

4MSI Common Approach on Organic Materials in Contact with Drinking Water

Part A – Methodologies for Testing and Accepting Starting Substances to be Included in the Positive List

Adopted by the 4MSI Joint Management Committee

2nd Revision

12 August 2020

France, Germany, the Netherlands, United Kingdom and Denmark work together in the framework of the 4MSI Common Approach as laid down in the Declaration of Intent (January 2011). This common approach aims for convergence of the respective national approval schemes for materials and products in contact with drinking water.

The 4MSI has adopted this document as a common basis for implementing the concept of a Positive List for the assessment of organic materials in their national regulations. The document is subject to revisions agreed by the 4MSI.

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

Bundesministerium für Gesundheit (Germany)
Ministère du Travail, de l'Emploi et de la Santé (France)
Ministerie van Infrastructuur en Waterstaat (The Netherlands)
Department for Environment, Food and Rural Affairs (United Kingdom)
Miljø- og Fødevareministeriet, and Trafik-, Bygge- og Boligstyrelsen (Denmark)

Introduction

This document has been prepared in accordance with the 4MS agreement on co-operation concerning convergence and mutual recognition. It deals with the management of a positive list for organic materials.

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. Substances of cementitious products are not included in the scope of this document. The procedure is composed on basis of information from the National Approval Systems of France, Germany, The Netherlands and UK.

This document is derived from:

- the EAS proposal mentioned in RG-CPDW 188, RG-CPDW 188 Annex 2, and RG-CPDW 186;
- German UBA-guidelines¹ and evaluation criteria for plastics and other organic materials in contact with drinking water
- the French Regulation on materials and products in contact with drinking water described in the Public Health Code and in Order of May 29, 1997², as well as Anses' opinions on positive lists of substances used in the composition of materials in contact with water for human consumption (2007) and on the assessment of the safety of organic materials in contact with drinking water (2013);
- the Dutch Regulation *Materials and chemicals in contact with drinking water and warm tap water* of June 29, 2011 (Dutch Official Gazette 2011, nr. 11911³);
- information on the UK approval procedure (case-by-case assessments).⁴

Related documents are:

- 4MSI Common Approach for Organic Materials - Part B: Positive Lists;
- 4MSI Common Approach for Organic Materials - Part C: Requirements and test methods for products made of organic materials in contact with drinking water;
- 4MSI Common Approach: TON and TOC requirements;
- 4MSI Common Approach: Certification and approval of products in contact with drinking water.

In its final form this document will be:

- Submitted to the 4MSI drinking water regulators as the basis for adoption at the national level;
- Provided to the European Commission as information relevant to the work ongoing under the Construction Products Regulation No. 305/2011/EC (CPR) and the Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption (DWD), to harmonize notified national regulation for the approval of substances and products in contact with drinking water;
- Made available to other Member States to inform them of the actions of the Joint Management Committee (JMC) to regulate organic substances under Article 10 of the DWD, and the requirement 3 of Annex 1 of the CPR.

The JMC 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.

¹ German UBA Guidelines: <http://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/bewertungsgrundlagen-leitlinien>

² French Regulation: <http://www.sante.gouv.fr/materiaux-entrant-en-contact-avec-l-eau-destinee-a-la-consommation-humaine.html>

³ Dutch Regulation: <https://zoek.officielebekendmakingen.nl/stcrt-2011-11911.html>

⁴ UK approval procedure: www.dwi.gov.uk, www.wras.co.uk

Abbreviations

ANSES – Agence Nationale de Sécurité Sanitaire de l'alimentation, de l'environnement et du travail
AP - Aids to Polymerization
AF – Assessment Factor
BMD – benchmark dose
BMDL – lower confidence limit of the BMD
BMR – benchmark response
 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
DWD – Council Directive 98/83/EC - Drinking Water Directive
EAS – European Acceptance Scheme
EC – European Commission
EFSA – European Food Safety Authority
EN – European Standard (French: Norme, German: Norm)
 F_r – Fraction or reduction factor
 F_g – Geometrical factor
 F_o – Operational factor
GC-MS - Gas Chromatography-Mass Spectrometry
ID – Internal Diameter
JMC – Joint Management Committee
LOAEL – Lowest-Observed-Adverse-Effect Level
 M_n – Migration rate for the n^{th} migration period
MS – Member State
 MTC_{tap} – Maximum Tolerable Concentration at the tap
 $MTC(T)_{\text{tap}}$ – Maximum Tolerable Concentration of a group of substances at the tap
 n – Sequence number of the migration period
NOAEL – No-Observed-Adverse-Effect Level
PDW – Product coming into contact with Drinking Water
PL – Positive List
PPA - Polymer Production Aids
RIVM – Dutch National Institute for Public Health and the Environment
QM – Quantity Maximum (see definitions)
QMA – Quantity Maximum per unit Area (see definitions)
RG-CPDW – Regulators Group on Construction Products in contact with Drinking Water
RMS – Responsible Member State
SCF – Scientific Committee on Food
SGOM – 4MSI Subgroup on 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
UBA – Umweltbundesamt
UF – Uncertainty Factor

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 product. It is intended to be present in the finished materials or products.

