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# COMMISSION DELEGATED REGULATION (EU) 2024/370

## of 23 January 2024

## supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down 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

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 11(8) thereof,

Whereas:

(1) Article 11 of Directive (EU) 2020/2184 requires Member States to ensure that certain materials that come into contact with water intended for human consumption do not directly or indirectly compromise the protection of human health, adversely affect the colour, odour or taste of the water, enhance microbial growth, or leach contaminants into the water at levels that are higher than necessary in view of the intended purpose of the material.

(2) For the purpose of ensuring uniform application of Article 11 of Directive (EU) 2020/2184, minimum hygiene requirements for materials that come into contact with water intended for human consumption have been established in Commission Implementing Decision (EU) 2024/368 ([2]).

(3) According to Article 11(8) of Directive (EU) 2020/2184, the Commission is to determine the conformity assessment procedures applicable to products covered by that Article. Those conformity assessment procedures are to be used to demonstrate that those products fulfil the requirements set out in Directive (EU) 2020/2184, thereby ensuring that only products that use final materials approved in accordance with Directive (EU) 2020/2184 are placed on the market, as required by Article 11(7) of that Directive.

(4) In order to ensure that the information regarding conformity of products with the minimum hygiene requirements established under Article 11 of Directive (EU) 2020/2184 is provided in a uniform manner for all products, that information should be provided in the form of a single EU declaration of conformity. By drawing up the EU declaration of conformity, the manufacturer, importer or authorised representative should assume responsibility for the compliance of the product with the minimum hygiene requirements set out in Implementing Decision (EU) 2024/368.

(5) Since accreditation is an essential means of verifying the competence of conformity assessment bodies, conformity assessment bodies should be accredited by a national accreditation body in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council ([3]) in order to be authorised as a notified body and allowed to carry out the conformity assessment procedures set out in this Regulation.

([1]) OJ L 435, 23.12.2020, p. 1.

([2]) Commission Implementing Decision (EU) 2024/368 of 23 January 2024 laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards the procedures and methods for testing and accepting final materials as used in products that come into contact with water intended for human consumption (OJ L, 2024/368, 23.4.2024, ELI: http://data.europa.eu/eli/dec_impl/2024/368/oj).

([3]) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218 13.8.2008, p. 30).

(6) To ensure a consistent level of quality in the performance of conformity assessment, it is necessary to set requirements for notifying authorities involved in the assessment of notified bodies. In particular, it should be ensured that the notifying authority is objective and impartial with regard to its activity. Furthermore, notifying authorities should be required to safeguard the confidentiality of the information they obtain, but should nonetheless be able to exchange information on notified bodies with national authorities, the notifying authorities of other Member States and the Commission to ensure consistency in the conformity assessment.

(7) Having regard to the resources necessary for setting up the required organisation by Member States and conformity assessment bodies, and to ensure that conformity assessment bodies meet the requirements for notification, the application of this Regulation should be deferred. It is necessary to avoid a situation where all applications for conformity assessments of products have to be processed by the notified bodies at the same time and to ensure that notified bodies can progressively build up appropriate capacity for the carrying out of conformity assessment of products. Therefore, the application of this Regulation should be further deferred for products that have been found in conformity with national hygiene requirements for products that come into contact with water intended for human consumption before the date of entry into force of this Regulation and for which the national conformity certificate of the product expires after that date,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Definitions**

For the purposes of this Regulation, the following definitions apply:

(1) ‘material’ means a solid, semi-solid or liquid that is used for the manufacturing of a product and that is:

(a) an organic composition prepared from one or more starting substances; or

(b) a cementitious composition prepared from one or more constituents; or

(c) a metallic, enamel, ceramic or other inorganic composition;

(2) ‘final material’ means material which is subject to testing and acceptance in accordance with the testing requirements and acceptance criteria set out in Implementing Decision (EU) 2024/368;

(3) ‘product’ means an object that comes into contact with water intended for human consumption, which is made of final materials and which is intended to be placed on the market;

(4) ‘assembled product’ means a product that consists of two or more components,, that are joined together and function as a whole unit and can be disassembled without destroying the components;

(5) ‘component’ means an identifiable part of an assembled product consisting of one or more materials;

(6) ‘test piece’ means a representative object of the final material that is used for the carrying out of testing in accordance with the procedures and methods for testing set out in Implementing Decision (EU) 2024/368;

(7) ‘minimum hygiene requirements’ means the hygiene requirements set out in Implementing Decision (EU) 2024/368;

(8) ‘manufacturer’ means any natural or legal person who manufactures products or who has products designed or manufactured, and markets those products under its name or trademark, or who designs and constructs products for its own use;

(9) ‘importer’ means any natural or legal person established within the Union who makes available products from a third country on the Union market;

(10) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on the manufacturer’s behalf in relation to specified tasks;

(11) 'conformity assessment' means the process demonstrating that a product complies with the minimum hygiene requirements;

