4MSI: Questions of webinar the 5th November 2020

Joint Management Committee of the 4MSI, 26th February 2021

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

Bundesministerium für Gesundheit (Deutschland)

Ministère du Travail, de l'Emploi et de la Santé (France)

Ministerie van Infrastructuur en Milieu (Nederland)

Department for Environment, Food and Rural Affairs (United Kingdom)

Miljøministeriet, and Trafik-, Bygge- og Boligstyrelsen (Denmark)

The following questions were asked at the 4MSi webinar the 5th November 2020. 4MSi have compiled the questions and formulated answers.

Questions related to the common approach for organic material in contact with drinking water Part C – testing and accepting		
	Question	Response provided by 4MSi members
1	There are a lot of abbreviations. Any chance of a glossary of terms?	Glossary is found in the document CA-OM part C, page 3.
2	Is there a plan to include specific exemptions for AP's and PPA's, as defined in the German regulation, like the possibility to apply water solubility modelling etc.	The substances have to be on the positive list, except when its use will not lead to migration of the substance itself or possible reaction/degradation product(s) above 0.1 µg/l, or when substances are used below 0.02% (weight percentage) in the formulation. As for all substances, MTC_{TAP} can be check by a migration modelling or a calculation.
3	Section 4.3.1 of the draft CA describes the possibility to use mathematically modelling to evaluate compliance thereby making migration testing unnecessary. Can you give some more specific examples of when a manufacturer of a PDW can expect that this option will be possible for the evaluation of his/her product? How often is the option expected to occur?	The maximum concentration of substances expected in the migration water can be determined by a migration modelling (CEN/TR 16364 technical report) or a calculation (Full transfer calculation). Application of diffusion models (CEN/TR 16364) requires the estimation of the diffusion coefficient of the studied substance in the material, and the partition coefficients for the substance between the material and the water. For these reasons, the diffusion models can only be applied to specific cases while the calculation can be generalised to all substances and materials. Certificating body will check and decide what is applicable. Usually, the migration test is still needed, but not all substances need to be analysed in the migration water. Substances with low use percentages and/or with a high MTC are more likely to be covered by modelling or calculations, but it also depends on the product. A rough estimate is that half the substances do not need to be analysed in the migration water.

4	Could you give more details about modelling methods?	There is a European technical report available: CEN/TR 16364:2012 "Influence of materials on water intended for human consumption - Influence due to migration - Prediction of migration from organic materials using mathematical modelling". This should be used as basis for a European approach. The CEN/TR 16364 technical report describes predictive diffusion models that seek to estimate the migration of substances contained in materials placed in contact with water. 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 estimation of the diffusion coefficient of the substance under investigation in the material, and the partition coefficients of the substance between the material and the water. Additionally, the concentration of the substance in the material has to be known. 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. The diffusion models can only be applied to specific cases. For reacting substances, the application of modelling is difficult.
5	For modelling. Are the Modelling Guidelines of UBA of application?	The CEN TR 16364 technical report should be used. It is similar to the UBA guidelines.
6	A question on the modelling: How is it ensured that we are using an approved / suitable / uniform method for modelling that reflects all the different water types in Europe?	According to CEN TR 16364 technical report, the applicant will argument its choices and the notified body will check its admissibility. On a European level it might be possible to ask for an approval of the modelling tool.

