Positive Lists for Organic Materials

4MS Common Approach

Part A – Compilation and management of a suite of Positive Lists (PLs) for organic materials
Part B – Assessment of products for compliance with Positive List requirements (Conversion Factors - CFs)

Adopted by the 4MS Joint Management Committee

France, Germany, the Netherlands and the United Kingdom (4MS) work together in the framework of the 4MS Common Approach. This common approach aims for convergence of the respective national approval schemes for materials and products in contact with drinking water.

The 4MS have adopted this document as a common basis for implementing the concept of positive lists for the assessment of organic materials in their national regulations. The document is subject to revisions agreed by the 4MS.

As a next step, the 4MS will prepare a suite of common Positive Lists.

Further information may be obtained from any of the competent authorities of the 4MS.

Bundesministerium für Gesundheit (Deutschland)
Ministère de la Santé et des Sports (France)
Ministerie van Infrastructuur en Milieu (Nederland)
Department for Environment, Food and Rural Affairs (United Kingdom)

Version December 16, 2011

Introduction

This document has been prepared in accordance with the 4MS agreement on co-operation concerning convergence and mutual recognition.

The document deals with two separate but related topics:

Part A - a compilation and management of a suite of Positive lists for organic materials, and
Part B - the assessment of products for compliance with Positive lists requirements (conversion factors)

Part A of this document describes the procedure leading to the acceptance of monomers, other starting substances, additives, polymer production aids (PPAs) and aids to polymerization (APs) to be used for the manufacture of an organic material from which a product coming into contact with drinking water (PDWs) is (partly) made. In addition, this procedure shall be used for the toxicological assessment of substances of constituents of cementitious products. Part A is composed out of information from the National Approval Systems of France, Germany, The Netherlands and UK.

Part B describes the conversion factors used to achieve a comparison between the results of the experimental migration test with the relevant migration limit mentioned in the Positive list.

This document is derived from:

- the EAS proposal mentioned in RG-CPDW 188, RG-CPDW 188 Annex 2 and RG-CPDW 186;
- German UBA-guidelines: http://www.umweltbundesamt.de/wasser/themen/trinkwasser/verteilung.htm;
- the French procedure described in The Public Health Code and Order of May 29, 1997, as well as information distributed by AFSSA during the 4MS adhoc group meeting on positive lists and conversion factors on18 September 2008 at Rijswijk (opinion and report on positive lists of substances used in the composition of materials in contact with water for human consumption – September 2007);
- the Dutch Regulation *Materials and chemicals in contact with drinking water and warm tap water* of June 29, 2011 (Dutch Official Gazette 2011, nr. 11911);
- information on the UK approval procedure (case-by-case assessments).

In its final form this document will be:

- Submitted to the 4MS drinking water regulators as the basis for adoption at the national level. Plans will be drawn up for the compilation of the 4MS Core List (see section 1.2.1);
- Provided to the European Commission as information relevant to the work ongoing under the Construction Products Directive to harmonize notified national regulation for the approval of products in contact with drinking water;
- Made available to other Member States to inform them of the actions of the 4MS to regulate organic substances under Article 10 of the Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption (DWD).

The 4MS would be happy to share their experience and practical knowledge in the hope that it will help to promote a wider, harmonized approach to the acceptance of organic substances.

Abbreviations

AFSSA – Agence Française de Sécurité Sanitaire des Aliments
AP - Aids to Polymerization
BfR - Bundesinstitut für Risikobewertung
BMD – benchmark dose
BMDL – lower confidence limit of the BMD
BMR – benchmark respons
C_n – Concentration of a measured substance for the n^{th} migration period
C_{tap} – The calculated concentration of a substance at the tap
CAS – Chemical Abstracts Service
CF – Conversion Factor
DNA - Deoxyribonucleic acid
DVGW – Deutsche Vereinigung des Gas- und Wasserfaches e.V
DW – Drinking Water
DWD – Council Directive 98/83/EC - Drinking Water Directive
DWPL – Drinking Water Positive List
DWPLL – Drinking Water Positive List Limit: MTC_{tap}, $MTC(T)_{tap}$, QM or QMA
EAS – European Acceptance Scheme
EC – European Commission
EFSA – European Food Safety Authority
EINECS – European Inventory of Existing Commercial chemical Substances
EN – European Standard (French: Norme, German: Norm)
F_f – Fraction or reduction factor
F_g – Geometrical factor
F_o – Operational factor
GC-MS - Gas Chromatography-Mass Spectrometry
ID – Internal Diameter
LOAEL – Lowest-Observed-Adverse-Effect Level
M_n – Migration rate for the n^{th} migration period
MC – Management Committee (4MS Common Approach)
MS – Member State
MTC_{tap} – Maximum Tolerable Concentration at the tap
$MTC(T)_{tap}$ – Maximum Tolerable Concentration of a group of substances at the tap
n – Sequence number of the migration period
NAS – National Approval System
NOAEL – No-Observed-Adverse-Effect Level
PDW – Product coming into contact with Drinking Water
PL – Positive List
PPA - Polymer Production Aids
QM – see definitions
QMA – see definitions
RG-CPDW – Regulators Group on Construction Products in contact with Drinking Water
SCF – Scientific Committee on Food
SGOM – 4MS Subgroup Organic Materials
SML – Specific Migration Limit
S/V – Surface area-to-volume ratio
t – Duration of the migration period in days
TDI – Tolerable Daily Intake
TOC – Total Organic Carbon
TTC – Threshold of Toxicological Concern
UBA – Umweltbundesamt
UF – Uncertainty Factor
WHO – World Health Organization

