

Version 10

Amendments:

- new questions B-18; B-21; B-22; B-23; C-6; C-17
- revision/amendment of C-3 and C-19 (formerly C-17)
- amendments in A-9; B-9; B-10; B-14; B-15; B-16 and C-14 (formerly C-13)
- editorial amendments, renumeration of questions where necessary

As of 26 May 2025

Frequently asked questions

Testing and certification practice for products in contact with drinking water: implementation of the evaluation criteria and the recommendation for attestation of conformity

The following list of frequently asked questions reflects some of the questions received by the German Environment Agency ("*UBA*") about their drinking water hygiene regulation documents that followed on from the work done by testing and certification bodies and from comments of interested parties.

In order to better orientate oneself about question subjects a categorisation into three main subject areas has been made:

- A General; legal relationships
- B Implementation of UBA regulations in certification processes
- C Material- and product-specific questions

On the instance of document amendments, the numbering order of questions may change. The table of contents provides orientation by clickable references. Regularly, the most recent version of a standard or its dated version explicitly mentioned in an evaluation criteria document is to be considered.

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Subject area A

General; legal relationships

Question A-1:

What is the significance of UBA Evaluation Criteria and Guidelines and of the UBA Recommendation for Attestation of Conformity?

Answer:

Guidelines and recommendations hitherto issued by *UBA* reflect current scientific and technical knowledge concerning required properties and assessment of materials and products in contact with drinking water. They are or had been in the status of recommendatory documents, but nevertheless come along as code of practice that is commonly consulted by other regulatory parties (like, e.g., DIN, DVGW, or VDI) and testing institutions when performing evaluation of concrete products.

By virtue of the 2012 amendment of the German Drinking Water Ordinance (*Trinkwasserverordnung*, TrinkwV, previous version), according to section 17 (3) *UBA* was mandated to determine and publish mandatory evaluation criteria to define requirements and testing criteria for products in contact with drinking water. These become legally binding from the date two years after they have been published for the use of materials regulated in these documents and products made thereof in constructions, installations and networks for drinking water distribution.

Meanwhile, most of the former material-specific guidelines and recommendations have already been transferred into mandatory evaluation criteria documents. The mandate for defining evaluation criteria has now been settled in section 15 of the revised TrinkwV dated 20 June 2023. Due to the revised European Drinking Water Directive (Directive (EU) 2020/2184) and the corresponding Legal Acts as from 23 January 2024, from now on new evaluation criteria will not be elaborated any more, but only existing documents will be updated.

In contrast to hitherto applied guidelines, mandatory evaluation criteria do not cover specifications on conformity attestation (granting of certification reports or certificates). To provide a suitable way for manufacturers to obtain certificates on drinking water suitability of their products, *UBA* issued its *Recommendation for Attestation of Conformity of Product Hygiene Suitability for Drinking Water*, which is not legally binding.

The recommendation, by applying the risk-based approach as defined in evaluation criteria, for products of the highest risk group implements system 1+ for certification procedures as has been defined by the European Commission by way of decision 2002/359/EC for construction products in contact with drinking water. System 1+ requires to commission the certification procedure to an accredited, independent party (certification body) and thus provides the best approach for a traceable and reliable attestation of product suitability.

Question A-2:

Is it possible that the transitional period for the changeover from guidelines and recommendations to evaluation criteria will be extended or that the legally binding nature will be suspended?

Answer:

The duration of the transitional period of 2 years from the date of stipulation until the legally binding nature of the notified and published evaluation criteria is set out in section 15 (2) of the Drinking Water Ordinance (TrinkwV), which is a federal law. It will not be possible to change or suspend this period before the date when legal bindingness becomes effective. This would require revision of the TrinkwV.

If amendments defining stricter material-specific requirements than before are made to an evaluation criteria document that is already legally binding, then again a two-year transitional period applies to these amended requirements until they attain legal bindingness. Amendments of an evaluation criteria document may also be settled in a way that specific requirements of the amendment will become applicable from a later point of time.

If previously non-regulated starting substances or materials are included in an evaluation criteria document as a result of a positive assessment, then respective products which fulfill applicable requirements can be used in contact with drinking water from the date of publication.

Ouestion A-3:

Is certification compulsory for products in contact with drinking water in Germany?

Answer:

The requirements of the *UBA* evaluation criteria only apply to products that are newly installed as part of the construction or maintenance of water supply systems.

According to the Drinking Water Ordinance (TrinkwV), there is no obligation for the products to be certified. In order to use products, however, in any case a declaration of conformity to the requirements of the *UBA* evaluation criteria is required by the manufacturers. They should refer to a valid attestation of conformity by an external certification body. If this is not the case, in case of doubt the manufacturer must present the results of the relevant compliance tests with the requirements of the *UBA* evaluation criteria.

<u>Remark</u>: By way of the implementation of the revised European Drinking Water Directive there will be both an obligation to have products in contact with drinking water certified and a corresponding market surveillance.

Question A-4:

What is the difference between an approval and a certification?

Answer:

An approval is issued by a government body, while a certification is carried out by an organisation under private law.

In connection with materials in contact with drinking water, *UBA* issues approvals for metallic materials and starting substances for enamels, ceramic materials and organic materials, which are then included in the relevant positive lists of the evaluation criteria.

Products in contact with drinking water are not envisaged to be approved by a government body. However, the conformity of products with the requirements of the *UBA* evaluation criteria can be proved by a certificate issued by a certifier accredited in this field.

Question A-5:

Are European certificates such as WRAS or ACS equivalent to certificates as per the German evaluation criteria?

Answer:

No. Test conditions and requirements for obtaining a WRAS, ACS or as well an NSF certificate are different to the relevant requirements of the *UBA* evaluation criteria. For this reason, equivalence cannot be accepted for these certificates across the board.

Germany, France, Netherlands, the United Kingdom and Denmark have agreed to harmonise tests and requirements for materials within the framework of the 4MS Initiative (4MSI). For this purpose, suitable regulation proposals (4MSI Common Approaches) have been developed, which have been fully implemented in the evaluation criteria by Germany. If these proposed regulations are also implemented in other countries, a general equivalence of the relevant certificates can be declared.

Ouestion A-6:

May products be sold when their test certificates are invalid or have expired or their declarations are unclear?

Answer:

The Drinking Water Ordinance (TrinkwV) regulates the <u>use</u> of materials in contact with drinking water. From the date of the evaluation criteria's legally binding nature (2 years after publication), only products that comply with the evaluation criteria may be used for the construction or maintenance of water supply systems.

The TrinkwV thus does not regulate the sale of products.

Question A-7:

Do requirements defined in UBA evaluation criteria also apply to existing installations?

Answer:

No, requirements in evaluation criteria only apply to the construction and maintenance (servicing, repair) of drinking water installations.

If however quality parameters are exceeded, the causes of the exceedance can be ordered to be eliminated as part of a public health authority's hygiene check, possibly by renovation or replacement of unsuitable components in drinking water installations if necessary. If consumers of drinking water of inferior quality suffer health impairments that can be traced back to hygienically improper installation components, the owner or operator of the drinking water installation is also subject to liability issues.

Question A-8:

Is it allowed to use products with invalid or expired test certificates or conformity attestations, or otherwise improper declaration, in drinking water installations?

Answer:

Section 13(2) Drinking Water Ordinance (TrinkwV) prohibits the use of products for the construction and maintenance of (drinking) water supply systems that do not meet the drinking water hygiene requirements set out by the relevant regulatory documents. Relevant certificates based on testing and evaluation by a certification body in accordance with the evaluation criteria, can prove the suitability of a product for drinking water hygiene.

However, certification of products for use in drinking water distribution systems is not mandatory (see question A-3). If products lacking a conformity attestation are to be used, it is necessary to at least make a statement on the product's hygienic suitability by a self-declaration referring to valid test certificates. Responsibility for established hygienic suitability then is the sole business of the manufacturer or provider of the product. Should it come to an exceedance of drinking water quality parameters caused by usage of such products, same considerations become relevant as in question A-7 above concerning issues of liability and to replace unsuitable products if necessary.

Question A-9:

Is it allowed to mount replacement parts without recent attestations according to applicable evaluation criteria into installations?

Answer:

Yes, replacement parts for which no attestations according to applicable evaluation criteria exist may be used for maintenance, if a compulsory replacement of a complete apparatus or major parts of an existing installation would represent an unreasonable hardship and thus be

disproportionate. Main prerequisite to act this way is that drinking water quality parameters are met, which can be proven by appropriate water sampling and parameter testing. If past operation of the drinking water installation does not give clues on possible water quality impairment, use of the corresponding replacement part is possible.

This also holds for components made of lead-containing copper alloys which, from 12 January 2028, are no longer considered as hygienically suitable and which have been marked correspondingly in the positive list of the 5th amendment of the evaluation criteria document for metallic materials.

Question A-10:

Is there a centralised data base for existing certificates on products in contact with drinking water, or is such a data base in preparation?

Answer:

Neither *UBA* nor other federal institutions keep or host a list or data base of certified products. Anyway, accredited certifiers are obliged to provide basic information (product identity, manufacturer/provider and applicable standards or regulations) concerning products certified by them in adequate form (online, data medium or printout; upon request if applicable). These specifications are defined in standard EN 17065. To the knowledge of *UBA*, those accredited bodies acting in the field of drinking water contact materials have implemented online navigation functionalities to search and download respective information on certificates issued by them.

Question A-11:

Which accredited certifying bodies for drinking water contact materials exist in Germany and how can these be found?