(12) 'conformity assessment body' means a body that performs conformity assessment activities, including testing, certification and inspection;

(13) 'notified body' means a conformity assessment body that has been notified in accordance with Article 5;

(14) 'accreditation' means accreditation as defined in Article 2, point (10), of Regulation (EC) No 765/2008;

(15) 'national accreditation body' means national accreditation body as defined in Aticle 2, point (11), of Regulation (EC) No 765/2008;

(16) 'making available on the market' means any supply of a product for distribution, consumption or use on the Union market over the course of a commercial activity, whether in return for payment or free of charge;

(17) 'placing on the market' means the first making available of a product on the Union market;

(18) 'reduced testing' means carrying out a test where only a part of the procedures and methods for testing set out in Implementing Decision (EU) 2024/368 are applied on test pieces which have been withdrawn by the notified body during the initial or annual inspection.

*Article 2*

**Conformity assessment procedures**

1. Where the product is categorised in risk group 1 or 2 under Implementing Decision (EU) 2024/368 or, in the case of a metallic composition, in product group A or B in Table 2 'Product group for metallic compositions' of Annex II to Commission Implementing Decision (EU) 2024/365 ([4]), both of the following conformity assessment procedures shall apply:

(a) Module B (EU type examination) as set out in Annex II to Decision No 768/2008/EC of the European Parliament and of the Council ([5]) carried out by a notified body with the following specifications:

(i) the conformity assessment shall contain an examination of a test piece (production type);

(ii) all relevant tests referred to in Implementing Decision (EU) 2024/368 shall be performed by the notified body or on behalf of the notified body;

(iii) test pieces for examination shall be withdrawn by the notified body when inspecting the production site pursuant to point (b)(ii) or (iii), except when the production of products has not yet started;

(b) Module D (Conformity to type based on quality assurance of the production process) as set out in Annex II to Decision No 768/2008/EC with the following specifications:

(i) the quality system shall be assessed by the notified body that has carried out the conformity assessment procedure referred to in point (a);

(ii) an initial inspection of the production site to assess the quality system and to withdraw test pieces for type examination shall be carried out by the notified body;

([4]) Commission Implementing Decision (EU) 2024/365 of 23 January 2024 laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council as regards methodologies for testing and accepting starting substances, compositions and constituents to be included in the European positive lists (OJ L, 2024/365, 23.4.2024, ELI: http://data.europa.eu/eli/dec_impl/2024/365/oj).

([5]) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(iii) an annual inspection of the production site to assess the quality system and to withdraw test pieces for the re-assessment of the type examination pursuant to point (a) or for a reduced testing pursuant to point (iv) of this point shall be carried out by the notified body;

(iv) annual reduced testing may be performed by the notified body or on behalf of the notified body, and tests may be carried out by the manufacturer as part of the quality system.

Where the conformity assessment procedures referred to in the first subparagraph demonstrate that the product complies with the minimum hygiene requirements, the notified body shall issue a certificate for both conformity assessment procedures referred to in points (a) and (b) of that subparagraph to the manufacturer, the importer or the authorised representative. The certificate shall contain the name and address of the manufacturer, the conclusions of the conformity assessment, any conditions for the certificate and the necessary data for identification of the approved type. The certificate shall have a validity of 5 years.

Based on the outcome of the annual inspection referred to in the first subparagraph, point (b)(iii), the notified body may withdraw the relevant certificates.

2. Where the product is categorised in risk group 3 or 4 under Implementing Decision (EU) 2024/368 or, in the case of a metallic composition, in product group C or D in Table 2 'Product group for metallic compositions' of Annex II to Implementing Decision (EU) 2024/365, both of the following conformity assessment procedures shall apply:

(a) Module B (EU type examination) as set out in Annex II to Decision No 768/2008/EC carried out by a notified body and with the following specifications:

(i) the conformity assessment shall contain an examination of a test piece (production type);

(ii) all relevant tests referred to in Implementing Decision (EU) 2024/368 shall be performed by the notified body or on behalf of the notified body;

(iii) test pieces shall be supplied by the manufacturer, the importer or the authorised representative to the notified body for examination;

(b) Module C (Conformity to type based on internal production control) as set out in Annex II to Decision No 768/2008/EC.

Where the conformity assessment procedures referred to in the first subparagraph demonstrate that the product complies with the minimum hygiene requirements, the notified body shall issue a certificate for the conformity assessment procedure referred to in that subparagraph, point (a), to the manufacturer, the importer or the authorised representative. The certificate shall contain the name and address of the manufacturer, the conclusions of the conformity assessment, any conditions for the validity of the certificate and the necessary data for the identification of the approved type. The certificate shall have a validity of 5 years. The manufacturer shall ensure and declare that the product concerned is in conformity with the type described in the EU type examination certificate and satisfies the requirements set out in this Regulation.