Definitions

Additive
An additive is a substance which is intentionally *added* to plastics to achieve a physical or chemical effect during processing of the plastic or in the finished material or article. It is intended to be present in the finished materials or articles.

Aids to Polymerization (AP)
Aids to polymerisation means substances which initiate the polymerisation reaction and control the macromolecular structure of the polymer.

Article
Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

Component (or sub-assembly)
A part manufactured out of a specific composition, brought to the market as a product, part of an assembled product, or as a spare part. For drinking water applications, components may be considered as products and be individually approved (e.g. o-ring, gasket) or they are tested in the finished product (e.g. in a valve).

Composite materials
Materials comprising different constituents which are mixed and bonded together but remain separately identifiable.

Composition
The description of the nature and proportions of different substances found within a material.

Compound
A substance formed from one or more elements chemically united in fixed proportions.

Constituent
1. Organic materials: Ingredient used to make a material or product.
2. Cementitious products: Mineral or preparation used to make a cementitious material or product and is defined in a technical specification

NOTE Most constituents are classified as construction products under the ConstructionProducts Directive

Drinking Water Positive List Limit
Restriction on the use of a positive list substance expressed as MTC_{tap}, $MTC(T)_{tap}$, QM or QMA

Formulation
See Composition.

Material
Prepared form of a substance, or of a combination of substances, suitable for use in a manufacturing process; it can be metallic, organic or mineral.

Material category
Sub-types within a material type, e.g. steel, iron, copper within metallic materials**.**

Material type
Category of materials of similar physical/chemical characteristics (e.g. organic, metallic).

Maximum Tolerable Concentration at the tap (MTC_{tap})
The maximum tolerable concentration at the tap is the maximum permitted amount of a substance in drinking water that should ensure that the material in contact with drinking water does not pose a risk to health.

Monomer
Monomer and starting substances mean the following type of substances:
- substances undergoing any type of polymerization process to manufacture polymers,
- natural or synthetic macromolecular substances used in the manufacture of modified macromolecules,
- substances used to modify existing natural or synthetic macromolecules

Polymer
Polymer means a substance consisting of molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer.

Polymer Production Aids
Polymer production aids (PPA) means any substance used to provide a suitable medium for polymers and plastic manufacturing. They may be present but are neither intended to be present in the finished materials or articles nor have a physical or chemical effect in the final materials or articles.

Preparation
A mixture or solution composed of two or more substances or sub-part of a material composition, containing several substances, usually called preparation in the case of organic materials and constituent in the case of mineral materials.

Product
Clearly identified manufactured item, in its finished form, that comes into contact with water intended for human consumption, or a component part of a manufactured item. A product can be homogeneous, non-homogeneous or may also consist of multiple components made out of one single or different compositions (e.g. a valve).. A homogeneous product is a product where the water contact surface is made from the same material as the remainder of the product (e.g. a solid wall pipe), whereas a non-homogeneous product is a product where the water contact surface is made from a material that differs from those comprising the remainder of the product (e.g. multilayered pipes).
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Type of products
- *Single material products*.
- *Assembled products*. These products comprise two or more components, possibly of different materials.
- *Multi-layer products*. These products comprises two or more layers bonded together to form a single item.

- *Formulated products*. These products are created by chemical processing after which the original constituents are no longer identifiable, e.g. lubricants and glues
- *Site applied products*. Products such as coatings and linings are placed on the market as ingredients that will be mixed and applied on site.

QM
Maximum permitted quantity of the 'residual' substance in the finished material or article expressed as mg/kg of polymer.

QMA
Maximum permitted quantity of the 'residual' substance in the finished material or article expressed as mg per dm^2 of the surface in contact with drinking water.

Substance
a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition or basic element of a material composition, which can be identified by its chemical structure (e.g. CAS or EINECS number).

Supporting documents
Making reference to the European Food Contact legislation, supporting documents are documents in which results of the self-assessment by industry of PPAs, APs, reaction/degradation products will be reported. For full transparency, such documents should be made available to the authorities on request.