Answer:

Nationally accredited certifying bodies in the field of drinking water contact materials are registered at the responsible German institution for accreditation, *Deutsche Akkreditierungsstelle (DAkkS)*, and can be found by distinct internet keyword search or by aid from consulting agencies. In data base queries, keywords related to the respective accreditation document are constructive, which in this case comprise "*Umweltbundesamt*" and "*Konformitätsbestätigung*". This also holds for search tasks in English language. URLs for data base queries are:

https://www.dakks.de/de/akkreditierte-stellen-suche.html or https://www.dakks.de/en/accredited-bodies-search.html

Certification bodies located in foreign countries and performing certification tasks according to *UBA*'s evaluation criteria and the Recommendation for Attestation of Conformity shall be searched for via respective local accreditation bodies.

Question A-12:

How can an attestation based on the extended transitional regulation with respect to COVID-19 pandemia be issued?

Answer:

An attestation based on the extended transitional regulation shall be issued by an accredited certification body. This certificate at least must state that for the respective components or products test reports exist which so far confirm product compliance of hygienic suitability according to the corresponding *UBA* guideline and that these test reports date back not earlier than ten years. The certification body must have available the current formulation and it must commit to inform the customer in due time on what testing and/or inspections still have to be done until 21 March 2023.

<u>Remark:</u> the extended transitional regulation with respect to COVID-19 pandemia is no longer applicable. Attestations on hygienic suitability based thereon were only valid for a limited time and meanwhile should have been replaced by regular certificates. Question A-12 is therefore scheduled to be removed in subsequent version 11 of this FAQ document.

Subject area B

Implementation of UBA regulations in certification processes

Question B-1:

What is the conversion factor F_c and how have conversion factors of different product groups been determined?

Answer:

The conversion factor F_c serves to convert a test result ($c_{measured}$) that has been obtained by a migration test according to DIN EN 12873-1 or DIN EN 12873-2 under unfavourable conditions, and this way calculate realistic figures for a substance concentration at the water tap (c_{tap}).

In the standards considered, test conditions for the migration test are specified in such a way that substance concentrations to be determined can be measured with greatest possible accuracy. This is accomplished by providing high substance concentrations in the test waters. For this reason, standards for testing specify tightened conditions with regard to test sample surface versus contact water volume (S/V) and to contact time (t).

By applying the conversion factor to the measurement results (cmeasured), the S/V ratio and the contact time are normalised as to realistic assumptions:

$$c_{tap} = c_{measured} \times \frac{F_c}{\left(\frac{S}{V}\right)_{test} \times t_{test}}$$

The conversion factor for pipes is derived from assumptions concerning a realistic surface/volume-ratio ($(S/V)_{assum}$) and a realistic contact time (t_{assum}):

$$F_c = \left(\frac{S}{V}\right)_{assum} \times t_{assum}$$

Pipes: Pipes are subdivided into three product groups according to the pipe inner diameter: pipes for drinking water installations (ID < 80 mm), house connection pipes (80 mm \leq ID < 300 mm) and pipes used in central water supply (ID \geq 300 mm). The assumed (S/V)_{assum} for the respective product group is the one with the smallest diameter range. For pipes of ID < 80 mm as product group, the S/V ratio of a pipe with ID = 10 mm applies. In addition, different realistic maximum contact times are assumed for the three product groups. For pipes in drinking water installations (ID < 80 mm) this contact time (t_{assum}) is taken as 12 h or half a day (0.5 d). The following table shows the assumptions and the conversion factors thus derived for the respective product groups:

Product group "pipes"	Fc [d/dm]	(S/V) _{assum} [dm ⁻¹]	tassum [d]
ID < 80 mm	20	40	0.5
80 mm ≤ ID < 300 mm	10	5	2
ID ≥ 300 mm	5	1.25	4

Ancillaries: Based on the three product groups for pipes, the conversion factors for the product groups: ancillaries, components of ancillaries and small components of ancillaries are calculated using assumed wetted surface proportions. For ancillaries themselves this includes assumption of a wetted total surface proportion of 10 %. Further subdivision into components of ancillaries and small components of ancillaries is carried out again in steps of 10 %.

Containers: containers including components and repair systems to be used with these are divided in those for drinking water installations and those in the field of drinking water supply. The former then are differentiated by volume, i.e. $< 10 \, l$ and $\ge 10 \, l$.

The assumptions for applicable S/V ratios and realistic maximum contact times for containers and the conversion factors F_c thus derived are shown as examples in the following table:

Product group "containers"*)	Fc [d/dm]	(0/V)assum [dm-1]	tassum [d]
Containers < 10 l in drinking water installations	4	4	1
Containers ≥ 10 l in drinking water installations	2	2	1
Container outside drinking water installations	1	0.25	4

^{*):} incl. components and repair systems with ≥ 10 % wetted surface area in the container

Analogously to the concept for ancillaries, for components and small components of containers displaying wetted surface proportions below 10 % and below 1 %, respectively, the conversion factor is reduced by a factor of 0.1 or 0.01, respectively.

Derivation of conversion factors for other product groups made of organic materials can be found in annex B of the *Common Approach* document part C of the 4MS Initiative, URL: <a href="https://www.umweltbundesamt.de/sites/default/files/medien/5620/dokumente/draft_common_approach_on_organic_materials_-part_c_procedure_and_methods_for_testing_and_accepting_products_0.pdf

The value of the conversion factor for individual product groups allows to infer their possible influence on drinking water quality and therefore serves – besides conversion of $c_{measured}$ into c_{tap} – also to carry out division into respective risk groups (see question B-2 below).

Question B-2:

How are conversion factors F_c and thus risk groups assigned to the products?

Answer:

A specific product is assigned to a product group with the associated conversion factor F_c on the basis of its dimensions or design and its intended use. A corresponding risk group applies to a range of values for F_c , from which the testing and evaluation effort for the respective product is derived.

 F_c for pipes and hoses are determined based on the inner diameter. If products with different diameters are grouped together for certification, the smallest inner diameter shall be used for testing and evaluation.

The category of ancillaries is subdivided according to the inner diameter of the pipes to which the products are connected.

Separate conversion factors F_c apply for containers as well as components and repair systems used therein. A general differentiation is made according to whether the container is used inside or outside of the drinking water installation.

Smaller F_c apply for components of ancillaries or containers depending on the proportion of wetted surface area in the ancillary or container, respectively.

Question B-3:

Are components of ancillaries that, due to their functionality, exhibit a predominant surface proportion to be included in the calculation of relative surface proportions of other components?

Answer:

In special cases of ancillaries, the functionality of the main component inherently requires a large wetted surface area. In order to obtain a device ready for operation, the main components will come along with other connected parts which in turn may have considerable wetted surface areas.

If the total wetted surface area of the ancillary including its main component would be considered for calculation of the relative wetted surface proportion and thus the risk group of the other components, these would be assigned an inappropriately low risk group. As a result, components with potentially relevant possible influence on drinking water quality would not be tested and evaluated properly.

In such cases the main component exhibiting a large effective surface area therefore is to be categorized as risk group P1 and to be tested and evaluated in relation to its composition. Subsequently, the wetted surfaces of all other parts and components are totalled and they are categorized into relevant risk groups according to their respective relative surface proportion. Components made from the same material must be added when doing so (see question B-4 below).

Examples for ancillaries bearing large-area functional components are mainly associated with water treatment applications, e.g. plate heat exchangers and modular devices with filter membranes, ion exchangers, non-woven and other packing materials.

For the evaluation of filter membranes, question C-18 holds further explanations.

Question B-4:

How must components made of the same materials be combined to determine the risk group?

Answer:

The proportions of surface area of components that come into contact with water and made of the **same base polymer** or the same metallic material <u>must be added together to determine</u> the risk group.

Example: A fitting contains several components made of the polymer POM, which are manufactured from identical or different pre-products. The surface area proportion of each individual component is less than ten percent, the total surface area proportion of all POM components is greater than ten percent. As a consequence, the polymer is generally to be assigned to risk group P1 and an attestation of conformity according to System 1+ is required for each of the components made of this polymer. By summing up wetted surface proportions, on one hand the potential cumulative risk for hygiene drinking water deterioration of the respective components is made allowance for. On the other hand, constructive modification by splitting into different subitems of the component cannot result in a lower risk group assignment.

For the issuance of respective conformity attestations, the following specifics apply:

- Components from the **same pre-product** of the base polymer can be combined for an attestation of conformity (see subsequent question B-5).
- For components of **varying pre-products** of a base polymer which cannot obtain a combined attestation of conformity only the components displaying the predominant surface proportion will require testing and evaluation according to risk group P1 if by wetted surface summation a portion of 10 % is exceeded in the final product or if a component itself already exceeds 10 %. Minor components made from different preproducts of the base polymer may still be tested and evaluated according to risk group P2 and respective certificates may be issued.
- For sealing gaskets of gap or ring type always risk group P2 applies, even if in a distinct case the wetted surface proportion of these gaskets made from the same base polymer amounts to more than 10 % in the ancillary.

Question B-5:

When can the attestation of conformity for different components made of organic materials be combined?

Answer:

Components of the same material <u>can be combined for a common attestation of conformity</u> if they are made from the **same pre-product (e.g., specific granulate** from one manufacturer). **In addition**, it must be ensured **that processing conditions specified** by the pre-product's manufacturer **are complied with**.

An attestation of conformity of the pre-product is sufficient for components of risk group P2.

For components of risk group P1 an attestation of conformity for the respective manufacturer of the component is necessary.

The common attestation of conformity for components (generally combining similar products or components that fulfil the abovementioned prerequisites) can also extend to different purchasers or end-product manufacturers and, if all relevant requirements are fulfilled, even to different colour hues of the pre-product (see question C-15/colourants and colour hues).

Question B-6:

Can an attestation of conformity for a pre-product or component also be obtained by the end-product manufacturer who processes or installs it?