7	In the table with the overview of testing requirements by risk group, the possibility to test a material on "formulation" level is given for some lower risk groups. However, in the draft section 4.3.2.2. related to sample selection and preparation, it is stated that testing on the formulation is only possible if there is no "processing change" required to make the final product/component (the example of cut gaskets is given). Doesn't this statement, for all practical purposes, remove the possibility to test on formulation for many products and components?	Yes, it's possible for all organic materials if the process is the same to produce finished components or samples for testing. Formulation testing is possible when manufacturing of representative samples from the material is possible. Examples are injection moulding products where a test sample is manufactured via injection moulding from the material. The last sentence in section 4.3.2.2 is wrong and should be corrected.
8	As migration testing as a stagnation test is performed in a laboratory, does not reflect the real life use situation, according to the testing standards, samples that are not identical finished product can be used, how to be sure that finished product complies with the requirements?	Proxy sample should be used only if the finished product or component cannot be tested. In case the test is not executed on the finished product or component but on purposely-produced test sample, a report of the production of the sample shall be available (check by certified body). Test results are converted to expected concentrations at the tap using the conversion factor. This takes the actual use of the final product into account.
9	What does it mean 2 Migration tests required? Two sperate Tests with reports on the same conditions or test at least with 2 measures (should be normal for analytics)? Same product in the same migration in both types of test.	For organic materials, in any case, two specimens of the product need to be tested. If the water is generally chlorinated in the country, a single test for each type of test water (chlorinated and chlorine-free) is required (two migration reports). For Member States where the water is not chlorinated, testing only with chlorine-free water is required. In that case, duplicate migration testing is required (two samples and two migration tests) but for analysis, the migration waters can be merged (one migration report).

10	When and how is the testing in chlorinated water required?	Member states will decide whether testing in chlorinated water is required.
11	Products are to be manufactured all over Europe I expect, shouldn't the tests be performed on worst case water so to speak, to ensure the compliance in both non chlorinated and chlorinated water?	Member States will decide whether testing with chlorinated water is required. For the acceptance in all Europe testing with non-chlorinated and chlorinated water will be required.
12	Regarding conversion factors presented in Part C. The application of equation (3) in Appendix 1 for pipes with ID between 20 and 80 mm and test temperature 60 or 85°C results in a higher expected concentration at the tap than measured in the test. In extreme cases C_{TAP} can be four times higher than C measured. This does not correspond to reality at all and leads to a wrong assessment of the product. Usually small pipes with ID <= 20 mm is tested. Therefore, this inconsistency has probably not yet been noticed.	Thanks for pointing this out. If the pipes with the larger diameters fail only due to the conversion to ID= 10 mm pipes, it will be possible to repeat the test with the smallest diameter.
13	Tests are very specific and expensive. Is there an effort to ensure no bottle necking and frequency of testing? At the moment is a concern to be raised.	The 4MSi is aware of the concern and tries to make a system without redundant testing. The 4MSI harmonisation aims at reducing testing, as ultimately only one approved application is needed to get access to markets of other countries as well. It is not expected that at EU level, the new system will lead to bottle necks in test capacity.

14	A per formulation requirement, subst. not monomer, not Nano, not CMR listed, etc. can be present if migration is < 0.1µg/l (right?); then in comparison, NIAS without SML/MTC can migrate up to 1 µg/l, thus with a higher migration as the substances not monomer, etc? Could you clarify? Practical requirements - GSMC looking for 1 ppb or greater then converted to at tap concentrations.	Indeed, a cut off value of 1 µg/L is set for migrating substances in the screening test; but this is only for non-intentionally added substances (NIAS) not yet covered by an entry of its precursor substance in the positive list. For all non-listed *intentionally added substances* (IAS) the < 0.1 µg/L applies, as well as for its reasonably expected reaction and/or degradation products. The 1 µg/l is for reaction and degradation products that arise during manufacturing of the product and which are found by GC/MS screening]. The MTC of 1.0 µg/l applies to unidentified substances and identified substances without a known $MTC_{TAP.}$ This is established bearing in mind analytical constraints, and remains compatible with a threshold of toxicological concern (TTC) set at 1.5 µg/day for substances whose toxicity is not known. This TTC 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)[1]. In addition, genotoxic concerns are low if all the starting substances have been assessed to be either not genotoxic or to react away into non-genotoxic substances.

[1] Kroes R., Renwick A.G., Cheeseman M., Kleiner J., Mangelsdorf I., Piersma A., Schilter B., Schilter B., Schlatter J., Van Schothorst F., Vos J.G., Würtzen G. (2004). Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. Food and Chemical Toxicology, 42: 65-83.

Rulis A.M (1986). De minimis and the threshold of regulation. In: Felix CW (ed.) Food protection technology, current and projected technologies for food protection – Recommendations and Implementations, pp. 329-37, Chelsea MI.

