Für Mensch & Umwelt

Umwelt Bundesamt

As at: 4 February 2025
3rd amendment

INFORMATION

Transposition of the Elastomer Guideline and the TPE Transitional Recommendation into the Evaluation Criteria Document for Plastics and other Organic Materials in Contact with Drinking Water

(Transitional Regulation of Elastomer Guideline)

English translation – only the German document version is legally binding

1 Validity of evaluation criteria

The German Environment Agency has specified evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL)[1] pursuant to section 15 (1) of the German Drinking Water Ordinance (TrinkwV).

Since 21 March 2021 these evaluation criteria are legally binding for plastics and other organic materials used for the reconstruction or maintenance of installations for the extraction, treatment or supply of drinking water.

By having set the 3rd amendment, elastomers and TPE are now in the scope of the evaluation criteria. The corresponding material-specific requirements are completed in KTW-BWGL Annexes "D Elastomers" and "E Thermoplastic Elastomers"[2]. Entry into force of mandatory requirements for products within the scope of Annexes D and E will be postponed until 1 July 2026 as per 5th amendment of the KTW evaluation criteria.

[1] https://www.umweltbundesamt.de/en/document/evaluation-criteria-document-for-plastics-other-1

[2] https://www.umweltbundesamt.de/en/document/polymer-specific-annexes-to-the-evaluation-criteria

Umweltbundesamt
Fachgebiet II 3.4
Heinrich-Heine-Straße 12
08645 Bad Elster
www.umweltbundesamt.de

Currently silicones are still not within the scope of the evaluation criteria. For the assessment of silicones in contact with drinking water a separate transitional recommendation [3] was prepared.

Evaluation criteria do not contain any requirements for issuing test certificates. Certificates confirming the hygienic suitability for drinking water can be issued in accordance with the UBA recommendation for attestation of conformity of the hygienic suitability of products[4]. Issuance of respective certificates for elastomers and thermoplastic elastomers has become feasible after publication of the 3rd amendment of the KTW-BWGL.

2 Validity of the Elastomer Guideline and the TPE transitional recommendation

The Elastomer Guideline and the TPE transitional recommendation shall be withdrawn on 1 July 2026.

Test certificates issued on the basis of the Elastomer Guideline or the TPE transitional recommendation will cease to be valid at that date.

Part 2 of the positive list of starting substances for the manufacture of elastomers in the Elastomer Guideline has ceased to apply on 31 December 2021. Test certificates for products containing starting substances from part 2 of the positive list have ceased to be valid from that date.

For products or components that have been manufactured from starting substances listed in the currently valid positive list, test certificates according to the elastomer guideline can still be issued or extended with a period of validity no longer than 30 June 2026. For this purpose, it is necessary to verify fulfillment of new requirements that arise from the updated positive list (Annex D of KTW-BWGL).

3 Transitional period

During the transitional period, after publication of amendments to the KTW-BWGL in the German Federal Gazette until the requirements of Annexes "D Elastomers" and "E Thermoplastic Elastomers" are valid and binding, test certificates based on the Elastomer Guideline or TPE transitional recommendation and additionally test certificates according to DVGW standard W 270, as well as certificates according to the UBA recommendation for attestation of conformity of the drinking water hygienic suitability of products can be used to prove the hygienic suitability of products or components in contact with drinking water.

UBA accepts that until, but not later than **28 February 2025**, product certification bodies shall use test reports according to the Elastomer Guideline, not issued earlier than ten years back, for certification of assembled products even if the formulations of the elastomer

[3] https://www.umweltbundesamt.de/en/document/transitional-recommendation-for-preliminary

