



Guidance on the Drinking Water Directive

*Volume V: Calibrants and representative samples of accepted compositions
in the context of the Drinking Water Directive*

Version 1.0

DRAFT

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Legal notice

This document aims to assist users in complying with their obligations under 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 (recast), hereafter referred to as the drinking water directive (DWD). However, users are reminded that the text of the DWD (Article 11(2)(a)) and Commission Delegated Regulation (EU) 2024/369 are the only authentic legal references and that the information in this document does not constitute legal advice. The primary function of the Guidance is to inform the applicant and nothing within it may be construed as legal advice. Usage of the information remains the sole responsibility of the user.

Notes for the reader

This guidance must be read in conjunction with the relevant DWD implementing legislation, particularly:

- 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;
- Commission Implementing Decision (EU) 2024/367 of 23 January 2024 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;
- Commission Delegated Regulation (EU) 2024/369 of 23 January 2024 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.

In addition, this guidance document is part of wider guidance on DWD applications comprising a total of five volumes. The remaining volumes are downloadable from ECHA's website at <https://echa.europa.eu/guidance-documents/guidance-on-dwd> and are:

- DWD Guidance Volume I on methodologies for testing starting substances, compositions and constituents for use in the manufacture of materials or products in contact with water intended for human consumption;
- DWD Guidance Volume II on methodologies for accepting starting substances, compositions and constituents for use in the manufacture of materials or products in contact with water intended for human consumption;
- DWD Guidance Volume III on the scope of DWD applications;
- DWD Guidance Volume IV on the contents of a notification of intention.

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1 Introduction

The Drinking Water Directive (Directive (EU) 2020/2184) requires that starting substances, constituents and compositions used in the manufacturing of materials that come in contact with water intended for human consumption are listed in one of the European positive lists (EU-PL) (Commission Implementing Decision (EU) 2024/367). The procedure on how to apply for inclusion of starting substances, constituents and compositions in the EU-PL is described in the Commission Delegated Regulation (EU) 2024/369.

According to Article 13(2) of this regulation, “within 2 months from the publication of an opinion of the Committee for Risk Assessment to include, maintain or amend an entry in one of the European positive lists, the applicant shall provide the Commission with a calibrant of its starting substance or organic cementitious constituent or a representative sample of the accepted composition of metallic materials, enamels, ceramic or other inorganic materials”.

This guidance defines a procedure and conditions for submission of calibrants and representative samples of accepted compositions to the European Union Reference Laboratory for Food Contact Materials (EURL-FCM). The EURL-FCM, hosted by the Joint Research Centre (JRC) of the Commission in Ispra, Italy, stores the calibrants and representative samples in a dedicated area for future reference.

2 Calibrants and representative samples of accepted compositions

The applicant shall provide calibrants or representative samples of accepted compositions and the following documents to the EURL-FCM:

— **Physical samples:**

- 250 g of the starting substance* and,
- 250 g of other relevant chemical species that have a Maximum Tolerable Concentration at the tap in organic materials ($MTC_{\text{tap, organics}}$), listed in the European positive list (EU-PL) for that starting substance*;

or

- 250 g of the organic cementitious constituent* and,
- 250 g of other relevant chemical species that have an $MTC_{\text{tap, cementitious}}$, listed in the EU-PL for that organic cementitious constituent*;

or

- 3 samples of the metallic composition[†] (size approximately 5 cm x 5 cm x max. 5 cm) or, if applicable and preferred by the applicant, 3 samples of the metallic composition with geometry as specified in EN 15664-1:2008+A1, paragraphs 5.4.2 and 5.4.3. Please note that the sample has to be virgin and not one already used in a migration test;

or

- 3 samples of the enamel, ceramic or other inorganic composition[†] (size approximately 10 cm x 10 cm x max. 5 cm) or, if applicable and preferred by the applicant, 3 samples of the enamel composition with geometry and preparation according to EN ISO 28764:2015;

— **Documentation:**

- Signed completed Declaration form (Annex I) (mandatory);
- Safety data sheets of the starting substance, organic cementitious constituent, other relevant chemical species or compositions (mandatory);

* In case the accepted starting substance, organic cementitious constituent or other relevant chemical species are already commercially available in small quantities (e.g. 250 g), there is no obligation to deliver a physical sample to the EURL-FCM. Instead, please provide the mandatory documentation and information under fields 11 and 12 in the Declaration form (Annex I) regarding the manufacturer of the substance.

[†] Representative samples of accepted compositions shall not be contaminated by ink or glue on their surfaces. It is recommended that the labels shall be placed on the packaging and not directly on the naked sample. Contact surfaces that do not come in contact with drinking water under real use should be marked (e.g. on the picture attached to the Declaration form of Annex I).

