Für Mensch & Umwelt

Umwelt Bundesamt

As at: 29 July 2021

RECOMMENDATION

Conformity attestation of product hygiene suitability for drinking water[1]

English translation – only the German document version is legally binding

3rd amendment:

- adaption of definition of terms section
- previous annex 7: integration into main part incl. specifications on conformity attestations for formulations, pre-products and intermediate products (new sections 6.5 and 6.6)
- additional editorial changes

[1] Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).
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German Environment Agency
Section II 3.4
Heinrich-Heine-Str. 12
08645 Bad Elster

www.umweltbundesamt.de

1 Foreword

This recommendation serves as a basis for the attestation of conformity of the hygiene suitability of products intended to come into contact with drinking water.

Products that come into contact with drinking water must be both technically and hygienically suitable for this application. The technical requirements on products coming into contact with drinking water and their performance reliability are set out in the relevant product-specific standards, and are therefore not covered in this recommendation.

The hygiene requirements arise from the German Drinking Water Regulation (TrinkwV). This regulation states that the German Environment Agency shall adopt binding evaluation criteria documents further detailing the general requirements of the Drinking Water Regulation for materials coming into contact with drinking water. Due to formal statutory reasons, however, no procedural steps are defined in these evaluation criteria for the attestation of conformity of products with applicable requirements.

This recommendation describes a procedure to certify hygiene requirement conformity for the materials in the product that come into contact with drinking water. This will allow manufacturers to demonstrate that the products they sell meet the requirements of § 17 Section 2 and 3 TrinkwV.

Testing and evaluation of hygiene suitability have not yet been harmonised in Europe, and therefore fall under the scope of national regulations.

Due to the lack of harmonised requirements on hygiene suitability for drinking water, the available EN product standards are not harmonised standards and CE marking based on these standards is not possible. In Commission Decision 2002/359/EC on construction products, the European Commission stipulates that the 1+ system must be used to certify the conformity of hygiene suitability for a future CE labelling.

The attestation of conformity described in this recommendation meets this 1+ system. The procedure, for products to which a conversion factor $F_c \geq 0.5$ d/dm applies, or for metallic materials that are used for of product groups A and B, requires external monitoring by a certification body to obtain a conformity attestation.

2 Scope of application

This recommendation may be used for conformity attestation of hygiene suitability for drinking water for all products coming into contact with drinking water. The certificate of conformity may also be part of a combined certification of hygienic and technical suitability.

3 Normative references

Ordinance on the quality of water for human consumption (TrinkwV), German Drinking Water Ordinance in the version published on 10 March 2016 (Federal Law Gazette I, p. 459), last amended by Article 1 of the Ordinance of 3 January 2018 (Federal Law Gazette I, p. 99), Federal Law Gazette 2018 Part I No 2, issued in Bonn on 8 January 2018, p. 99-114 (2018).

Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Council Regulation (EEC) No 339/93, Office Journal of the European Union L 218/30, 13 August 2008.

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, Office Journal of the European Union L 218/82, 13 August 2008.

Regulation (EU) No 305/2011 of the European Parliament and the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC.

German Environment Agency Evaluation Criteria Document for plastics and other organic materials in contact with drinking water (KTW-BWGL).

German Environment Agency Evaluation Criteria Document for enamels and ceramic materials in contact with drinking water (Enamel/Ceramics Evaluation Criteria).

German Environment Agency Evaluation Criteria Document for metallic materials in contact with drinking water (Metals Evaluation Criteria).

German Environment Agency Guideline for hygienic assessment of elastomers in contact with drinking water (Elastomer Guideline) and transitional regulation.

German Environment Agency Recommendation on the provisional hygienic assessment of products made from thermoplastic elastomers in contact with drinking water (TPE Transitional Recommendation).

German Environment Agency Transitional Recommendation for preliminary evaluation of hygiene suitability of silicones in contact with drinking water (Silicone Transitional Recommendation).

DVGW standard W 270: Microbial enhancement on materials to come into contact with drinking water – Testing and assessment.

DVGW standard W 347: Hygiene requirements for cement-bound materials intended for use in drinking water supply systems – Testing and evaluation.

For references without specified status datum, the respective recent document version applies.

4 Definition of terms

Assembled product *(4.27 „Zusammengesetztes Produkt“)*

See KTW-BWGL.

Certification body *(4.26 „Zertifizierungsstelle“)*

A certification body is an independent body with the required competence (demonstrated by a corresponding accreditation as per DIN EN ISO/IEC 17065) to assess the characteristics specified in this recommendation.

Component *(4.3 „Bauteil“)*

See KTW-BWGL or Enamel/Ceramics Evaluation Criteria.

Conformity attestation *(4.10 „Konformitätsbestätigung“)*

A conformity attestation is a certificate from a certification body under the 1+ system (meeting Annex V to Regulation (EU) No 305/2011) attesting to compliance with the requirements on hygiene suitability. It has the status of a certificate.

Conversion factor *(4.11 „Konversionsfaktor“)*

See KTW-BWGL or Enamel/Ceramics Evaluation Criteria.

Factory-made product *(4.4 „Fabrikmäßig hergestelltes Produkt”)*

A factory-made product is a product which is manufactured or applied in a factory as part of a defined production process.

Family of products or components (product line) *(4.5 „Familie von Produkten oder Bauteilen”)*

A family of products or components are products or components for which a common attestation of conformity may be issued.

Formulation *(4.19 „Rezeptur“)*

See KTW-BWGL.

Functional barrier *(4.6 „Funktionelle Barrriere“)*

See KTW-BWGL.

Intermediate product *(4.28 „Zwischenprodukt“)*

See KTW-BWGL.

Manufacturer *(4.9 „Hersteller“)*

A manufacturer is any natural or legal person that manufactures a product or component, and/or arranges their development or manufacturing, and that markets them under its own name or trademark.

Material (organic) *(4.12 „Material“)*

Organic material is organic matter from one or more starting materials with a precisely defined formulation and production process.

Material (inorganic) *(4.25 „Werkstoff")*

Inorganic material (also termed basic material) is inorganic matter (metals, enamels, ceramic materials or cement-bound substances) made from one or more substances of precisely defined composition.

Mixture (preparation) *(4.7 „Gemisch (Zubereitung)")*

Mixtures or preparations denote a mixture or solution composed of two or more substances (corresponds to definition in REACH regulation). These may contain both pre-products or intermediate products as defined in KTW-BWGL or substances not covered by any of these definitions.

Multilayer product *(4.13 „Mehrschichtig aufgebautes Produkt")*

See KTW-BWGL.

Pre-product *(4.24 „Vorprodukt")*

See KTW-BWGL.

Product *(4.15 „Produkt")*

See KTW-BWGL or Enamel/Ceramics Evaluation Criteria.

Product for on-site-application *(4.16 „Produkt zur Vor-Ort-Anwendung")*

A product for on-site application is a product intended for use on the worksite. Intermediate products like cold-curing epoxy resins are a class of on-site application products reacting to the final product only with just the final application step.

Product group *(4.17 „Produktgruppe")*

A product group encompasses various products or components with the same conversion factor (organic materials, enamels/ceramic materials) or weighing factor (metallic materials) that are comparable in terms of their frequency of use in drinking water distribution and their surface-to-volume ratio.

Raw materials *(4.21 „Rohstoffe")*

Raw materials are substances or mixtures of substances used by the manufacturer.

Risk group *(4.20 „Risikogruppe")*

See KTW-BWGL or Enamel/Ceramics Evaluation Criteria.

Starting material *(4.2 „Ausgangsstoff")*

See KTW-BWGL.

Suitability in principle *(4.14 „Prinzipielle Eignung")*

Drinking water hygienic suitability in principle of a pre-product or intermediate product will be tested for and approved at a pre-stage after positive evaluation of the formulation and by employing a representative test specimen. Additional proof of hygienic suitability of a distinct manufactured product or component is carried out according to its type and risk group.

Trader / Distributor *(4.8 „Händler / Vertreiber“)*

A trader/distributor is any natural or legal person in the supply chain, other than the manufacturer, that provides a product on the market.

Test specimen *(4.18 „Prüfkörper“)*

See KTW-BWGL or Enamel/Ceramics Evaluation Criteria.

Total barrier *(4.22 „Totale Barriere“)*

See KTW-BWGL.

Type testing *(4.23 „Typprüfung“)*

A type testing is the basis for every procedure to achieve product hygiene conformity attestation for drinking water. It shall be conducted at the start of conformity testing and repeated once every five years. The type testing shall examine all requirements on the product/component.

User *(4.1 „Anwender“)*

A user prepares or manufactures a product or component intended to come into contact with drinking water from a pre-product or intermediate product.

Other definitions apply from the German Environment Agency Evaluation Criteria Documents for organic materials, for enamels and ceramic materials as well as for metallic materials.

5 Hygiene requirements on materials in contact with drinking water

5.1 General

Pursuant to § 17 Section 3 TrinkwV, the German Environment Agency shall determine the specific hygiene requirements on materials coming into contact with drinking water in the form of legally binding Evaluation Criteria Documents.

