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## **Guidelines for building components approved for use with drinking water**

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## 1. Introduction and reading guide

Building components in contact with drinking water can be marketed and sold in Denmark if they are documented with either:

- a Danish GDV approval, or
- a German DVGW certificate, or
- a Dutch ATA approval/The Kiwa Water Mark, or
- a Swedish type approval

The Danish GDV scheme covers only the health-related requirements of building components that are in contact with drinking water. Mechanical-physical properties are not within the remit of the approval scheme.

Building components not requiring approval for drinking water can be subject to documentation requirements in accordance with other legislation, e.g. the Danish Veterinary and Food Administration's requirements for food contact materials. The website for the Danish Veterinary and Food Administration can be found [here](#).

### 1.1 Regulatory basis

The guidelines for approval of building components that come into contact with drinking water are based on Executive Order no. 1007 of 29 June 2016 on the placement on the market and sale of building components that come into contact with drinking water (hereafter referred to as the "Executive Order").

The requirements of the scheme for building components in contact with drinking water are also based on Executive Order on water quality and inspection of installations for water supply by the Danish Ministry of the Environment and Food (known as the Executive Order on Drinking Water).

The scope of building component types covered by the scheme are specified in section 2.5.

The annexes of the Executive Order includes a list of the health-related requirements, which the building component must comply with in order to obtain and maintain approval.

Table 1 in Annex 1 includes the test requirements for building components and subassemblies that consist of materials other than metal. This also includes testing requirements for "Other substances", i.e., substances for which quality requirements are set out in Annex 1 a-d of the Executive Order on Drinking Water, and which are not specifically mentioned in Table 1, Annex 1 of the Executive Order for building components in contact with drinking water. Other substances hazardous to human health that are not specifically mentioned in the two

executive orders, but which may be in and migrate from building components into drinking water must be included in the toxicological assessment of, and the test programme for the building component.

Table 2 in Annex 1 includes the testing requirements for building components and subassemblies made of metal. The table concerns testing requirements for lead, cadmium and nickel.

All the executive orders mentioned can be found at the website of the Danish Transport, Construction and Housing Authority [here](#).

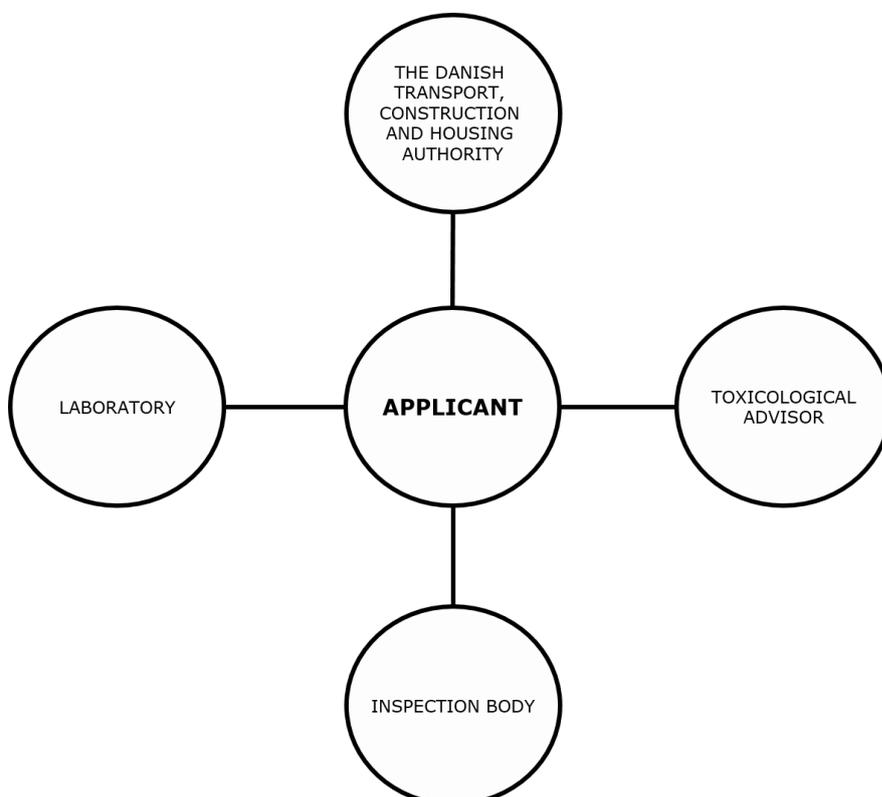
### 1.2 Addition material

The present "Guidelines for building components approved for use with drinking water" provide general guidance to the GDV scheme and contains instructions and advice to understand the regulatory basis of the above mentioned executive orders.