15	How long do these tests take? Or how long to get a substance approved?	Duration for tests: - Organic Materials: 10 days or 31 days (extended testing) for migration test (EN 12873). Microbiological test up to 6 months (EN 16421) - Metallic Materials: 26 weeks or 52 weeks (extended testing) for metal release (EN 15664-1). Currently: - Assessment and preparation of opinion by one MS can take 3 months maximum. - Review of the opinion by other MS: 4 - 6 (PL for organic material) or 3 - 6 (composition List for metallic materials) months.
16	On page 19 it is stated that the S/V ratio used for migration testing should be large enough to be able to verify the MTC_{TAP} in the migration water. What impact does the 4MSI think this will have on the possibility to develop a test method for assembled products? Will additional testing of all the very small (and therefore minor) components be required?	Development of CEN Standard for assembled products is under discussion. The test method on assembled products will have to take into account this point. It is not excluded that specific test components will have to be performed in parallel of the test on an assembled product. But at this stage (the work on the test method on assembled product is not yet started), it is too early to envisage. For small components (Risk group 4 and 5) no specific migration test is required. This applies to component testing as well as for testing assembled products.
17	In the requirements for the formulation is the phrase that "Pigments and colorants that are authorized on national level" are accepted. Does this mean that if the pigment is accepted in Denmark it will automatically be accepted in Germany?	No. If colorants and pigments comply with purity requirements (Annex C) and do not migrate at or above 0.1 µg/L, they don't have to be on PLs. Otherwise they will have to comply to national provisions of the country of application.

18	The NIAS test with the sum of max 5µg/l for unknowns or unidentified substances in cold water could be challenging, taking into account that not all substances and degradation products will be identified during GC-MS Screening. Is there a plan including a transition phase (e.g. 5 years) in which the applicant is informed about the excess of this new requirement in order to adapt or optimize the production process?	The sum is only for the substances that are estimated to be above the threshold of 1 µg/l in the screening chromatogram. Also, the sum of 5 µg/l is not yet agreed upon in 4MSi / part C; it is intended to first gain experience with this requirement before a decision is made. The test method is already in application in some countries. Feedback on its application and problems encountered for results interpretation and compliance should be organised.
19	As the water quality is very different in Europe. How will you ensure uniformity in terms of reference water used for taste and odour testing?	For taste and odour, a comparison test is used. The test contains controls like round robin tests and positive controls with specified substances and contamination levels. There are requirements for test water in EN 1420 Standard (no odour, no flavour and conformity with EN 1622): The reference water can be local tap water or bottled water. It shall be appropriate to the region.
20	Testing: you mentioned 3e day, while in the sheet it is mentioned 30e day? Which is correct?	It should have been 31 days. For cold water migration test, the requirement $C_{TAP} \leq MTC_{TAP}$ applies to the 3rd migration period (10 days); or, in case extended testing is needed, at the 9th migration period (31 days). For warm/hot water migration test, the requirement $C_{TAP} \leq MTC_{TAP}$ applies to the 7th migration period (10 days); or, in case extended testing is needed, at the 22nd migration period (31 days)

21	How do you define starting substances? Is it the same as in 10/2011?	A substance is 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. Unfortunately, the definition of starting substance is not the same as in 10/2011. With starting substances is meant: all intentionally added substances (IAS) based on the formulation.
22	How do you ensure that the drinking water parameters in the Directive are in compliance on assembled products? - I have noted that substances with a migration less than 0,1 ug/l are automatically on the positive list. If a product is assembled from more substances, we must be sure that there is no problem at the tap. Degradation / by products from anti-oxidants would be on that list as well - right?	Substances with a migration less than 0,1 ug/l are not automatically on the positive list. If they are on the list, they have been assessed. Substances not on the list and can only be used if the substance itself but also its impurities and reaction and degradation product do not migrate (< 0.1 µg/l) and only if they are not CMR, Nano, or used as monomer. The assessment of an assembled product based on the testing and assessment of the different components considers a worst-case contact of 100%, 10%, 1% surface fraction of each component. These surface fractions are part of the conversion factors to be applied for the different components. This ensures that MTC_{TAP} for each investigated substance will also be met for the assembled product, even when different components will leach the same substances. This even applies to the use of multiple use of products in the installation system or the use of different products leaching the same substances in the installation system. Degradation products from antioxidants: It is intended to add restrictions for 10 degradation products of anti-oxidants with the next update of the Common Approach for Organic Materials.