Aids to Polymerization (AP)

Aids to polymerization means substances which initiate the polymerization reaction and control the macromolecular structure of the polymer (i.e. catalysts).

Component

A part manufactured out of a specific material, 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).

Composition

The constituents found within a material or product.

Compound

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

Constituent

Ingredient used to make a material or product.

Drinking Water Positive List Limit

Restriction on the use of a Positive List substance expressed as MTC_{tap} or $MTC(T)_{tap}$.

Formulation

Constituents and its concentrations to make a product or material.

Ingredient

Substance or mixture used to manufacture the product or material.

Material

Prepared from a substance or from a combination of substances, suitable for use in a manufacturing process

Composite materials. Materials comprising different constituents which are mixed and bonded together but remain separately identifiable material categories e.g. glass reinforced plastic (GRP).

Material category

Sub-types within a material type, e.g. plastics, coatings, rubbers, silicones, lubricants, within the organic materials. Membranes and ion exchange resins will fall under material category "plastics" in the Positive List, and adhesives will fall under "coatings".

Material type

Type 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

Monomers 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 any macromolecular substance obtained by:

- (a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or
- (b) chemical modification of natural or synthetic macromolecules; or
- (c) microbial fermentation.

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 products nor have a physical or chemical effect in the final materials or products.

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).

Type of products

- *Single material products.*
- *Assembled products.* These products comprise two or more components, possibly of different materials.
- *Multi-layer products.* These products comprise two or more layers bonded together to form a single item.
- *Other products* These products are without a predefined shape, usually a liquid or granulate, e.g. lubricants and adhesives
- *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 product expressed as mg/kg of polymer.

QMA

Maximum permitted quantity of the 'residual' substance in the finished material or product expressed as mg per dm² 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.

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.

1 Positive List (PL)

1.1 Principles and approach

A positive list (PL) consists of the substances permitted to be intentionally used in the production of organic material used in products in contact with drinking water (PDWs).

For the inclusion of a substance on the PL, a toxicological assessment of the substance, including its possible reaction and/or degradation products is required. As a result of the assessment substances may be restricted in form of a limit value in the drinking water ('maximum concentration at the tap' (MTC_{tap}), or its presence in the material may be restricted in form of a QM or QMA, or with other kinds of restrictions (like molecular weight or viscosity).

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 what is already in operation at the European level for foodstuff (positive list) (Commission Regulation (EU) No 10/2011, hereinafter referred to as: 10/2011/EC).
- Substances appearing on the 10/2011/EC list can be regarded as acceptable for all materials in contact with drinking water when used with the same function as the function listed for the plastic, but with different arrangements for the calculation of migration limits (see section 3). Additional requirements (for example obligation to analyse specifically by-products in migration tests or supplementary restrictions for the by-products) can exist for some substances for other material categories than plastics.
- When new substances are proposed for addition to the drinking water positive list, the preferred route to approval will be to subject them to an assessment by EFSA as a substance used in a FCM application.
- 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).

The 4MS have also recognized that not all substances on the current national lists have been subject to full assessment in accordance with these principles. These Substances have been included in the **Combined List**.

Substances which are agreed upon as having been fully evaluated or do not need additional evaluation will be entered onto the 4MS **Core List**. The Core List will be the future Positive List and will be regularly updated. The Core List, or a reference to the Core List, has to be taken up in each of the member states regulation or guidance.

1.2 Structure of the Positive List

The Positive List (the Core List) will include substances permitted to be used in all types of organic materials. The list will contain monomers and other starting substances, additives, PPAs and AP's. Pigments and colorants can be included in the list, but other pigments or colorants than in the list can be intentionally used if their use is safe.

Substances used in the manufacture of materials or products may contain impurities originating from their manufacturing process. These impurities are non-intentionally added substances (NIAS). As far as they are relevant for the risk assessment the main impurities of a substance should be considered and if necessary be included in the specifications of a substance. However it is not possible to list and consider all impurities, therefore they may be present in the material or product but not included in the list.