Part A – Compilation and management of a suite of Positive Lists (PLs) for organic materials

1 Positive lists (PLs)

1.1 Principles and approach

A PL consists of the substances approved for the production of a certain organic material used in PDWs.

For the listing of a substance an assessment of the substance including its toxicological evaluation and its possible reaction products is required. As a result of the assessment a substances may be restricted in form of a limit value in the drinking water (DWPLL: MTC_{tap} or $MTC(T)_{tap}$) or its use within the material is restricted in form of a QM or QMA.

The 4MS have compared their current practices for the assessment of substances and the use of positive lists and have identified some shared principles on which to base their common approach:

- Practice for drinking water can be based on that already in operation at the European level for foodstuff positive lists (Commission Regulation (EU) No 10/2011, hereinafter referred to as: 10/2011/EC) and administered by EFSA.
- Substances appearing on the 10/2011/EC list can be regarded as acceptable for contact with drinking water, but with different arrangements for the calculation of migration limits (see section 3)
- When new substances are proposed for addition to the DWPLs, the preferred route to approval will be to subject them to EFSA assessment.
- Some substances and/or applications will mean that the EFSA process is not appropriate, and in such circumstances the 4MS will make their own assessment based on EFSA principles (see section 2)

They have also recognized that some of the substances on the current national lists have not been subject to full assessment in accordance with these principles. In the first instances only substances which are agreed as having been fully evaluated will form the **4MS Core Lists**. Other substances currently listed at the national level, and which are included in the so-called **Combined List**, can remain in use until 5 years from the date of issue of the Report, and during that time will be assessed for admission to the 4MS Core Lists.

1.2 Structure of positive lists

Based on the assessment of materials and articles intended to come into contact with foodstuff as laid down in 10/2011/EC and on daily practice concerning the assessment of PDWs in Germany, France, The Netherlands and the UK different PLs have to be applied for the following materials:

- Plastics
- Rubber products
- Coatings
- Lubricants

NOTE: A further separate positive list for silicones is proposed. Silicones are used as silicone rubber, as additive in other materials and as basic oils in lubricants. EFSA evaluates only the silicons used as an additive in food contact materials.

1.2.1 Plastics

The PL for plastics is divided into the following 3 sections:

1 General

Description of which substances are included or not included (but may be used or may be present in the end product such as salts of authorized acids, impurities[1], decomposition products), general restrictions such as TOC and chlorine demand, reference, CAS and EINECS numbers, list of abbreviations, etc..

2 Monomers, other starting substances, additives, polymer production aids (PPAs) and aids to polymerization (APs)

2.1 Monomers, other starting substances, additives, PPAs and APs which are EFSA assessed (Union list substances of 10/2011/EC). This information will be referred to but not reproduced.

2.2 Monomers, other starting substances, additives, PPAs and APs assessed by MS according to the EFSA rules. This so-called **4MS Plastics Core List** will be developed within a period of 5 years following coming into force of this Positive List 4 MS Common Approach as MS produce and agree "Opinions" on the acceptability of currently listed substances.
The structure of the 4MS Plastics Core list will follow that of the 10/2011/EC Union list.

2.3 Monomers, other starting substances, additives, PPAs and APs now accepted in the 4MS and mentioned in the so-called **Combined List**, which will be subject to review for transfer to the 4MS Core list under 2.2. Items on the national lists will continue to be accepted within that country until transferred to the 4MS Plastics Core List or another material specific 4MS Core List. Items not transferred will be deleted at the end of the 5 year transitional period.

3 Pigments and colorants
The current French list will provide the input to the reviews needed to gain 4MS acceptance**.**

1.2.2 Rubber products

In Germany the positive list for rubber products has been revised. The revised list has been sent to the European Commission for notification (Notification no. 2011/467/D). In The Netherlands the positive list for rubber products and the material based lists for plastics have been knocked into one. In view of the present document the 'old' positive list for rubber products will be re-established.

1.2.3 Coatings

The current German list will provide input to the reviews needed to gain 4MS acceptance.

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 give the following definition :
Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any **impurity** deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

1.2.4 Lubricants

The current German list will provide input to the reviews needed to gain 4MS acceptance.

2 Assessment of new substances

2.1 Non-EFSA assessed substances

Substances that cannot be subject to the EFSA assessment will have to be assessed according to the common procedure described below. There is not expected to be a large volume of such substances coming forward, but the process will also have to deal with the backlog of substances currently listed at the national level but which have not been subject to the level of evaluation now required. The procedure described below shall also be used for the assessment of additives (e.g. additions, admixtures, fibres) to cementitious products coming into contact with water intended for human consumption.

2.2 Common procedure

The common procedure will be based on the continued operation of national assessment systems, but with their outcomes subject to peer review by the other MS. Thus a manufacturer may approach a national regulatory body (or its appointed agencies) for evaluation of a new substance. There are obvious practical advantages for a manufacturer in the 4MS countries to work with his “home” assessment body, but he would not be required to do so. Applicants from outside the 4MS area would be free to use any of the national arrangements.

