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Information by certified body OFI CERT

Suitability of products regarding contact with drinking water: Assessment and certification process¹

General information about assessment and certification according to the corresponding product
certification regulations

¹ This is the English version of the document, in case of doubt the German version prevails over the English version

Media Owner: OFI Technologie & Innovation GmbH
Franz-Grill-Strasse 3, Arsenal, Objekt 213, 1030 Wien

T +43 1 798 16 01-790 • **F** +43 1 798 16 01-977
I www.oficert.at • **E** OFI-CERT-UBA@ofi.at

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This certification information is continuously adapted to quality standards.

Written input on improvement are welcome.

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1 Scope und general information

This document contains general information about OFI CERT processes regarding products in contact with drinking water and their evaluation and certification.

This is a direct consequence of the national implementation of the European drinking water directive into the German drinking water directive. In future issues of this document, changes of the drinking water directive will be incorporated.

2 Fundamental documents

- 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)
- Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance),
- Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' Text with EEA relevance.
- Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonized conditions for the marketing of construction products and repealing Council Directive 89/106/EEC Text with EEA relevance.
- UBA Evaluation Criteria and Guidelines as issued by the Umweltbundesamt Germany (<https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/evaluation-criteria-guidelines#introduction>) see Annex C of this information

3 Conformity assessment – general procedure

In chapter 7 of the UBA Recommendation for the conformity assessment the procedure for the assessment and review of the constancy of performance is given (see table 1 of this information) as 1+ system for organic or enamel/ceramic products, which have an conversation factor $F_c \geq 0,5$ d/dm according to chapter 7 of the UBA KTW EC and for metallic products which have more than 10% of the total wetted surface in a final assembled product (category A and B according to chapter 4.5 of the UBA Metallic EC).

Further in the same chapter of the recommendation, the system for the assessment and review of the constancy of performance (see table 1 of this information) is given as "simplified procedure" for products which are not part of the 1+ system.

For so called "intermediate- and pre-products" a special form of certification according to chapter 6.6 of the recommendation is given, these are products, which have to be further processed before the can be used in their final scope.

The corresponding procedure has to be chosen for the initial and ongoing certification.

Table 1: systems for evaluation and verification of constancy of performance

System	Tasks producer	Tasks of certified body	Type of conformity assessment
1+	Performing Factory production control (FPC); additional tests done on samples taken from the factory according to a predetermined test schedule (annual inspection).	Initial inspection of factory and FPC; determination of product type through type testing (initial testing including sampling) or type calculation through document reviews of product descriptions; annual supervision; assessment and evaluation of the FPC; Random Sampling of products and testing before circulation (audit testing).	Certificate (assessment of conformity) of the certified body on the conformity of the FPC and the product
Simplified procedure	Performing Factory production control (FPC).	determination of product type through type testing or type calculation through document reviews of product descriptions.	Certificate (assessment of conformity) of the certified body on the conformity of the product
Pre- and intermediate-products	Performing Factory production control (FPC).	determination of product type through type testing (initial testing including sampling) or type calculation through document reviews of product descriptions	Certificate (assessment of conformity) of the certified body on the conformity of the product and products made out of the same material of lower risk groups

4 Conformity assessment – 1+ system

4.1 Application and needed documents

The producer with or without a third party (certified body) is tasked with the assessment and review of the constancy of performance. The following documents must be submitted by the applicant to make certification by certified body OFI CERT possible:

- Engrossed and duly executed „Antrag auf Zertifizierung Trinkwasser (GP33-015)“ or “Antrag auf Zertifizierung Trinkwasser VVF (GP33-F021) “;
- [Certification contract](#) (see chapter 4.5.1 of this information)
- [Authorization or consent form of the producer](#), if the applicant is not the producer;
- [Product documents](#) with cited markings and scope of certification;
- Proof of factory production control implementation;
- Proof of a certified [quality management system acc. to EN ISO 9001](#) (if available);
- Documents and reports of the initial type test (if available)

4.2 Definition of the system of assessment and evaluation of the constancy of performance

The UBA KTW EC must be used for the hygienic assessment of organic materials in contact with drinking water. This document also defines the system for attestation of conformity with 1+ (see table 1 of this information) for this area of use.

4.3 Parties involved in the conformity assessment process

In agreement with the applicant, the inspector for the conformity representative for the assessment body is chosen, who performs the initial inspection of the production facilities, sampling, documentation of the FPC and reviews the declaration of performance of the applicant for any aberrations with the type test.