Substances which are in the Union list of 10/2011/EC are regarded as acceptable for use in all types of materials in contact with drinking water when used with the same function as the function listed for the plastic. The substances in the Union list of 10/2011 are allowed to be used in PDWs but will not be reproduced in the Core List.

In the 4MSI positive lists, in the column 'material' it is specified in which category of material(s) (like plastics, rubbers, coatings, silicones, lubricants) the substance is allowed to be used. If this column is empty, the substance is permitted for use in all categories of materials. Membranes and ion exchange resins will fall under material category "plastics"; adhesives will fall under "coatings". In the column "restrictions and specifications" requirements for e.g. one category of material could be specified. Other columns in the list will include: 'PM/Ref number', 'CAS number', 'use as monomer or other starting substance?' 'use as PPA or additive?' 'technological function' 'MTC_{tap}', and 'MTC(T)_{tap}'.

1.3 Recycled and regenerated substances and materials

The use of recycled plastics is restricted to the use of offcuts, failed products and scraps generated by the producer that are uncontaminated and not yet placed on the market (Recycling of material within a factory). The material is simply returned to the beginning of the process and is therefore equal in composition.

The use of regenerated substances in the formulation of DWP is not permitted. The percentage of impurities and impurity profiling may differ from one manufacturing batch to another. A substance, analytically well characterized, is usually used in the toxicity studies, which is not feasible for recycled substances.

2 Assessment of substances

Substances that have not been or cannot be subject to an assessment performed by EFSA have to be assessed according to the common procedure described below. This applies to both the backlog of substances currently listed at the Combined List that are still in use, as well as to newly used substances.

2.1 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's. The draft opinions will be reviewed by the appropriate bodies within each of the other MS's, who will offer their comments. When consensus is achieved, the substance will either be added to the Core List, or will be rejected. The procedure is described in the scheme in Annex A: Opinion process for assessment of substances.

2.2 Required Information and Assessment Procedure

Requests for inclusion of new substances in the Core List should be submitted to one of the national regulatory bodies. Applicants are free to use any of the national arrangements, but the information should be sent to only one of the MS's. Submission of these requests shall be pursuant to the requirements of the questionnaire of the EFSA "Note for guidance"⁵, in the chapter 'Explanatory Guidance of the 'SCF Guidelines for food contact materials''. which contains a more

⁵ EFSA (2008) Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials (Last updated: 8 may 2017): <https://www.efsa.europa.eu/en/efsajournal/pub/m-21>

detailed description of the data needed for the safety assessment of the substance, as requested by this SCF guidelines (2001)⁶. Data requirements are subdivided into items 1 to 8.

- 1 Identity of the substance**
Name, CAS number, synonyms, impurities, its breakdown and reaction products
- 2 Physical and chemical properties**
- 3 Intended application 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 Data on migration of the substance**
- 6 Data on residual content of the substance in the material**
- 7 Microbiological properties of the substance**
- 8 Toxicological data**

Item 8 of the questionnaire describes the scientific requirements for the toxicological data to be submitted, whose extent is determined by the level of migration of the requested substance in water. In addition, all relevant toxicological data available should be submitted. In requests pertaining to substances which have already been subjected to a toxicological assessment by EFSA for food contact materials, the requirements of Points 1 to 4 are adequate. Nevertheless, if the toxicological assessment is old, additional information could be required. In addition, a suitable analytic procedure for the maximum tolerable migration period shall be submitted. More details on the information required are mentioned in the chapter “Explanatory Guidance” of the EFSA Note for Guidance.

2.3 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 in each case relevant for inserting a substance into a positive list for PDW. For the assessment of a substance there is need for information about the exposure of the substance or its reaction products or impurities.

The migration of substances used to indicate whether or not the reduced set of toxicological data, mentioned in the EFSA Note for Guidance, may be applicable has to be determined in accordance with EN 12873 series for cold water (23°C) or in certain cases, estimated by calculation or modelling from residue in the material. Data obtained with the EFSA migration testing as mentioned in the Note for Guidance may be used.

Toxicological requirements depend of the expected exposure through migration (see SCF Guidelines / EFSA Note for Guidance):

- The core set (full set) of toxicological data is needed 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) is above 250 µg/l. This value is converted from the value of 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).
- 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), 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 EFSA Note for Guidance.

⁶ SCF (2001) Guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorization. https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out82_en.pdf

- In cases where the expected concentration in drinking water is below 2.5 µg/l, information showing absence of genotoxic potential is generally sufficient. When results are negative, two genotoxicity tests (an Ames (OECD 471) and an *in vitro* micronucleus (OECD 487)) as requested in the EFSA Note for Guidance, and recommended by EFSA in 2011⁷, may be sufficient.