Thus far, the German Environment Agency has published Guidelines and Recommendations on materials in contact with drinking water. DVGW regulations also currently provide hygiene requirements (e.g. standard W 347). These Guidelines, Recommendations and Regulations shall be used until legally binding German Environment Agency Evaluation Criteria are determined (as has been accomplished already for metallic materials, organic materials and enamels/ceramic materials).

The hygiene requirements have been drafted for individual materials and are assigned to corresponding regulatory documents below.

5.2 Metallic materials

Metallic materials must appear on the positive list of metallic materials hygienically suitable for drinking water, which is part of the Evaluation Criteria for metallic materials in contact with drinking water. In addition, the usage restrictions in the positive list shall also apply (product groups, use with specific drinking water types).

Note: *For metallic coatings, the general drinking water hygiene suitability of which cannot be determined and for which therefore no entry in the positive list of metallic materials suitable for drinking water exists, no obligatory testing standards are currently in force.*

5.3 Organic materials

Organic materials like:

- plastics
- coatings
- lubricants
- elastomers
- thermoplastic elastomers
- silicones

shall meet the requirements of the Evaluation Criteria for organic materials, including the requirements defined therein on the results of the test as per DIN EN 16421:2015-05[2].

5.4 Enamels and ceramic materials

Enamels and ceramic materials shall meet the requirements of the Evaluation Criteria Document for enamels and ceramic materials.

5.5 Cementitious materials

Cementitious materials shall meet DVGW standard W 347 (denoted there as cement-bound materials). This standard sets out provisions on the permitted starting materials (positive list) and on a migration test procedure. Cementitious materials with organic content shall also meet DVGW standard W 270.

Note: *Requirements on the composition, testing and evaluation of cementitious materials will be regulated in the future within the framework of implementation of the revised European drinking water directive For the transitional period, the German Environment Agency has published an information (https://www.umweltbundesamt.de/en/document/information-on-the-evaluation-of-starting).*

5.6 Multilayer materials

Multilayer materials shall be subject to the material-specific requirements for the materials in question. In cases of multiple layer material build-up, one layer may constitute a total barrier. If this is the case, the requirements shall only apply to the layers on the side towards the drinking water. The total barrier itself does not require to be evaluated.

[2] Until publication of corresponding annexes of the Evaluation Criteria Document on organic materials, the annexes of the relevant transitional provisions shall apply (Elastomer Guideline, TPE Transitional Recommendation, Transitional Recommendation for Silicones).

6 Principle of product conformity attestation

6.1 General

The evaluation and testing of hygiene requirement compliance for products in contact with drinking water shall be conducted under the 1+ system, analogously to Regulation (EU) No 305/2011 (see the product-specific testing requirements in Table und Table). This entails conformity certification by a certification body. The duties of the certification body in this shall be:

- initial inspection of the manufacturing plant and of factory production control,
- monitoring of test specimen sampling and type testing of the product,
- continuous surveillance, assessment and evaluation of factory production control,
- audit-testing.

The certification body is free to transfer tasks arising from a certification procedure (initial inspection, external monitoring, sampling and testing of test specimens, calculations, modelling) by subcontracting another notified body within the accreditation scheme of the certifier. Therefore, this recommendation document will not further specify the body actually performing a task.

Due to difficulties with the realization of initial inspections, external monitoring and test specimen sampling that occurred in 2020 in conjunction with the emerging COVID-19-pandemia, it is possible to obtain conformity attestations based on type testing (simplified procedure) until 21st March 2023, even in such cases where this recommendation stipulates certification based on the 1+ system.

To accomplish this for organic materials, test reports that had been created for the purpose of obtaining former KTW certificates or according to the DVGW standard W 270 may be used. As a prerequisite to proceed this way it is required that

- test reports must not be older than ten years,
- the evaluation of formulations and of test results have to be performed on the basis of the KTW-BWGL or renewed where necessary.

The continuous surveillance, assessment and evaluation of factory production control shall be conducted as inspection task by the certification body as part of external monitoring at the manufacturer´s site.

The manufacturer shall provide the certification body with the information needed for evaluation (e.g. formulations or descriptions of the production process). Additionally, the manufacturer shall conduct:

- factory production control (FPC).

6.2 Conformity attestation of drinking water hygienic suitability

Product conformity attestation of drinking water hygienic suitability has to be performed in a material-specific manner. For products made up of different components (assembled products; see Figure 1), this means that as a general rule from this recommendation, every component

produced from a single-layer or multilayer material shall have a separate certificate of hygiene suitability for drinking water. It is thus convenient to readily prepare conformity attestations for all individual components beforehand. For the attestation of conformity for an assembled product, it shall suffice if the corresponding certificates are available for the individual components (see the example in Annex 6).

Obtaining a conformity attestation for a component should mainly be in the responsibility of the respective manufacturer, but in principle may also be obtained by the assembler of a final product who implements the component. To do so, it is necessary to provide the certifier with required information on formulation and processing parameters, and that processing conditions are defined and continuously documented among provider and assembler (communication along the supply chain).

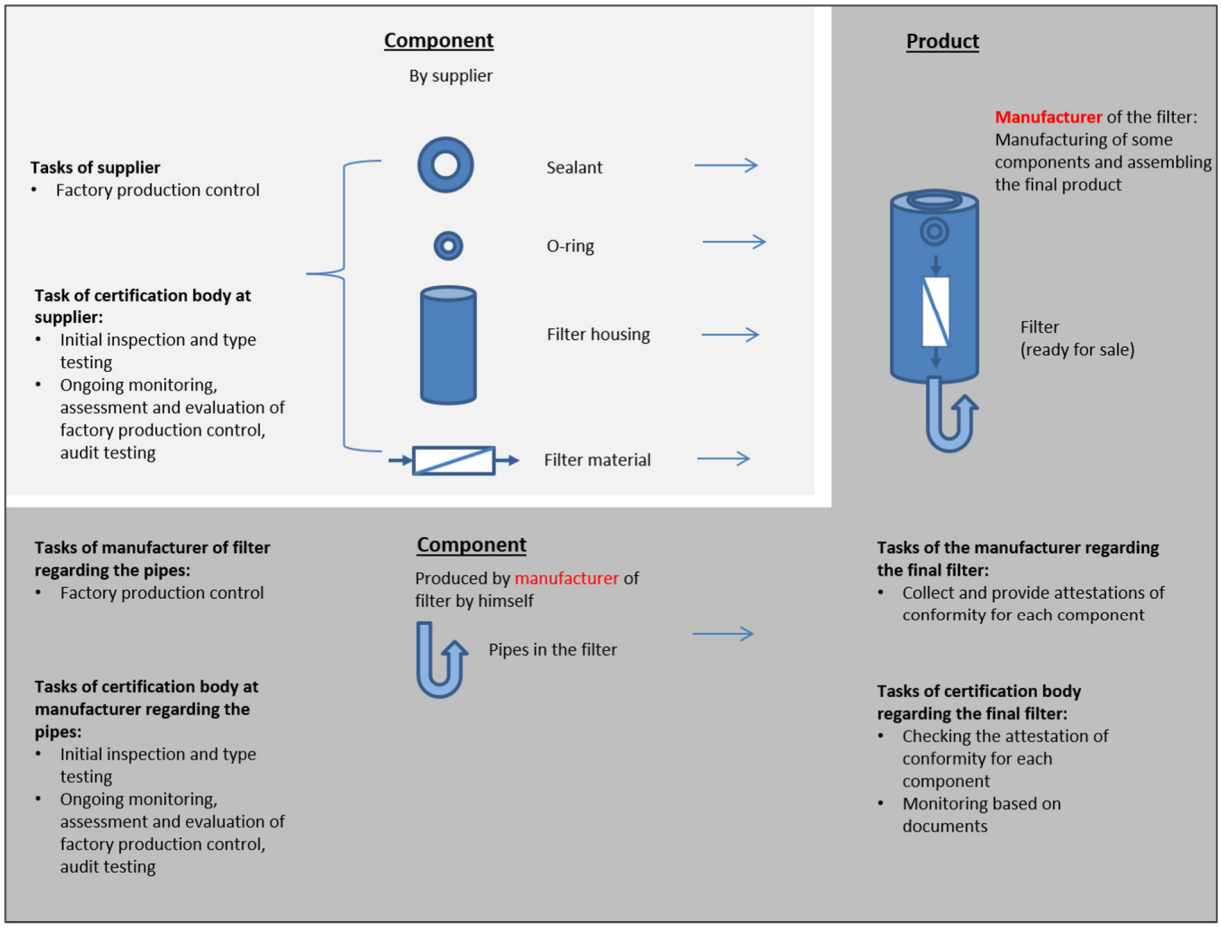

Figure 1 Tasks for attestation of conformity for a combined product.
See explanatory notes and further details in Chapter 7 and Annexes 3, 5 and 6.

It is possible to issue a common attestation of conformity with hygiene requirements for a family of products or components (e.g. pipes, rubber sealing rings or injection-moulded components of various geometries). The preconditions for this are:

- the production process shall be comparable; and
- the material shall have the same composition and/or the material shall have the same formulation.