23	How will site-applied products/materials be handled? Who will apply: Lab, Manufacturer, other?	For the testing of site applied organic materials: the CA refers to EN 12873-2. In general, the certification or approval might be applied by the manufacturer of the pre-product or by the company applying the product. For cementitious materials: e.g. pre-packaged mortar or rehabilitation resin can be tested and approved in advance like factory made products. On site mixed products (e.g. for concrete): no rules established at 4MSi level, compliance to PL to be checked, formulation shall be controlled
24	The 4MSI has developed Common Approaches for Metallic, Organic and Cementitious materials. What requirements can we expect will come into place for the inorganic, non-metallic materials, such as carbides?	The elaboration of Common Approach for enamels and ceramic materials is ongoing.
25	What is to be done when an unknown NIAS substance is detected at a migration level exceeding 1 ppb? Will the substance be accepted based on a self risk assessment? Substance identification is challenging at these low migration levels.	The use of the GC-MS screening method is not yet implemented in all MS's. But if an unknown substance is exceeding 1 ppb, the product is not acceptable. The same applies for identified substances for which no MTC or risk assessment is available. When a risk assessment of the substance from a generally recognized institute (e.g. EFSA, BfR, …) Is available, this might be used, but this is still open for discussion.

26	For drinking water contact we're dealing with very low migration thresholds of 0.1 ppb and 1 ppb. Are the available analytical methods sensitive enough to detect at these extreme low levels? I hear from test labs that often no analytical?	All test methods currently used are applicable to the required detection limits. 0.1 µg/L is the acceptance criteria at the tap of consumer and correspond to higher limit in migration water. The S/V ratio used should be large enough and the QL of the method should be able to verify the concentration in migration water corresponding to the acceptance criteria. But for assembled products, the S/V ratio can't be increased when testing. It has to be checked whether the actual S/V ratio in the product is sufficient to be able to verify the MTC tap.
27	Are analytical methods available to detect down to 0.1 ppb?	Usually they are, otherwise work is needed.

Questions related to the draft common approach on certification and approval of products		
	Question	Response provided by 4MSi members
28	How can ensure that a finished product, which consists of different components in different materials, both of organic and metals, together does not exceed the limit values, if each individual component is tested individually? How to ensure that surface treatment such as chrome plating does not migrate nickel from the finished product?	Using the CF and a certain surface fraction in the final products and the installation system. Difficult issue and no proposal yet accepted. EN standard for testing exits (EN 16058). However, this is long term test (6 months testing) and not really applicable for all taps on the market. No short-term tests are known to characterize the nickel release of products in real use.
29	From a consumer point of view i would prefer that unknown means no thanks, until we know enough to estimate the substance. C_{TAP} and MTC_{TAP} - explain the correlation to the drinking water parameters in the directive please?	Unknown substances correspond to NIAS, all starting substances should be known. NIAS are not expected reaction products, impurities or contaminations. Sometimes, it is not possible to identify NIAS or isolate NIAS to evaluate its toxicity. C_{TAP} is the concentration at consumer's tap calculated from test results using conversion procedure with conversion factors as described in the document CA-ON. MTC_{TAP} is the maximum tolerated concentration at consumer's tap. It is the drinking water limits. For DWD parameters MTC_{TAP} is 10% of the parameter value (due to the fact that other sources of the substance in the drinking water exist). For parameters not listed in the DWD MTC_{TAP} is derived from toxicity data as detailed in 4MSi procedure (PL).