Other studies/information may be deemed necessary based on structural alerts regarding other toxicological endpoints, including endocrine effects and/or for substances with a high potential to accumulate in humans, and similarly additional data may be required for nanomaterials, even if the bulk material has been evaluated and approved for FCM^{5,8,9}.

As default CF, 20 d/dm, is used, but case by case, another CF can be applicable. The same applies to temperature and other worst-case assumptions; if it is justified to use other parameter values than the worst-case, this is acceptable. 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.

Biocides are only accepted as in-can preservatives for PDWs and it must be shown, that there is no antimicrobial activity on the surface of the PDW. The Commission Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products has to be observed additionally.

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 epichlorohydrin. 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. The use of substances with genotoxic properties should however be avoided as much as possible.

⁷ EFSA (2011). Scientific opinion on genotoxicity testing strategy applicable to food and feed safety assessment. <https://www.efsa.europa.eu/en/efsajournal/pub/2379>

⁸ EFSA (2016). Scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. <https://www.efsa.europa.eu/en/efsajournal/pub/4357>

⁹ EFSA (2018). Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health: <https://www.efsa.europa.eu/en/efsajournal/pub/5327>

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 lowest No–Observed–Adverse–Effect Level (NOAEL) obtained in a battery of animal experiments by an assessment factor¹⁰ (AF, see the REACH-R.8-Guideline¹¹) 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:

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

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

If a NOAEL for the most critical effect 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 (i.e., with an extra AF for LOAEL-to-NOAEL extrapolation).

In addition to the described NOAEL or LOAEL approach, a generally accepted Benchmark Dose (BMD) method (EFSA, 2017)¹² may also be used to derive a MTC_{tap} , using software programs BMDs¹³ of US-EPA or PROAST¹⁴ of RIVM. The BMD is reported with its lower (5th percentile) and upper (95th percentile) confidence limits: BMDL and BMDU respectively. The BMDL for the most critical effect (the lowest BMDL) should be used as a point of departure (POD) for deriving the TDI, as follows:

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

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

¹⁰ EFSA calls uncertainty factor, UF.

¹¹ “Guidance on information requirements and chemical safety assessment Chapter R.8: Characterization of dose [concentration]-response for human health”
https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf

¹² EFSA (2017). Update: Use of the benchmark dose approach in risk assessment. *The EFSA Journal*, Vol. 4658, pp. 1-41. www.efsa.europa.eu/en/efsajournal/pub/4658

¹³ <https://www.epa.gov/bmds>

¹⁴ <https://www.rivm.nl/en/proast>

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.

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 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} .

For substances that have an SML “not detectable” (ND, with a detection limit of 0.01 mg/kg food) in the food Regulation, an MTC_{tap} of 0.1 µg/L is applicable.

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:

$$MTC_{tap} = 0.1 \mu\text{g/l} = 0.0001 \text{ mg/L}$$

(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.

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

If for the relevant substance a specific migration limit (SML) is mentioned in 10/2011/EC an MTC_{tap} can be derived according to formula B, except for those substances to which an allocation factor has already been applied to derive the SML (e.g. melamine and some phthalates). For those substances, formula C will be used to set the MTC_{tap} .

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

If the SMLhigh then it should be checked with the following formula that determination of parameter TOC is sufficient.

If $SML \times \frac{M_{Carbon}}{M_{total}} \geq 10 \frac{mg}{kg}$ ($\sim 10 \frac{mg}{L}$ TOC), then no MTC has to be checked. (M = molecular weight)

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 an MTC_{tap} can be derived according to formula C after setting a TDI on the basis of the required toxicological data (see 3.1).