This attestation of conformity may also include components used for different products (product groups, product lines; see Figure 2). The conformity attestation must indicate the components or products to which it applies (see Annex 3).

The certification body may also combine the conformity attestations for assembled products if they are made from the same components, but with different geometries. For assembled products however, the certifier must sum up all wetted surface contributions of components made of the same material in order assign the correct risk group commonly applicable to these components.

Among ancillaries which carry a central component exhibiting a predominant wetted surface portion inherently necessary due to its functionality, this component has to be excluded from calculation of relative wetted surface portions of the remaining components. This is in order to avoid assigning an inappropriately low risk group for these minor components. Typical cases to act this way are products for water treatment (e.g., filter membrane modules, plate heat exchangers).

Evaluation of formulations of mixtures, pre-products and intermediate products and, under certain circumstances, the conformity attestation for pre-products and intermediate products, may also be conducted independently from the final product; see sections 6.5 and 6.6.

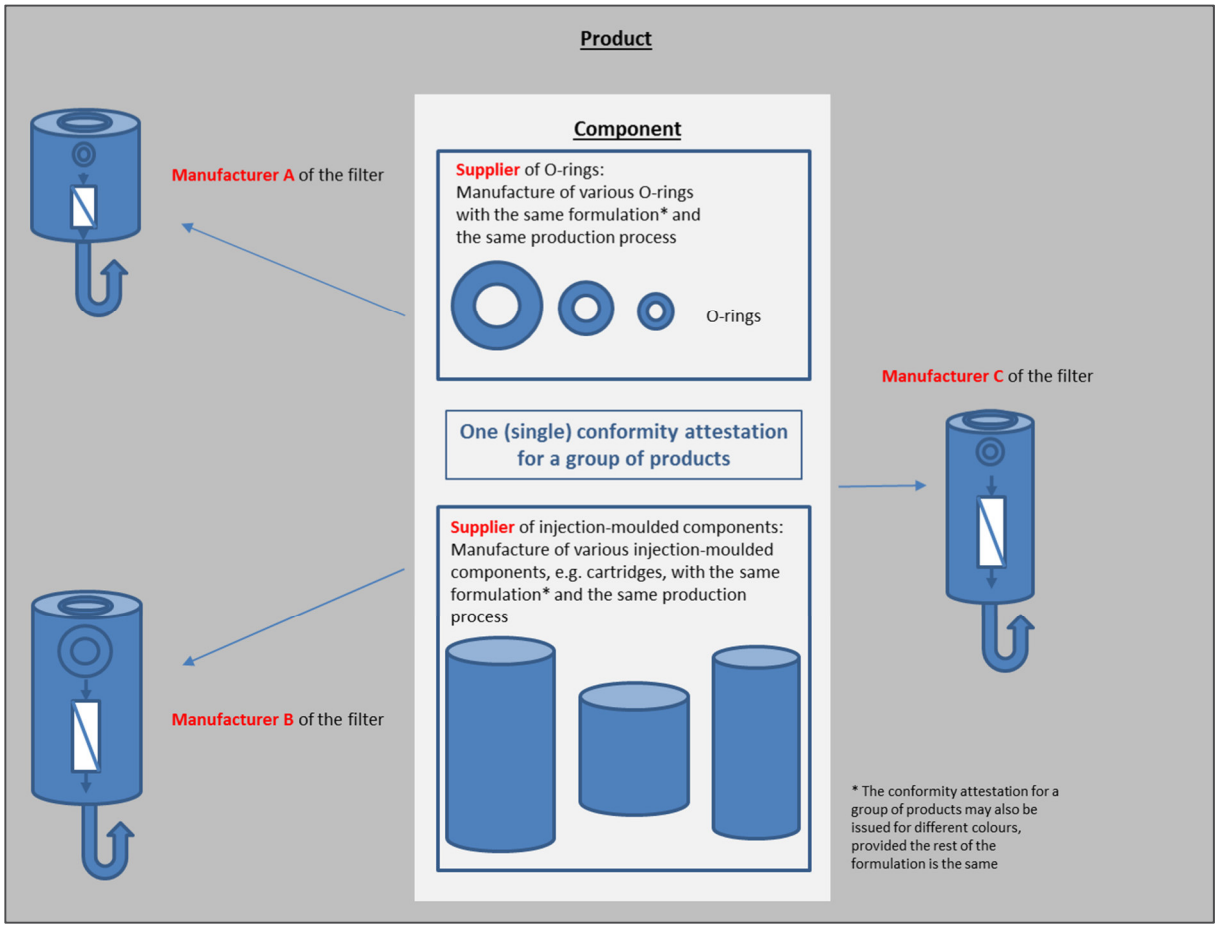

Figure 2 Attestation of conformity to a supplier for a group of products. Manufacturer A, B and C may rely on supplier´s conformity attestations for their final products.

6.3 Types of conformity attestation

6.3.1 Conformity attestation following the 1+ -system

Conformity may be certified under the 1+ -System for

- products and
- components or component groups

(see Table and Table).

An attestation of conformity for components and component groups may be used to complement an attestation of conformity for an assembled product.

6.3.2 Conformity attestation based on type testing

The process for certifying the conformity of components with only a small portion of surface area coming into contact with drinking water – which therefore have less of an impact on drinking water quality at the tap – has been simplified (see Table).

Table 1 denotes product groups for which a simplified conformity attestation process is possible.

Table 1 Simplified conformity attestation process

Material	Product groups	Conformity attestation process
Organic materials	Product groups with F_c < 0.5 d/dm according to the Evaluation Criteria Document	Type testing every five years
Enamels and ceramic materials	Product groups with F_c < 0.5 d/dm according to the Evaluation Criteria Document	Type testing every five years
Metals	Product group C according to Evaluation Criteria Document for metallic materials	Company certificate 2.2 for starting material (e. g. bar stock) and type testing of composition every five years
	Product group D according to Evaluation Criteria Document for metallic materials	Type testing every five years

For pre-products and intermediate products which allow manufacture of products or components without having added further substances, it is possible to obtain a conformity attestation based on type testing. Such a conformity attestation facilitates conformity attestation of products or components made from these pre-products or intermediate products. For certain components, a conformity attestation for a pre-product is actually sufficient (see 6.5).

As with the 1+ system, simplified conformity attestation shall be performed by the certification body.

If an attestation of conformity is based solely on a type test, then the respective certificate must clearly indicate this fact.

External monitoring is not conducted in cases of a simplified attestation of conformity. The manufacturer shall bear full responsibility for quality assurance in the manufacture of the component. **With attestation of conformity of pre-products, however, monitoring of manufacture and sampling of test specimens by the certifying body is required (see 6.6).**

For components of risk group P4 no separate attestation of conformity is possible.

6.4 Test specimens for type testing and external monitoring

Evaluation of drinking water hygiene requirements shall be conducted on the product or component. In exceptional cases however (see Annex 5), representative specimens (e.g. test plates) may also be tested, especially if products themselves are not suited for direct testing due to their dimension or geometry. Representative test specimens shall be produced under the supervision of the certification body, or the certification body shall otherwise verify that the test specimens were produced under conditions comparable to those of the product (e.g. by fingerprint methods or other methods of identity testing/verification for different specimens/products).

For an attestation of conformity for a family of products or components (see 6.2), test specimens shall be taken that may be regarded as representative of the family. The specimens should be expected to exhibit substance release that are high for the product line. During annual monitoring, the certification body may collect different test specimens.

Sampling of test specimens by the certification body has to be performed at a place in the in-house logistics after in-house clearance for sale has been passed or in a central- or distribution warehouse of the manufacturer.

6.5 Attestation of conformity for formulations of mixtures, pre-products and intermediate products

6.5.1 Application

Evaluating formulations of organic materials that come into contact with drinking water is of crucial importance to the conformity attestation of end products. This can be very time-consuming as in most cases different sub-formulations for mixtures (e.g. glass fibre sizing agents), pre-products (e.g. plastic granulates) and intermediate products (e.g. coating hardeners) have to be obtained and evaluated.

The safety data sheet for the individual products does not usually indicate the various ingredients. In addition, end product manufacturers in most cases have no knowledge of the formulation of purchased mixtures, pre-products and intermediate products. For this reason, the various upstream suppliers must disclose the respective formulations to the end product certification body by means of a declaration of formulation (see annex 2).

If the certification body can evaluate the formulation of a mixture, a pre-product or an intermediate product, then this is one way of simplifying the evaluation of end products. This is especially true if mixtures, pre-products and intermediate products are used for different end products. In this case, the sensitive formulation information has to be fully disclosed to only one certification body.

However, a prerequisite for this is that the manufacturer of the mixture, pre-product or intermediate product has to allow his certification body to provide information on relevant constituents to the certification body of the final product. The relevant constituents are those substances that have to be checked in the migration test of the final product.

As an outcome of a positive formulation evaluation, the certifier may issue an attestation of conformity for the formulation ("formulation certificate"). This may both be part of product certifications of the certificate owner himself as well as be relied on by downstream users for their own product certifications.