Answer:

If the component manufacturer is not identical to the end-product manufacturer, the attestation of conformity should preferably be arranged by the component manufacturer.

In principle, however, the next processor or end-product manufacturer can also have such components or pre-products certified. For this purpose, however, the necessary information on the composition of the materials used must be submitted to the certification body of the end-product manufacturer. In case of organic materials, the end-product manufacturer must precisely specify the production process to the supplier. The supplier must provide the end-product manufacturer with the processing parameters for each batch delivered and used to manufacture the components. This is the only way to ensure third-party monitoring for the components in risk group P1 on the premises of the end-product manufacturer. The factory production control is monitored based on the documented processing parameters and the incoming goods inspection at the end-product manufacturer.

Question B-7:

Which frame conditions apply for external supervision of test sample withdrawal for P1 products?

Answer:

For products and components of risk group P1, according to system 1+ external supervision of test sample withdrawal is generally required. In cases of supply of components destined for subsequent assembly or of products destined for further processing this may also be conducted at the purchaser of such components or products provided that harmonised controls and documentation along the supply chain are implemented in consultation with the certifying body (cf. preceding question B-6). External supervision requires physical presence of the person(-s) commissioned to perform the inspection at the manufacturing site or in the central- or distribution warehouse after in-house clearance for sale.

This is the course of action for current manufacturing processes in cases of initial inspection or continuation of an existing certification order, while it should also be followed, if possible, for withdrawal of initial test samples in cases of a new product or supplier qualification to be established. In certain cases, for example if only prototype samples have hitherto been

produced and regular fabrication has not yet been installed, it can be agreed to send prototype samples to the testing or certification body directly.

When arranging such a simplified course of action the certifying body should draw special attention to the documentation of stipulated manufacturing conditions and of possible deviations in product properties, and should implement suitable measures for external monitoring if the certification process is continued.

Question B-8:

How can the quality-assured sampling of test specimens be ensured if test specimens can be taken by manufacturers and sent to the testing body within the simplified conformity procedure (otherwise a task of the certification body or inspection body)?

Answer:

The simplified conformity attestation procedure can be applied to components in risk groups P2 to P4. The Recommendation for Attestation of Conformity does not currently provide for any third-party monitoring at the manufacturer's premises for these components and leaves the responsibility for sampling and shipment of test samples to the testing or certification body with the manufacturer.

For obtaining an attestation of conformity of pre-products (e.g. plastic granulates) however, the manufacture of the test sample shall be monitored within the scope of an inspection (see subsequent question B-9).

Question B-9:

Why is supervised test sample withdrawal necessary for pre-product certificates and what at least must this external monitoring include?

Answer:

Pre-product certificates can be used without further testing for the conformity attestation of components of risk groups P2 and P3 that have been manufactured from this pre-product. Additionally, the pre-product certificate is also valid for the proof of microbiological requirements of ancillaries and pipes of risk group P1 (except pipes with $F_c > 10 \text{ d/dm}$). Because of the wide coverage of validity of pre-product certificates it is essential that test samples employed for product testing have been manufactured according to determined specifications. Under these circumstances, supervision of respective test specimen sampling cannot be waived since especially the validity of the attestation of conformity on microbiological requirements for ancillaries of risk group P1 would then not be given. External supervision cannot be replaced by "identity testing/verification" from e.g. fingerprint methods or lead substances in these cases.

External supervision anyhow only comprises the manufacture of the test sample but **not** manufacture of the pre-product. Test samples may either be fabricated at the premises of the

pre-product manufacturer or it can be arranged to give this over to another manufacturer or institute as service provider. It is essential that the auditor must be able to clearly identify the granulate used and to verify the manufacturing conditions.

If a pre-product manufacturer does not apply for a pre-product certificate but still place an order for microbiological testing, then test sample withdrawal should likewise be done under external supervision. Only if this is fulfilled it is possible to use the test report for the certification of components that have been fabricated from the pre-product.

Within a transitional period until March 2024, test reports can also be accepted for which no audit of test sample manufacture was planned.

Ouestion B-10:

How can a component or a precursor from a supplier, the certificates of which are not yet available, be implemented in a buyer's own product certification?

Answer:

It requires close cooperation between supplier and buyer. In this context, it is possible for the buyer, being aware of the supplier's ongoing certification efforts, to submit a self-declaration for the supplier's products first. The buyer can also start their own certification efforts for their own products in which the parts supplied are to be used, even before the supplier's attestation of conformity procedure has been completed. However, certification of an assembled product cannot be completed by issuing a certificate until the full set of certificates on supplied components and precursors has been provided.

Ouestion B-11:

Can an attestation of conformity also be issued for a component assembly and what information shall be included therein?

Answer:

A component assembly comprises various pre-assembled components that are used in end products (e.g. a cartridge in an outlet fitting). Component assemblies can be obtained from upstream suppliers.

The proportion of wetted surface area in the end product being ultimately installed by an installation company, though not definitely clear beforehand, decides the component's risk group. Nevertheless, an attestation of conformity can also be issued for component assemblies. However, the attestation must show the requirements to be met or the restrictions on use (in particular the maximum proportion of surface area) in the end product and the overall wetted surface area of the delivered assembly in cm². This information is required both by the manufacturer of the assembled final product (e.g. a fitting manufacturer) for the purpose of defining his product design, and by the certification body in order to check the validity of a partial certificate of components and component assembly(-ies). If the noted maximum proportion of wetted surface area is not exceeded in the end product, individual

components of the component assembly need not to be considered for the evaluation of further components of the final product.

Question B-12:

Which risk groups apply to on-site products and under which circumstances is it possible to apply a simplified conformity attestation procedure?

Answer:

According to the *UBA* Recommendation for Attestation of Conformity, attestations for products intended for installation site application (on-site products) are limited to the general suitability of the products. They only cover fabrication of the final product under optimised conditions. It would be advisable to establish conformity attestations that also cover on-site application in practice for the product, but this cannot be regulated by an *UBA* recommendation since it would be necessary to implement technical requirements of application.

Due to the ambiguous nature of on-site product application (large-scale application or confined to a maximum of 10 % surface area of the structure – risk group P1 or P2) it is not useful to differentiate certificates in this respect. Therefore, *UBA*'s recommendation handles certification for these on-site products uniformly as risk group P1 under the scheme of the 1+-system. External inspection thus required will in this case be relevant for the manufacturing of the intermediate product intended for on-site application and sampling of a representative test specimen obtained under conditions of use as recommended by the manufacturer.

In contrast, for on-site products intended for small-area application like repair systems in domestic installations it is possible to differentiate cases of practical use. From the envisaged minor wetted surface area in drinking water contact (< 1%) a corresponding conversion factor and risk group P3 result, allowing the simplified conformity attestation procedure. Products must be labelled with explicit notes that their use is restricted to cases of small-area application.

Ouestion B-13:

Which surface/volume ratios are to be applied on product testing of ancillaries for containers?

Answer:

According to the *UBA* KTW evaluation criteria, for evaluation of additional and substance-specific requirements migration testing has to be done according to parts 1 or 2 of standard DIN EN 12873 by applying a surface/volume ratio of 5 dm⁻¹. Preparation of migration waters for the odour parameter has to be done following standard DIN EN 1420. Regulatory coverage of both these standards is however currently restricted to products for pipe (network) systems, which means that ancillaries for containers are not within the scope of the standard. For determination of threshold odour numbers (TON) of containers, existing standard

DIN EN 14395-1 is applicable which also defines surface/volume ratios for preparation of migration waters for ancillaries for containers. This standard however is not referred to in evaluation criteria.

It is intended to amend standard DIN EN 1420 and to combine it with DIN EN 14395-1. Until this has been accomplished and reference is made in evaluation criteria to the amended standard, ancillaries for containers can be tested according to DIN EN 1420. A surface/volume ratio of $1.5~\rm dm^{-1}$ shall be adjusted for preparation of migration waters serving to determine colouring, turbidity, foaming and TON parameters. This has already been specified with the $2^{\rm nd}$ amendment of KTW evaluation criteria (table 4; resp. table 5 in KTW-BWGL $4^{\rm th}$ amendment and higher).

Question B-14:

How to perform testing and evaluation of possible risks for substance transfer from layered material combinations if these products are not regarded as typical multilayer products with permanently attached layers?

Answer:

In multilayer products, the different material layers generally are inseparable. Testing of such products follows specifications given in KTW evaluation criteria chapter 5.7, the purpose of which is to adequately reflect potential substance transfer from all layers into the drinking water. Due to diffusion, substance transfer may occur from layers other than the one being in direct contact with drinking water.

Among products displaying no permanent combination of layers involved (e.g., pipes with externally attached insulation material or nested (inserted) tubing combinations), testing and evaluation of outer layers (incl. formulation review) is currently not envisaged. Nevertheless, experience shows that even such layered material combinations exert noticeable substance release into contact waters originating from rear layers, depending on the type of layer contact from e.g. layer gap distance and contact area allowing diffusion.

Currently *UBA* does not have sufficient information on substance release behaviour of separable, not permanently attached layered material combinations. It is therefore not yet possible to define distinct testing requirements for such material combinations. To be able to do so, certifiers are asked to acknowledge *UBA* should they receive requests for assessment of non-permanent material combinations.

In *UBA*'s view it is not required in these cases to assess material formulations of outer layers. There should however be performed an extended (31 days) warm water migration testing and migration waters be analysed by GC/MS screening according to standard DIN EN 15768. This serves to assess possible contributions from rear layers to migration while it does <u>not</u> replace cold water testing which is obligatory for all products (KTW-BWGL Ch. 6.3.1). Prior to migration testing, the product shall undergo a storage period of at least 30 days at room temperature, as is required for testing of permanently attached multilayer products.

