for food and feed notified to the European Commission under the reference 2004/328/F: http://ec.europa.eu/enterprise/tris/index_fr.htm*

ANNEX 3: MAXIMUM PERCENTAGE BY WEIGHT (P) OF A CONSTITUENT IN A MATERIAL SO THAT THE CALCULATED CONCENTRATION IN WATER AFTER MIGRATION (C_2) IS LESS THAN 0.1 µg/L

Product categories		S/V in dm^{-1}	S/V in m^{-1}	$p(\%) = \frac{C_2.10^{-2}}{S/V.e.d}$ C_2 = 0.1 µg/L e = 0.0001 m
Group A Pipes and their linings	Domestic installations, buildings (Ø < 80 mm)	40	400	**0.025 / d**
	Service piping (80 mm ≤ Ø < 300 mm)	5	50	**0.2 / d**
	Mains piping (Ø ≥ 300 mm)	1.33	13.3	**0.75 / d**
Group B Fittings and accessories	Domestic installations, buildings (Ø < 80 mm)	8	80	**0.125 / d**
	Service piping (80 mm ≤ Ø < 300 mm)	1	10	**1 / d**
	Mains piping (Ø ≥ 300 mm)	0.25	2.5	**4 / d**
Group C Parts for fittings and ancillaries	Domestic installations, buildings (Ø < 80 mm)	0.8	8	**1.25 / d**
	Service piping (80 mm ≤ Ø < 300 mm)	0.1	1	**10 / d**
	Mains piping (Ø ≥ 300 mm)	0.025	0.25	**40 / d**
Group D Storage systems	In domestic installations, buildings	4	40	**0.25 / d**
	In water supply	0.25	2.5	**4 / d**
Group E Repair products for storage systems	In domestic installations, buildings– Products covering the total surface or a substantial part of that (e.g. coatings)	4	40	**0. 25 / d**
	In domestic installations, buildings– Products covering less than 1 % of the total surface	0.04	0.4	**25 / d**
	In water supply – Products covering the total surface or a substantial part of that (e.g. coatings)	0.25	2.5	**4 / d**
	In water supply – Products covering less than 1 % of the total surface	0.0025	0.025	**400 / d**

Where **d** is the density of the material considered in kg/m^3 (data provided by the manufacturer).

ANNEX 4: PROPOSAL FROM A TRADE UNION

The trade union:

- applied its methodology to three substances as an example,
- generalised its methodology to all the substances and proposed a threshold of investigation for the material's formulation below which compliance with the positive lists would not be required.

Health risk assessment methodology applied to three substances as an example

The methodology was applied to a solvent used as a catalyst stabiliser (substance 1), a surfactant (substance 2) and a preservative (substance 3).

The migration level of the substances was calculated using the method recommended in the DGS's Practical Guide of 1999 (total migration in 100 days from the wettable thickness). In addition, substance 1 was measured according to the XP P 41-250-2 Standard.

The TTC value of the three substances was determined using a single (Q)SAR (Quantitative Structure-Activity Relationship) software package, in this case Toxtree. A specific migration limit suited to PDW (SML_{TTC-DW})[15] was calculated assuming that drinking water contributed by default 10% of the value of the TTC for conventional daily consumption of 2 litres of water.

When toxicological data on the substance were available, an SML suited to PDW (SML_{DW})[14] was calculated assuming that drinking water contributes by default 10% of the tolerable daily intake (TDI) for conventional daily consumption of 2 litres of water.

Table I: Summary of evaluations of the three substances (S/V=24 m^{-1} and e=0.0001 m)

Substance	Amount in the formulation of the material (%)	Cramer class determined using Toxtree	SML_{TTC-DW} (µg/L)	SML_{DW} (µg/L)	Migration according to the method in the DGS Practical Guide of 1999 (µg/L)	Migration measured according to the XP P 41-250-2 Standard (µg/L)
1	0.1 0.05	I	90	9900	33.6	0.2
2	0.03	III	4.5	4650	10.6	-
3	0.00001425	III	4.5	60	0.00513	-

Proposed threshold of investigation for the material's formulation below which compliance with the positive lists would not be required

The trade union states that it tested the Toxtree software on 62 polymerisation aids (PAs), for some thirty substances for which there was a tolerable daily intake (TDI), the TTC was always well below the TDI. However, the software categorises CMRs in Class III, and the trade union recommends first ensuring that the substance shows no warning signs of a possible carcinogenic and/or genotoxic effect and is not an organophosphate, as well as conducting a literature search on the substance's toxicity in order to use actual TDI values.

[15] The SML_{TTc-DW} and SML_{DW} correspond to the MTC_{tap}.

The trade union offers two thresholds of investigation for substances used in the composition of a material, depending on whether the selected limit at the consumer's tap is 1 µg/L (regulatory threshold for PDW) or 0.15 µg/L (TTC of genotoxic substances without applying the division factor corresponding to the fraction of consumption provided by water) using the method recommended in the DGS's Practical Guide of 1999:

Table II: Proposed tolerated thresholds of non-compliance

Threshold used at the consumer's tap in µg/L	**p (concentration in the material) in ppm (S/V=24 m^{-1} and e=0.0001 m)**		**p (ppm)**
	PVC (d=1400 kg/m^3)	**HDPE (d=960 kg/m^3)**	
1	29.8 (0.003 %)	43.4 (0.004 %)	41666.7/d (4.17/d %)
0.15	4.5 (0.00045 %)	6.5 (0.00065 %)	6250/d (0.625/d %)