- Picture of the representative sample with indication of the surfaces that do not come in contact with drinking water[†] (mandatory);
- Spectroscopic data for the starting substance, organic cementitious constituent or other relevant chemical species (e.g. a .csv file);
- Document on purity for starting substances, organic cementitious constituents and other relevant chemical species (preferably a certificate);
- Test report confirming that the metallic, enamel, ceramic and other inorganic composition of the representative sample is within the ranges stated by the applicant;
- For calibrants of multi-constituent starting substances or organic cementitious constituents: a test report confirming that the calibrant corresponds to the qualitative and quantitative composition stated by the applicant.

If some of the documents listed above or in Annex I were already submitted to ECHA during the application process, please do not submit them again with the calibrant or representative sample.

The above-listed documents shall be supplied in electronic format to JRC-EURL-FCM@ec.europa.eu **in advance of the shipment** of the samples.

The physical samples and a printed copy of the Declaration form in Annex I shall be shipped to:

European Commission
Directorate General Joint Research Centre
Directorate F - Health and Food

EURL Food Contact Materials
TP 260
Via E. Fermi 2749
I-21027 Ispra (VA)
Italy

3 Shipment

The applicant is responsible for ensuring suitable and safe transport conditions of the physical samples. Care should be taken to prevent and minimise risk of breakage of fragile samples and containers during transport; each sample should be separately packaged to avoid any possible damage during transportation.

The container / bill of shipment shall carry the indication “Laboratory samples – no commercial value”.

Materials shall be packaged and labelled as required by applicable transport regulations.

Upon their receipt, the EURL-FCM will assess the status of the samples. They will be considered valid if:

- The calibrants / representative samples provided are of sufficient quantity (see Section 2 above), and
- They are properly packaged and labelled, and
- They are accompanied by the required documentation (see Section 2 above).

If the applicant considers that special shipment conditions (refrigerated/frozen samples) are required, the EURL-FCM needs to be contacted in advance of the shipment to be informed about the expected delivery date and time, specifying the required storage conditions. Such conditions shall also be specified in the Declaration form.

The storage temperature should be clearly indicated on the outer side of the container.

In case of applications for modification/renewal of an existing authorisation, the applicant should contact the EURL-FCM prior to any shipment to check whether the authorisation amendment remains within the scope of the analytical method linked to the authorisation, and whether there would be a need to re-send a calibrant or representative sample.

In case of any questions, please contact:

JRC-EURL-FCM@ec.europa.eu

Annex I

DECLARATION FORM

Form to be filled in for each starting substance, organic cementitious constituents, other relevant chemical species, metallic composition and enamel, ceramic or other inorganic composition and submitted (a) electronically and (b) as a printed copy together with the calibrant/representative sample of the composition.

Contact information	
1. Name of the applicant	
2. Address of the applicant	
3. Contact details (email address, phone number)	
4. Name, address and contact details of the person/company that shipped the sample (if different to above)	
Sample information	
5. Type of calibrant/representative sample	<input type="checkbox"/> starting substance <input type="checkbox"/> organic cementitious constituent <input type="checkbox"/> other relevant chemical species <input type="checkbox"/> metallic composition <input type="checkbox"/> enamel, ceramic or other inorganic composition
6. Substance name/composition description (including specification of metallic substrate for coated samples)	
7. Trade name of the substance (if appropriate)	
8. European Positive List number (if available)	
9. Drinking Water Directive application number (issued by ECHA)	
10. Chemical Abstracts Service (CAS) name and CAS registry number (if available)	
11. Degree of purity in % (e.g. including certificate of purity, if available)	

12. Name of the manufacturer of the substance (for substances commercially available)	
13. Link to the website where it is possible to purchase the substance in small quantity (e.g. 250 g)	
14. Information on recommended storage conditions	
15. Calibrant expiry date for starting substances, organic cementitious constituents and other relevant chemical species	
16. Other relevant information	
Documents	
17. Documents provided (check the boxes where relevant)	<i>Filled in and signed Declaration form</i> <input type="checkbox"/> printed copy shipped together with sample in the container and <input type="checkbox"/> copy delivered electronically
	<i>Safety data sheet</i> <input type="checkbox"/> delivered electronically
	<i>Picture with indication of surfaces of representative sample that do not come in contact with drinking water</i> <input type="checkbox"/> delivered electronically
	<i>Spectroscopic data</i> <input type="checkbox"/> delivered electronically or <input type="checkbox"/> submitted to ECHA
	<i>Certificate of purity</i> <input type="checkbox"/> delivered electronically or <input type="checkbox"/> submitted to ECHA
	<i>Test report conforming the chemical composition of multi-constituent starting substance/constituents or composition</i> <input type="checkbox"/> delivered electronically or <input type="checkbox"/> submitted to ECHA

Signature _____

Date _____

Applicant's authorised representative

I hereby declare to have read and understood how my personal data is processed in accordance with the privacy statement declaration available at [hyperlink to the DPO Register - link to be provided soon by the DPO officer].

Signature _____

Date _____

Applicant's authorised representative

[placeholder picture mentioned in footnote]

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EU law and related documents

For access to legal information from the EU, including all EU law since 1951 in all the official language versions, go to EUR-Lex (eur-lex.europa.eu).

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