6.5.2 Evaluation of a formulation

Evaluation of formulations shall be carried out by an accredited certification body. This is the only way to ensure that an end product that contains the mixture, pre-product or intermediate product as a source ingredient obtains a conformity attestation as per this recommendation.

Within the scope of the evaluation, the certification body shall check the requirements according to 5.2 of the KTW evaluation criteria and confirm the conformity. The provisions of 7.4.1 of this recommendation apply.

In addition to the formulation, the manufacturer must provide the certification body with the following information:

- Trade name of the mixture, pre-product or intermediate product;
- Exact description of the application;
- Maximum required quantity of the mixture, pre-product or intermediate product in the end product;
- Type of end product according to the product groups in Table 7 of the KTW evaluation criteria.

First, the certification body checks the formulation's information for plausibility. It also checks purity requirements and other specifications if these are required for listed starting materials.

The certification body stipulates in the evaluation which substances shall be determined as additional and formulation-specific individual substance requirements in the end product migration test.

The number of substances to be determined in the migration test might be reduced by the fact that the quantity of substances falls below the formulation cut-off limit when the intended use in the end product is taken into account. The certification body will record the relevant consideration performed.

The number of substances to be determined can also be reduced by estimating the potential mass transfers by taking into account the intended application of the end product. The certification body will record the relevant estimation performed.

6.5.3 Conformity attestation of a formulation

The certification body can attest the conformity of the composition of a mixture, pre-product or intermediate product with the relevant positive lists and their restrictions as a result of the formulation evaluation. This attestation must clearly indicate the following:

- Trade name of the evaluated mixture, pre-product or intermediate product and the manufacturer;
- Description/specification (e.g. purity) of the mixture, pre-product or intermediate product;
- Maximum required quantity of the mixture, pre-product or intermediate product in the end product;
- Type of end product or component according to the product groups in Table 7 of the KTW evaluation criteria;
- Specification of the positive list (version/date) used for the evaluation.

If an additional substance related migration evaluation has been carried out for a formulation constituent assuming complete transfer, the following data is also required:

- absolute quantity of the mixture, pre-product or intermediate product used for a product in contact with one litre of water.

For migration modelling of a product or component that contains the mixture, pre-product or intermediate product further information on its use is required:

- Structure of the product (monolayer or multilayer);
- Thickness of the individual layers;
- Polymer in the individual layers including density;
- Surface/volume ratio considered;
- Conversion factor used.

The following note is needed in all cases:

- **Additional substances must be tested in the end product migration test. The attesting body communicates them to the end product certification body, provided the relevant requirements for confidentiality are met.**

The certification body shall keep a list of those mixtures, pre-products and intermediate products with trade names and the corresponding manufacturers for which it has issued a conformity attestation for the formulation.

The certification body must ensure contractually that it will be immediately informed of any changes in the formulation and will take these into account for the attestation.

In addition to the above listed attestation information, the certification body shall establish a procedure with their client as to how to communicate the substances to be determined in the end product migration test to the certification bodies of end products. If necessary, appropriate

confidentiality declarations shall be made by the parties concerned. The passing on of knowledge regarding the formulation components to end product manufacturers is not envisaged and is not necessary.

6.6 Attestation of conformity for pre-products and intermediate products

6.6.1 Distinction between pre-product and intermediate product

Pre-products (e.g. plastics granulates) for the manufacture of components or products are molten and shaped by extrusion, injection moulding or other techniques. The polymer is intended not to undergo further changes, i.e. no crosslinking or other reaction shall take place any more. Nevertheless, with the shaping process modifications of the polymer may occur, e.g. changes in chain length or enhanced formation of degradation products of stabilisers. For components or products of risk group P1 it is therefore necessary to have components/products fabricated by an individual manufacturer tested regarding compliance with basic, formulation-specific and additional requirements (see Table 2 of KTW evaluation criteria).

For components of risk group P2 it is sufficient to have attested conformity of the pre-product (granulate). In this case representative test specimens using the granulate must be manufactured (favourably employing a manufacturer routinely producing such components). To obtain an attestation of conformity for the pre-product, fabrication of these test specimens has to be supervised by the certification body.

Intermediate products (e.g. hardening binding agent systems comprised of resin and curing agent) undergo chemical changes before the material coming into contact with drinking water is being formed. For intermediate products (e.g. coatings) attestations of conformity can be issued as well, provided that these are suited for manufacture of products or components without having added any additional substance. Representative test specimens must be manufactured too in this case. Anyway, such conformity attestations can only confirm drinking water hygienic suitability in principle. Due to the significant influence of the chemical reaction in manufacture of the final material, components/products of risk group P2 fabricated by an individual manufacturer or user must also be tested regarding compliance with basic, formulation-specific and additional requirements.

Table 2 provides an overview on which parts of an attestation of conformity for a pre-product or intermediate product can be used for obtaining an attestation of conformity of products/components made from them.

Table 2 Usability of conformity attestations for pre-products and intermediate products for evaluation of downstream products and components

Contents of a conformity attestation for … / Products	… pre-products	… intermediate products
pipes*) (F_c > 10 d/dm)	evaluation of formulation	evaluation of formulation
P1 products/components incl. pipes (F_c ≤ 10 d/dm)	evaluation of formulation microbiological evaluation	evaluation of formulation microbiological evaluation
P2 components	complete evaluation (additional testing and evaluation not necessary)	evaluation of formulation microbiological evaluation
P3 components	complete evaluation (additional testing and evaluation not necessary)	complete evaluation (additional testing and evaluation not necessary)

*): including coated pipes (interior pipe renovation)

Attestations of conformity for pre-products and intermediate products can only be issued if from the respective pre-product or intermediate product fabrication of products or components is possible without having added further substances.

6.6.2 Evaluation and conformity attestation of a pre-product

The certification body can carry out a complete test of the requirements of the KTW evaluation criteria for pre-products (especially plastic granules that are not involved in chemical reactions). A prerequisite is the formulation evaluation (see section 6.5.2). The attestation of conformity issued accordingly will cover the whole set of requirements laid down in the KTW evaluation criteria (incl. microbiological requirements) provided a component has been tested which was manufactured from this pre-product. The test specimens for the migration test shall be as close to actual manufactured components for end products as possible and shall be manufactured and sampled under external monitoring.

This conformity attestation for a pre-product is fully sufficient for components of risk group P2 and P3 according to the KTW evaluation criteria.

For components of risk group P1, this conformity attestation is sufficient for formulation evaluation. For P1 products that are not pipes with Fc > 10 d/dm it is also sufficient to confirm conformity with the microbiological requirements.

The microbiological test as per DIN EN 16421 can be carried out on representative test specimens according to 6.4 of the KTW evaluation criteria for various components (except pipes with F_c > 10 d/dm). The evaluation of the test report according to DIN EN 16421 with the requirement according to 5.6 of the KTW evaluation criteria is part of the evaluation of the pre-product.

The certification body can attest the conformity of components manufactured from pre-products to the requirements of the KTW evaluation criteria including microbiological requirements as a result of the formulation evaluation.

This attestation must clearly indicate the following:

- Trade name of the evaluated pre-product and the manufacturer;
- Details of use and reference to the manufacturer's instructions for use;
- Type of end product/component according to the product groups of Table 7 of the KTW evaluation criteria used for the evaluation;
- Indication of the positive list (version/date) used for the evaluation;
- Surface-to-volume ratio considered;
- Conversion factor used;
- Description of processing conditions;
- **A note that this attestation only applies to components of product groups P2 and P3 according to Table 2 of the KTW evaluation criteria, provided that the user obeys to specified processing conditions.**

The certification body shall keep a list of the pre-products with trade names and the relevant manufacturers for which it has issued a conformity attestation.

The certification body must ensure contractually that it will be immediately informed of any changes in the formulation and will take these into account in the attestation.

6.6.3 Evaluation and conformity attestation of an intermediate product

According to the introductory description of differences between pre-products and intermediate products (degree of possible alterations in chemical nature of a material during final product manufacture), an important difference results for conformity attestations of P2 products (cf. table 2): For P2 pre-products, all requirements are covered, while for P2 intermediate products only the formulation evaluation and microbiological requirements are covered.

For intermediate products intended for on-site application an additional restriction exists, namely that conformity attestations for intermediate products specifically for manufacture of risk group P2 components cannot be issued. This is due to the fact that it is not possible to clearly differentiate cases of P1 and P2 for on-site product applications.

To obtain an attestation of conformity for an intermediate product, it is required to perform testing of a test specimen manufactured from this intermediate product. To do so, the

manufacturer of the intermediate product can employ a test specimen fabricated at a production site of an intermediate product user. The test specimen shall be manufactured under external monitoring conditions.