In extended warm water testing, it is advantageous to investigate in parallel solely the direct water contact layer the same way to elucidate to what extent outer layers contribute to

migration. This partial test should however not substantiate a certificate for the wetted inner layer if this is typically intended or conceivable to be combined with additional, non-permanently attached outer layers thereafter being used in drinking water contact. With such "assembled hoses", microbiological testing should always include (also) the entire hose.

If in fact only a monolayer hose is submitted for approval, it is compulsory to include a note in the certificate saying that its use in multilayer or "assembled" hoses will make re-testing of the combined product necessary. Alternatively, conformity attestation must contain a reference that for the multilayer/combined product under consideration, only the wetted inner pipe or tubing has been tested for drinking water suitability.

UBA kindly asks to be provided with respective testing results in order to be able to adapt provisions formulated in its evaluation criteria documents.

Question B-15:

Which requirements apply regarding impurities of starting substances for organic materials and how is compliance verified?

Answer:

According to the KTW evaluation criteria document, two general types of purity requirements for starting substances are identifiable: on one hand those setting individual specifications associated with formulation-specific requirements, on the other hand the general requirement that starting substances must "be of a technical quality and purity suitable for the planned and foreseeable purpose of the product" (KTW-BWGL Ch. 5.2.1).

Former specification requirements relate to explicitly defined, maximum admissible contents of specific impurities of e.g. fillers, colourants or oligomeric constituents, and those defined as additional requirements in positive lists of polymer-specific annexes of the KTW evaluation criteria (column "Other restrictions"). In case of a certification the manufacturer may prove fulfilment of these requirements by submitting respective analysis reports. Alternatively, the certification body shall verify fulfilment of requirements by commissioning analyses of respective starting substances to a testing body. If analysis reports are not available, it is accepted to perform migration testing for the respective parameters on the component or final product, provided that MTCtap values for these parameters (see e.g. Annex 1 of the KTW-BWGL) have been set.

Concerning general purity requirements for starting substances, the manufacturer's responsibility must be stressed explicitly. In view of their knowledge on the composition of substances and mixtures the manufacturer must be aware of possible health risks and must eliminate them if such risks occur.

In order to ensure that certification bodies are in the position to evaluate drinking water hygiene suitability of used materials also with regard to possible impurities, the manufacturer must generally specify, for all starting substances,

• all impurities with relative mass percentages above 1 %, and

 all substances that are classified under CLP Regulation No 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, with relative mass percentages above 0.1 %.

The manufacturer must confirm and prove to the certifier that the specifications he provided concerning impurities correspond to these requirements. Specific verification of the respective requirements is conducted over the course of formulation review according to KTW-BWGL Ch. 6.1. In addition, the manufacturer – having in mind manufacturer's responsibility – must confirm that the substance or mixture is suitable for the manufacture of drinking water contact materials.

Safety data sheets normally only cover those impurities that are relevant for a substance or mixture classification according to the REACH regulation and therefore are of only limited significance. To set up the safety data sheet, the manufacturer anyhow must have available the above-mentioned data concerning impurities.

Question B-16:

Which tests are required to be carried out (eventually by placing an order) by the certification body to verify fulfilment of requirements of evaluation criteria, or what type of information or document may be provided by the applicant or (pre-) supplier?

Answer:

The course of action for obtaining relevant information required by the certification body to evaluate whether a specific requirement is met or not depends on the type of requirement to be checked:

- If the requirement is defined for the product or component (**final product**), the certification body must place a corresponding order for testing with an appropriately accredited testing body or physically test this itself.

 Examples are migration requirements (MTC_{tap}); QM/QMA; microbiological requirements.
- If the requirement is defined for a **starting substance**, fulfilment of the requirement can also be demonstrated to the certifying body by means of a manufacturer's confirmation including the related analysis report. The corresponding order for testing/analysis shall regularly be commissioned by the manufacturer or if applicable by a pre-supplier involved; otherwise, the certification body would have to organise and to commission analytical testing of the starting substance. For fillers and colourants (see question C-14), parameters of purity requirements can be checked by migration testing instead. As MTC_{tap} for the various metal ions, 10 % of the respective threshold value of the German TrinkwV applies.

The manufacturer of the starting substance is generally obliged to confirm to the certification body whether or not the starting substance is classified as nanosized material per definition of Commission Recommendation (EU) 2022/C 229/01¹. In case

¹ Commission Recommendation of 10 June 2022 on the definition of nanomaterial 2022/C 229/0; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022H0614%2801%29

nanosized material is declared, the manufacturer must provide an analysis report on particle size distribution.

Ouestion B-17:

Which steps apply to formulation review in cases where totalled formulation constituents remaining below 0.02 % exceed the allowed formulation cut-off limit of 0.1 %?

Answer:

The formulation cut-off limit defined in the KTW evaluation criteria on organic materials comes as an "and" criterion combining the maximum allowed weight percentage for individual constituents and the maximum allowed weight percentage for the sum of these. In formulation review, it is both considered for checking coherence with positive lists (Ch. 5.2.2 a)) and for determining the relevant migration parameters (Ch. 6.1).

When checking the criterion of a maximum allowed amount of 0.1 % for the total of all substances summarized for "low use" application, both evaluated (positively listed) and non-listed substances are considered. If as a result the allowed limit of 0.1 % for the sum is exceeded, then the corresponding formulation constituents among the "< 0.02 %" cohort displaying highest contents are to be inspected individually. Normally, migration waters will thus have to be examined for existing migration restriction for these constituents (e.g., c_{tap} < 0.1 $\mu g/l$). Only when the allowed limit of 0.1 % as sum of the remaining substances is not (or not anymore) exceeded, these other substances left need not to be examined due to their low-use character.

Ouestion B-18:

Can manufacturers themselves consider the formulation cut-off limit to decide which starting sustances they disclose to the certifying body in their formulation declaration?

Answer:

No. Formulation constituents below 0.02 % weight content too must initially be declared to make sure that the certifier is in the position to check the complementary criterion of max. 0.1 % (w/w) for the total of starting substances of the "< 0.02 %" cohort (see question B-17 above). Over the course of this check it may for example be decided to omit e.g. non-listed peroxides with initiator function (see question C-16) or solvents from further consideration. Subsequently, the certifier will define those marginal formulation constituents that need not to be regarded in the assessment.

Question B-19:

Which prerequisites apply for having relevant substance migration data generated by alternative estimations instead of regular determination via analysis?

Answer:

Estimation of total migration or modelling according to the modelling guideline 2 may be used as an alternative to analytical determination of relevant substances in migration waters. As an important prerequisite for this, contents of these relevant substances in the final product (c_0) must be known. Contents can be calculated from application amounts. Solvents must be disregarded in calculations based on application amounts because these are removed from the product to a large degree.

As a consequence of dedicated processing steps (like e.g. washing- and drying processes), substance contents may be altered as compared to contents estimated from application amounts. If an increase or significant reduction of contents of relevant substances is suspected, analytical determination of contents in the final product must be conducted.

In cases of starting substances that react as intended, reaction- and degradation products are to be identified and to be considered in addition. For non-listed substances, it is necessary to identify relevant substances as reaction- and degradation products and to determine contents of these substances. Formation of such substances may vary depending on the type of organic material, even if starting substances are identical (see question C-16/peroxides).

Question B-20:

How are different suppliers of starting substances considered in certification processes?

Answer:

In order to always secure sufficient supply of starting materials, manufacturers normally rely on several suppliers. If a specific supplier fails to be available, even a rapid switchover to another supplier might be necessary.

In such cases the consequences for certification differ. Generally, it must be discerned if a starting substance is a singular substance, or if it is a mixture of substances of which the exact composition is eventually not known by the respective manufacturer or processor.

a) Starting substance is singular substance: the respective manufacturer may switch to another supplier without having informed the certification body if the alternative starting substance bears the same specification, especially in terms of purity. Should the alternative starting substance display a lower purity grade or other impurities, the certification body must be informed which then has to undertake a risk assessment. Only in severe cases of uncertainty the certification body may request for re-testing of products that have been manufactured with the alternative starting substance.

² Guideline for the Mathematical Estimate of the Migration of Individual Substances from Organic Material in Drinking Water: https://www.umweltbundesamt.de/en/document/modelling-guideline

b) Starting substance is mixture of substances: if a starting substance consisting of a mixture of substances is purchased from an alternative supplier, it is always necessary to inform the certification body. The certifier must request for the composition of the mixture of the alternative supplier and then must evaluate whether re-testing of products manufactured with this alternative starting substance is necessary. Withdrawal of test specimens, on the occasion of initial inspections or during routine monitoring, cannot – and not even needs to – reflect all possible (alternative) suppliers at once. This may be subject to an appropriate rotative withdrawal scheme appointed with the certification body.

Ouestion B-21:

How shall the methodical inaccuracy of the test on microbial growth for elastomers, chemically crosslinked thermoplastic elastomers and silicones be defined to have a basis for verifying the requirement of a non-rising trend of measurement results?

Answer:

When performing the test on microbial growth according to DIN EN 16421 method 2 or DVGW standard W 270, it is required that the sequence of measurement results (arithmetic means) for the harvested amount of biofilm must not show a rising trend (M2 or M3 incl. optional monthly results from extended testing). Due to the inherent low accuracy of the method, the pair of initial test results used in average determination for the monthly test result may sometimes differ to a higher degree than the acceptable parameter uncertainty. Depending on the convention on methodical uncertainty, divergent interpretation of measurement results may occur.

In order to come to a consistent procedure, it is therefore agreed that, regarding the criterion for the evaluation of the trend of measurement results, the acceptable increase of a subsequent monthly measurement result shall not be larger than twofold the allowed added volume range (+ 0.03 ml) as defined in the testing standard. This volume range is related to the standard deviation of \pm 0.03 ml for the method which originally had been derived from baseline investigations.

