Live Q & A - Quo Vadis

Drinking Water Contact Materials in Europe

Dr. Rainer Brandsch

European Legislation (DWD)

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

Article 11

Minimum hygiene requirements for materials that come into contact with water intended for human consumption

1. For the purposes of Article 4, Member States shall ensure that materials that are intended to be used in new installations or, in the case of repair works or reconstruction, in existing installations for the abstraction, treatment, storage or distribution of water intended for human consumption and that come into contact with such water do not:

(a) directly or indirectly compromise the protection of human health as provided for by this Directive;

(b) adversely affect the colour, odour or taste of the water;

(c) enhance microbial growth;

(d) leach contaminants into the water at levels that are higher than necessary in view of the intended purpose of the material.

Implementing & Delegated Acts

Short name	Regulatory content	Link
1.IA Implementing decision	**Methodologies for testing/accepting substances, compositions & constituents in European positive lists**	https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13894-Drinking-water-methodologies-for-testing-accepting-substances-compositions-constituents-in-European-positive-lists_en
2.IA Implementing decision	**Establishing the European positive lists of starting substances, compositions, and constituents**	https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13896-Drinking-water-establishing-the-European-positive-lists-of-starting-substances-compositions-and-constituents_en
3.DA Delegated regulation	**Adding or removing starting substances, compositions or constituents from the European positive lists**	https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13712-Drinking-water-Adding-or-removing-starting-substances-compositions-or-constituents-from-the-European-positive-lists_en
4.IA Implementing decision	**Procedure and methodologies for testing and accepting final materials**	https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13893-Drinking-water-procedure-and-methodologies-for-testing-and-accepting-final-materials_en
5.DA Delegated Regulation	**Conformity assessment procedure for products that come into contact with drinking water**	https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13895-Drinking-water-conformity-assessment-procedure-for-products-that-come-into-contact-with-drinking-water_en
6.DA Delegated Regulation	**Marking of products in contact with drinking water**	https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13713-Drinking-water-Marking-of-products-in-contact-with-drinking-water_en

Definitions - Notified Body

Article 1

Definitions

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

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

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 authorized representative's organization or the products it assesses.

Notified Body

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.

Conformity assessment proc. (risk group 1 or 2)

notified bod

Article 2

Conformity assessment procedures

1. Where the product is categorised in risk group 1 or 2 under Commission Implementing Decision (EU) …/… [*OP: please fill in the reference of C(2024)238*] 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) …/… [*OP: please fill in the reference of C(2024)239],* 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 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 Commission Implementing Decision (EU) …/… [*OP: please fill in the reference of C(2024)238*] 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;

Conformity assessment proc. (risk group 1 or 2)

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;

(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.

Conformity assessment procedures

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.

Conformity assessment proc. (risk group 3 or 4)

2. Where the product is categorised in risk group 3 or 4 under Commission Implementing Decision (EU) …/… [*OP: please fill in the reference of C(2024)238*] 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 Commission Implementing Decision (EU) …/… [*OP: please fill in the reference of C(2024)239*], 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 Commission Implementing Decision (EU) …/… [*OP: please fill in the reference of C(2024)238*] 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.

EU declaration of conformity (by manufacturer)

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.

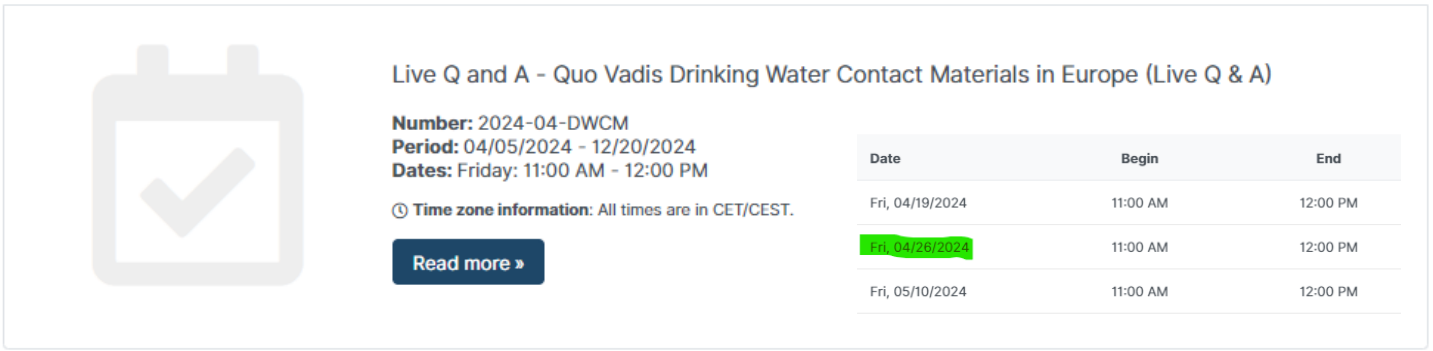
The EU declaration of conformity shall have the model structure set out in the Annex and shall be continuously updated. It shall be translated by the manufacturer, or its authorised representative, into the language or languages required by the Member State in which the product is placed on the market.

Testing Laboratory vs. Certification body

Certification body:
A certification body is an independent body that has the necessary competence (proven by appropriate accreditation in accordance with DIN EN ISO/IEC 17065) to assess the characteristics specified in this recommendation.

Testing laboratory:
A testing laboratory is a laboratory accredited in accordance with DIN EN ISO/IEC 17025 that has the necessary competence to carry out the required tests.

On our own behalf - training program



Live Q and A - Quo Vadis Drinking Water Contact Materials in Europe (Live Q & A)

Number: 2024-04-DWCM
Period: 04/05/2024 - 12/20/2024
Dates: Friday: 11:00 AM - 12:00 PM

Time zone information: All times are in CET/CEST.

Read more »

Date	Begin	End
Fri, 04/19/2024	11:00 AM	12:00 PM
Fri, 04/26/2024	11:00 AM	12:00 PM
Fri, 05/10/2024	11:00 AM	12:00 PM

training.DWCM - EU - Certification of DWCM (Workshop)

Period: 04/24/2024 - 04/24/2024
Dates: Wednesday: 10:00 AM - 3:00 PM

Time zone information: All times are in CET/CEST.

Read more »

training.DWCM - DE, EU - Formulation Review (Workshop)

Number: DW-2024-06
Period: 06/20/2024 - 06/20/2024
Dates: Thursday: 10:00 AM - 3:00 PM

Time zone information: All times are in CET/CEST.

Read more »

safecert®

A better way to comply !

Thank you for your attention !

Dr. Rainer Brandsch - Managing Partner

SAFE+ Certification GmbH (Certifying body)

SAFE+ Algorithmics GmbH (Digital Lab)

Tel.: +49/173/6662097

e-Mail: rainer.brandsch@safecert.org
rainer.brandsch@saferithm.com