

## INFORMATION

# Hygienic requirements of materials in contact with drinking water

## New European Regulation pursuant to Directive (EU) 2020/2184



### 1 Introduction

The current legal situation, the future European regulation as amended and the corresponding transitional regulations for materials in contact with drinking water shall be described below.

### 2 Legal situation to date

So far, the German Environment Agency (UBA) has specified requirements for materials in contact with drinking water on the basis of Section 15 of the German Drinking Water Ordinance (TrinkwV). To this end, the UBA has published three binding material-specific evaluation criteria:

- Evaluation criteria for metallic materials in contact with drinking water (metal-related evaluation criteria),
- Evaluation criteria for enamels and ceramic materials in contact with drinking water (enamel/ceramic-related evaluation criteria) and
- Evaluation criteria for plastics and other organic materials in contact with drinking water (plastic-related evaluation criteria)

These evaluation criteria substantiate the general hygienic requirements for materials determined in Section 14 TrinkwV. In addition to test specifications with test parameters, test criteria and methodological requirements for assessing hygienic suitability, evaluation criteria also contain positive lists. As to evaluation criteria for metallic materials this corresponds to the positive list of metallic materials appropriate in view of drinking water hygiene; as to enamel/ceramic-related evaluation criteria, positive lists are meant to comprise potential ingredients (materials); and in case of plastic-related evaluation criteria positive lists shall contain starting substances.

Materials within the scope of these evaluation criteria may only be used for the construction or maintenance of water supply systems if they fulfil the requirements of the respective evaluation criteria.

The TrinkwV does not stipulate the form in which a manufacturer shall provide evidence that a product complies with the requirements (attestation of conformity). Pursuant to Section 16 TrinkwV, however, it is assumed that the materials used for a product comply with the generally recognised rules of technology and the general requirements for materials according to Section 14 TrinkwV and the evaluation criteria specified by the German Environment Agency according to Section 15 TrinkwV if this is confirmed by a certificate from a certifier accredited for the certification of products in drinking water supply. The UBA recommends certification and has published a recommendation 'Attestation of conformity of product hygiene suitability for drinking water'.

### **3 New European rules on materials in contact with drinking water**

The national legal situation described under 2 will be replaced in future (from 31 December 2026) by a new EU legal framework for materials in contact with drinking water.

#### **3.1 Legal acts**

Article 11 of Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption describes general minimum hygiene requirements for materials that come into contact with water intended for human consumption and authorises the European Commission to adopt legal acts to specify these general minimum hygiene requirements. To this end, the European Commission published six legal acts with annexes in the Official Journal of the European Union on 23 April 2024.

Table 1 below provides an overview of the content and the date of application of the legal acts.

**Table 1 Overview of legal acts according to Article 11 of Directive (EU) 2020/2184**

No. <sup>1</sup>	Legal act	Contents	Effective from	Transitional regulations
1	<p>Commission <b>Implementing Decision (EU) 2024/365</b> of 23 January 2024</p> <p>laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards <b>methodologies for testing and accepting starting substances, compositions and constituents to be included in the European positive lists</b></p> <p><a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024D0365">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024D0365</a></p>	<p>Methods and requirements for the evaluation of starting substances, compositions and constituents for inclusion in the positive lists of Implementing Decision (EU) 2024/367</p>	31 December 2026	None
2	<p>Commission <b>Implementing Decision (EU) 2024/367</b> of 23 January 2024</p> <p>laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council by <b>establishing the European positive lists of starting substances, compositions and constituents authorised for use in the manufacture of materials or products that come into contact with water intended for human consumption</b></p> <p><a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024D0367">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024D0367</a></p>	<p>Positive lists of:</p> <ul style="list-style-type: none"> <li>Starting substances for organic materials</li> <li>Compositions of metallic materials</li> <li>Organic constituents of cementitious materials</li> <li>Compositions for enamels, ceramic materials and other inorganic materials</li> </ul>	31 December 2026	Starting substances, compositions and constituents that were approved nationally in the period from 13 July 2021 to 31 December 2026 can be used in the national scope for the manufacture of products in contact with drinking water by 31 December 2032.
3	<p>Commission <b>Delegated Regulation (EU) 2024/369</b> of 23 January 2024</p>	<p>Definition of the procedure for the evaluation of starting substances, compositions and constituents by ECHA</p>	31 December 2026	None

<sup>1</sup> This is an unofficial numbering system that is sometimes used in practice for reasons of simplification. The legal acts relating to nos. 1 to 3 concern the European positive lists and their criteria. The legal acts relating to nos. 4 to 6 concern the testing, conformity assessment and labelling of products.

