

As at: 25 March 2022
3rd amendment

INFORMATION

Replacement of German Environment Agency (UBA) guidelines by evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL transitional arrangement)

English translation – only the German document version is legally binding

1 Evaluation criteria document

The UBA has published the evaluation criteria document for plastics and other organic materials in contact with drinking water (KTW-BWGL)¹ pursuant to Section 17 (3) of the Drinking Water Ordinance (TrinkwV).

As of 21 March 2021, this evaluation criteria document has become mandatory for plastics and other organic materials used for the construction or maintenance of installations for the production, treatment or distribution of drinking water. It is mandatory for the regulation of plastics, coatings and lubricants as material types that hitherto have been regulated in respective guidelines.

By virtue of transition from guidelines to evaluation criteria there have been no substantial changes in requirements. It must be observed, though, that references to national BfR recommendations have been deleted, from which it follows that migration testing for additional parameters will be necessary in certain cases.

After publication of the 3rd amendment of the KTW-evaluation criteria on 16 March 2022 (status 7 March 2022), elastomers and thermoplastic elastomers fall within the scope of the evaluation criteria. Requirements applicable to these material types will become mandatory on 1 March 2025.

Currently silicones, and multilayer products with drinking water contact layers made of silicones completely or partially, are still excluded from the scope of the evaluation criteria document.

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¹ <https://www.umweltbundesamt.de/dokument/evaluation-criteria-document-for-plastics-other>

A separate transitional recommendation was issued for silicones². Elastomers in contact with drinking water can continue to be evaluated under the Elastomer Guideline³ and thermoplastic elastomers under the existing TPE transitional recommendation⁴ until 28 February 2025.

2 Withdrawal of guidelines and TPE transitional recommendation

2.1 Withdrawal of the KTW, Coating and Lubricant Guidelines

The following guidelines have been withdrawn on 21 March 2021:

- KTW Guideline⁵
- Coating Guideline⁶
- Lubricant Guideline⁷

Test certificates issued on the basis of the aforementioned guidelines thus have lost their validity as of 21 March 2021. This holds irrespective of a later expiration date (validity period) possibly stated in the certificate.

2.2 Withdrawal of the Elastomer Guideline and the TPE transitional recommendation

The Elastomer Guideline and the TPE transitional recommendation will be withdrawn by effect of 1 March 2025. Until that date, test certificates issued on the basis of these two regulations remain valid. This however does not hold for test certificates related to products manufactured from starting substances listed on part 2, which became invalid on 31 December 2021, of the Elastomer Guideline positive list.

3 Evidence of the drinking water hygienic suitability of products

3.1 Materials in the scope of the evaluation criteria

The drinking water hygiene requirements for materials laid down in the evaluation criteria document for plastics and other organic materials in contact with drinking water (KTW-BWGL), pursuant to Section 17 (3) of the Drinking Water Ordinance (TrinkwV) are legally binding. Any product containing such materials shall be tested and evaluated against these requirements. These include products in the scope of the polymer-specific annexes of the

² <https://www.umweltbundesamt.de/en/document/transitional-recommendation-for-preliminary>

³ <https://www.umweltbundesamt.de/en/document/guideline-for-hygienic-assessment-of-elastomers-in>

⁴ <https://www.umweltbundesamt.de/en/document/recommendation-on-the-provisional-hygienic>

⁵ <https://www.umweltbundesamt.de/en/document/guideline-on-the-hygienic-assessment-of-organic>

⁶ <https://www.umweltbundesamt.de/en/document/guideline-for-hygienic-assessment-of-organic-0>

⁷ <https://www.umweltbundesamt.de/en/document/guideline-for-the-hygienic-assessment-of-lubricants>

evaluation criteria document, as well as multi-layer products comprised of drinking water contact layers that also fall within this area of application.

Evidence of the drinking water hygienic suitability of products made from plastics, organic coatings and lubricants may be proven by certificates according to the UBA recommendation for attestation of conformity.

Evidence of the drinking water hygienic suitability of products made from elastomers and thermoplastic elastomers (TPE), over the course of the transitional period until legal bindingness of respective requirements on 1 March 2025, can be proven either by **certificates according to the UBA recommendation for attestation of conformity or still by test certificates on the basis of the Elastomer Guideline or TPE transitional recommendation**, provided these products have been manufactured exclusively from starting substances according to the currently valid positive list (i.e., polymer-specific annex D of KTW-BWGL). Such test certificates however will become invalid on 28 February 2025 at the latest.

On legal grounds, evaluation criteria as per German TrinkwV do not specify any requirements of how to demonstrate evidence of drinking water hygienic suitability of products, i.e. they do not determine procedures for attestation of conformity with respect to drinking water hygienic suitability regarding requirements defined in these evaluation criteria.