3. Where the product is an assembled product, the applicable conformity assessment procedure shall be determined by the individual component with the highest risk group categorisation (RG1 is the highest risk group, RG4 is the lowest risk group) under Implementing Decision (EU) 2024/368 or, in the case of metallic compositions, the highest categorised product group in Table 2 'Product group for metallic compositions' of Annex II to Implementing Decision (EU) 2024/365.

4. The applicable conformity assessment procedure for the manufacture of an individual component of an assembled product shall be determined by the risk group of that individual component under Implementing Decision (EU) 2024/368 or, in the case of metallic compositions, the product group of the individual component in Table 2 'Product group for metallic compositions' of Annex II to Implementing Decision (EU) 2024/365.

5. Where compliance of a product with the applicable minimum hygiene requirements has been demonstrated by the conformity assessment procedure referred to in paragraph 1 or 2, manufacturers, or their authorised representatives, shall draw up an EU declaration of conformity.

By drawing up the EU declaration of conformity, or by having it drawn up by its authorised representative, the manufacturer, assumes responsibility for the compliance of the product with the minimum hygiene requirements.

The EU declaration of conformity shall have the model structure set out in the Annex and shall be continuously updated. It shall be translated by the manufacturer, or its authorised representative, into the language or languages required by the Member State in which the product is placed on the market.

*Article 3*

**Notifying authorities**

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 5.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article, to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 4. In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body, referred to in paragraph 3.

*Article 4*

**Requirements relating to notifying authorities**

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

*Article 5*

**Requirements relating to notified bodies**

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in this Article.

2. A conformity assessment body shall be established under national law and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the manufacturer's, the importer's or the authorised representative's organisation or the products it assesses.

4. A conformity assessment body shall be accredited by a national accreditation body in accordance with Regulation (EC) No 765/2008. The accreditation shall be based on international standard EN ISO/IEC 17065:2017. The accreditation certificate shall attest that the conformity assessment body is competent to perform the conformity assessment procedures referred to in Article 2 of this Regulation.

5. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, importer, supplier, purchaser, owner or user of products which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of products that are necessary for the operations of the conformity assessment body or the use of products for personal purposes.

A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing or use of products which they assess or represent parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

6. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

7. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks which are assigned to it by Article 2 and in relation to which they have been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each product in relation to which it has been notified, a conformity assessment body shall have at its disposal, or in place, the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which the conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;

(c) policies and procedures that distinguish between tasks it carries out as a notified body and other activities;

(d) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

8. The personnel responsible for carrying out the conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the minimum hygiene requirements and their standards set out in Implementing Decision (EU) 2024/368; and

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

9. The impartiality of the conformity assessment bodies, their top-level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

10. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

11. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 2, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

12. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, relevant standardisation activities.

*Article 6*

**Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 5 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary, and the work carried out by them under Article 2.

*Article 7*

**Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by the following:

(a) a description of the conformity assessment activities;

(b) a description of the conformity assessment procedures set out in Article 2 for which the conformity assessment body claims to be competent;

(c) accreditation certificates issued by national accreditation bodies attesting that the conformity assessment body fulfils the requirements laid down in Article 5 and that its subsidiaries or subcontractors fulfil the requirements laid down in Article 6.

*Article 8*

**Notification procedure**

1. Notifying authorities shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 5.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities and of the conformity assessment procedures set out in Article 2 as well as the accreditation certificates referred to in Article 7(2), point (c).

4. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the notification.

Only such a body shall be considered a notified body for the purposes of this Regulation.

5. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

*Article 9*

**Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

*Article 10*

**Changes to notifications**

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 5 or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of the notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying authorities and market surveillance authorities at their request.

*Article 11*

**Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 31 December 2026.

However, for products which are assessed to be in conformity with national hygiene requirements for products that come into contact with water intended for human consumption and for which the national conformity certificate is still valid on 31 December 2026, it shall apply from 31 December 2032.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 January 2024.

*For the Commission*
*The President*
Ursula VON DER LEYEN

*ANNEX*

**EU DECLARATION OF CONFORMITY**

1. Product No ..... (*unique identification of the product*).
2. Name and address of the manufacturer and, where applicable, its authorised representative: .....
   .....
3. This EU declaration of conformity is issued under the sole responsibility of the manufacturer: .....
4. Object of the declaration (*identification of the product allowing traceability*), including a colour image of sufficient clarity to enable identification of the product: .....
5. The object of the declaration described in point 4 is in conformity with:
   — Commission Delegated Regulation (EU) 2024/370,
   — other Union harmonisation legislation where applicable.
6. References to the specifications in relation to which conformity is declared: .....
   .....
7. The notified body ..... (*name, number*) performed .....(*description of intervention*) and issued the certificate ..... (*number*).
8. Additional information: .....

Signed for and on behalf of:

(*place and date of issue*):

(*name, function*) (*signature*):