No. <sup>1</sup>	Legal act	Contents	Effective from	Transitional regulations
	<p>supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down the <b>procedure regarding inclusion in or removal from the European positive lists of starting substances, compositions and constituents</b></p> <p><a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R0369">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R0369</a></p>		<p>Notification of intention (Article 2): 31 December 2025</p>	
4	<p>Commission <b>Implementing Decision (EU) 2024/368</b> of 23 January 2024</p> <p>laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards the <b>procedures and methods for testing and accepting final materials as used in products that come into contact with water intended for human consumption</b></p> <p><a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024D0368">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024D0368</a></p>	<p>Testing of and requirements for the final materials (testing of products and components)</p>	<p>31 December 2026</p>	<p>None</p>

No. <sup>1</sup>	Legal act	Contents	Effective from	Transitional regulations
5	<p>Commission <b>Delegated Regulation (EU) 2024/370</b> of 23 January 2024</p> <p>supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down <b>conformity assessment procedures for products that come into contact with water intended for human consumption and the rules for the designation of conformity assessment bodies involved in those procedures</b></p> <p><a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R0370">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R0370</a></p>	<p>Conformity assessment procedures for products</p>	<p>31 December 2026</p>	<p>For products where evidence is provided that they comply with the UBA evaluation criteria and/or further national regulatory documents on 31 December 2026: 31 December 2032.</p> <p>Separate regulation for lead-containing alloys in Germany (see section 4.3).</p>
6	<p>Commission <b>Delegated Regulation (EU) 2024/371</b> of 23 January 2024</p> <p>supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by establishing <b>harmonised specifications for the marking of products that come into contact with water intended for human consumption</b></p> <p><a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R0371">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R0371</a></p>	<p>Labelling of products</p>	<p>31 December 2026</p>	<p>None</p>

## 3.2 Product testing and conformity assessment

With the 4th legal act, the European regulation defines standardised minimum requirements for materials in contact with drinking water. The testing modalities and requirements specified in this document largely correspond to the procedure defined by several EU Member States as part of the 4MSI cooperation, which was implemented in Germany in the course of laying down the UBA evaluation criteria. However, the new European regulations also stipulate binding requirements for cementitious materials and additional tests (e.g. with chlorinated test water or GC-MS screening).

In principle, the European minimum requirements could be supplemented by additional national requirements or regulated more strictly. There are currently no plans to set additional or stricter requirements in Germany.

Pursuant to the 5th legal act, a certification obligation applies to products made of final materials intended to come into contact with drinking water. This certification is not possible for site-applied products, as the final materials are only produced on the construction site. The UBA will publish information at a later date on how evidence of the hygienic suitability of on-site manufactured products shall be provided.

The certificates shall be issued by conformity assessment bodies (also known as certification bodies) that are accredited and have been notified to the European Commission. For a conformity assessment body based in Germany, this means that in addition to its accreditation by the German Accreditation Body (DAkkS), it also has to be submitted to the EU Commission and the other Member States by the notifying authority (DE). The notifying authority for Germany shall be determined by law. The certificates can be issued from 31 December 2026 at the earliest, as the legal acts will only apply from this date.

Products certified in accordance with the European specifications shall be labelled with a symbol specified in the 6th legal act (see Figure 1) and can be used in Germany without further evidence for the construction and maintenance of water supply systems.



**Figure 1: Symbol for labelling products in contact with drinking water**

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From 31 December 2032 at the latest, products intended for contact with drinking water may only be placed on the market if they comply with European requirements and are labelled accordingly. Compliance with the requirements shall be the subject of market surveillance.

### 3.3 Positive Lists

The requirements for final materials in the 4th legal act refer to the positive lists of the 2nd legal act. All entries in the positive lists are labelled with an expiry date. If starting substances, compositions or constituents are to be used beyond the respective expiry date or additional starting substances, compositions or constituents are to be used for the manufacture of products in contact with drinking water, an application shall be submitted to the European Chemicals Agency (ECHA). The procedure to be followed shall be laid down in the 3rd legal act. The intention to submit an application shall be notified to ECHA within 12 months prior to the actual application. This should enable manufacturers to pool their efforts.

The 1st legal act describes the methods and requirements for the assessment of starting substances, compositions and constituents. The applicant shall submit an appropriate evaluation which will be reviewed by ECHA's Committee for Risk Assessment (RAC).

## 4 National regulations during the transitional period

### 4.1 Evaluation criteria

The national regulations shall apply up to 31 December 2026. The UBA will therefore continue to update evaluation criteria by this date.

After 31 December 2026 evaluation criteria can no longer be updated or used for evaluation purposes. However, attestations of conformity with the national requirements existing on 31 December 2026 can still be used in the national scope until 31 December 2032 and can also be extended up to this date (see section 5 for such cases). The UBA will therefore not withdraw evaluation criteria until 31 December 2032.

### 4.2 Evaluations of starting substances and materials

Until 31 December 2026, the UBA will continue to carry out evaluations of starting substances for organic materials, metallic materials, enamels and ceramic materials. In order to be able to consider evaluations carried out by the UBA for an update of evaluation criteria in the fourth quarter of 2026, the UBA has set the deadlines listed in Table 2 up to which applications for the various evaluations will be accepted.