The attestation of conformity for the intermediate product must indicate basic information as mentioned above for pre-products (see 6.6.2) and the respective **note**:

> **"This attestation only confirms drinking water suitability in principle. For products or components of risk groups P1 and P2 that are factory-made from this intermediate product it is required to perform additional migration testing of fabricated products/components. For intermediate products intended for on-site fabrication of products of risk groups P1 and P2, in all application cases it is necessary to test the drinking water, having regard of the *UBA-Empfehlung zur Beurteilung materialbürtiger Kontaminationen des Trinkwassers*** ("recommendation for evaluation of material-derived contaminations of drinking water"; in German)**, for relevant additional requirements according to the KTW evaluation criteria. For container coatings, a qualification according to DVGW standard W 316 is an alternative possibility to provide a quality-assured application."**

As with pre-products, the certification body shall keep a list of the intermediate products with trade names and the relevant manufacturers for which it has issued conformity attestations. It must be ensured contractually as well that it will be immediately informed of any changes in the formulation and will take these into account in the attestation.

7 Material-specific attestation of conformity of hygiene suitability for drinking water

7.1 Overview

Table and Table summarise the material-specific principles of conformity attestation for products or components. The manufacturer shall provide the certification body with the information as per Annex 1. In addition, Table describes the principles for assembled products.

7.2 Metallic materials

The manufacturer shall notify the certification body of all metallic materials used for the product or component.

Hygiene requirement conformity shall be certified for metallic materials coming into direct contact with drinking water.

If metallic materials not appearing on the positive list for metallic materials of suitable hygiene for drinking water are coated, proof shall be submitted that the coating will be resistant for the expected service life of the product and that the coating fully covers the metal surface.

Type testing
The certification body shall verify that the materials coming into contact with drinking water as indicated by the manufacturer appear on the positive list of materials of suitable hygiene for drinking water, for the relevant area of application. In addition, the certification body shall take products and components during the initial inspection in order to verify the composition of the individual basic materials by analysing them or having them analysed.

Factory Production Control (FPC)
The certification body, together with the manufacturer establish a procedure by which the hygiene suitability of the finished products or components for drinking water is to be verified in the factory production control. An installed, functioning QM system may be used for this purpose.

For factory production control, applicable terms would be:

- acceptance test certificate 3.1 as per DIN EN 10204 by the material supplier; or
- regular inspection of material composition in the finished product or component in the factory.

For foundries, the composition of the cast component shall be checked in the factory.

External monitoring
The certification body shall monitor the factory production control regularly (see Table). This shall include verifying use of the materials indicated by the manufacturer.

Moreover, the certification body shall regularly (see Table) take products and components (see 6.4) from the factory and verify the composition of the individual materials by analysing them or having them analysed.

7.3 Metallic coatings

Note: Binding testing requirements are not currently available for metal coatings. The manufacturer shall be responsible for certifying hygiene suitability for drinking water for metal coatings that cannot be included in the positive list of the Evaluation Criteria Document for metallic materials. An attestation of conformity from a certification body must clearly indicate that release of substances from coatings coming into contact with drinking water was not tested. Certification bodies are advised not to issue any certificates of conformity for the hygiene suitability of products with these kinds of non-listed coatings for drinking water.

7.4 Organic materials

7.4.1 General

The formulation shall be disclosed to the certification body. In general, suppliers are to be involved in this, according to the supply chain. For full disclosure of the finished product formulation, the manufacturer is obliged to provide the certification body with the required

information on the supply chain for its product, including details on all suppliers. Any change in the supply chain shall be reported to the certification body immediately, so it can rule out any resulting changes in the finished product formulation.

The certification body performs review and evaluation of a formulation on the basis of a corresponding manufacturer´s evaluation order. Formulation evaluation may be commissioned either for the sole purpose of issuing a conformity attestation of the formulation, or be part of a conformity attestation process for a pre-product or intermediate product or for a component or product fabricated from these.

The applicant together with the certification body define the type, structure and range of application of the components or products intended to be manufactured from the formulation. Subsequently, the certifier defines which regulatory basis and which risk group(s) apply. The applicant is obliged to provide the respective information from his own data or, if necessary, by organising third-party participation e.g. from suppliers.

Suitable communication shall be agreed on among applicant, third-party actors and certifier, including arrangements of confidentiality and obligations on mutual information. This for example serves to have the applicant informed by the certification body in cases of problems with a formulation constituent. It is especially important to implement contractually that the certification body must be informed immediately should there be any change concerning the formulation with respect to constituents or suppliers.

For substances adding less than 0.02% (w/w, with respect to the finished components), the certification body may waive further disclosure of the formulation if the substances adding less than 0.02% (w/w) do not exceed a total value of 0.1% (w/w). The form according to Annex 2 shall be used to submit the formulation. For multilayer products, the formulation shall be submitted separately for each layer.

For products with a total barrier, the layers on the side not in contact with drinking water shall not be assessed. The term ‘total barrier’ applies e.g. to a continuous aluminium layer with a thickness of at least 9 µm or a continuous glass layer.

In cases of composite materials containing a functional barrier, e.g. a layer of an ethylene vinyl alcohol copolymer, all layers shall be assessed.

The certification body shall ensure that the test specimens used for testing are made from the indicated starting materials (e.g. by using a fingerprint method).

7.4.2 Factory-made products manufactured from organic materials

Type testing

The type testing shall preferably be conducted on test specimens (see 6.4) collected during the initial inspection of the production site. The certification body verifies the conformity of the indicated formulation with the positive lists from the Evaluation Criteria Document for organic materials. This shall also include verifying the technological functions of the formulation components and restrictions on the use of starting materials (e.g. purity of the starting materials used, maximum application quantity, residual content). Based on the formulation

submitted by the manufacturer and/or the suppliers, the certification body shall specify the test parameters according to the Evaluation Criteria Document for organic materials. The certification body shall conduct complete testing of the test specimens collected during the initial inspection based on the Evaluation Criteria Document for organic materials.

Factory production control
The certification body, together with the manufacturer establish a procedure by which the hygiene suitability of the finished products or components for drinking water is to be verified in the factory production control. An installed, functioning QM system may be used for this purpose.

For pipes ($F_c \geq 5$ d/dm), in addition to verification of the starting materials and production procedure at defined intervals closely coordinated with the certification body, the manufacturer shall also conduct migration tests. Migration water testing for the odour threshold value or analysis of a representative substance may be suitable methods for factory production control. As an alternative to migration testing, the manufacturer may apply other methods, such as fingerprint methods, if this is coordinated with the certification body.

External monitoring
The certification body shall regularly monitor the factory production control (see Table). This includes examination of documents to verify use of the formulation components indicated by the manufacturer. This shall also encompass verification that upstream products exhibit the required purity and that the specified dosing is actually applied.

The certification body shall regularly take representative samples from all production sites and test them for the basic requirements of the Evaluation Criteria Document for organic materials. In addition, parameters whose levels (c_{tap}) are close to the reference concentration in the type test shall be retested.

The certification body shall take representative samples from the factory at regular intervals (see Table) and conduct complete type testing (or have this conducted by subcontracting).

7.4.3 Products for on-site application made from organic materials (e.g. coatings)

The attestation of conformity corresponding to this Recommendation is limited to the suitability in principle of the products: it does not cover certification of individual users.

On-site application (at construction sites) has a significant influence over the quality of finished products. Therefore, additional measures shall be required taking into account the formulation details and the defined processing instructions and/or technical bulletins of the manufacturer, to ensure proper on-site application.

A simplified conformity attestation is not an option for products for on-site application because the specific resulting finished products may also yield applications of extensive areal coverage or high surface/volume ratios. For this reason, there is also no distinction between products of risk groups P1 and P2 in this case. For products of risk group P3, however, the simplified procedure may be applied since here the wetted surface portion is very small. The respective limitations of use must be observed and shall be notified in the certificate.

It is advisable for the manufacturer to deliver the product for on-site application along with a notice of mandatory adherence to the permitted applications and processing instructions and an indication that failure to comply shall invalidate the existing conformity attestation for the product, i.e. the hygiene conformity of the finished products manufactured by the end user would no longer be guaranteed for drinking water. It is not the manufacturer, but rather the end user that bears responsibility for this. An additional guarantee must be provided for existing hygiene suitability of the individual fabricated final product. This can be accomplished by having tested the final product, or by a separate certification of the end-user concerning his capability to perform proper application of the intermediate product.

Type testing

The type test shall preferably be conducted with representative test specimens produced during the initial inspection of the production site (e.g. manufacturer of coatings for on-site application) under the supervision of the certification body. The certification body verifies the conformity of the indicated formulation with the positive list from the Evaluation Criteria Document for organic materials. This shall also include verifying the technological functions of the formulation components and restrictions on the use of starting materials (e.g. purity of the starting materials used, maximum application quantity, residual content). In addition, the conformity shall also be verified for the application instructions/processing conditions and the production of the test specimens. Based on the formulation submitted by the manufacturer and/or the suppliers, the certification body shall specify the test parameters according to the Evaluation Criteria Document for organic materials. The certification body shall conduct complete testing of the test specimens collected during the initial inspection based on the Evaluation Criteria Document for organic materials.

Factory production control

The certification body, together with the manufacturer and located at the production site establish a procedure by which the hygiene suitability of the manufactured products for drinking water is to be verified by means of representative test specimens in the factory production control. An installed, functioning QM system may be used for this purpose.