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

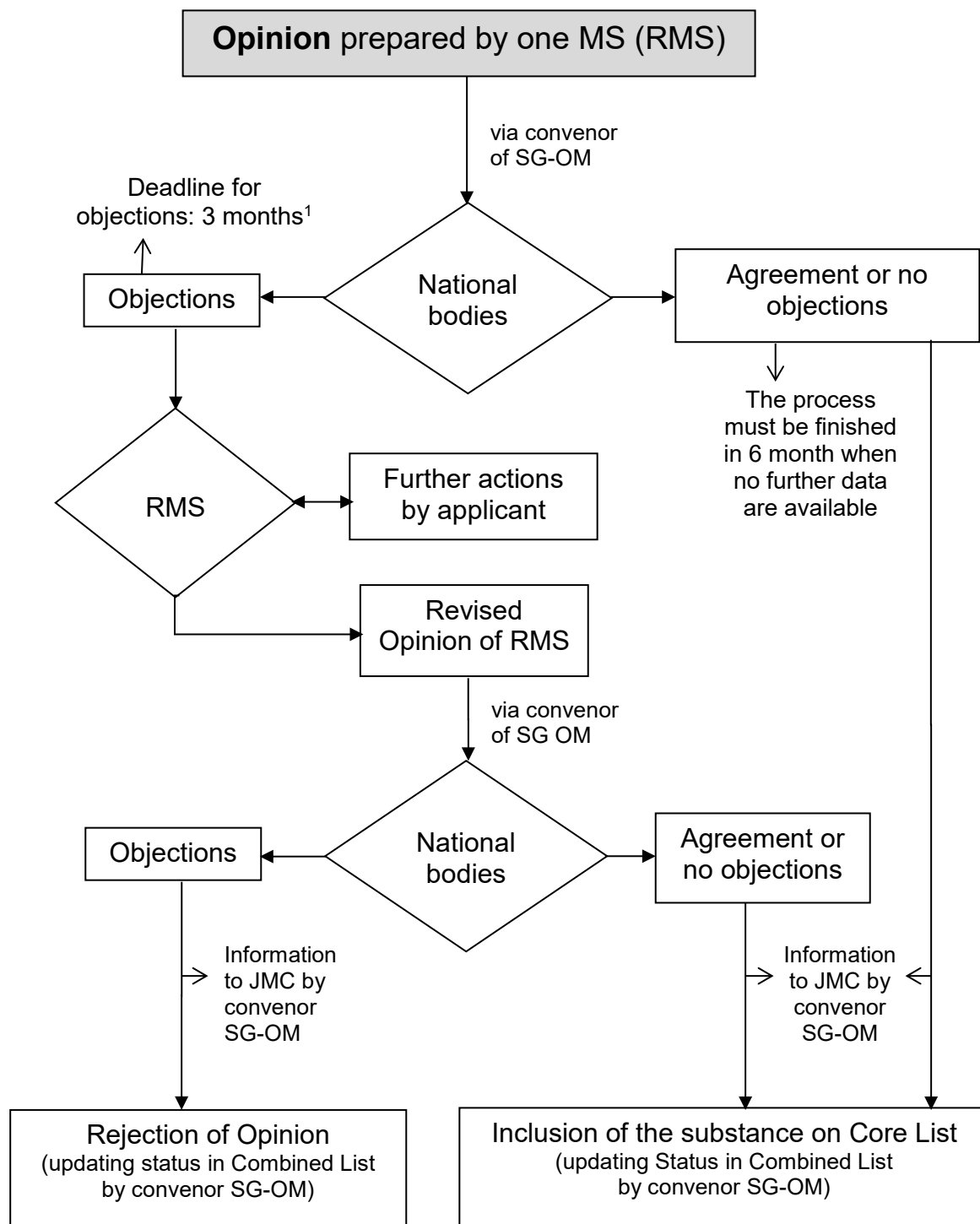
For substances for which only genotoxicity data are available, which shows the substance can be considered not genotoxic, an MTC of $2.5 \mu\text{g/l}$ is set .
Furthermore, for substances that result into migration not exceeding $250 \mu\text{g/l}$, no full dataset on toxicity is requirements and usually not enough data will be available to derive a TDI. In these cases, instead of the 'TDI', the (lowest) NOAEL from the 90-day repeated oral dose study(ies) divided by an appropriate assessment factor should be taken. An assessment factor of 100 is used by default, but application of extra uncertainty factors might be needed. An MTC_{tap} which is derived on a limited toxicological dataset can be at maximum $250 \mu\text{g/l}$.

3.4 Additional or alternative restrictions

For substances for which it is not possible to analyze its presence in the migration water (for example. isocyanates are hydrolyzed), a QM or QMA limit can be set. A QM or QMA could be derived in the same way as for substances used in food contact materials: the TDI should not be exceeded if 100% of the residue of the substance migrates. By default, a surface area of 6 dm^2 in contact with 1 liter is used to calculate the QM or QMA.

In addition, there can be a need to set further restrictions and specification, for example: specification of purity, or a limitation in its use in specific polymers or maximum use percentage, or specifications for nanostructured substances.

Annex A - Opinion process for assessment of substances



¹ If an objection within this timeframe is not possible, the member sets a fixed date to send the objection. If no objection is submitted by a member state this is taken as agreeing to the opinion.