It is thus stipulated that, due to the inherent methodical inaccuracy, a volume difference of max. + 0.06 ml between two successive monthly measurement results (mean of two parallel determinations) is admittable without being regarded as rising trend. At the same time the requirement specified in the standard applies which says that the growth volume of neither sample may exceed the absolute value of 0.12+0.03=0,15 ml/800 cm² (M2) or 0.20+0.03=0,23 ml/800 cm² (M3), respectively.

Therefore, evaluation of some numerical examples for the requirement M2 would read as follows (test results 2a /3a in ml/800 cm²):

2a: $0.09 \text{ ml/}800 \text{ cm}^2 / \textbf{3a:} 0.15 \text{ ml/}800 \text{ cm}^2 \rightarrow \text{passed, difference } +0,06 \text{ ml still acceptable (border case)}$

2a: $0.08 \text{ ml}/800 \text{ cm}^2 / 3a$: $0.15 \text{ ml}/800 \text{ cm}^2 \rightarrow \text{failed, difference } +0.07 \text{ ml too high}$

2a: $0.03 \text{ ml/}800 \text{ cm}^2 / \textbf{3a:} 0.10 \text{ ml/}800 \text{ cm}^2 \rightarrow \text{failed, difference } +0.07 \text{ ml too high}$

2a: $0.12 \text{ ml/}800 \text{ cm}^2 /$ **3a:** $0.16 \text{ ml/}800 \text{ cm}^2 \rightarrow \text{failed, absolute margin of } 0.15 \text{ ml/}800 \text{ cm}^2$

exceeded

Question B-22:

In manufacture of non-woven (fleece) materials, is it required to provide formulation data and to perform testing for utilised scrubbing fluids?

Answer:

In manufacture of non-wovens, the final step involves application of detergent scrubbing fluids by which remnants of spin-finish are removed.

It can be assumed that all ingredients of such scrubbing fluids are highly water soluble and will be removed in the course of the subsequent flushing of the ready final product. It is the manufacturer's responsibility to consider this issue in preparing a hygienically flawless product. As far as this is kept in mind, declaration of ingredients and testing are not necessary.

Ouestion B-23:

How to implement compulsory positive listing of PFAS in the framework of certification processes?

Answer:

According to the 4th amendment of the KTW-BWGL, by entry of its mandatory status at 13 September 2026 positive listing of per- and polyfluorinated starting substances (PFAS) will become obligatory. This means that products obtaining a certificate after 13 September 2026 or certificates of which thereafter are to be extended, may not contain formulation constituents that are not included in the respective positive lists of the KTW evaluation criteria. Exceptions to this provision related to the use of non-listed substances on grounds of low-use (5.2.2 a) KTW-BWGL) or low substance migration (5.2.2 b) KTW-BWGL) are then no longer applicable for PFAS.

In order to implement this requirement, certification bodies should request a manufacturer's declaration that PFAS are not used for manufacture even in marginal amounts (< 0.02 %).

Existing certificates do not have to be withdrawn nor is it required to restrict the validity period afterwards. Beyond or when approaching the end of the validity period it is however necessary to perform a formulation assessment again, which in case non-listed PFAS are used will lead to formulation refusal.

Subject area C

Material- and product-specific questions

Question C-1:

Why does UBA recommend chrome-plated fittings should only be certified if nickel release has been tested and evaluated?

Answer:

Pre-coating with nickel, which is necessary for chromium-plating the fittings with regard to galvanisation, can lead to nickel scattering on the inner surfaces of the fitting in contact with drinking water. As a consequence, stagnant water in such fittings can in some cases considerably exceed the nickel limiting value of $20~\mu g/l$ of the drinking water ordinance in the outflowing first approx. 0.2 litres. To ensure that chrome-plated fittings comply with the limiting value for nickel in drinking water, they must be subjected to a lengthy and costly long-term test. It has not yet been possible to develop an equivalent short-term test to assess nickel release.

This currently leads to an unsatisfactory situation because, though a sophisticated standardised European test method for determining nickel release from fittings (DIN EN 16058) exists, this standard cannot be used to test all fittings due to high cost and effort involved. For this reason, *UBA* has published test criteria (see below) but has not included them as part of the binding evaluation criteria for metallic materials in contact with drinking water.

One possibility to reduce nickel release is the so-called "plugging". In this method, all openings in the fitting are closed by hand in order to minimise nickel scattering on the inner surfaces. The compliance with the nickel limiting value can be confirmed in a certification procedure for products of manufacturers who plug their fittings. For this purpose, a sample fitting must be selected and tested according to DIN EN 16058 and the production process must also be monitored.

Other technical options for reducing nickel scattering are also conceivable, that is why "plugging" cannot be made mandatory for certification.

Even though the *UBA* evaluation criteria for metallic materials do not regulate nickel release from chrome-plated fittings in a mandatory way, the limiting value for nickel in the Drinking Water Ordinance still applies. For this reason, *UBA* advocates that chrome-plated fittings should not be certified if they have not been tested and evaluated for nickel release.

If nickel release has not been tested and evaluated according to DIN EN 16058, it is the manufacturer's responsibility to confirm compliance with the nickel limiting value and the other requirements in the form of a self-declaration (manufacturer's declaration). However, this cannot result in a relevant product certification.

The criteria for assessment of nickel release referring to test results determined as per DIN EN 16058 and further explanations on this problem can be found in the *UBA* information leaflet 'Release of nickel by chrome-plated drinking water taps and other components' on the

Question C-2:

Which tests are required for the certification of products made from stainless steel and other passive materials?

Answer:

The positive list of the evaluation criteria document for metallic materials in contact with drinking water mentions passive materials only in a general way. As a requirement it is only stipulated that materials must be in the state of passivity when respective products are used in a distinct application. Passivity depends on the type of material (composition) and the specific application. For example, certain types of steel display passivity when used as pump axis, but they do not when used as pipe material. It is therefore not possible to derive explicit criteria for stainless steels that would have to be considered if these were to be tested according to DIN EN 16056 in order to confirm passivity. Should a steel quality declared as stainless turn out to be non-passive in a distinct application, this would lead to pitting corrosion and first of all cause technical failure but not exceedance of drinking water parameter values. It is for these reasons that the certifying body is not required to test for the passivity of stainless steels on the occasion of certification. It is sufficient if the manufacturer confirms the passivity for the application. The certifying body solely has to check that the respective material is known as stainless steel and is listed correspondingly in standard DIN EN 10088 or DIN EN 10283 for example. According to the Recommendation for Attestation of Conformity of Product Hygiene Suitability for Drinking Water, for type testing and external monitoring of metallic products or components of product groups A or B the certifying body must verify the composition of the metallic material. Related to the manufacturer's responsibility to confirm passivity, it is sufficient if the material composition has been documented within the framework of factory production control by way of one of the following schemes, and if this is verified for products of product group A and B by the certification body:

- regular, continuous analysis of material composition, or,
- continuous provision of acceptance test certificates 3.1 as per DIN EN 10204.

In this context see also subsequent question C-3.

For products or components of product groups C and D, the simplified procedure for attestation of conformity applies. In this case it is sufficient to have the material composition tested every five years or to provide a company certificate 2.2 as per DIN EN 10204.

Beside stainless steel other passive materials can be used. These however must be listed explicitly in the positive list of the evaluation criteria document for metallic materials if they are to be used in products or components of product groups A, B or C. Testing for passivity according to DIN EN 16056 is only necessary for having the material listed in the positive list, while this is not necessary as part of a certification of respective products or components. The certifying body however must check for products or components of product groups A, B and C if the chemical composition complies with the composition as listed in the evaluation criteria. For components of product groups A and B this requires an attestation of conformity

following system 1+ as per the Recommendation for Attestation of Conformity. For components of product group C, the simplified conformity attestation procedure may be used. For passive materials of product groups A, B and C the procedure for attestation of conformity is analogous to the procedure for any other metallic materials listed in the evaluation criteria document for metallic materials.

For product group D other passive materials may be used that do not need to be listed explicitly in the positive list of the evaluation criteria document for metallic materials. Likewise, passivity is not required to be tested by the certifying body in this case. It is sufficient if the manufacturer confirms the passivity for the application. For products or components of product group D also the simplified conformity attestation procedure applies. In this case again it is sufficient if the composition is analysed every five years or a company certificate 2.2 is submitted, as has been described for stainless steels.

Question C-3:

How can manufacturers of metallic materials and components made thereof have their factory production control carried out and documented?

Answer:

Manufacturers of metallic materials and components must conduct a factory production control (FPC) for all product groups A through D foreseen in the evaluation criteria for metallic materials in order to secure compliance with the material composition as set out. If however for the metallic product or component, no matter of which product group A through D, an attestation of conformity following system 1+ as from the recommendation for attestation of conformity already exists, then no further testing of incoming goods is required.

FPC for metallic products and components of product groups A and B

According to the *UBA* Recommendation for attestation of conformity of product hygiene suitability for drinking water, system 1+ applies for conformity attestation of metallic products and components of product groups A and B. From this it follows that the certification body must supervise the internal control (FPC) for such products and components. Details of the FPC with respect to material composition will depend on whether the raw material undergoes founding/recasting or only mechanical processing in the plant.

<u>Testing of material composition from fabrication of cast products or components</u>

As for cast products or components, continuous analysis of the composition of the cast pieces within the factory is indispensable as part of the FPC. Recasting, e.g. for fabrication of more differentiated blanks/semi-finished stock, or remelting potentially may alter the elemental composition and the liberation behaviour of elements from the material. It is therefore the final fabrication step with an inherent potential for the modification of material composition that determines drinking water hygiene suitability of components or products made thereof.