The inspector is provided by certified body OFI CERT with all documents listed in chapter 4.1 of this document.

4.4 Evaluation criteria

On basis of the assignment technical specification (chapter 2) and any agreements between certified body OFI CERT and the applicant, the evaluation criteria for the initial inspection and the FPC as well as the type test are sent to the applicant through the conformity assessment body.

The evaluation criteria are categorized into two different groups:

- Requirements for the FPC
- Tests and reports (FPC, type testing)

4.4.1 Requirements for the FPC

The initial inspection by the nominated inspector of the certified body OFI CERT reviews, if the technical know-how and personnel resources are available to ensure a continuous and production according to specification as well as the correct FPC is possible.

4.4.1.1 Producer with a certified quality management system

If a valid, certified quality management system according to EN ISO 9001 was submitted by the applicant, its implementation into the organization of the applicant is reviewed by the inspector in the initial inspection. This review, if positive, confirms, that the general requirements for the organization and the quality manual are fulfilled.

- The tests for raw materials, intermediate and finished products as well as for the production process, the frequency of such tests and rules for retests, as given by the FPC must exist;
- Processes for handling, storing, packaging, marking and labeling of the product must exist. Facilities for storage, which must be able to prevent damage or destruction of the product must exist;
- Proof of a person authorized and tasked by the management of the applicant's organization with the management and supervision of the FPC must exist. The person must secure the implementation and continuous compliance with the requirements of the relevant product standards and possess the necessary know-how;
- Documentation of conformity after testing or control must exist.

4.4.1.2 Producer without a certified quality management system

If the applicant has no certified EN ISO 9001 quality management system in place, he must make sure to successfully implement (e.g. in SOPs, manuals, etc.) and fulfill the following requirements, which is controlled by the inspector in the initial inspection.

- Definition of quality goals must exist;
- Structure of organization must exist;
- Definition of responsibility, authority and cooperation of all personnel of the organization (leading, executing, supervising) who may influence the quality of the product (e.g. Personnel tasked with the documentation of quality deficiencies or is tasked with the definition of actions in case of quality deficiencies) must exist;

- Definition of the [scope of the factory production control](#) must exist;
- Methods for [description and control of raw-material and added substances](#) must exist;
- [Methods for production control](#), amongst other things procedures, methods and systematic policies linked to production must exist;
- The [tests for raw materials, intermediate and finished products as well as for the production process, the frequency of such tests and rules for retests](#), as given by the FPC must exist;
- All needed [facilities, testing devices and the personnel](#) for the implementation and execution of the necessary tests must be available. The testing devices must be properly maintained and calibrated;
- [Proof of a person authorized and tasked by the management of the applicant's organization with the management and supervision of the FPC](#) must exist. The person must secure the implementation and continuous compliance with the requirements of the relevant product standards and possess the necessary know-how;
- Methods and procedures for [personnel training](#) in all quality impacting tasks must exist;
- [Proof of a person authorized and tasked by the management of the applicant's organization with the management and supervision of the FPC](#) must exist. The person must secure the implementation and continuous compliance with the requirements of the relevant product standards and possess the necessary know-how;
- Control of [execution and review of the FPC by the management of the company with regard to suitability and effectiveness by the means of documentation records](#) must exist;
- [Documentation of conformity](#) after testing or control must exist;
- Procedures for treatment of [products with non-conformities](#) must exist;
- [Traceability of products](#) must be possible;
- [Documentation](#) must be kept for at least 10 years.

4.4.2 Tests and reports

The initial test (type test) is done according to the scope and requirements of the KTW EC (see chapter 5 of the KTW EC general part).

[The inspector tasked by the conformity assessment body](#) duly performs sampling and provides the samples to the testing laboratory.

The test report must include all specifics as given by the KTW EC (see chapter 6.3.4 of the KTW EC general part).

The FPC is evaluated according to the valid checklist provided by OFI CERT (for initial inspection and annual inspection) "[GP33-MD03-CERT – Auditcheckliste ZI-21 \(Version 1.4b - 2021-08-11\)](#)".

4.5 Certification

The certification – issuance of conformity assessment – is done on basis of all documents as given in chapter 4.4 of this document and after signing the necessary certification contract as described in chapter 4.5.1 of this document.