2.3 National arrangements

The national arrangements will continue to operate largely as at present, but instead of producing findings and recommendations for local decision, will create assessment information in common forms (Opinions) that embody the application of the EFSA principles. These draft opinions will be reviewed by the appropriate bodies within each of the other MS, who will offer their comments. When consensus is achieved, the substance will be added to the one of 4MS Core Lists.

> *Note: At some stage the 4MS will need to publish contact points and application arrangements, which will need review to ensure that they can deliver the information needed to meet the new common requirements.*

2.4 Required Information and Assessment Procedure

The assessment procedure to obtain the insertion of a new substance is based on the information mentioned in the SCF/EFSA Note for Guidance (http://www.efsa.europa.eu/en/scdocs/doc/21r.pdf). Consequently, the following information mentioned in chapter II of the Note for Guidance have to be supplied with for insertion of a substance into the positive lists:

1. **Identity of the substance**
   Name, synonyms, impurities, its breakdown and reaction products
2. **Physical and chemical properties**
3. **Intended use of the substance**
4. **Authorization of the substance**
   Information concerning authorization for use of the substance in EU Member States and other countries, e.g. USA, Japan
5. **Migration data on the substance**
6. **Microbiological properties of the substance**

7 Toxicological data

More details on the information required are mentioned in chapter III of the Note for Guidance.

NOTE: For PDWs the required information on the microbiological properties of a substance remains open for future discussion. As mentioned in the Note for Guidance evidence has to be provided that any migration is not intentional but only incidental. Dependent on national legislation the assessment of antimicrobial substances has to be carried out by bodies covered by a national Plant Protection Products and Biocides Act.

2.5 Some additional remarks on the assessment procedure

Data on the residual content of a substance in food contact materials as required according to the Note for Guidance is not relevant for inserting a substance into a positive list for PDW.

The migration of substances used to indicate whether or not the reduced core set of toxicological data, mentioned in chapter II of the Note for Guidance, may be applicable has to be determined in accordance with EN 12873 series for cold water (23°C). Data obtained with the EFSA migration testing as mentioned in the Note for Guidance may be used if the testing has been carried out with simulant A (distilled water or water of equivalent quality).

The reduced core set of toxicological data may be required if in the migration water of the 3rd migration period the expected concentration of a substance in drinking water, by using a conversion factor representing the worst case situation (CF=20 d/dm, see 5), is in the range from 2.5 – 250 µg/l. These values are converted from the values of 0.05 – 5 mg/kg food mentioned in the Note for Guidance, taking into account a 10% default value and a daily consumption of two litres of drinking water by a person weighing 60 kg (see 3.2).

In cases where the expected concentration in drinking water is below 2.5 µg/l information on the 3 genotoxicity tests mentioned in chapter III of the Note for Guidance may be sufficient. If a substance can be considered genotoxic then the MTC_{tap} for this substance is set at 0.1 µg/l (see 3.1.1 and 3.3).

Dependent on the chemical properties of a substance restrictions may also be expressed as a QM or QMA-value, the maximum permitted quantity of the 'residual' substance in the finished material or end product.

3 Determining the MTC_{tap}

3.1 Functional mechanisms of substances

Exposure to some substances can be associated with a variety of bodily dysfunctions which have health implications. The mechanisms of action of the substances causing these dysfunctions can be divided into two different groups: a stochastic (non-threshold) and a non-stochastic (threshold) mechanism of action.

3.1.1 Stochastic mechanism of action

With a stochastic mechanism of action the chance of a given effect occurring increases as the dose of the substance concerned increases (within a certain dose range). It is not generally possible to discern a threshold dose at or beneath which the change of the effect taking place is zero. Mechanisms of this type are generally associated with irreversible molecular-scale effects such as irreversible DNA changes. Examples of substances with a stochastic mechanism of action are acrylamide, vinyl chloride and epichloro hydrin. In general, for substances with a stochastic mechanism of action which are not mentioned in Directive 98/83/EC a MTC_{tap} of 0.1 µg/l is applicable.

3.1.2 Non-stochastic mechanism of action

With a non-stochastic or deterministic mechanism of action an adverse effect only takes place once the dose of the substance concerned exceeds a certain threshold level. Above that level the size of the effect will increase as the dose increases. For substances with a deterministic mechanism of action health-based recommended exposure limits (Tolerable Daily Intake – TDI) are calculated by dividing the No–Observed–Adverse–Effect Level (NOAEL) obtained in animal experiments by an assessment factor[2] (AF, see the REACH-R.8-Guideline[3]) accounting for interspecies uncertainty and intraspecies uncertainty and variability. Often an overall AF of 100 is used, although additional AFs may be required, e.g. for differences in exposure duration and deficiencies in the toxicological database. This results in the following formula:

$$\textbf{TDI (mg/kg body weight)} = \frac{\textbf{NOAEL (mg/kg body weight)}}{\textbf{Overall AF}}$$

The TDI is the basis for setting up a MTC_{tap} for substances with a deterministic mechanism of action.