Frequency of analyses and analysis method will be defined by the manufacturer and the certification body together. A test certificate 3.1 as per DIN EN 10204 eventually issued for the cast components may be used by a subsequent customer if only mechanical processing is conducted by this customer (see below).

Testing of material composition in case of exclusively mechanical processing

If purchased materials undergo mechanical processing only, determination of the material composition on incoming goods FPC is sufficient. This can be accomplished via two routes:

1) Analysis of the material composition for each individual shipment received,

In this case the effort for analytical determination of the material composition can be reduced if an up-to-date company certificate 2.2 as per DIN EN 10204 is attached to each lot; and it can be further reduced if by appointment with the certification body it is verifiable that existing company certificates 2.2 are appropriately linked to random sampling as part of an ISO 9001 quality management system installed.

2) Test certificate 3.1 as per DIN EN 10204

The material composition of each individual shipment is documented by a test certificate 3.1 as per DIN EN 10204. An existing test certificate 3.1 can be passed on to subsequent customers along the supply chain if only mechanical processing occurs. To employ this option, it is indispensable that the respective test certificate can definitely be traced back to the relevant lot for which the original test certificate 3.1 after DIN EN 10204 has been issued, which must be safeguarded by appropriate QS systems installed among players participating in the supply chain ("paper trail").

FPC for metallic products and components of product groups C and D

According to the *UBA* Recommendation for attestation of conformity, for metallic products or components of product groups C and D the simplified procedure for attestation of conformity applies. In this case company certificates 2.2 are sufficient for internal control. Test certificates and analyses of material composition obtained during internal controls are not verified by the certification body. The manufacturer has the full responsibility for continuous quality assurance.

Question C-4:

How are auxiliary chemicals added to galvanic baths to be evaluated?

Answer:

Galvanic baths used for electrochemical precipitation of platings on metallic parts, e.g. for nickel- or chromium plating of outer surfaces of fittings made from copper alloys, in addition to substances providing the plating itself also contain other inorganic or organic chemicals. For the passivation of surfaces different organic and/or inorganic substances are used as well.

On the instance of a product certification the certifying body must verify that the chemical substances used do not remain on plated or processed surfaces and thus cannot migrate into drinking water. This requires the manufacturer or the supplier of the used chemicals to disclose the formulation of the bath fluids or process fluids to the certifier. The certifier defines the test program for the final product correspondingly. If the certifier recognises substances to be present in the formulation that might cause health risks, then migration testing according to DIN EN 12873-1 is necessary in order to prove that no relevant substance transfer into drinking water occurs.

If it can be demonstrated to *UBA* that components or products which have been processed with galvanic or post-treatment bath fluids generally do not release substances into drinking water in hygienically relevant amounts, then *UBA* will publish the corresponding manufacturing processes. Certification of products obtained this way will then be facilitated in the future.

Question C-5:

How can cast metal components be certified which have been impregnated in order to guarantee achieving their technical performance features?

Answer:

During manufacture of cast metal pieces, it may come to the formation of microscopic cavities (pores, cracks, occlusions) even if the casting process has been operated thoroughly. Such cavities can increase the risk for technical failure of the cast component as a result from leakage or increased corrosion. In order to make sure that technical requirements are fully met, all cavities can be sealed by subjecting the cast components to a fluid impregnating system which penetrates faulty zones and solidifies there. This is more economic than having freshly fabricated parts smelted and cast again.

Sealing of microscopic cavities can be accomplished by two types of impregnating systems, one of which is based on water glass (silicate), while the other is based on reactive organic resins.

Water glass-based impregnating systems

These are not covered by any of the evaluation criteria as yet defined by *UBA*. In consideration of information on formulations and conditions of use received in between, a regulatory information dealing with these impregnating systems is currently elaborated by *UBA*.

Impregnating systems based on reactive organic resins

For organic resins, it is generally possible to test and evaluate these according to the KTW evaluation criteria Annex B, provided that conditions of use are indicated correctly. This especially requires localisation of faulty zones in the component including estimation of wetted surface proportions which actually have been impregnated.

Certification of cast components that have been subjected to impregnation is based on evaluation of the impregnating system used, followed by evaluation of cast components processed this way. Evaluation of the impregnating system first requires formulation review according to KTW-BWGL.

Evaluation of impregnated cast components, with testing for migration requirements as basis, may be conducted either

- by using an impregnated "worst case" cast component, or,
- by using a coated test plate, the measured migration data of which have been converted with regard to wetted surface proportions.

Both variants have weaknesses in terms of significance of measuring results in tests to verify requirements. In case an impregnated cast component is used, estimation is difficult as to which extent the test water is actually in contact with organic surfaces of backfilled cavities,

and as consequence, to which extent assumptions regarding sufficient wetted areal coverage available for effective substance migration and microbial impairment of the contact water are correct. In this context, e.g. washing steps as part of subsequent post-processing will not only remove residues of impregnating resin from surfaces but to some degree also from cavity openings. If in turn coated test plates are used, curing conditions differ considerably from conditions applied in impregnating processes, which means that comparability in terms of chemical and microbial impairment of the contact water might not be given.

Regarding testing for microbial growth, additional difficulties exist. Method 2 (biofilm volume method) of standard DIN EN 16421 is not suited to be applied to impregnated cast components simply for practical reasons. For method 1 (ATP/biomass production method) of standard DIN EN 16421, uncertain and variable results must be expected here bearing in mind the overall low number of cavities per unit area. Additionally, for both methods it can be assumed that presence of metallic surfaces will inhibit microbial growth, in particular where copper as commonly used alloy constituent is used.

As a consequence from these restrictions, assessment of microbial requirements is dispensible for applications in cast component impregnation, provided that it can be demonstrated that no remnants of impregnating agent are present on the component's surface and that respective wetted surface proportions do not exceed 1 %. A suitable method is to be agreed on with the certification body which allows testing for possible remnants of impregnant, as for example by means of a fluorescent dye added to the impregnant or if the impregnant fluoresces itself.

Following positive evaluation of the impregnating system, a corresponding P3 intermediate product certificate can be issued. This certificate is sufficient for the application case described here, and components impregnated this way do not require additional testing.

Certifying bodies shall request for a statement from any individual founder if (occasional) impregnation of cast pieces is intended during manufacturing.

Question C-6:

Which platings are covered by positive list entries "Galvanic Sn/Niplatings on external surfaces" (3.2) and "Galvanic Cu/Sn-platings on external surfaces" (3.3) of the positive list of hygienically suitable metallic materials?

Answer:

For certain metallic platings, drinking water hygiene suitability can generally be approved according to the evaluation criteria for metallic materials in contact with drinking water (see Ch. 3.2 therein). This approval results in an entry in the positive list and the plating is furthermore regarded as a metallic material. Then, for the purpose of drinking water hygienic evaluation of metal release, it is not necessary to perform additional product testing.

The case considered here concerns metallic platings which are basically deposited on non-wetted external surfaces but scatter on inner surfaces in contact with drinking water (see bullet point 2 in Ch. 3.2.1 of the metals evaluation criteria). By means of testing according to DIN EN 15664-1 or DIN EN 16058, respectively, of various products plated at different

manufacturing sites with such platings, it could be demonstrated that these do neither lead to elevated metal release from the base material nor was there elevated release of elemental concentrations (Cu/Sn, or Sn/Ni) into the drinking water from the plating itself. Additionally, testing of various products showed that metal release from such platings remains constant in time. Accordingly, drinking water hygiene suitability of these platings could be approved in general. Products having been plated in this manner must comply with requirements set out in the positive list, which then makes additional product testing for metal release following DIN EN 16058 dispensable.

Both these platings are deposited on a metallic base material via galvanic (electrochemical) processes. In more detail, this comprises a cathodic deposition of a metallic layer onto electrically conducting parts from an electrolytic solution of the respective metal salts. This is achieved by immersion of components (components of product groups B and C according to the evaluation criteria for metallic materials in contact with drinking water) into the respective galvanic baths. The plating will be deposited on outer surfaces and also scatter on inner surfaces. Inner surfaces will display gradually decreasing layer thicknesses, and some areas of the inner surface might also be devoid of scattering. This depends on the geometry and dimension of the component as well as from its orientation in the galvanic bath. The degree of scattering of platings on the inner surfaces can hardly be controlled in galvanic processes. Evidence shows that in case of galvanic platings it is mainly the transition region between plating and base material which may lead to enhanced metal release.

"External surface" in this context is to be understood as the surface intentionally covered by a complete plating layer of uniform thickness. In the regular case, these are not surfaces for drinking water contact. Frequently, inner surfaces which come into contact with drinking water are more or less affected by scattering. Corresponding examples are connectors, fittings, valves. On the other hand products exist the external surface of which is dedicated to drinking water contact, as for e.g. the exposed sphere of ball valves or the top of a softening installation.

Positive list entries "Galvanic Sn/Ni-platings on external surfaces" and "Galvanic Cu/Sn-platings on external surfaces" cover any of the applications for such platings, even if the external surface comes into contact with drinking water.

Question C-7:

What is the current and near-future mode of regulation to evaluate starting substances for the production of cementitious materials in contact with drinking water?

Answer:

DVGW standard W 347 currently regulates testing and evaluation of cementitious materials in contact with drinking water. The positive list as part of this standard will however not be pursued. According to section 15 (1) of the Drinking Water Ordinance (TrinkwV), *UBA* has been legitimated to define evaluation criteria for materials in contact with drinking water, which consequently also pertains to cementitious materials.