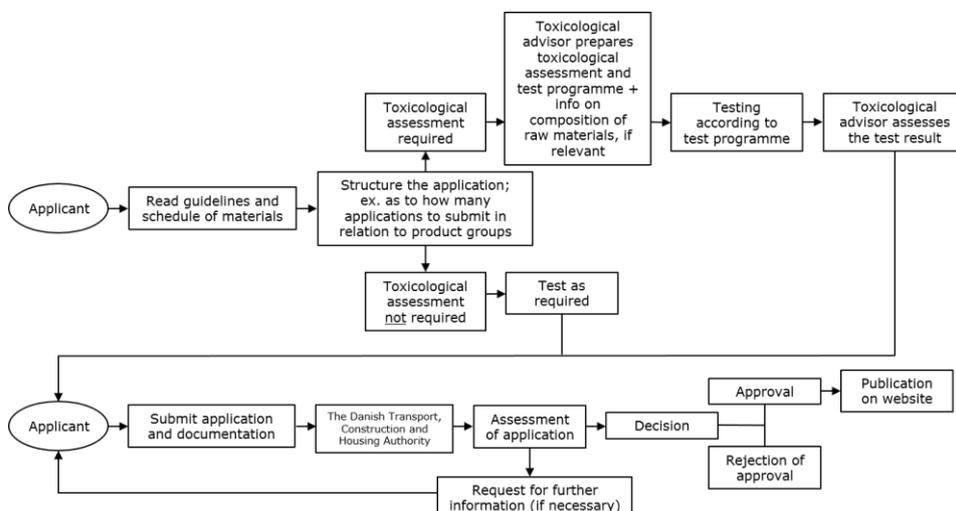
This guideline is an addition to the other guidance material (see Annex 1) whereas a list of terms is found in Annex 2.

### 1.3 Parties and application flow

There are a number of parties in the approval scheme involved in the application process. The diagram below shows the principal parties in the application process:



The flowchart below shows the application process and the contact there could be between the applicant and the applicant's toxicological advisor, and between the applicant and the Danish Transport, Construction and Housing Authority, prior to the application and during the processing of the case.



#### 1.4 The Danish Transport, Construction and Housing Authority

The Danish Transport, Construction and Housing Authority is the regulatory authority for building components in contact with drinking water and performs the case processing and issuing of approvals in the GDV scheme. The Authority can be contacted by e-mail at [GDV@tbst.dk](mailto:GDV@tbst.dk). Decisions made by the Danish Transport, Construction and Housing Authority cannot be appealed to another administrative authority, but decisions can be objected directly to the Danish Transport, Construction and Housing Authority.

The Danish Transport, Construction and Housing Authority cannot offer actual consultancy regarding specific applications, for example prepare a test programme, advise on the relations between the applicant and the advisors, laboratories and inspection bodies which the applicant uses. Nor can the Danish Transport, Construction and Housing Authority recommend advisors, accredited laboratories or accredited inspection bodies to the applicant.

Guidance materials for preparation of GDV is published on the website of the Danish transport, Construction and Housing Authority. The guidance material can be found [here](#).

As part of its market surveillance, the Danish Transport, Construction and Housing Authority verifies that building components that are marketed and sold for use with drinking water in Denmark, are legally approved.

Market surveillance by the Danish Transport, Construction and Housing Authority could, for example consist of inspection of stocks etc., and checking traceability back to the approval holder, including marking, product name and approval number.

Infringements can result in an order to cease marketing and sales and may be reported to the police.

More detailed information on the liability regulations in relation to marketing and sale can be obtained from the Danish Transport, Construction and Housing Authority. Information concerning building components and market surveillance is found [here](#).

