

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 (23.04.2024)

Ref.	Topic	Legal act title	Web link
1.IA	Information requirements	Commission Implementing Decision (EU) 2024/365 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	https://eur-lex.europa.eu/eli/dec_impl/2024/365/oj
2.IA	EUPLs	Commission Implementing Decision (EU) 2024/367 laying down rules for the application of Directive (EU) 2020/2184 of the European Parliament and of the Council by 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	https://eur-lex.europa.eu/eli/dec_impl/2024/367/oj
3.DA	DWD application process	Commission Delegated Regulation (EU) 2024/369 supplementing Directive (EU) 2020/2184 of the European Parliament and of the Council by laying down the procedure regarding inclusion in or removal from the European positive lists of starting substances, compositions and constituents	https://eur-lex.europa.eu/eli/reg_del/2024/369/oj
4.IA	Testing materials	Commission Implementing Decision (EU) 2024/368 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	https://eur-lex.europa.eu/eli/dec_impl/2024/368/oj
5.DA	Product conformity assessment	Commission Delegated Regulation (EU) 2024/370 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	https://eur-lex.europa.eu/eli/reg_del/2024/370/oj
6.DA	EU marking	Commission Delegated Regulation (EU) 2024/371 supplementing Directive (EU) No 2020/2184 of the European Parliament and of the Council by establishing harmonised specifications for the marking of products that come into contact with water intended for human consumption	https://eur-lex.europa.eu/eli/reg_del/2024/371/oj

►► Published in the Official Journal yesterday - 23.04.2024

Definition

➤ Germany

Formulation <i>[„Rezeptur“]</i>	Formulation is the list and relative amount of starting substances used to manufacture the material.
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➤ Europe

(16) ‘**formulation**’ means the list of all substances used in the preparation of an organic material or of a cementitious material and their relative quantities;

Formulation - Sub-formulations - several levels

Handelsname	Lieferant	Stoffname	CAS Nr.	Funktion	Anteil [gew. %]	Bemerkung

Handelsname	Lieferant	Stoffname	CAS Nr.	Funktion	Anteil [gew. %]	Bemerkung

Handelsname	Lieferant	Stoffname	CAS Nr.	Funktion	Anteil [gew. %]	Bemerkung

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Handelsname	Lieferant	Stoffname	CAS Nr.	Funktion	Anteil [gew. %]	Bemerkung

The manufacturer and/or its supplier(s) shall submit a complete compilation of key information on all formulation constituents to the certification body, in a form exemplified below:

No.	Raw material / trade name	Chemical description	CAS-number	Function of the raw material	Percentage by weight (in % w/w)	Specification (e.g. purity)

Formulation review (Germany)

- In the table, the manufacturer shall enter all formulation **components**, including additional formulation components of the preparation, such as **solvents** and **impurities** (see 7.4.1).
- A current data safety sheet or technical data sheet for the starting materials or preparation can generally provide information on starting material purity and on the other substances contained in the formulation.
- If the manufacturer does not possess complete formulation details, the supplier shall submit the respective information (supplier contact details required).
- For products with several layers, the composition of each layer must be disclosed for assessment of the product formulation.
- The declaration of formulation is integral part of required information **the manufacturer must provide to the certification body** in order to have the formulation evaluated.

Formulation review (Europe)

2.2. Formulation review

A formulation review is required in accordance with the requirements in Table 1.

2.2.1 Required information

For a formulation review of a final organic material the following information is required:

- (a) list of all starting substances (including their impurities and other specifications) used to produce the final organic material including all monomers, additives, aids to polymerisation, polymer production aids, pigments, colorants and fillers;
- (b) the respective percentage by mass (m/m %) of all starting substances and substances used to produce the final material, adding up to 100 %.
- (c) any other information considered relevant for the assessment of the formulation of the final organic material.

2.2.2 Relevant substances

The formulation shall be evaluated and compared with the accepted starting substances of the European positive list of starting substances for organic materials set out in Annex I of Commission Implementing Decision (EU) .../... [OP: please fill in the reference of C(2023)7001]. One of the objectives of the evaluation is to define the relevant substances, which shall be analysed in the migration water.

Formulation types

- **NOT-REACTED** formulation
=> required for formulation review (application of 0,02% cut-off limit) according to KTW-BWGL and European legislation

- **REACTED** formulation
=> required for migration calculation/modeling according to KTW-BWGL

Formulation types

➤ Example polypropylene (PP):

- NOT-REACTED:

99.70% propene

0.04% catalyst

0.06% solvent

0.07% phosphatic antioxidant

0.03% phenolic antioxidant

0.10% acid scavenger

- REACTED:

99.78% polypropylene

0.01% Aluminum from compounds

< 0.01 solvent

0.07% phosphatic antioxidant

0.03% phenolic antioxidant

0.10% acid scavenger

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 »](#)

Termine (34)

Information zur Zeitzone: Alle Zeiten sind in MEZ/MESZ.

Datum	Beginn	Ende
Fr., 19.04.2024	11:00	12:00
Fr., 26.04.2024	11:00	12:00
Fr., 17.05.2024	11:00	12:00
Fr., 24.05.2024	11:00	12:00
Fr., 31.05.2024	11:00	12:00



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.

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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