According to the revised European Drinking Water Directive (Directive (EU) 2020/2184), European positive lists for materials in contact with drinking water will be defined in the

future. For this reason, *UBA* will not set up national evaluation criteria for cementitious materials in advance of a European regulation. Evaluations of starting substances that are not covered by DVGW standard W 347 nevertheless can be conducted by *UBA* if this is applied for. Detailed information can be found at URL:

https://www.umweltbundesamt.de/en/document/information-on-the-evaluation-of-starting

Ouestion C-8:

In what detail are formulation ingredients of cementitious materials to be disclosed to the testing body in order to obtain a test certificate according to DVGW standard W 347?

Answer:

Full details of the formulation including all starting substances of additions (inorganic additives), admixtures, fibers, auxiliary construction materials and other accessory ingredients are to be disclosed to the testing body. A manufacturer's confirmation stating that e.g. a dispersion corresponds to BfR recommendation XIV is not sufficient.

Question C-9:

How can inorganic coatings be evaluated?

Answer:

Beside organic coatings, which can be evaluated according to the KTW evaluation criteria annex B, also inorganic coatings are available. These are fabricated in part also from organic materials, but result in a mainly inorganic matrix after application. Such mainly inorganic coatings neither fall within the scope of annex B of the KTW evaluation criteria nor within the scope of the evaluation criteria for enamels and ceramic materials.

Accordingly, for coatings of this type *UBA* has not yet defined specific evaluation criteria. Considering future European regulations for materials in contact with drinking water according to the revised European Drinking Water Directive (Directive (EU) 2020/2184), *UBA* will not define new evaluation criteria that would anticipate harmonised European regulations.

As a consequence, for materials not yet regulated the following requirements must be observed in order to ensure drinking water hygiene suitability of products used in contact with drinking water:

- The material used must comply with general requirements according to section 14 Drinking Water Ordinance (TrinkwV):
 - "Materials used in the construction or maintenance of water supply systems which come into contact with raw water or drinking water may not
 - 1. directly or indirectly compromise the protection of human health as provided for under this Ordinance,
 - 2. adversely affect the colour, odour or taste of the water,
 - 3. enhance microbial growth or

- 4. release substances into the water in quantities larger than what is unavoidable in complying with the generally recognised codes of practice and standards"
- As far as no concretisation of the above cited general requirements is made by definition of material-specific requirements in an evaluation criteria document by *UBA*, it is the responsibility of the manufacturer to prove compliance with general requirements.

Question C-10:

Is it allowed to further use products with bituminous coatings after entry into force of the KTW evaluation criteria on 21 March 2021?

Answer:

Until 21 March 2021, proof of drinking water hygienic suitability of bituminous coatings could be demonstrated according to DVGW standard W 348. This standard has been withdrawn at the datum mentioned, because it is the end of period after which the KTW evaluation criteria have become mandatory for organic materials in contact with drinking water.

Bituminous coatings fall within the scope of annex B of the KTW evaluation criteria. Necessary starting substances for fabrication of bituminous coatings are not listed in the respective positive list as a consequence of insufficient risk assessments. For this reason, bituminous coatings may exclusively be used for components of risk groups P3 and P4. Relative surface proportions therefore must remain below 1 % of the wetted surface of the ancillary (as for example a fitting). If this is not the case, products of that kind may not be installed since 21 March 2021.

Question C-11:

Which drinking water hygiene requirements apply to sealing materials?

Answer:

Tapes and threads (filaments) from polytetrafluoroethylene (PTFE) for metallic threaded joints in drinking water installations are small-area products for ancillaries. Normally it can be assumed that wetted surface area will remain below 1 % with respect to the ancillary. For such components in drinking water installations a conversion factor of 0.02 d/dm applies, corresponding to risk group P3 for these products.

Non-hardening pasty sealing compounds for hemp exert a negligible effect on drinking water quality. Normally it can be assumed that wetted surface area will remain below 0.1 % with respect to the ancillary. The conversion factor for products with negligible effect on drinking water quality for pipes with inner diameter < 80 mm is 0.002 d/dm. Thus, the applicable risk group for these products is P4.

This assignment requires that the installation company adheres to proper workmanship when using the sealing materials.

It is inherent that sealing materials will continue to remain permanently in the installation. Therefore, application instructions for such materials should emphasise the relevance of clean working practice to ensure that wetted surface proportions correspond to dedicated product categories.

Requirements on sealing materials and respective testing hitherto had been regulated in the German standard DIN 30660:1999-12 which meanwhile has been withdrawn. Hygienic requirements defined therein pertained to appearance (visual, odour, flavour), total organic carbon (TOC) and chlorine demand. The latter parameter is not determined to be tested anymore in recent KTW evaluation criteria. The amended version DIN 30660:2022-04 has been published recently which in terms of drinking water hygienic requirements refers to the KTW-BWGL.

Question C-12:

How to evaluate cyanoacrylate adhesives when used for the fabrication of elastomer sealing rings from bulk stock?

Answer:

Cyanoacrylate (CA) adhesives serve for instant, durable joining of cut ends of bulk stock rubber piping (sealing cords) when preparing custom-fit elastomer sealing rings. In the finished seal ring from such applications, the cured CA adhesive is only present in the joining gap where former facing ends of the cut piece of rubber sealing cord have been brought together. The expected wetted contact area at the joining gap is small and for this application of the adhesive leads to categorization in risk group P3 as per KTW evaluation criteria.

In migration testing of CA glued rubber sealing cord, only basic requirements have to be tested for and in doing so the S/V ratio for the respective seal has to be adjusted (S/V \geq 5 dm⁻¹ for TOC and S/V = 0.2 dm⁻¹ for organoleptic parameters; see table 5 of the KTW-BWGL). Microbiological requirements need not to be tested.

Question C-13:

How to evaluate solvents in formulations?

Answer:

As derived from existing results from migration testing or modelling, solvents are subject to possible migration from products into drinking water. It is therefore necessary to clearly denominate these production aids in formulation declarations and to take into account requirements and migration restrictions. Estimation of substance transfer into drinking water or of residual contents in a product solely from comparing boiling points and process temperatures (i.e. assumption of complete volatilization) does not regard current knowledge and is thus not appropriate.

Positive lists of *UBA* evaluation criteria documents comprise some solvents including migration restrictions defined for them. Should there be used non-listed solvents, then a restriction of MTC_{tap} = $0.1 \, \mu g/l$ applies.

 $\it UBA$ recommends manufacturers and users to submit petitions for solvents intended to be used, such that possible definition of migration restrictions higher than 0.1 $\mu g/l$ can be evaluated. In some cases, this might employ existing substance listings for cases of other material applications and/or listings from other positive lists.

Alternatively, for the determination of substance transfer the determination of residual contents is sufficient in specific cases:

- For solvents that are not classified under CLP Regulation No 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, residual contents in the final product can be employed for the assessment of the product. As a basis for this, it is required to submit a specification document (analysis report) by which it is proven that the solvent does not fall into substance category 1A or 1B of the CLP Regulation. If residual contents exceed 0.02 %, the migration restriction of 0.1 μ g/l for non-listed substances has to be tested for.
- For solvents that are classified under CLP Regulation No 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, basically the migration restriction of 0.1 μg/l must always be checked.

Question C-14:

How does the certification body have to verify requirements for colourants as per chapter 5.4.3 of the KTW evaluation criteria document?

Answer:

The formulation of the colourant product must be disclosed to the certification body by the colourant manufacturer.

Compliance of coulourants with regard to purity requirements may be confirmed by colourant manufacturers by submitting analysis reports in line with relevant parts of standard DIN 53770 to the certification body. If substantial analysis reports are not available, it is acceptable to prove the fulfilment of purity requirements by migration testing on relevant parameters instead. Applicable MTC_{tap} for respective metal ions amount to 10 % of the corresponding threshold value of the TrinkwV (see Annex 1 of the KTW-BWGL).

For colourants that may contain primary aromatic amines as impurity or liberate these as reaction- or degradation product during polymer processing, the colourant manufacturer must notify the certification body of the relevant primary aromatic amines. Additionally, it is always the task of the certification body to have these amines analysed in migration waters of end products and to verify compliance with migration restrictions for total primary aromatic amines.

Azo colourants which are prone to decompose into primary aromatic amines having been classified as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction according to CLP Regulation No 1272/2008 may not be accepted as formulation constituent.

Question C-15:

How to deal with checking the requirements for colourants with regard to different colour hues?

Answer:

If the use of different colourants does not make it necessary to check additional restrictions concerning migration, product tests of colour variants can be limited to checking the colouring parameter in migration waters.

The KTW evaluation criteria for plastics and other organic materials in contact with drinking water requires the EN ISO 7887:2012-04 / Method C (410 nm) to be used for checking the colouring parameter. It is the certification body's responsibility to decide if other methods of determining the release of colouring substances can be used. In this case, the certification body must be able to provide evidence that the method is equivalent to the determination according to the KTW evaluation criteria.

Evaluating the colourants formulation by certification bodies is of great importance since the masterbatch can vary considerably, even if the colour is the same. The additional requirements for colourants according to KTW evaluation criteria 5.4.3 must be observed.

Question C-16:

Are non-listed peroxides allowed as starting substances for organic materials?

Answer:

Peroxides are used as initiators for polymerization and for cross-linking of polymers (e.g., polyethylene, rubbers or silicones). In both cases peroxides serve to elicit formation of radicals, while the peroxide as well as its reaction products shall not be incorporated into the polymer. Due to the reactivity of peroxides a large number of reaction- and degradation products occur.

According to the *Union Guidelines* to Commission Regulation (EU) No 10/2011, initiators and cross-linking agents which are not incorporated into the polymer must be regarded as aids to polymerisation. These are not required to be evaluated and thus need not to be listed in a positive list if the aid to polymerisation and its reaction- and degradation products do not migrate into drinking water ($c_{tap} < 0.1 \, \mu g/l$).