If a NOAEL is not available, then the Lowest-Observed-Adverse-Effect Level (LOAEL) may be used. This has to be accounted for in calculating the overall AF (AF for LOAEL-to-NOAEL extrapolation).

[2] EFSA calls uncertainty factor, UF.

[3] "Guidance on information requirements and chemical safety assessment Chapter R.8: Characterization of dose [concentration]-response for human health" (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1319614960#r8).

In addition to the described NOAEL/LOAEL approach a generally accepted Benchmark Dose (BMD) method (EFSA, 2009)[4] may also be used to derive a MTC_{tap}, using software programs BMDS[5] of US-EPA or PROAST[6] of RIVM.

NOTE: In the BMD approach, first a dose–response model is fitted to the toxicity data. Subsequently, the (benchmark) dose is derived which corresponds to a predetermined percentage change in benchmark response (BMR) (compared to the background) in the case of continuous toxicity data (e.g. organ weights and blood enzyme concentrations). By default a BMR of 5% is used for continuous data. For quantal data (yes/no scores such as pathology results) the default BMR is 10% extra risk. When knowledge exists about the response resulting in a biological or toxicological relevant effect (in case of continuous responses) or when another incidence (for quantal effects) is considered more relevant, then the BMR can be adjusted accordingly.
The BMD is reported with its lower (5th percentile) and upper (95th percentile) confidence limits: BMDL and BMDU respectively. When multiple BMDLs are obtained from accepted models (P≥0,1 and smaller Akaike Information Criterion or according to the log-likelihood), then the lowest should be used as a point of departure for deriving the TDI, as follows:

$$\textbf{TDI (mg/kg body weight)} = \frac{\textbf{BMDL (mg/kg body weight)}}{\textbf{Overall AF}}$$

Using the BMD method an AF for LOAEL-to-NOAEL extrapolation is not necessary.

3.2 Allocation to drinking water (default values)

If appropriate information on levels of exposure to a substance from food, air and drinking water is not available, an allocation factor may be applied reflecting the likely contribution of drinking water to the TDI for this substance. In conformity with the derivation of limit values in EC Directive 98/83/EC (DWD) it has been agreed that, in the absence of adequate exposure data, the allocation of the TDI to drinking water should have an arbitrary (default) value of 10%. Deviations are possible if based on well-founded arguments.

Because exposure to the substances named in the DWD can take place via drinking water without this water having been in contact with products in which the same substances occur a supplementary provision has been drawn up to the effect that no more than 10% of the maximum value of the parameter with a non-stochastic mechanism of action named in the EC Directive 98/83/EC on health grounds may originate from a product that comes into contact with the drinking water. This means that for DWD parameters with a non-stochastic mechanism of action the allocation factor due to migration from products is 1%.

The Union list of substances of 10/2011/EC is the cornerstones for laying down a MTC_{tap}. In this list specific migration limits (SMLs) are laid down for a large number of substances. The SML is the maximum acceptable quantity of a substance (originating from packaging material) per kg food, assuming that an adult with a body weight of 60 kg consumes 1 kg food per day. When SMLs are laid down, exposure routes other than food are not taken into account. This means that the SML in this case corresponds with the TDI per person (mg/kg body weight converted into mg/person in the event of a daily intake of 1 kg food). Taking into account the abovementioned allocation for drinking

[4] EFSA (2009). Guidance of the Scientific Committee on a request from EFSA on the use of the benchmark dose approach in risk assessment. *The EFSA Journal*, Vol. 1150, pp. 1-72. www.efsa.europa.eu/en/efsajournal/doc/1150.pdf
[5] epa.gov/NCEA/bmds/
[6] www.proast.nl

water of 10% (default value) and a consumption of two litres drinking water per day, the SML is divided by a factor of 20 to arrive at a MTC_{tap}.

In practice, it can hardly ever be ascertained that exposure to a specific substance will solely take place via drinking water. The approach that drinking water may not contribute more than 10% of the TDI therefore applies, including for substances for which there are as yet no limit values in the EC Directives 98/83/EC and 10/2011/EC and for which a TDI and MTC_{tap} have to be derived (see 2.1, 2.2 and 2.3).

3.3 Arithmetical derivation of the MTC_{tap}

Based on what has been mentioned in 3.1 and 3.2 the following arithmetical derivations can be used.

(1) For substances with a stochastic mechanism of action:

MTC_{tap} = 0.1 µg/l

(2) For substances with a deterministic mechanism of action:

If for the relevant substance a parametric value in Directive 98/83/EC exists a MTC_{tap} can be derived according to formula A. If only a WHO Guideline value exists the MTC_{tap} is derived analogously.