[Recommendations and measures which are for example given within the scope of the inspection of the FPC have to be implemented before a certificate can be issued.](#) The implementation is reviewed by certified body OFI CERT.

4.5.1 Certification contract

After the application and the evaluation of the product documents (e.g. BOM lists) a certification contract is signed, to make execution of all future inspections possible, between OFI CERT, the applicant and the producer.

In this contract the rights and duties of all contracting parties are defined as well as the products which are subject to an FPC.

4.5.2 Measures management

After the conclusion of the initial inspection of the production site and the FPC, the inspector, tasked by certified body OFI, documents any observations in written form on a checklist (a help for the right use of the checklist is provided by OFI CERT in the document “[Checklistenklärung für Auditoren](#)”).

The evaluation of the checklist and the observations within is done by OFI CERT and if needed recommendations and measures for improvement are given back to the applicant.

[Measures for improvement are ranked according to their influence on product quality and stability of production processes by OFI CERT and deadlines for their implementation are assessed.](#)

The review on implementation of the recommendations and measures is done by the testing- or inspecting body which means, by the inspector tasked by OFI CERT. In case of a failure to meet the deadline, OFI CERT must be informed immediately. OFI CERT will then decide about the further course of action.

In case of initial inspection – if conformity assessment is the main goal – a missed deadline automatically means, that the conformity assessment can't be issued.

4.5.3 Issue of conformity assessments

After a positive conclusion to the initial test, inspection and FPC review, a conformity assessment is issued.

The right to use the conformity mark, its suspension or withdrawal is published on the homepage of OFI CERT and if needed also in other print media, together with the certificate number and the date of issuing or withdrawal.

Further, a full register of valid conformity assessments will be published by OFI CERT regularly. See <http://www.oficert.at> for further information on the validity of conformity assessments.

4.6 Conformity assessment as part of annual supervision

The [annual supervision \(inspection\) of the FPC](#) is regulated by the KTW EC and by the 1+ system. It is done at least [once a year per manufacturing site by the OFI CERT tasked inspector](#). In this inspection [sampling for the supervision tests is also done](#) for the [certified products](#). The [sites of sampling](#) (manufacturing sites) are defined in the certification contract.

The methods for each different product are defined by the UBA recommendation “Conformity attestation of product hygiene suitability for drinking water” (see chapter 7 of the recommendation).

4.6.1 Needed documents

For the supervision the applicant has to submit the following documents to certified body OFI CERT:

- [Product documents](#) with cited markings and a [changelog](#) about changes in the scope of certification²;
- Proof of a [certified quality management system according to EN ISO 9001](#) (if available).

4.6.2 Evaluation criteria

See chapter 4.4 of this information.

² If changes were made, the inspector must decide after consulting with the certified body how to further proceed.

4.6.3 Supervision tests and reports

The product tests done during the FPC are carried out and documented by the producer.

The results of the tests have to be documented by the producer.

The samples which are taken while doing the inspection are sent to the testing body tasked by OFI CERT for an annual supervision test.

The conformity assessment body inspects the FPC and evaluates it, the findings of this evaluation and if necessary any measures for improvement are documented and communicated back to the applicant in written form.

4.6.4 Certification

Certification is done on the basis of the documents as stated in chapter 4.6.3 of this document. Measures, e.g. issued after the review of the FPC, have to be implemented before the deadlines given after which the conformity assessment can be reissued.

4.6.5 Measures management

After the conclusion of the inspection of the production site and the FPC, the inspector, tasked by certified body OFI, documents any observations in written form on a checklist (a help for the right use of the checklist is provided by OFI CERT in the document “[Checklistenerklärung für Auditoren](#)”).

The evaluation of the checklist and the observations within is done by OFI CERT and if needed recommendations and measures for improvement are given back to the applicant.

Measures for improvement are ranked according to their influence on product quality and stability of production processes by OFI CERT and deadlines for their implementation are assessed.

The review on implementation of the recommendations and measures is done by the testing- or inspecting body which means, by the inspector tasked by OFI CERT. In case of a failure to meet the deadline, OFI CERT must be informed immediately. OFI CERT will then decide about the further course of action.

In case of supervision – FPC for continued certification - a missed deadline automatically means, that the conformity assessment will be withdrawn or expire and therefore the right to use the conformity assessment sign is lost.