Even if the application is submitted on time, the UBA cannot guarantee that an evaluation will still be possible within the intended schedule. It shall be taken into account that:

- the examination of the application and the decision-making process as well as the involvement of the BfR (in the case of not fully assessed starting substances for organic materials) or the expert committee for metallic materials in contact with drinking water (in the case of metallic materials) takes a certain amount of time;
- before an evaluation criterion can be updated, the UBA shall consult the federal states, the German Federal Armed Forces, the Federal Railway Authority and the specialist groups and associations involved pursuant to Section 14(7) TrinkwV;
- the notification procedure pursuant to Directive (EU) 2015/1535 (so-called Transparency Directive) with the EU Commission with a standstill period of at least 3 and a maximum of 6 months follows the finalisation of the draft of the amended respective evaluation criteria; and
- publication of the amended document in the Federal Gazette shall be required.

**Table 2 Deadlines after which the UBA no longer accepts applications for national evaluations**

Type of application		Deadline
Metallic materials		
	Application for the inclusion of a new reference material	30 June 2025
	Application for the inclusion of a commercially sold material	30 June 2025
	Application for the inclusion of a commercially sold material without examination pursuant to DIN EN 15664-1	30 June 2025
Organic starting substances		
	Application for the inclusion of a substance that has not been fully assessed	31 March 2025
	Application for the inclusion of a substance already assessed by EFSA	30 June 2025
	Application for inclusion of a substance already evaluated by another authority/international organisation	30 June 2025
Enamels and ceramic materials		
	Consideration of other materials	30 June 2025

The UBA recommends that potential applicants contact the UBA at an early stage so that any outstanding issues or, for example, the categorisation of applications into the appropriate type of application, especially in the area of starting substances for organic materials, can be clarified in good time.

Nationally evaluated starting substances, compositions and constituents were reported to ECHA by 12 July 2021. They were taken into account in the positive lists of the 2nd legal act. For starting substances, compositions and constituents evaluated by the UBA after 12 July 2021, it is necessary to submit a new application to ECHA in order for them to be included in the respective European positive list. However, the starting substances, compositions and constituents assessed by the UBA in the period from 13 July 2021 to 31 December 2026 can still be used in the national scope for the manufacture of products until 31 December 2032.

### 4.3 Lead-containing materials

In Germany, the lowered threshold value for lead of 5.0 µg/l in drinking water shall apply from 12 January 2028. It must be ensured that no more products that will cause this threshold value to be exceeded are installed from this date. Therefore, products made of certain lead-containing alloys currently listed in the positive list of the UBA evaluation criteria document for metallic materials can no longer be used for the construction or maintenance of water supply systems in Germany from this date. With the 5th amendment to the new version of the evaluation criteria for metallic materials, the UBA shall identify the materials that may no longer be installed in water supply systems from 12 January 2028.



This first European positive list only contains metallic materials that have been assessed for compliance with the parameter value of 5.0 µg/l of the EU Drinking Water Directive. This means that the compositions listed in the European positive list can also be used after 12 January 2028.

## 5 Attestation of conformity during the transitional period

### 5.1 EU attestation of conformity

Products placed on the market for the first time from 31 December 2026 will have to be certified and labelled in accordance with the European procedure. These products may be used in all EU Member States.

### 5.2 Transitional regulation

Products for which a correct attestation of conformity (certificates or manufacturer's self-declarations) will have been issued on 31 December 2026 on the basis of the UBA evaluation criteria and/or further national regulatory documents shall be certified in accordance with the European procedure from 31 December 2032. If these products are not yet certified in accordance with the European procedure during the transitional period, the national requirements for these products shall continue to apply.

This means that, depending on the design of the certificate in question - with a fixed expiry date or a formally unlimited period of validity as long as surveillance is continued - an extension or continuation of the certificate is possible for the purposes of an existing certification order within the transition period until 31 December 2032 at the latest.

Attestations of conformity for products made of lead-containing alloys that must no longer be installed in Germany from 12 January 2028 (see section 4.3) shall be limited to this date. Changing materials shall require a re-evaluation of the product. For this reason, existing attestations of conformity cannot be extended if a material is changed during the transition period. These products shall then be assessed according to the European procedure and can only receive a European attestation of conformity. If certificates based on the UBA evaluation criteria have been issued for these products with a longer validity, the certification bodies must withdraw the certificates by 12 January 2028.

Irrespective of the above, the UBA recommends converting national certificates into new EU certificates as soon as possible. This also reduces the risk of a processing backlog occurring at the certification bodies shortly before the end of the transition period and as a result not all the desired EU certificates being available in time.

## 6 European unregulated materials

Materials used as treatment substances or filter media (e.g. ion exchangers, adsorber resins, hybrid adsorbers and filter membranes) are excluded from the European regulation. These are covered by national regulations in accordance with Section 20 TrinkwV. For the material-specific properties, the UBA shall continue or update the previous evaluation criteria for organic materials specifically for these materials.