A $$MTC_{tap}\ (mg/l) = \frac{\text{Parametric value in 98/83/EC (mg/l)}}{10}$$

If for the relevant substance a specific migration limit (SML) is mentioned in 10/2011/EC a MTC_{tap} can be derived according to formula B.

B $$MTC_{tap}\ (mg/l) = \frac{\text{SML (mg/kg of food) x 1 (kg)}}{\text{2 (L) x 10}}$$

If for the relevant substance a health-based guideline value is *not* mentioned in the Directive 98/83/EC and a SML is also *not* available then a MTC_{tap} can be derived according to formula C after setting up a TDI on the basis of the required toxicological data (see 2.4).

C $$MTC_{tap}\ (mg/l) = \frac{\text{TDI (mg/kg body weight) x 60 (kg)}}{\text{2 (L) x 10}}$$

Part B – Assessment of products for compliance with Positive list requirements (Conversion Factors - CFs)

4 PL compliance and migration testing

4.1 Review of PL compliance

When a product is submitted for approval for contact with drinking water, part of the information required will be full details of the formulation for comparison with the PL.

In principle all substances have to comply with PL requirements.

However, a substance may be accepted without addition to the relevant positive list, if it can be demonstrated by migration testing or validated modelling (e.g. Piringer) and using an appropriate conversion factor (see section 5) that the expected concentration of the substance in drinking water shall be < 0.1 µg/l, and following case-by case review at the national level and agreement by the other MS if it is used for a specific application (see also 2.1).

NOTE 1: Decisions on the acceptance of substances of which concentrations < 0.1 µg/l of drinking water are expected and which will not to be added to the relevant positive list need to be documentated during the certification procedure. The other MS have to be informed afterwards (via a feedback procedure).

NOTE 2: The MTC_{tap} value of 0.1 µg/l is based on the provisional DWD guideline value for individual pesticides (except aldrin, dieldrin, heptachlor and heptachlor epoxide) which means that these compounds may not be detectable. As mentioned in 3.1.1 this limit value is also applicable to genotoxic substances. It has been recognized, however, that the value of 0.1 µg/l may be rendered out of date by analytical improvement. A more scientific base for the 0,1 µg/l value will depend on a further discussion on the TTC. Limits on the acceptable amount (percentage in the material and/or PDW) of non-listed substances have yet to be determined.

NOTE 3: It should be recognized that not all chemicals used in the manufacture of PDWs will migrate into the water. Many form a stable part of a polymer, other will disappear during production, while yet others will decompose completely.

4.2 Migration testing and evaluation of results

When PL listed substances restricted with a MTC_{tap} are identified, a migration test according to EN 12873 has to be carried out to ensure that migration is within acceptable limits.

However, for certain types of plastics the availability of generally recognized diffusion models based on experimental data allows the estimation of the migration level of a substance under certain conditions, therefore avoiding complex, costly and time-consuming testing

Migration testing may be not necessary when a product is seen to pose a low risk to drinking water ("minor product", e.g. a product with a conversion factor < 0.01 $d.dm^{-1}$). Even here the requirement to submit full details of formulation must be met.

5 CFs

The S/V ratio of the test sample and the contact time used in the migration test according to EN 12873 are different to the real use of the end products in practice. Therefore, the concentrations determined in the migration test have to be converted. The application of CFs(dimension day/dm) aims to recognize the level of impact on drinking water quality that will arise from the product in its normal operating situation.

The purpose of a CF is to achieve a comparison between the results of the experimental migration test or modelling with the relevant MTC_{tap}.

CFs are dependent on the application of a product. Therefore, a CF is made up of a geometrical factor (F_g – Surface-to-Volume ratio – dimension dm^{-1}), which is determined by the PDW, and an operational factor (F_o – dimension day) which is calculated from the residence or contact time of the water. Thus:

$$CF = F_g \times F_o \qquad [d\ dm^{-1}] \qquad (1)$$

In accordance with EN 12873-1 the results of the experimental migration test are calculated as follows:

$$M_n = C_n / (S/V \,.\, t) \qquad [mg\ dm^{-2} d^{-1}] \qquad (2)$$

where

n	is the sequence number of the migration period (1, 2, 3,…..10)
M_n	is the migration rate for the n^{th} migration period
C_n	is the concentration of the measured substance in mg/l for the n^{th} migration period
t	is the duration of the migration period in days
S/V	is the surface area-to-volume ratio in dm^{-1}

The estimated concentration at the consumer's tap (C_{tap}) is calculated from:

$$C_{tap} = M_n \times CF = C_n / (S/V \,.\, t) \times CF \qquad [mg\ dm^{-3}] \qquad (3)$$

Equations (2) and (3) imply the assumption that the migration rate is constant in time, independent of the concentration already present in the drinking water.