4.6.6 Issue of conformity assessments

After the positive conclusion of the annual supervision test and the review of the FPC a conformity assessment can be issued only, if changes to the products where applied for.

The continuation of the conformity assessment is given, after a positive end result of the annual supervision test and the inspection of the FPC.

The right to use the conformity mark, its suspension or withdrawal is published on the homepage of OFI CERT and if needed also in other print media, together with the certificate number and the date of issuing or withdrawal.

Further, a full register of valid conformity assessments will be published by OFI CERT regularly. See <http://www.oficert.at> for further information on the validity of conformity assessments.

5 Conformity assessment – simplified procedure system

5.1 Application and needed documents

The producer with or without a third party (certified body) is tasked with the assessment and review of the constancy of performance. The following documents must be submitted by the applicant to make certification by certified body OFI CERT possible:

- Engrossed and duly executed „[Antrag auf Zertifizierung Trinkwasser \(GP33-015\)](#)” or “[Antrag auf Zertifizierung Trinkwasser VVF \(GP33-F021\)](#)” including notification of [Conditions for the issue of conformity attestations and the use of conformity marks](#);
- [Authorization or consent form of the producer](#), if the applicant is not the producer;
- [Product documents](#) with cited markings and scope of certification;
- Documents and reports of the initial type test (if available)

5.2 Evaluation criteria

On basis of the assignment technical specification (chapter 2) and any agreements between certified body OFI CERT and the applicant, the evaluation criteria for the type test are sent to the applicant through the conformity assessment body.

5.2.1 Tests and reports

The initial test (type test) is done according to the scope and requirements of the KTW EC (see chapter 5 of the KTW EC general part).

[Samples are provided](#) after consultation of OFI CERT to the testing laboratory.

The test report must include all specifics as given by the KTW EC (see chapter 6.3.4 of the KTW EC general part).

5.3 Certification

The certification – issuing of a conformity assessment – is done on basis of the documents listed in chapter 5.2 of this information.

5.3.1 Certification contract

No certification contract is necessary.

5.3.2 Issue of conformity assessments

After a positive conclusion to the initial test, a conformity assessment is issued.

The right to use the conformity mark, its suspension or withdrawal is published on the homepage of OFI CERT and if needed also in other print media, together with the certificate number and the date of issuing or withdrawal.

Further, a full register of valid conformity assessments will be published by OFI CERT regularly. See <http://www.oficert.at> for further information on the validity of conformity assessments.

6 Conformity assessment – pre- and intermediate- products

6.1 Application and needed documents

See chapter 5.1. of this information

6.2 Parties involved in the conformity assessment process

In agreement with the applicant, the inspector for the conformity representative for the assessment body is chosen, who performs sampling for the type test.

The inspector is provided by certified body OFI CERT with all documents listed in chapter 6.1 of this document.

6.3 Evaluation criteria

On basis of the assignment technical specification (chapter 2) and any agreements between certified body OFI CERT and the applicant, the evaluation criteria for the type test are sent to the applicant through the conformity assessment body.

6.3.1 Tests and reports

The initial test (type test) is done according to the scope and requirements of the KTW EC (see chapter 5 of the KTW EC general part).

[The inspector, tasked by OFI CERT, samples the necessary samples](#) and sends them to the testing laboratory.

The test report must include all specifics as given by the KTW EC (see chapter 6.3.4 of the KTW EC general part).

6.4 Certification

The certification – issuing of a conformity assessment – is done on basis of the documents listed in chapter 6.3 of this information.

6.4.1 Certification contract

No certification contract is necessary.

6.4.2 Issue of conformity assessments

After a positive conclusion to the initial test, a conformity assessment is issued.

The right to use the conformity mark, its suspension or withdrawal is published on the homepage of OFI CERT and if needed also in other print media, together with the certificate number and the date of issuing or withdrawal.

Further, a full register of valid conformity assessments will be published by OFI CERT regularly. See <http://www.oficert.at> for further information on the validity of conformity assessments.

7 Changes in the evaluation criteria (e.g. standards)

If the evaluation criteria change, which are the basis for the conformity assessment (e.g. new issue of a standard), the certified body OFI CERT has to inform the companies which have a product certified, to enable them to do a retest and reevaluation before the lawful deadlines expire. If the deadlines expire without such tests and reviews, this may result in the withdrawal or expiration of the certificates.