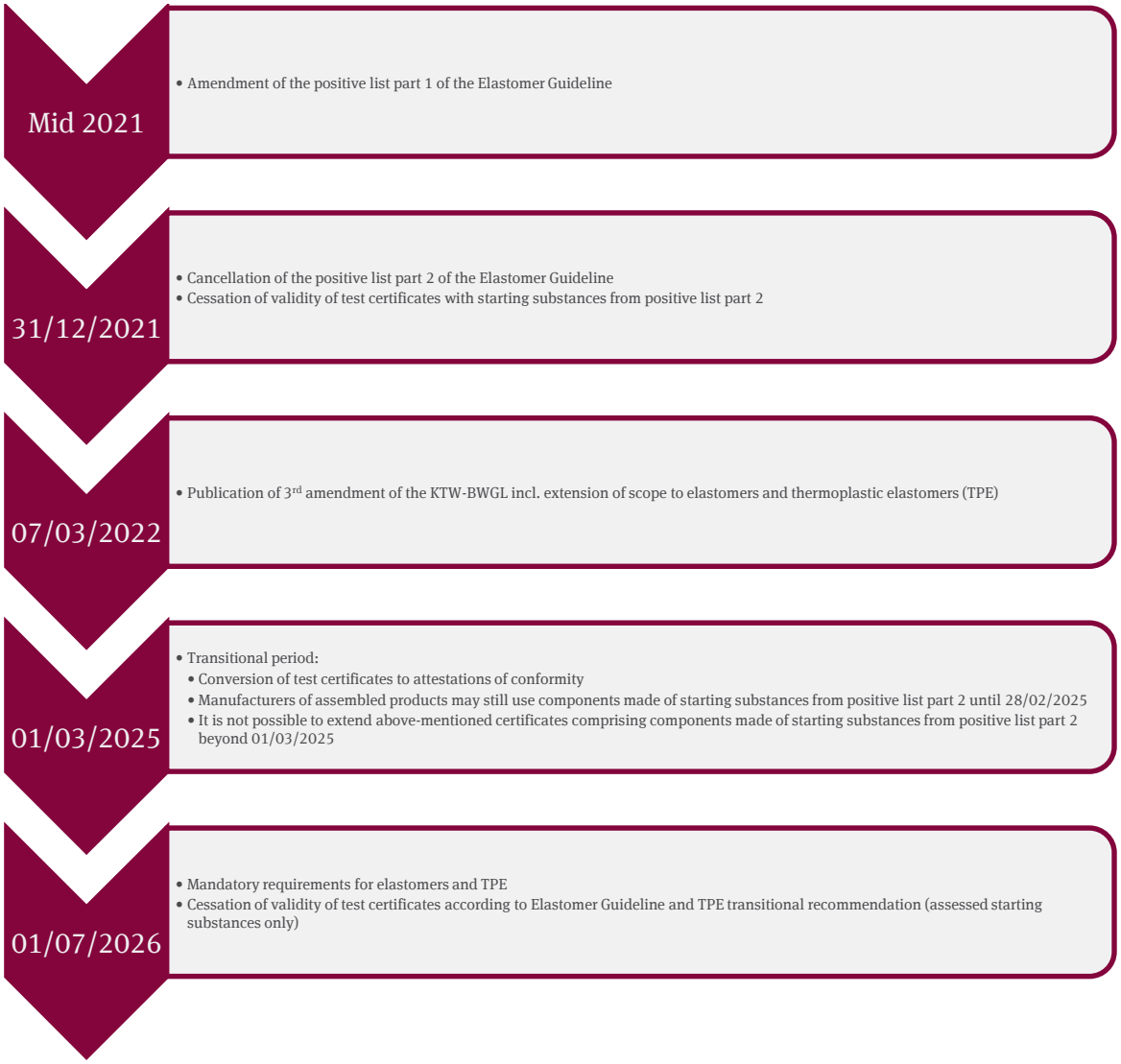
[4] https://www.umweltbundesamt.de/en/document/recommendation-for-attestation-of-conformity-of

components used therein still contain raw materials from part 2 of the positive list of the Elastomer Guideline, which is no longer valid now. Extension of certificates for assembled products comprising components that do not correspond to the positive list of Annex D of the KTW evaluation criteria is not possible for the time beyond 1 March 2025.

Test certificates according to the Elastomer Guideline for products or components that have been manufactured exclusively from starting substances listed in the previous part 1 of the positive list, can be extended until 30 June 2026 at the latest if additional specific migration requirements arising from the positive list have been tested for. These test certificates can be converted to attestations of conformity (certificates) of risk group P2 without additional testing during the transition period. For attestations of conformity (certificates) of risk group P1, it is required to undergo an initial inspection of the manufacturing site and that sampling of test specimens is done by the certifying body or an inspection body determined by the certifier. In this case, existing test certificates can only be considered if test specimens had been sampled accordingly.

Uncured elastomer compounds are regarded as intermediate products by definition. Attestations of conformity of intermediate products can only confirm their drinking water hygienic conformity in principle. For products of risk groups P1 and P2 manufactured thereof it is thus necessary to obtain an attestation of conformity of the cured component or product. If former test certificates are to be converted into attestations of conformity it is therefore essential to discern whether the test certificate applies to a compound (mixture) or to a cured component/product.

Timeline


Mid 2021
• Amendment of the positive list part 1 of the Elastomer Guideline
31/12/2021
• Cancellation of the positive list part 2 of the Elastomer Guideline
• Cessation of validity of test certificates with starting substances from positive list part 2
07/03/2022
• Publication of 3rd amendment of the KTW-BWGL incl. extension of scope to elastomers and thermoplastic elastomers (TPE)
01/03/2025
• Transitional period:
• Conversion of test certificates to attestations of conformity
• Manufacturers of assembled products may still use components made of starting substances from positive list part 2 until 28/02/2025
• It is not possible to extend above-mentioned certificates comprising components made of starting substances from positive list part 2 beyond 01/03/2025
01/07/2026
• Mandatory requirements for elastomers and TPE
• Cessation of validity of test certificates according to Elastomer Guideline and TPE transitional recommendation (assessed starting substances only)