In addition to verification of the starting materials and production process, the manufacturer shall conduct regular migration tests. Migration water testing for the odour threshold value or analysis of a representative substance may be suitable methods for factory production control. As an alternative to migration testing, the manufacturer may apply other methods, if this is coordinated with the certification body.

External monitoring
The certification body shall regularly monitor factory production control in the production site (see Table). This includes examination of documents to verify use of the formulation components indicated by the manufacturer, and it also encompasses verification that upstream products exhibit the required purity and that the specified dosing is actually applied.

The certification body shall have representative samples regularly produced by all production sites and shall test these for the basic requirements of the Evaluation Criteria Document for organic materials. In addition, parameters whose levels (c_{tap}) are close to the reference concentration in the type test shall be retested.

The certification body shall have representative samples produced by the factory at regular intervals (see Table) and shall conduct complete type testing or have this conducted.

7.5 Enamels

The certification body may only issue an attestation of conformity jointly for enamellers and enamel frit manufacturers.

The manufacturer of the enamel frit and enameller shall provide the certification body with the information corresponding to Annex 1.

Type testing
The certification body shall conduct a complete test and assessment based on the Evaluation Criteria Document for enamels and ceramic materials. To achieve this, the certification body shall have test plates enamelled at the enamelling factory during the initial inspection, under supervision, and shall subsequently test these.

Factory production control
The certification body, together with the enamel frit manufacturer establish a procedure by which the hygiene suitability of the finished products or components for drinking water is to be verified in the factory production control. An installed, functioning QM system may be used for this purpose.

The enamel frit manufacturer shall regularly check the composition of the enamel frit or shall have this checked by a third party.

The enameller shall conduct an incoming goods inspection on the supplied enamel frits. Moreover, it shall check the component enamelling process to ensure consistent quality of the enamelled components. An installed, functioning QM system may be used for this purpose.

External monitoring
The certification body shall regularly monitor factory production control by the frit manufacturer and enameller (see Table).

At regular intervals (see Table), the certification body shall have test plates enamelled, under supervision, and shall conduct complete testing as per the Evaluation Criteria Document for enamels and ceramic materials.

7.6 Ceramic materials

Type testing

The certification body shall conduct a complete test and assessment based on the Evaluation Criteria Document for enamels and ceramic materials. To achieve this, the certification body shall use test plates that it collected during the initial factory inspection.

Factory production control

The certification body, together with the manufacturer shall establish a procedure by which the hygiene suitability for drinking water of the finished products or components is to be verified in the factory production control. An installed, functioning QM system may be used for this purpose.

The manufacturer shall regularly check the composition of the products or shall have this checked by a third party.

External monitoring

The certification body shall monitor the factory production control regularly (see Table).

At regular intervals (see Table), the certification body shall collect components from the factory and conduct complete testing as per the Evaluation Criteria Document for enamels and ceramic materials.

7.7 Cementitious materials

The attestation of conformity procedure for cementitious materials will be supplemented as soon as a corresponding European harmonized regulatory document has been defined.

Table 3 Principles for material-specific conformity attestation under the 1+ system for products or components

	Material	Type testing	Self-monitoring (by manufacturer)	External monitoring (by certification body) every year	every 5 years
Factory-made products	Metallic materials (Product groups A and B according to the Evaluation Criteria Document for metallic materials)[3]	The certification body shall collect test specimens during the initial factory inspection, to test the basic material composition	Analysis of material composition during: Incoming goods inspection or production; or acceptance test certificate 3.1 for the starting material	Verification of self-monitoring, collection of test specimens and analysis of material composition	-
	Organic materials (plastics, coatings, elastomers, thermoplastic elastomers, silicones) ($F_c \geq 0.5$ d/dm)[4]	The certification body shall collect test specimens during the initial factory inspection for complete testing according to the Evaluation Criteria Document for organic materials, including under DIN EN 16421	Incoming goods check, testing for conformity of raw materials	Verification of the raw materials used, collection of test specimens and testing for basic requirements and selected parameters under the additional requirements of the Evaluation Criteria Document for organic materials, verification of self-monitoring	Collection of test specimens and complete testing according to the Evaluation Criteria Document for organic materials and DIN EN 16421

[3] For product groups C and D, an attestation of conformity under the 1+ system is not prescribed (see 6.3)

[4] For products with an $F_c < 0.5$ d/dm, an attestation of conformity under the 1+ system is not prescribed (see 6.3). This usually also applies to lubricants, which according to the Evaluation Criteria Document for organic materials (KTW-BWGL) are attributed with an F_c of 0.2 or less

	Material	Type testing	Self-monitoring (by manufacturer)	External monitoring (by certification body) every year	every 5 years
	(Contd.: Organic materials)		For pipes ($F_c \geq 5$ d/dm): migration testing on the product and identification of the odour threshold value, or a suitable alternative parameter		
Factory-made products	Enamels ($F_c \geq 0.5$ d/dm)	The certification body shall have test specimens (typically enamelled plates) produced, under its supervision, at the enameller´s site during initial factory inspection for complete testing as per the Enamel/Ceramics Evaluation Criteria Document	Analysis of the composition of the enamel frit and enamelling	Verification of self-monitoring	Collection of test specimens or components manufactured under supervision and complete testing as per the Enamel/ Ceramics Evaluation Criteria Document
	Ceramic materials ($F_c \geq 0.5$ d/dm)	The certification body shall collect test specimens during the initial inspection for complete testing as per the Enamel/Ceramics Evaluation Criteria Document	Regular inspection of the composition of finished products	Verification of self-monitoring	Collection of test specimens and complete testing as per the Enamel/ Ceramics Evaluation Criteria Document

	Material	Type testing	Self-monitoring (by manufacturer)	External monitoring (by certification body) every year	every 5 years
Products for on-site application	Organic materials (e. g. coatings)	The certification body shall collect test specimens produced during the initial inspection of the starting material manufacturer (e.g. coating plant), under supervision, for complete testing as per the Evaluation Criteria Document for organic materials, including under DIN EN 16421	Incoming goods inspection, testing of conformity of raw materials, odour testing on representative test specimens or suitable alternative processes	Verification of the raw materials used, collection of test specimens produced under supervision and testing for basic requirements and selected parameters under the additional requirements as per the Evaluation Criteria Document, verification of self-monitoring	Collection of test specimens produced under supervision and complete testing as per the Evaluation Criteria Document and DIN EN 16421

Table 4 Principles for material-specific conformity attestation based on type testing for products or components (simplified procedure)

	Material	Type testing	Self-monitoring (by manufacturer)	External monitoring (by certification body) every year	External monitoring (by certification body) every 5 years
Products for on-site application	Organic materials (F_c < 0.5 d/dm)	The attestation of conformity is based on the type test, which shall be repeated once every five years using a suitable test specimen	Incoming goods inspection, testing of conformity of the raw materials and finished products	N/A	N/A Exception: With conformity attestation for a pre-product (see sec. 6.6) external monitoring of manufacture and sampling of test specimens
	Organic materials (e.g. repair systems) F_c < 0.05 d/dm (risk group P3 acc. to KTW-BWGL)	The attestation of conformity is based on the type test, which shall be repeated once every five years using a suitable test specimen	Incoming goods inspection, testing of conformity of the raw materials, odour testing of representative test specimen or other appropriate method	N/A	N/A
	Enamels and ceramic materials (F_c < 0.5 d/dm)	The attestation of conformity is based on the type test, which shall be repeated once every five years using a suitable test specimen	Incoming goods inspection, regular inspection of the composition of finished products	N/A	N/A

	Metals (product groups C and D according to the Evaluation Criteria Document for metallic materials	The attestation of conformity is based on the type test, which shall be repeated once every five years using a suitable test specimen	Company certificate 2.2 for the starting material	N/A	N/A

Table 5 Conformity attestation under the system 1+ for assembled products

	Type testing	Self-monitoring (by manufacturer)	External monitoring (by certification body) every year
Assembled product	None	Verification that the attestations of conformity are up-to-date for the components and the corresponding incoming goods	Verification of the attestation of conformity and of self-monitoring

Annex 1 Information for preparation of an attestation of conformity

The manufacturer shall provide the certification body with the information below on its product/component.

a) Precise description of the product / component

b) Manufacturing site(s)

c) List of all materials coming in contact with drinking water

- for metallic materials: standardised and/or precise material designation
- for organic materials: complete formulation disclosure by all parties throughout the supply chain, with separate submission for each layer in cases of multilayer materials
- for enamels:
  - Enamel frit manufacturer: enamel frit designation, enamel frit composition with tolerances for the individual enamel frit components and production site
  - Enameller: enamel production site, description of the procedure and indication of the enamelled products
- for ceramic materials: composition, description of the production process
- for cementitious materials: complete formulation disclosure by all parties throughout the supply chain; for mixing plants only for their own production process

d) Total product and/or component surface area coming into contact with drinking water and the relative proportion of surface area of the respective materials

e) Area of application: cold-, warm- or hot water, product group according to Evaluation Criteria Document with conversion factor F_c

f) For products for on-site application: application instructions

Annex 2 Declaration of formulation by the manufacturer for organic materials

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)

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.