8 Validity

This certification information is valid from 2022-06-01 until further notice.

Annex A – Summary of documents needed for certification

Documents needed for the initial certification according to the 1+ system:

- Engrossed and duly executed „Antrag auf Zertifizierung Trinkwasser (GP33-015)“ or “Antrag auf Zertifizierung Trinkwasser VVF (GP33-F021) “;
- Engrossed and duly executed certification contract;
- Authorization or consent form of the producer, if the applicant is not the producer;
- Product documents with cited markings and scope of certification;
- Formulations;
- Certified quality management system (if available);
- Documents and reports regarding the type test (if available).

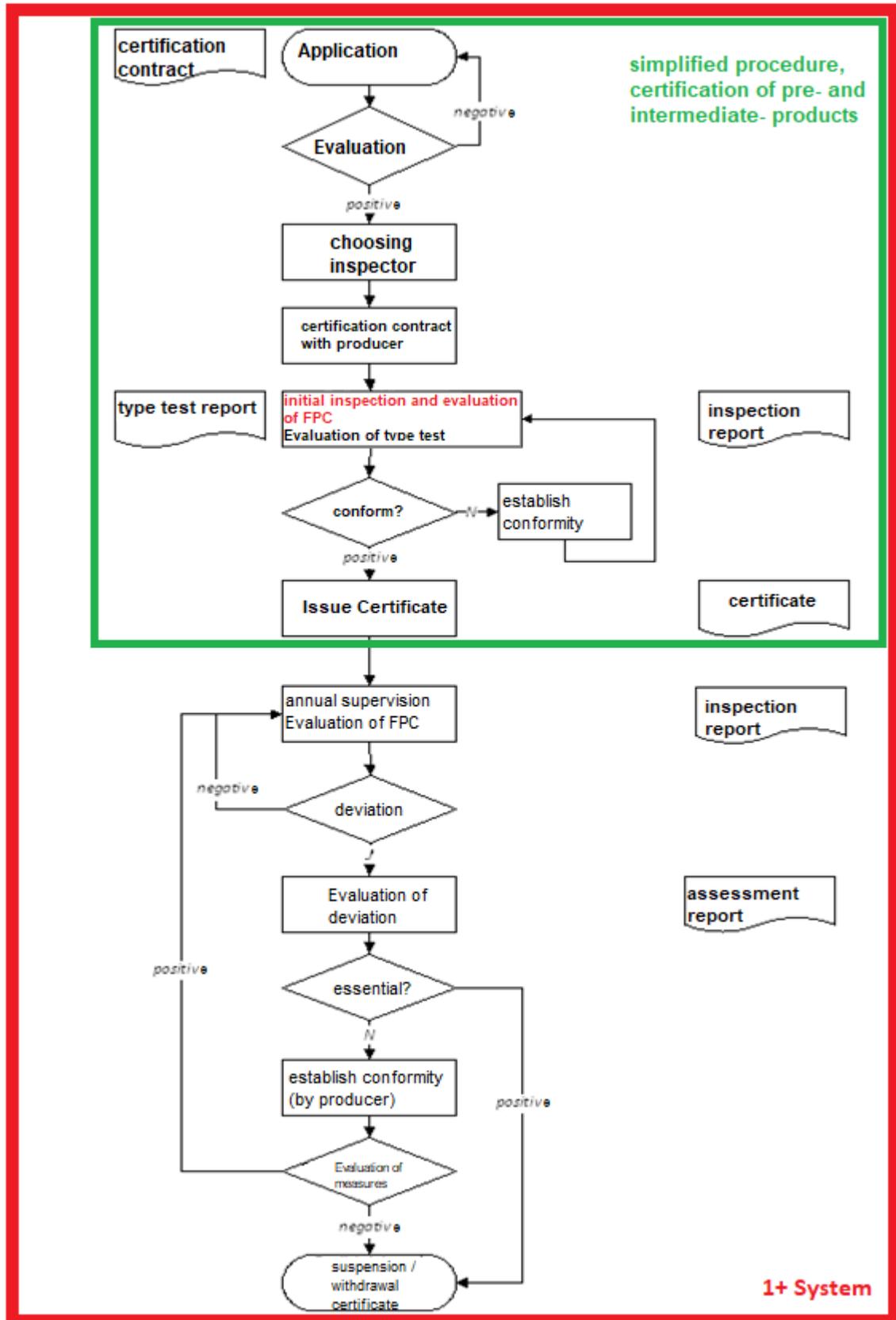
Documents needed for the prolonged certification:

- Proof of implementation of the measures for improvement.