30	Can you please explain in more detail the logic/link between the product types, conversion factors, risk group and resulting testing and certification requirements? Is it based on empirical evidence? And are there limitations to the concept of the CFs?	Risk groups of products (RG) depend of conversion factors (CF). RG1 corresponds to highest CFs and RG5 to smallest. Requirements decrease from RG1 to RG5. The surface/volume ratio and the stagnation times used for migration testing in accordance with the EN 12873 Standards do not reflect the reality of a water supply system. Conversion factors (CFs) are used to determine the actual impact of materials on the quality of DW based on the concentrations found in migration tests. CFs are established based on the following assumption: $\mathbf{CF = F_g \times F_o\ [day/dm]}$ where: - F_g (geographic factor) is the S/V ratio representative of reality (dimension: dm^{-1}), - F_o (operational factor) is water's assumed residence time in the system (dimension: day). That correspond to 0.5 day for domestic installations, 2 days in service piping and 4 days in main piping CF for fittings & ancillaries are 10% of CF for pipes and their linings CF for components of fittings & ancillaries are 10% of CF for fittings & ancillaries CF for small components of fittings & ancillaries are 10% of CF for components of fittings & ancillaries Same logic for storage systems.

31	Can you please elaborate which products fall into the "treatment steps" category and "abstraction devices"?	Products for treatment steps are considered to be part of a centralized water treatment plant. Abstraction devices are used to deliver water from a reservoir or from ground water or other to the water treatment plant. See Annex C of Common Approach on certification and Approval of Products. If a product can be used in different part of the water supply system, approval for worst case condition is sufficient for all applications.
32	And what about products not listed in Annex B - who decides what category/CF that products fall into? For example, pipes in large buildings with ID bigger than 80 mm - then the CF is not 20 - right?	The ID for pipe (or S/V ratio for other product or component) defines the conversion factors to be applied. The given explanation for the use of the products (domestic installations, service piping or main piping) only helps to classify the different product groups.
33	Certification cost 7000-8000 euro per component, we produce hand shower, where we have maybe 2-3 components in contact with water. how we can cover the cost? due to the fact the selling price of hand shower is around 6- 7 euro?	Components made of the same granulate can be combined in one certificate, even when the components are used for different products. For components of risk group 3 (RG3) (surface fraction < 10% of the product) even a certification issued for the granulate producer is sufficient.
34	The new DWD Article 11 points to a 1+ System of conformity, or equivalent, except where this would be DISPROPORTIONATE. How can disproportionality be evaluated?	In the 4MSI draft documents this is covered by the risk groups (RG). For components /products of RG4 & RG5 a 1+-System is not required.
35	How is difference between Components of fittings, ancillaries and Small Components of fittings, ancillaries determined?	Components of fittings, ancillaries: Components (sum of components made of similar materials) of assembled products with a wetted surface fraction ≤ 10% of the assembled products. Small components of fittings, ancillaries: Components (sum of components made of similar materials) of assembled products with a wetted surface fraction ≤ 1% of the assembled products.

36	It is proposed in the draft proposal to "sum" the surface area of materials which are the same generic material (EPDM), but not the same specific material (tradename). What is the rationale for this and how will it work in practice?	The sum of the surface fraction for the same generic material (polymer e.g. EPDM) is used to define the conversion factors to be applied and the risk groups (RG). This is done as the same generic materials will release the same or similar substances into the drinking water. For the certification of components, one certificate might be valid for different components (even used for different products) made of one specific granulate (tradename). For components of RG2 the certificate is valid for the injection moulder. For components of RG3 a certificate of the granulate producer is even sufficient for all components made of this granulate.
37	Could the 4MSI envision a scheme in which an ISO9001 certified manufacturer submits the samples to a 3rd party test laboratory for testing and then, based on the results of that testing, the manufacturer is responsible for collecting his/her technical documentation and drawing up the declaration of conformity? Or alternatively, the declaration of conformity could be given by the 3rd part lab based on test results (like in France today) and then production control is secured through ISO 9001 certification of the manufacturer? In other words, a controlled "self-declaration system" where testing is done by an independent 3rd party? Would this be considered "broadly equivalent" to the scheme presented today?	According to the 4MSI draft documents this is possible for components of RG4. For products/components of RG1 to RG3 especially the sampling of the test samples is of importance ad should be dealt with by the certifier. For the factory audit ISO 9001 certification will be recognized.
38	Same granulate means same (tradename)? Or all, e.g., PEs, even from different producers, in total?	Same granulate means same tradename (and so formulation).