When using peroxides as initiators, small amounts (< 0.1 %) are applied. Therefore, only low concentrations of reaction products are expected. In this case it is acceptable to use non-listed peroxides if it can be demonstrated that the peroxide and its reaction- and degradation products do not migrate into drinking water at concentrations above 0.1 μ g/l. Within the product certification procedure, the certification body is obliged to have this demonstrated.

When using peroxides as cross-linking agents, required quantities are usually higher, above 1 %, and a large number of reaction- and degradation products may occur in considerable amounts. Reaction- and degradation products of a peroxide can be different for the various organic materials that have been produced with it. Time and effort for the identification and assessment of all reaction products is extensive. In addition, it must be suspected that

reaction products migrate into drinking water at concentrations above 0.1 μ g/l. For these reasons *UBA* regards it as necessary to have peroxides used as cross-linking agents evaluated for the respective polymers and to have them listed in the applicable positive list. *UBA* thus considers substances for cross-linking as similar to monomers and other starting substances, irrespective of whether they are incorporated into the polymer or not. For these substances an evaluation and positive listing is required before they may be used. Please also refer to subsequent question C-17 in this context.

Apart from that, it remains valid that for application amounts of the peroxide below 0.02 % related to the final product, no further evaluation of the peroxide including related impurities and reaction- and degradation products is necessary.

Question C-17:

Is it allowed to use non-listed substances in minor amounts for polymer fabrication if these become part of the polymer matrix like monomers do?

Answer:

Starting substances are regarded as monomers and not as aids to polymerisation (AtP) if they over the course of the polymer buildup are permanently incorporated into the polymer matrix. This for example applies to agents for crosslinking, chain termination or chain extension which is the regular application purpose. For these substances, even more than for AtP which do <u>not</u> remain in the polymer matrix, it is therefore basically required to have them evaluated and listed in the positive list. At the same time by their permanent fixation to the polymer matrix a lower risk for migration into drinking water results.

It is therefore acceptable to use non-listed monomers and other matrix-bound substances if the following prerequisites are met:

- application amounts are restricted to less than 0.5 % related to the formulation of the organic material, and
- requirements set out in 5.2.2 b) KTW-BWGL are fulfilled.

Question C-18:

Which requirements apply to filter membranes and what are current testing procedures for them?

Answer:

Filter membranes installed as terminal filters or for the purpose of centralised or non-centralised water treatment are formulated as plastics and thus fall under the scope of annex A of the evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL). Due to their large surface area being in contact with drinking water, these are assigned to the group of ancillaries and thus bear risk group P1. To evaluate other components of a filter module and to define the relevant risk group, the wetted surface of the filter membrane itself has to be omitted. Otherwise, from the large membrane surface these other components would fall into an inadequately low risk group.

For filter membranes, KTW-BWGL currently stipulates product testing according to part 1 of DIN EN 12873 in order to assess conformity with migration-based requirements. By doing so, the inner surface of the membrane is neglected and only the outer surface is considered to calculate expected concentrations at the tap, c_{tap} .

For the testing of filter membranes, the specific testing standard DIN EN 12873 part 4 is available. *UBA* however has not been in the position yet to define requirements that would allow evaluation of testing results generated within the frame of this standard. To do so, it would be necessary to establish a procedure to convert measured concentrations into expected concentrations ctap. Systematic comparative testing employing both parts 1 and 4 of DIN EN 12783 would be necessary in this respect. While to our knowledge ACS approvals based on testing in accord with DIN EN 12873-4 are provided by France, *UBA* however does not have sufficient information on parameters to be included and their evaluation. Further, there are no harmonised concepts yet within the European 4MSI collaboration how to deal with the evaluation of filter membranes.

If testing results according to DIN EN 12873-4, which for example have been obtained to receive an ACS approval, were to be accepted, complete test reports for membranes or respective components (filter modules) would be necessary. Test reports would require to document the way the formulation assessment has been done and, depending on formulation, which test parameters have been defined and measured. In this context it is also required to specify designated purposes of the products.

Question C-19:

How does UBA regulate the drinking water hygienic requirements for organic ion exchange resins?

Answer:

Ion exchange resins must comply with both section 20 and section 14 of the Drinking Water Ordinance (TrinkwV). Currently, ion exchange resins are exempt from the scope of the KTW evaluation criteria. Ion exchange resins are also exempt from the scope of the European regulations for materials in contact with drinking water as per EU Drinking Water Directive (Directive (EU) 2020/2184). Therefore it is planned to elaborate a national recommendation for ion exchange resins with respect to the hygienic suitability of the material, which perspectively shall be transferred to an evaluation criteria document.

Question C-20:

Are connecting hoses of outlet fittings to be assessed as part of the fitting or separately?

Answer:

Connecting hoses are to be considered as part of the fittings for calculating the proportion of surface area.

Irrespective of this, connecting hoses must always be tested and evaluated individually, equivalent to pipes. A conversion factor $F_c = 20 \text{ d/dm}$ applies to them.

Question C-21:

Which hygienic requirements apply to inlet hoses for washing machines, dishwashers and similar household appliances?

Answer:

Requirements for drinking water contact materials according to evaluation criteria must be fulfilled until the tapping point or the first safety device, as has been prescribed in the German Drinking Water Ordinance (TrinkwV). Due to fluid category 5 as is defined in standard DIN EN 1717:2011-08 and will be present in mentioned household appliances, a free outlet is generally required as safety device.

Those sections of the inlet hose which are situated upstream of the free outlet (safety device) come into contact with drinking water and, via the piping system, in principle are hydraulically connected to taps for withdrawal of water for human consumption.

If for the inlet hose its drinking water hygienic suitability cannot be proven, among other risks it must be expected that microbial contamination can occur and again a safety device sufficient for fluid category 5 (free outlet) is necessary. However, according to EN 1717 table 3 this is lowered to category 3 (e.g., HD type: pipe breathing unit for jointed hose fittings in combination with backflow preventer) for taps with jointed hose connections in domestic premises.

It follows that if a safety device of **sufficient** performance is installed between the inlet hose and other parts of the installation, hose or pipe material without specific drinking water hygienic suitability may be used.

Nevertheless, it has to be kept in mind that according to TrinkwV water for the purpose of dishwashing or laundry must have drinking water quality. For this reason, inlet hoses should provide adequate hygienic suitability.

Question C-22:

Is it allowed to install shower heads or other terminal fittings which intentionally add substances to the drinking water?

Answer:

According to section 18 (3) TrinkwV, legitimate reasons for making changes to the physicochemical properties of drinking water on treatment and distribution are strictly defined. Provided that it is necessary to do so, then according to section 19 (2) and (3) TrinkwV (raw water and) distributed drinking water may only be subjected to treatment agents per definition, and among these, only to such agents that are approved as per the positive list according to section 20 TrinkwV ("§ 20-list"; "§ 11 list" as to the former version of the TrinkwV) for the respective purpose. If such an approval does not exist, addition of these substances is not allowed. This also applies to water used for showering, because such water is classified as water intended for human consumption and therefore must have drinking water quality.

Question C-23:

Is it allowed to use frost protection wires as internal heating element in drinking water lines?

Answer:

By insertion of internal frost protection wires into drinking water lines extra risks arise for hygienic deterioration. On the occasion of insertion, foreign matter or contaminations may enter the inner parts of the pipes. Though hygienic suitability might be proven for these wires, substance release inevitably associated with them must be regarded as avoidable contamination. Moreover, the penetration points where the wire enters and leaves the pipe pose a permanent contamination risk.

In *UBA*'s opinion and referring to section 13 (5) of the Drinking Water Ordinance (TrinkwV), it is not allowed to use internal frost protection wires in drinking water lines. The reason is that internal heating wires inserted into the drinking water medium constitute items that do not directly serve the purpose of drinking water supply. This can also be derived from the imperative to minimize quality impairment laid down in section 6 (5) TrinkwV and section 7 (4) TrinkwV stating that any additional contamination risk has to be avoided if alternative techniques of current best practice are available.

Stationary installations for drinking water distribution

DIN EN 805:2000 in combination with DIN EN 806-2:2005 as part of current technical rules and standards define that for buried lines in public drinking water distribution these must be installed in frost-free level. As for (domestic) drinking water installations, it is stipulated that outside line sections of premises have to be drained during winter seasons.

According to standard DIN EN 806-2:2005 chapter 14.1, installation of pipes in locations encountering risks of frost action shall be avoided. If this cannot be ruled out, the cited standard determines to thermally insulate the pipes according to Ch. 14.1.6 and, according to Ch. 14.1.7, determines to provide a trace heating if necessary. A trace heating is to be understood as device that prevents pipe freezing by external heating.

Installations for temporary drinking water distribution

For temporary water distribution applications, such as at fairs and festivals during the cold season or in the backup and emergency supply of drinking water, alternative methods of frost protection are too expensive or associated with other risks. Therefore, the use of internal frost protection wires is possible for this application if the hygiene suitability of the heating cable for drinking water is confirmed and <u>factory-configured</u> hoses with heating cables are used.

Question C-24:

How to evaluate glass electrodes for pH measurement used in quality control in waterworks?

Answer:

Products and components made of glass have to be tested and evaluated according to the evaluation criteria for enamels and ceramic materials. By virtue of the 1st amendment of this evaluation criteria document, a risk-based approach has been integrated for evaluation, which means that products and components will be assigned different risk groups. Glass electrodes to be used in waterworks belong to the lowest risk group P4. According to this regulation, no requirements related to composition will be defined for such products and migration testing will not be necessary either.

Due to the high inertness of the special-purpose glass in combination with only sparse punctual application of glass electrodes for pH measurement, the other materials used in it do not alter the overall assignment to risk group P4, even when used as sensor in a fitting.