The results of the 3rd migration period according to EN 12873 (both for testing at 23 ºC and elevated temperatures) are used to estimate the concentration at the tap (C_{tap}). This value is compared with the respective MTC_{tap}.

If equation (3) shows that the relevant MTC_{tap} cannot be met after three migration periods, and if it can be expected or shown that the migration rate will decrease in time, the migration testing (both for testing at 23 ºC and elevated temperatures) can be extended to a total migration time of 30 days at the utmost.

At variance with Annex C of EN 12873-1 and EN 12873-2 the migration periods for cold water testing (23℃) are: 3d, 3d, 3d – 4d, 3d – 4d, 3d – 4d, 3d. All migration samples obtained with a migration period of 3 days have to be analyzed for the relevant substances.
For testing at elevated temperature (60℃ to 85℃) the migration periods are: 1d, 1d, 1d - 3d, 1d, 1d, 1d, 1d - 3d, 1d, 1d, 1d, 1d – 3d, 1d, 1d, 1d, 1d – 3d, 1d, 1d, 1d. All migration samples obtained on the 3rd 1d-migration period have to be analyzed for the relevant substances. If the migration is stopped after the 2nd week the migration samples of the 1st, 2nd, 3rd, 6th, 7th and 8th migration period have to be analyzed for the relevant substances.

The following product groups and relevant CFs are applicable:

Table 1: Product groups and CFs

Product group	CF in d/dm
A. Pipes and their linings:	
1 ID < 80 mm (domestic installations, buildings) [1)]	20
2 80 mm ≤ ID < 300 mm (service piping)	10
3 ID ≥ 300 mm (mains piping)	5
B. Fittings, ancillaries [2)]	
1 ID < 80 mm (domestic installations, buildings)	4
2 80 mm ≤ ID < 300 mm (service piping)	2
3 ID ≥ 300 mm (mains piping)	1
C. Components of fittings, ancillaries [3)]	
1 ID < 80 mm (domestic installations, buildings)	0,4
2 80 mm ≤ ID < 300 mm (service piping)	0,2
3 ID ≥ 300 mm (mains piping)	0,1
D. Storage systems	
1 In domestic installations, buildings	4
2 In water supply	1
E. Repair products for storage systems	
1 In domestic installations, buildings:	
1.1 products covering the total surface or a substantial part of that (e.g. coatings)	4
1.2 products covering < 1% of the total surface	0,04
2 In water supply:	
2.1 products covering the total surface or a substantial part of that (e.g. coatings)	1
2.2 products covering < 1% of the total surface	0,01

Footnotes to Table 1:
1) If from a series of different diameter pipes made from the same raw and ancillary materials under the same manufacturing process (a so-called product family) the smallest diameter pipe is assessed and approved, then the whole series of different diameter pipes is allowed to be used for all application areas within the product group without further testing.
2) Complete functional unit made up of one or more components or materials, parts of which are in contact with water, e.g. taps, valves, pipe connectors and flexible hose assemblies.
3) O-rings, components of assembled products. If an assembled product is tested as a unit (not disassembled) then it attracts a CF from Group B.

The CFs for pipes are estimated according to the following assumptions:

Product Group	Fg = S/V Worst Case Surface/ Volume ratio in dm^{-1}	F_O = t Assumed Residence Time in d	CF = $F_g \times F_o$
Mains piping (ID ≥ 300 mm)	1.33	4	**5**
Service Piping (80 mm ≤ ID < 300 mm)	5	2	**10**
Domestic installations, buildings (10 mm ≤ ID < 80 mm)	40	0.5	**20**

The CFs for the fittings and ancillaries of product group B express the extent to which the CFs of the pipes (and their linings) of product group A are reduced due to the fact that the water only comes into contact with the product over part of the length of the pipe (reduction or fraction factor F_f). For fittings and ancillaries this factor is fixed at 0.2:

$$\text{CF group B} = \text{CF group A} \times 0.2 \qquad (4)$$

Analogically, an F_f of 0.1 is fixed for the components of fittings and ancillaries of product group C, expressing the extent to which the CFs of product group B are reduced:

$$\text{CF group C} = \text{CF group B} \times 0.1 \qquad (5)$$

NOTE: There are some products for which a CF < 0,01 d/dm could be calculated, and such a low value may indicate that some reduction in testing could be permitted. The 4MS will gather information on present practice and give further guidance in due course.

Annex A: Some aspects considered in the development of the Positive List 4MS Common Approach

1 General

At this moment (date of this document) positive lists are operative in Germany, France and The Netherlands. This annex describes the results of a first discussion on the similarities and differences between the approval systems and positive lists used in these Member States. It does not review the whole approval and positive list systems. Positive lists are also operative in Denmark, Italy, the Czech Republic, Bulgaria and Romania. This document does not deal with these lists.