39	What means formulation? EPDM in general or the actual formulation?	Constituents (or elements, or substances) and its concentrations to make a component, a product or material. The applicant must disclose 100% of the formulation of each material of the product or component: - list of all ingredients (substances or blend of substances) used in the formulation to produce the material (all monomers, additives, pigments, fillers, catalysts etc.) - their respective percentage in the formulation. Based on the information provided by the applicant, the notified body has to obtain the chemical compositions of each ingredient (compound / masterbatch / preparation / mixture). In this approach, each ingredient supplier needs to be contacted. In case an ingredient contains no specific brand name (but the name of the substance), the supplier has to confirm it is only one substance (including impurities) or whether the substance contains intentionally added additives. If it is only one substance, no further information is requested and it is compared to the PLs. If the ingredient contains one or more additives, the notified body reviews this additionally supplied information and verifies that it is also permitted.
40	Since manufacturing parameters can have a decisive influence on the outcome of the migration, how can it be controlled?	The manufacturing parameters will have to check under the 1+-system conformity assessment procedure, which will be required according to article 11 paragraph 8 of the new drinking water directive.
41	What is exactly meant with a formulation, includes it all pigments, etc, will it be on brand names or generic?	See answer given earlier.

42	Can you provide more details very specifically to the requirements defined for the inner hose in the example given in Annex E1 “flexible hoses”? How can the overall product be RG2, but the component becomes RG1? What is the rational for this? Will there be other “exceptions” like this?	Hoses are regarded as part of the piping system. This is the reason, why for hoses the conversion factor for pipes and not for ancillaries has to be applied.
43	Is it possible that the granulate producer (and not a component supplier) is the owner of a RG2 certificate if the material in question is, e.g. only specified for injection moulding? Who would provide samples for type testing in such a case?	Owner of the granulate may apply and samples are taken correctly, it’s a test specimen produced and tested. To be defined by the certifier to decide. A certificate of the granulate producer will be valid for the formulation review, specific migration testing, EMG and screening of NIAS for RG2 components or products. The injection moulder will have to test additionally for organoleptic and TOC for his specific products.
44	Expected time line for approval of a faucet for example.	Depend if the different components were already certified. If all components are already certified, the certificate of the assembled products will depend only on the audit of the factory production control. It is not possible to give an exact answer. A rough guess would be from 3 month up to about 1.5 years. But this really relies on the aspects such as the process of the certification.
45	Has this system versus the current level of testing and certification in the 4MS been assessed? (e.g. safer water, cost to manufacturers, etc.)?	See Impact studies from UE (DWD recast).
46	Is there a plan to trial the proposals with current certification bodies and some manufacturers, so that the proposals can be tested and refined?	Introducing this system in DE with the certification bodies is currently being done.

47	The current categories given for CF are based on worst case S/V values of the category. What happens if the range starts with a smaller S/V value? (e.g. pipe range starting from 40 in category A1?	The product with the smallest ID of the range is tested and the real S/V ratio is used to make the calculations. If the smallest ID will be 40 mm the conversion factor for pipes ID < 80 mm (product group A1) will apply.
48	If/when this common approach is adopted do you envisage that there will be more, less or the same amount of testing being carried out as now? If more, are there enough test houses to do this work?	Depends as a single country or EU union – also depends on current member state requirements. If we consider that one certification will be valid for the whole EU the total testing will be much less.
49	Still on CF - how to calculate CF if the highest dimensions are out of the limited value but applied for same location (e.g. category A1, for pipes up to 160mm?	The smallest dimension is tested and the most restrictive CF is used in a view to cover all the pipe dimensions.
50	Different products mean different components surface in contact with water. So, what is Rg3 in one product could be RG2 for another one. In the end we will have to test everything. How can this be avoided?	If a component falls in two risk groups, producers are expected to choose the higher risk group for assessment as that will allow their component to be used in both risk groups.
51	Will there be guidance to ensure a common approach across certification bodies?	The delegated acts will provide this under the drinking water directive article 11.
52	Products from RG1 category shall be tested as final products according to the System 1+. How the labs will deal with this requirement? Today it is problem to test large or complex products. Which approach for RG1 products coated with two different organics coatings?	EN12873-1 & 2 standards are proposing some devices to test large or complex (multilayers for example) products.
53	What will happen to existing hygienic product certifications, attestations of conformity, done in accordance with the UBA Recommendation system 1+ following different product risk group structure (P1-P4)? Is there a framework draft, so that the certification body and certification holders can upgrade and extend the certification to the 4MSI common approach for these?	Germany is at the moment introducing a system in line with the 4MSI draft document. At the moment is not decided how close the new European system will be with the 4MSI proposal. Depending on the differences, a transition period will be defined.