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.

Annex 3 Contents of an attestation of conformity for factory-made products

Attestation of conformity for a product / a group of factory-made components /// a pre-product / an intermediate product for factory application
by certification body '...(*Title*)...'
regarding the hygiene suitability for drinking water of

Product: Name of the product or component / trade name
Material/polymer
Product group
(Certification body *registration number*, if applicable)
Manufacturer: Company (*Name*)
(*Adress*)

☐ **Based on a type test (without external monitoring; simplified procedure)**
☐ **Under system 1+ with external monitoring** of the following production sites: (*Adresses*)

Reference / Attestation:
We hereby certify that the product / component indicated above

- based on the certification programme '...(*Title*)...' of the certification body (*Name, Adress*),
- the submitted product information, including the formulation details
- and evaluation report No (r*eport number*)

meets the requirements of the Evaluation Criteria Document / Guideline Document of the German Environment Agency[5]:

'...(*Title*)...'

for the temperature range (degrees Celsius) and is in compliance with the above document.
(Optional: the requirements on product groups with lower conversion factors (F_c) are also met).
(if applicable, pre-product/intermediate product certificate: additional data see sec. 6.6)
or
This attestation of conformity also applies to the following products / components:
Product / component: (*Designation / Name*)
Product / component: (*Designation / Name*) etc.

The evaluation reports with numbers (*report number*) are part of this attestation of conformity.

This attestation of conformity is valid from the date of issue and its validity will endure as long as the preconditions specified below under "Remarks" are fulfilled.

Place, date Name
Certification Body Manager

[5] Any applicable transitional provisions must be indicated here.

Remarks:

The attestation of conformity is issued under the precondition that the starting materials used to manufacture the products and/or their composition and/or components, including their manufacturers and supply chain, have been disclosed in full and the product does not contain any further substances.

This document shall be invalid

- in cases of changes to the composition of the product or the processing conditions that have not been agreed upon with the certification body,
- failure to meet the conformity requirements, or
- termination of the 1+ system monitoring programme by the certification body and manufacturer.

The findings of our tests and the evaluations apply for the test objects examined and the provisions of the law applicable at the time of testing. Without our express written approval, it is only permitted to publish or reproduce this document in full and unedited.

Annex 4 Contents of an attestation of conformity for products for on-site application

Attestation of conformity for an intermediate product for on-site application
by certification body '...(*Title*)...'
regarding the hygiene suitability for drinking water of

Product:	Name of the product for on-site application / trade name
	Material/polymer
	Product group
	(Certification body *registration number*, if applicable)
Manufacturer:	Company (*Name*)
	(*Adress*)

☐ **for product groups with $F_c \geq 0.05$ d/dm (corresponding to P1 and P2 according to KTW evaluation criteria, table 2) under system 1+ with external monitoring** of the following production sites: ...(*Adresses*)...

☐ **for product groups with $F_c < 0.05$ d/dm (corresponding to P3 according to KTW evaluation criteria, table 2) based on type testing (without external monitoring; simplified procedure)**

Reference / Attestation:
We hereby certify that the product for on-site application indicated above

- based on the certification programme '...(*Title*)...' of the certification body (*Name, Adress*),
- the submitted product information, including the formulation details, the permitted applications and processing instructions,
- and evaluation report No (r*eport number*)

in cases of **proper use, is suitable in principle** for the production of on-site finished products that meet the requirements of the Evaluation Criteria Document / Guideline Document of the German Environment Agency[6]:

'...(*Title*)...'

for the temperature range (degrees Celsius) and are in compliance with the above document.

The evaluation reports with numbers (*report number*) are part of this attestation of conformity.

This attestation of conformity is valid from the date of issue and its validity will endure as long as the preconditions specified below under "Remarks" are fulfilled.

Place, date

Name
Certification Body Manager

[6] Any applicable transitional provisions must be indicated here.

Remarks:

The attestation of conformity is issued under the precondition that the starting materials and/or their composition and formulation used to manufacture the product for on-site application, including their manufacturers and supply chain, have been disclosed in full and the product does not contain any further substances.

This document shall be invalid in cases of

- changes to the composition of the product or the processing conditions that have not been agreed upon with the certification body or
- failure to meet the conformity requirements or
- termination of the 1+ system monitoring programme by the certification body and manufacturer

This attestation of conformity does not cover use of the product for on-site applications. The user must observe the manufacturer´s application instructions and should hold a separate certification for proper application of this product. Transfer of the certification statement on product suitability in principle made herewith into a pretension claiming product suitability in all application cases is not valid. Operation of a product fabricated from an on-site application, the proper manufacture and hygiene suitability of which cannot be demonstrated, is prohibited since entry into force of the KTW evaluation criteria dating 21st March 2021.

The findings of our tests and the evaluations apply for the product samples examined, the test samples made from these according to the application instructions and the provisions of the law applicable at the time of testing. Without our express written approval, it is only permitted to publish or reproduce this document in full and unedited.

Annex 5 Test specimens for type testing and external monitoring

	Material	Test specimens for testing as per DIN EN 16421	Test specimens for other tests
Factory-made products	**Metallic materials**	N/A	Product/component
	Plastics Pipes	Product/component or representative test plates	Product/component
	Plastics Other		Product/component or representative test specimen
	Silicones Hoses		Product/component
	Silicones Other		Product/component or representative test specimen
	Organic coatings		Product/component or representative test specimen
	Elastomers Hoses		Product/component
	Elastomers Other		Product/component or representative test specimen
	Lubricants	N/A	Applied on plates (where possible)
	Enamels	N/A	Product/component or representative test specimen
	Ceramic materials	N/A	Product/component
Products for on-site-application	**Organic materials**	Representative test plates	Representative test specimen

Whether testing for requirements is performed with final products/components or with representative test specimens/test plates will, beside the material type, depend both on the type of application and the product´s risk group.

The further specifications in Table 2 of the Evaluation Criteria Document for organic materials in contact with drinking water shall apply.

Annex 6 Examples of attestation of conformity under the 1+ -system

Example 1

Finished product manufacturer has injection-moulded components produced from a defined material (attestation of conformity under contract from the finished product manufacturer)

Scenario:

For various injection moulders, a manufacturer of assembled products has components made from a defined material with a prescribed formulation with the same process parameters. The finished product manufacturer incorporates the components produced by the injection moulders into the assembled products.

Conformity attestation for the injection-moulded component:

The certification body may combine the attestation of conformity for components of comparable geometry and the same composition, even if produced by different injection moulders or production sites, for a finished product manufacturer. The preconditions on this are that the same raw materials must be used and the production process must be comparable. In addition, at the end, the attestation of conformity must clearly indicate the components to which it applies.

The certification body, along with the manufacturers involved, shall determine the test specimen expected to exhibit the maximum possible substance release for the group of components covered by the attestation of conformity. Test specimen collection for the type test may be performed at the finished product manufacturer. External monitoring of factory production control shall also be carried out at the finished product manufacturer. The precondition here that the finished product manufacturer must have a clear quality control procedure at incoming goods and must also have the injection moulder document the process parameters.

Conformity attestation of the injected-moulded components shall be certified under contract from the finished product manufacturer. In this case it is also possible to issue a conformity attestation for the pre-product (granulate) itself (up to risk group P1; see sec. 6.6).

Conformity attestation for the assembled product:

In the factory production control, the finished product manufacturer must ensure that valid attestations of conformity are available for all components. In addition, it shall also use the documents to ensure that the goods supplied are in accordance with the components for which the attestation of conformity was issued. The certification body shall conduct external monitoring based on documents and verify the validity of the attestations of conformity for the individual components as well as the factory production control of the finished product manufacturer.