2 Approval systems and positive lists

2.1 Germany

According to Regulation 1935/2004/EC for food contact materials the German UBA guidelines have separate positive lists for the organic materials distinguished in the German Regulation. For plastics the monomers, other starting substances, additives and PPAs in 10/2011/EC and in EFSA opinions are accepted. The restrictions are expressed as MTC_{tap} = 1/20 SML or as QM/QMA-values. National accepted additives in several BfR-recommendations are not accepted anymore since 2010. For rubber products, lubricants and coatings separate lists are used in order to include specific reaction products and by-products and following the Regulation 1935/2004/EC. For rubber products the attention is focused on specific starting substances, vulcanizing and anti-ageing agents, fillers and colorants. Germany does not deal with case-by-case acceptance of substances to be used for organic materials. Substances which are not mentioned in the present positive list for plastics have to be evaluated by EFSA. Substances used for rubber products and coatings which are not mentioned in the positive lists have to be evaluated by the German toxicity committee (Bedarfsgegenständekommission des Bundesinstituts für Risikobewertung) according to the Note for Guidance for including in the national list. Certification by DVGW Cert GmbH is based on UBA guidelines and its positive lists.

2.2 France

In France the basis of the positive list is formed by the Commission Regulation 10/2011/EC (Substances assessed by EFSA according to the SCF-FCM guidelines and grouped into list 0 to 4 as mentioned in annex 5 to chapter III of the Note for Guidance). Additionally, several resolutions of the Council of Europe (AP (92)2, (2004)4, (2004)1, 2004)5), two orders (from 1992 and1994), a circular note and a memorandum are applicable. Substances which are not mentioned in European lists are evaluated by the French toxicity committees and listed in French lists (orders, circular notes, memorandum and Afssa or Anses favorable opinions) separately. Due to the fact that a substance is added to the EU or the national list based solely on its toxicity, independent of its application, separate lists for the use of a substance in for instance plastics, rubber products or coatings are not made. In France the approval of a product is handled by three laboratories, accredited by the Ministry of Health.

2.3 The Netherlands

At this moment one positive list for all organic materials is still operative. In this list a distinction between monomers, other starting substances, additives, PPAs and APs is not made. However, the Governmental Regulation of 2003, in which this list is included, has been replaced with the revised July 2011 version. It has been agreed that the positive lists according to the structure mentioned under section 1.2 of this document will be included in due course
The substances included in the present list are used in the products for which a Toxicological Aspects Certificate has been issued so far. Insertion of a substance mentioned in a specification is only carried out following permission of the applicant. Insertion is also carried out after request of a producer of the relevant substance. The required toxicity data are evaluated by the Toxicity subcommittee of the Dutch Committee of Experts on Materials and Chemicals for Drinking Water Supplies. The latter committee decides on the insertion of the relevant substance. Substances included in 10/2011/EC are not evaluated again, only the specific migration limit or TDI is used to calculate a MTC_{tap}. In some cases it is not allowed to use the toxicity data of a substance provided by one applicant to approve the same substance in a product of another applicant. If an applicant does not agree with insertion into the public list then the relevant substance is included in a separate non public list archived and maintained by the Secretariat of the Dutch Committee of Experts. In this way confidentiality and secrecy can be further guaranteed according to the certification system used in the Netherlands. Certificates are issued by a Notified Body (Kiwa), not by a laboratory.

3 Additives, unsuspected substances, reaction products

Starting substances, polymerization aids (catalysts, initiators), cross-linking agents and fillers are mentioned in the Dutch positive list.

In France theses substances are taking into account during the checking of the compliance of the formulation with the positive lists. The unsuspected substances (reaction products) are measured by using GC-MS. The polymerization aids have to be listed into the Resolution of the Council of Europe AP (92) 2 on aids to polymerization (provided that the maximum starting quantities used stay below 1% in total.

4 Pigments and colorants

In the Dutch Governmental Order of July 2011 a list of approved pigments and colorants is included. A similar list does not exist in Germany, but general requirements in BfR recommendations exits. In France the circular on pigments and colorants (1959) is used (updated in the draft order on coloring).

5 Non-public lists

It has been decided by the 4 MS Group in its meeting of January 29, 2009, that the common approach has to be based on a public positive list only. Non-public lists as maintained by The Netherlands are not useful in view of mutual recognition.

6 MTC_{tap} and conversion factors

Conversion factors are used in Germany and The Netherlands to compare the results of the migration testing (expressed in mg/dm^2) with the MTC_{tap} expressed in mg/dm^3.

In France conversion factors are not used and Specific Migration Limits are considered a 'MTC_{tap}'. It has also been agreed that 20% of the guideline value of Directive 98/83/EC may emanate from a PDW. According to this rule specific surface / volume ratios have been chosen for migration testing. It is further agreed that France will introduce EN 12873 for migration testing.