54	Time line question - use best and worst case please! I believe it is mandatory to agree on acceptable time lines for a lab to perform the tests?	We cannot give an answer to this question, as it is to be discussed with the EU commission and the other member states in the harmonization work. But we understand the need for there to be a balance.
55	How will you organise an efficient dialogue in order to take all questions and contributions into account? A specific new long Q&A session seems to be necessary. The best implementation of the new requirements will happen if the users understand, contribute to and agree with. Do you think that all countries, especially those which have no requirement today will implement equally in their law?	The current covid-19 situation complicates the need for a physical workshop about this topic. Furthermore, the new drinking water directive is now to be implemented, and we imagine that the EU commission will seek to administrate workshops, where stakeholders are also involved. It is important to hear your questions and aspects in this.
56	Who will check if a product will have the right certification? We have to compete everyday with hundreds of Chinese companies. They don't use certified material, but they still able to sell. How do you think we can compete in price level when we will have to spend 7000-8000 euro per components?	This is not yet established in the drinking water directive, but a system for both the role of certification bodies and marked surveillance will be established as a result of the harmonisation in each member state.

57	Regarding the Analysis methods: As far as I know, Standards don't state the limits of detections and limits of quantification. Dividing MTC by 20 often lead to lower value than such limits. On another hand, if an analysis result is under the quantification limits, multiply by CF makes no technical sense. How the 4MSI will include in the scheme this limits and the way test Labs can interpret the results in a Pass/fail criterion? How to test a product that consist of a pipe od 3.5m diameter, then RG1 category? In France and within ACS scope, we test representative samples and demonstrate that it is suitable. But we understand now that all these jobs have been done in vain.	Lot of discussion were conducted in France for cementitious products. Collected information was used for 4MSI proposal elaboration.
58	How to deal with confidential substances?	Limit the diffusion of confidential data to notified bodies and always under confidentiality agreement or through MS government legislation.
59	Will the Guideline for the Mathematical Estimate of the Drinking Water from UBA be accepted as reference for running the modelling evaluations?	Not decided yet. Full transfer calculation (from the quantity of substance in the finished product or from the quantity of substance used to manufacture 1 kg of product) is a possibility described in the Common Approach.

60	How will sufficient testing capacity be ensured so as to avoid delays in time-to-market? Could the 4MSi foresee some set-up (certification of manufacturers own lab according to relevant standards) in which manufacturers could test their materials and products themselves (within their own CERTIFIED laboratory facilities)?	We doubt that much more testing will be required. The testing will be harmonized and the need to test products differently for getting access to different MS will be obsolete. 4MSi recognises that there is some uncertainty in this area particularly in terms of the number of new products entering the market. However, existing national approval schemes use the testing methods proposed by in 4MSi and can meet the current demand. Individual countries continue to monitor laboratory capacity within their schemes. The risk group approach allows for reduced testing in some circumstances and permits testing on either the formulation or the product meaning a particular formulation used in numerous products need only be tested once. The certification approach is also risk based and allows producer declaration for the smallest components. Given these factors, we doubt that much more testing will be required. The testing will be harmonized and the need to test products differently for getting access to different MS will be obsolete.
61	If this is adopted will this become a legal requirement to sell only compliant products? Who will police and ensure that all products on the market place have the same approval, so we are working at the same level and the greatest investment?	Question for the COM. However, article 11 in the new drinking water directive states, that the member states must make sure, that only materials that comply with the directive and which are to be used in products in contact with drinking water are to be found on the marked.
62	Do you expect that all Member States will accept a scheme like the one presented here? And how can this be ensured? Industry has some concerns that this scheme will either be considered "too difficult" or "not enough" by some Member States and therefore we will not achieve full harmonization.	Question for the COM, 4MSi cannot answer this.