Evidence of the products' compliance with the drinking water hygienic requirements can be provided by an accredited certifier in the drinking water sector pursuant to Section 17 (5) TrinkwV. Certificates of drinking water hygienic suitability of products can be issued on the basis of the recommendation for the attestation of conformity of the drinking water hygienic suitability of products⁸.

According to Section 17 (5) TrinkwV there is no obligation for product certification. However, UBA strongly suggests to have products certified following the abovementioned recommendation document, as in this way evidence of drinking water hygienic suitability can be demonstrated reliably. Should a product manufacturer decide to declare conformity by issuing a self-declaration, he in any case would have to ground this on formulation evaluation and product testing having been performed according to applicable evaluation criteria, or on respective existing valid test reports. The test results shall be documented in the corresponding test reports which must comply with the applicable European standards DIN EN 12873-1 or 12873-2 and DIN EN 1420 and DIN EN 16421. Test reports must clearly indicate which products or components have been tested.

3.2 Materials not included in the scope of the evaluation criteria

Evidence of the drinking water hygienic suitability of silicones, which do not fall within the scope of the evaluation criteria document yet, can be provided by test certificates/certificates based on the silicone transitional recommendation.

The German Environment Agency also intends to include regulation of silicones in its evaluation criteria document.

⁸ <https://www.umweltbundesamt.de/en/document/recommendation-for-attestation-of-conformity-of>

4 Extended transitional regulation for the attestation of conformity

4.1 Attestation of conformity following system 1+

The UBA recommendation for attestation of conformity employs the 1+ system as defined in the European construction products regulation for the certification of products and components of risk group P1. To have this accomplished, it is required to perform an initial inspection of the manufacturing site and supervised on-site sampling of test specimens for type approval. As hitherto practiced for issuing test certificates referring to guidelines, test specimens generally were not drawn under external supervision conditions, but were sent to the testing facility under the sole responsibility of the manufacturer. For this reason, it is generally necessary for products and components of risk group P1 to perform a new product testing of samples drawn at the factory site under external supervision in order to obtain a certificate according to the UBA recommendation for attestation of conformity.

To perform conformity attestation processes in line with this recommendation, a transitional regulation until 21 March 2021 had been in place which was linked to the transitional period effective between publication and entry into force of the KTW evaluation criteria. In the years 2020 and 2021 however, due to restrictions aiming at controlling the COVID-19-pandemia, only limited execution of initial inspections and external monitoring by certification bodies was possible. Because of these circumstances, until **21 March 2023** the certification bodies can utilize test reports on test samples that had not been drawn under external supervision for evaluation purposes. It is thereby possible until 21 March 2023 to consider test reports for evaluation purposes which had been issued in order to obtain test certificates referring to guidelines which meanwhile have been withdrawn. Test reports however shall be not older than ten years.

Both the evaluation of the formulation and the drinking water hygienic evaluation of test results have to be conducted according to requirements set out in the KTW evaluation criteria document and thus have to be renewed. To conduct formulation evaluation, actual formulation details must be available to the certifier. If this evaluation shows that substances have to be analyzed in migration test waters which in the testing framework according to guidelines had not been analyzed, then respective test reports referring to guidelines and DVGW standard W270 still are sufficient until 21 March 2023 for obtaining an attestation of conformity. It is essential that certification bodies notify manufacturers about missing list entries of starting substances or the lack of test results for specific substances.

After this extended transitional period has ended, certification bodies must have completed initial inspections of manufacturing sites for all certified products and must utilize current test reports for evaluations according to the recommendation for attestation of conformity.

The mode of validness (validity period or conditional with respect to approval steps still to be passed) of certificates/conformity attestations issued under the premises of this transitional regulation may be arranged by the respective certification body in its own responsibility.

4.2 Attestation of conformity following simplified procedure

The UBA recommendation for attestation of conformity allows to execute a simplified certification procedure – based on type testing – for components of risk groups P2 and P3. For such conformity attestations it is still possible to utilize test reports that have been issued in line with former guidelines.

If formulation assessment reveals that additional parameters must be tested for in migration testing, then corresponding to definitions in sec. 4.1 these analyses have to be made up too until 21 March 2023.

4.3 Restricted capacities for executing certification processes

Due to restructuring of certification schemes following transposition to certificates according to evaluation criteria instead of former KTW guidelines, accredited certification bodies currently experience limitations that prevent completion of certification processes in due time. For this reason, certifiers issue confirmatory letters which may be relied on by manufacturers to set up self-declarations. Such confirmatory letters at least must state that

- test reports exist for the respective product/component which provide evidence that hygienic suitability of the product was attested in accordance with the relevant UBA guideline and with DVGW standard W270, and
- test reports are not older than ten years.

The certification body must be provided with recent information on formulations and is obliged to keep the manufacturer timely informed about whether testing and/or inspections still have to be completed until 21 March 2023.