Documents needed for the initial certification according to the simplified procedure and pre- and intermediate product certification:

- Engrossed and duly executed „Antrag auf Zertifizierung Trinkwasser (GP33-015)“ or “Antrag auf Zertifizierung Trinkwasser VVF (GP33-F021) “;
- Engrossed and duly executed certification contract;
- Authorization or consent form of the producer, if the applicant is not the producer;
- Product documents with cited markings and scope of certification;
- Formulations;
- Certified quality management system (if available);
- Documents and reports regarding the type test (if available).

Annex B – certification procedure



Annex C – further applicable documents

- UBA Metal Evaluation criteria: Issue 25. May.2021
Evaluation criteria for metallic materials in contact with drinking water (Metal-EC)
- UBA recommendation of conformity: Issue 29. July.2021
Conformity attestation of product hygiene suitability for drinking water (UBA Recommendation)
- UBA KTW-Evaluation criteria general part: Issue 07. March.2022 (only available in German)
Bewertungsgrundlage für Kunststoffe und andere organische Materialien in Kontakt mit Trinkwasser (KTW-BWGL) – Allgemeiner Teil
- UBA KTW-Evaluation criteria polymer specific part: Issue 07. March.2022 (only available in German)
Anlagen der Bewertungsgrundlage für Kunststoffe und andere organische Materialien im Kontakt mit Trinkwasser (KTW-BWGL) – Polymerspezifischer Teil
- UBA Enamel and ceramic evaluation criteria: Issue 06. August.2021
Evaluation Criteria Document for enamels and ceramic materials in contact with drinking water (Enamel and Ceramics Evaluation Criteria Document)
- UBA recommendation silicone: Issue 25. May.2022
Transitional recommendation on provisional assessment of drinking water hygiene of silicones in contact with drinking water (Silicone Transitional Recommendation)
- UBA De Minimis Guideline: Issue 18. April.2011
Assessment of substances with a specific technological function and low required quantities relating to the formulation review in accordance with the guidelines of the Federal Environment Agency on the hygienic assessment of organic materials in contact with drinking water (De Minimis Guideline)

Annex D – scope of inspection and testing

Table D.1: scope for type test, initial inspection, self-monitoring and FPC for metallic materials and products

Attribute	Initial inspection/ type test	FPC	Annual supervision
Material composition	<p>Check if material is listed on positive list</p> <p>Check of supplier by reviewing of his documents (inspection certificate acc. to DIN EN 10204, 3.1 certificate with composition analysis)</p> <p>Test of material composition on samples taken in the initial inspection by IB</p>	<p>Review of supplier by reviewing his documents</p> <p>inspection certificate acc. to DIN EN 10204, 3.1 certificate with composition analysis</p> <p>composition analysis implemented in the incoming goods inspection</p>	<p>annually review of FPC sampling for testing in TL</p>

CB = Certification body

TL = Test laboratory

IB = Inspection body

Table D.2: scope for type test, initial inspection, self-monitoring and FPC for organic materials and factory produced products

Attribute	Initial inspection/ type test	FPC	Annual supervision
Material composition	Disclosure of formulation by supplier Review of formulation acc. to material specific positive list Check of supplier by re-viewing of his documents	Check of supplier by reviewing his documents Assessment of conformity of used raw materials If available raw material analysis implemented into incoming goods inspection	<p style="text-align: center;">annually review of FPC</p>
Test of hygienic parameter acc. to KTW EC	Sampling done by CB/IB in initial inspection Type test acc. to KTW EC including microbial suitability acc. to EN 16421	Migration test with determination of threshold odor number (TON) or total organic carbon (TOC) or other relevant substance ³ Alternative: external tests (frequency determined by CB)	<p style="text-align: center;">annually review of FPC Assessment of conformity of used raw materials Sampling for annual supervision test</p> <p style="text-align: center;">All 5 years Sampling by CB/IB and type testing acc. to KTW EC in TL</p>

CB = Certification body
 TL = Test laboratory
 IB = Inspection body

³ For pipes and hoses with an $F_c \geq 0,5 \text{ d/dm}$

Table D.3: scope for type test, initial inspection, self-monitoring and FPC for organic materials and products for on site application (e.g. coatings)