63	What happen if a country will not accept the implementation? for example ACS is not ok to test only components, but the complete product. in this case we will have to make two different certifications?	Question for the COM. Requirement will be European.
64	Concerning Conversion Factors, sub-categories are defined for fittings and ancillaries according their diameter: the larger the diameter, the smaller the surface in contact with water, and consequently the risk, conversion factor CF and risk group. The same reasoning should apply to storage systems / water heaters. Based on calculation, the following values should be implemented: <50 l: CF=3 / ≥50 l and < 500 l: CF=2 / ≥500L: CF=1.5	A proposal for this is on the table.
65	Will requirements in water directive be included in European product standards on for instance water pipes etc.?	Question for DG GROW (Eu commission), 4MSi cannot answer this.
66	What is the level of agreement between all 4MSI on this?	Members of the 4MSi work towards the goal of harmonization, this is our common agreement. We have then drafted approached to systems that we see can reach this goal, however there are elements which are still to discussion also within the 4MSi.
67	This topic is too important and we seem to have insufficient time to answer all questions. Could 4MSi organize a second session specific to address all open questions?	The 4MSi will talk about the possibility, but future workshops in this topic might be invited from the EU commission as a result of the implementation of article 11.
68	It can be a problem for a single laboratory to perform all analyses substances that are contained in the list. Are there requirements for accreditation and a certain detection limit, how can you ensure comparable results from different laboratories?	Question to COM and JRC (precision in implementing acts)
69	How will site applied product be tested under a system 1+? Application of these products are often dependant on practice, where certification bodies do not always have on a regular basis	See answer given to similar question above.

70	Testing labs need to know exactly which tests to implement, analytical performances needed (QL, uncertainties), etc. in order to and get the accreditation on time to be able to perform testing.	This information on tests to be implemented have to be supplied to the testing labs by their regulators, and in sufficient time.
71	Can you please share a list of 4MSi representatives and associated countries?	In 4MSI website, there is a contact list for each country: https://www.umweltbundesamt.de/sites/default/files/medien/5620/dokumente/4msi_contact_list.pdf
72	To whom we can talk and discuss for the problems we will have to face off as producer?	In 4MSI website, there is a contact list for each country: https://www.umweltbundesamt.de/sites/default/files/medien/5620/dokumente/4msi_contact_list.pdf
73	How to test a product that consist of a pipe od 3.5m diameter, then RG1 category? In France and within ACS scope, we test representative samples and demonstrate that it is suitable. But we understand now that all these jobs have been done in vain.	For large diameters, the EN12873 is allowing to sit and soak the products if it is homogeneous. If not, some glass devices (plaques, pipes) can be used to test sections of the pipe. EN 14944 standard includes specifications for testing proxy samples when it's not possible to test final product.
74	I have a separate question which I am hoping you can advise me on (or one of your colleagues). Today we manufacture a material which is included on both the EU positive list (EU 10/2011) and under the BfR regulation, it will be following a CLH dossier review move to become a reproductive toxin category 1b in 2021. Would the listing as a reproductive toxin category 1b mean that this product could not be used in formulations that are then incorporated into drinking water applications? The product we make is an antioxidant that would potentially migrate out of rubber seals between polyolefin pipes. I can see no clear guidance so would appreciate your advice.	The prevention of chemical risk in the workplace is based primarily on the replacement of a hazardous product with a non-hazardous or less harmful product (substitution). Thus, for hazardous chemicals and CMR category 1A or 1B chemicals, the search for a substitute is a requirement for employers and supersedes all other measures for risk reduction, when the risk cannot be excluded (requirement established by European Directives). ECHA in charge of establish, review and update EU Positive Lists (PLs) should decide its listing in PLs. Of course, it should be possible to remove a substance from PLs with regard of new toxicity data.

75	Could we have a flow chart of how the new process works?	A flow charts on how the systems work can be found in: • Part 3.3 of the common approach for metallic materials part B • Annex A of the common approach for organic materials part A • Part D of the common approach for cementitious products • Annex on the common approach for certification and approval The final process of the full system is yet to be decided with the other member states, as it depends on the implementing acts and the delegated acts in the new drinking water directive.