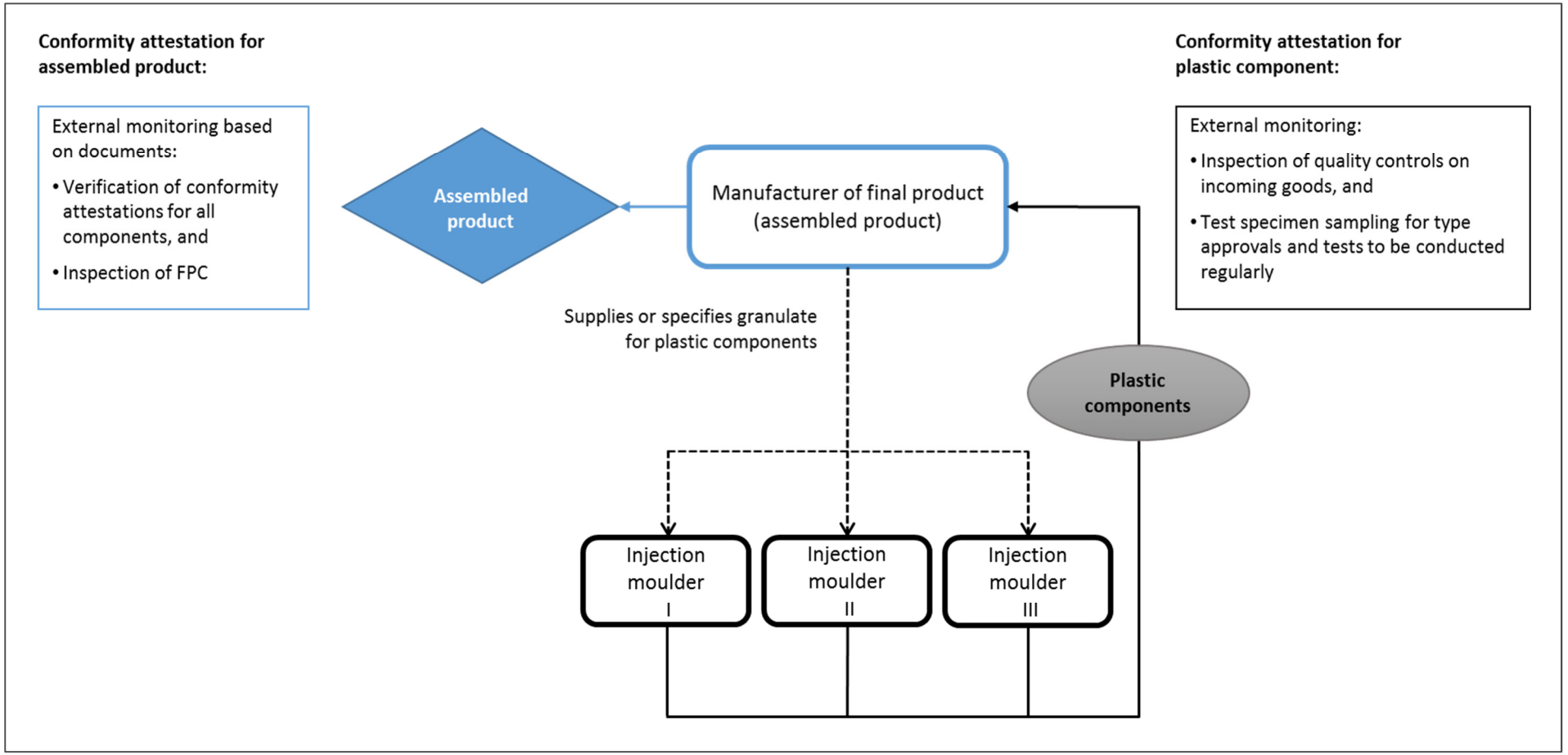

Figure 3 Diagram of conformity attestation under system 1+ for a finished product manufacturer (example 1)

Example 2

Manufacturer of elastomer components supplies multiple clients who incorporate the elastomer components into assembled products (conformity attestation under contract from the component manufacturer)

Scenario:

The manufacturer of assembled products produces one component itself and purchases the rest. One of the purchased components is an elastomer component. The elastomer component manufacturer also produces other elastomer components of different dimensions but with the same process, process parameters and raw materials. It supplies these to other clients as well.

Conformity attestation for the elastomer component:

The attestation of conformity may be combined for all elastomer components made with the same process, process parameters and raw materials. The attestation of conformity must clearly indicate the components to which it applies. The certification body, along with the elastomer component manufacturer, shall determine the test specimens expected to exhibit the maximum possible substance release for the group of components covered by the attestation of conformity.

Sampling for the type test and for the regular product tests as well as external monitoring on the factory production control shall be performed at the elastomer component manufacturer.

Conformity attestation for the component manufactured in-house by the finished product manufacturer:

Test specimen collection for the type test and for the regular product tests as well as external monitoring on the factory production control shall be performed at the manufacturer. The attestation of conformity may be combined for multiple components here as well if they are manufactured with the same raw materials and the same process (see above).

Conformity attestation for the assembled product:

In the factory production control, the finished product manufacturer must ensure that valid attestations of conformity are available for all components. In addition, it shall also use the documents to ensure that the goods supplied are in accordance with the components for which the attestation of conformity was issued.

As part of external monitoring for the component manufactured in-house, the certification body may also verify the attestations of conformity for other components and the factory production control related to the combined product.

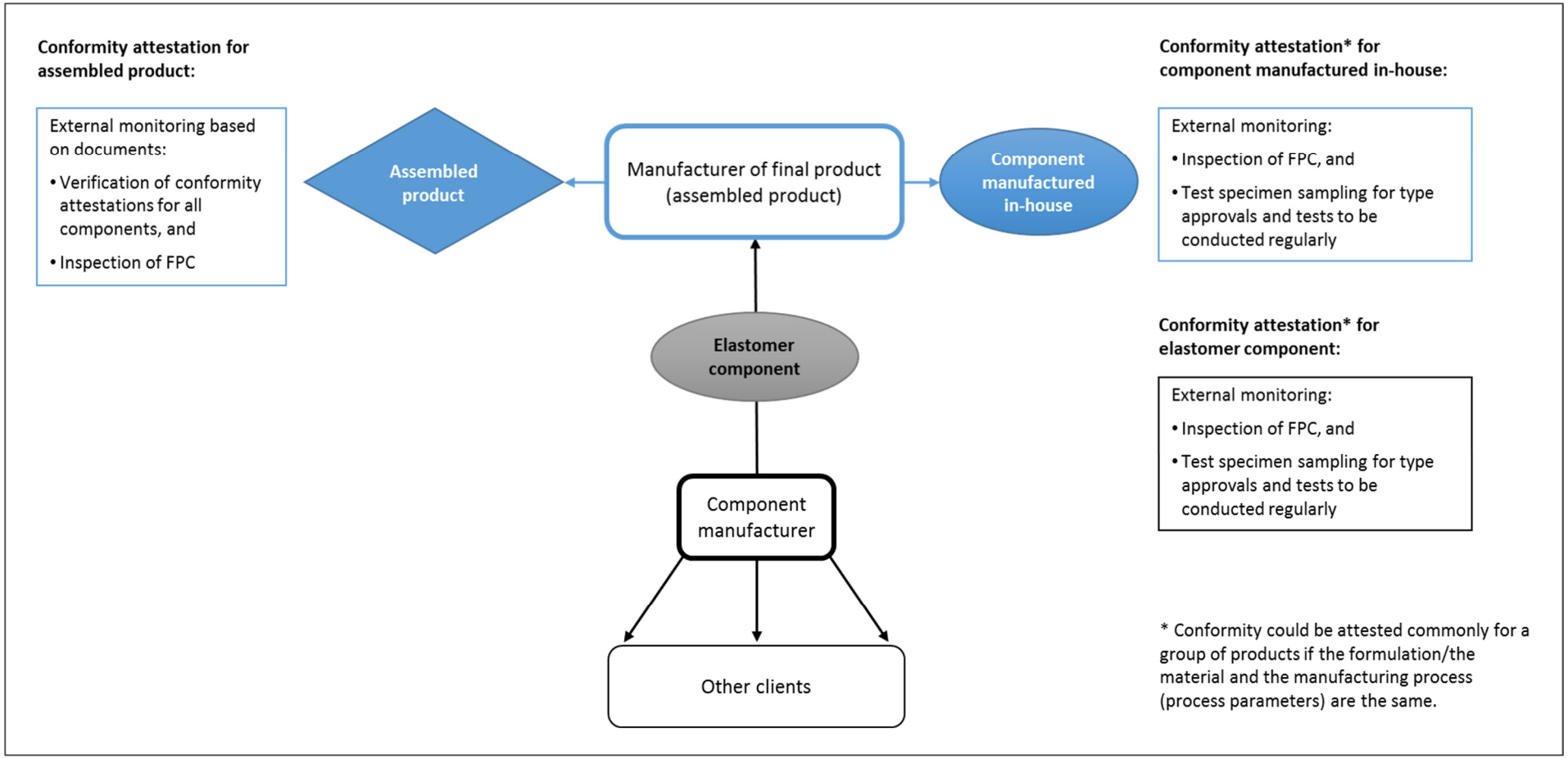

Figure 4 Diagram of conformity attestation under system 1+ for a component manufacturer and a finished product manufacturer who assembles components both from suppliers and from own fabrication (example 2)

Example 3

Manufacturer of enamelled products purchases enamel frit to make its products (certificate of conformity for frit manufacturer and enameller)

Scenario:

The frit manufacturer produces special frit for an enameller. This enameller uses the frit to make various enamelled products.

Conformity attestation for the enamelled component:

The attestation of conformity may only be issued for the frit manufacturer along with the enameller.

Test specimen collection for the type test and for the regular product tests as well as external monitoring on the factory production control shall be performed at the enameller. For this purpose, the enameller must produce test plates under the supervision of the certification body.

In addition, external monitoring shall be conducted on the factory production control at the frit manufacturer. For the factory production control, the frit manufacturer shall regularly test the frit composition or have it tested by a third party.

The attestations of conformity may be combined for enamelled components produced with the same frit and process. The attestation of conformity shall clearly indicate the components to which it applies.