Attribute	Initial inspection/ type test	FPC	Annual supervision
Material composition	Disclosure of formulation by supplier Review of formulation acc. to material specific positive list Check of supplier by re-viewing of his documents Review of processing specification	Check of supplier by reviewing his documents Assessment of conformity of used raw materials If available raw material analysis implemented into incoming goods inspection	<p style="text-align: center;">annually review of FPC</p>
Test of hygienic parameter acc. to KTW EC	Production of coated plates acc. to processing specifications under supervision of CB/IB Sampling done by CB/IB in initial inspection Type test acc. to KTW EC including microbial suitability acc. to EN 16421	Migration test with determination of threshold odor number (TON) or total organic carbon (TOC) or other relevant substance ⁴ Alternative: external tests (frequency determined by CB)	<p style="text-align: center;">annually review of FPC Assessment of conformity of used raw materials Sampling for annual supervision test</p> <p style="text-align: center;">All 5 years Sampling by CB/IB and type testing acc. to KTW EC in TL</p>

CB = Certification body
 TL = Test laboratory
 IB = Inspection body

⁴ For pipes and hoses with an $F_c \geq 0,5 \text{ d/dm}$

Table D.4: scope for type test, initial inspection, self-monitoring and FPC for enamel materials and products

Attribute	Initial inspection/ type test	FPC	Annual supervision
Material composition	Disclosure of formulation by supplier of enamel frit Review of formulation acc. to material specific positive list Check of supplier by re-viewing of his documents Review of processing specification	Check of supplier by reviewing his documents Assessment of conformity of used raw materials Composition analysis of the enamel frit (can be an external test)	<p style="text-align: center;">annually review of FPC</p>
Test of hygienic parameter acc. to Enamel/ceramic EC	Production of enamel plates acc. to processing specifications under supervision of CB/IB Sampling done by CB/IB in initial inspection Type test acc. to Enamel/ceramic EC	Check of supplier by reviewing his documents Assessment of conformity of used raw materials Composition analysis of the enamel frit (can be an external test)	<p style="text-align: center;">annually review of FPC</p> <p style="text-align: center;">all 5 years Sampling and type testing of enamel plates acc. to processing specifications under supervision of CB/IB by TL</p>

CB = Certification body
 TL = Test laboratory
 IB = Inspection body

Table D.5: scope for type test, initial inspection, self-monitoring and FPC for ceramic materials and products

Attribute	Initial inspection/ type test	FPC	Annual supervision
Material composition	Disclosure of formulation by supplier Review of formulation acc. to material specific positive list Check of supplier by re-viewing of his documents Review of processing specification	Check of supplier by reviewing his documents Assessment of conformity of used raw materials Composition analysis (can be an external test)	<p style="text-align: center;">annually review of FPC</p>
Test of hygienic parameter acc. to Enamel/ceramic EC	Sampling done by CB/IB in initial inspection Type test acc. to Enamel/ceramic EC	Check of supplier by reviewing his documents Assessment of conformity of used raw materials Composition analysis of the product (can be an external test)	<p style="text-align: center;">annually review of FPC</p> <p style="text-align: center;">all 5 years Sampling and type testing of products acc. to processing specifications under supervision of CB/IB by TL</p>

CB = Certification body
 TL = Test laboratory
 IB = Inspection body

Table D.6: scope for type test, initial inspection, self-monitoring and FPC for assembled products

According to their definition assembled products are usable final products which are build out of parts and/or part units. For each material used and part the material specific proof of suitability has to be shown.

As part of the type testing, the wetted surface of each material and part in contact with drinking water will be calculated on basis of BOM lists and drawings provided by the producer. This calculation determines the tests and documents needed for each part. These documents are reviewed for their validity.

As part of the initial inspection, the implemented measures for assurance of the hygienic suitability of each used part/material (FPC) are reviewed.

Attribute	Initial inspection/ type test	FPC	Annual supervision
Materials in contact with drinking water Bestimmung der Flächenanteile der trinkwasserberührten Werkstoffe/Materialien	Review of FPC (use of drinking water suitable materials) Review of validity of the hygienic relevant documents	Incoming goods inspection and validity check of hygienic relevant documents Securing drinking water suitability during montage	annually review of FPC Review of validity of the hygienic relevant documents