The Danish Environmental Protection Agency provides consultancy to the Danish Transport, Construction and Housing Authority with regard to testing methods and threshold values for types of building components that come into contact with drinking water.

### **1.5 Eligible applicants for the GDV scheme**

Companies have several possibilities to legally market and sell building components in contact with drinking water in Denmark. The building component must either be:

- GDV approved in Denmark or
- DVGW certified in Germany or
- ATA approved/The Kiwa Water Mark in the Netherlands or
- Type approved in Sweden by either SP Sveriges Tekniska forskningsinstitut or Kiwa Sverige

Companies may choose to apply for GDV approval. If the building component is GDV approved, the approval holder can legally mark the product with the "Godkendt til drikkevand" marking, as shown here:



It is voluntary to use the marking for building components approved after July 1 2016. Only GDV approved building components may use the mark. The marking can also be issued electronically for digital reading as an alternative to the physical marking on the building component/packaging. By digital marking a barcode can be placed on the

building component/packaging with a link to a website, where the relevant and legal information (such as GDV approval number and with the "Godkendt til drikkevand" marking) can be found. As a minimum, the building component should be marked with the approval number. For more information, see the guidelines to health related documentation [here](#).

There can be more than one importer or distributor, which each can be an independent approval holder for the same building component. Approval holders are each responsible to meet the requirements of the approval with regard to annual inspection, self-check, marking etc.

An approval requires that the applicant has procured the necessary documentation for the application. If the applicant is solely an importer or distributor, and not the manufacturer, the applicant must, in collaboration with the manufacturer, procure the relevant documentation.

If the building component is sold under its own name, there must be clear traceability to the approval, and the relevant company must be aware that the company is jointly responsible for ensuring that the building component is legal.

A building component may not be imported and marked with another approval holder's approval number with reference to the specific type of building component being already approved, unless the importer has an agreement with the approval holder.

### **1.6 The responsibilities of the applicant**

The company applying for approval of a building component is responsible for the contact to the Danish Transport, Construction and Housing Authority in the processing of an application. Therefore, it is important that the company designate a contact person to represent the company as the applicant. The contact person must be capable of managing the application process and providing all relevant information for the case.

If necessary, the contact person should be supplied with a written power of attorney to act on behalf of the company in relation to the Danish Transport, Construction and Housing Authority. For example, if the contact person is a toxicological advisor employed outside the company. There are no requirements as to the form of the power of attorney. For example, it can be an email sent to the Danish Transport, Construction and Housing Authority with a notification that another party may act on behalf the company with a description of the

limitations for the power of attorney. If the contact person is employed by the applying company and as part of his/her position is entitled to act as contact person, a power of attorney is not needed.

The applicant must complete and document the application to an extent that enables the Danish Transport, Construction and Housing Authority to process it and reach a decision on approval or rejection of approval. All documentation should be in either Danish or English.

The processing of the application can only begin when all relevant documentation has been submitted. Therefore, applications should not be submitted until all documentation and relevant testing of the building component is available. Applications that do not fulfill the requirements for documentation cannot be processed and will be rejected.

### **1.7 Use of toxicological advisor**

In a number of cases, it is required that a toxicological advisor carry out a toxicological assessment. It can either be an external advisor or an internal employee with the necessary qualifications to perform a toxicological assessment and prepare a relevant test programme and subsequently assess the results of the testing. The schedule(s) of materials states when a toxicological advisor is required.

The toxicological advisor must have the toxicological expertise to advise applicants about assessment and testing based on a human-toxicological foundation. The toxicological assessment should be carried out based on the chemical composition of the materials and it should identify all the chemical compounds in the materials. Furthermore, it should contain a description of the toxicological properties of these compounds. Based on this assessment, a test programme is established for testing the building component, as documentation for the toxicological and hygiene properties and the assessment of this.

The applicant is responsible for ensuring that the building component is tested at an accredited laboratory based on the test programme, and that a subsequent assessment of the results of the testing from the toxicological advisor is available.

### **1.8 Treatment of confidential information by the Authority**

In certain cases, it can be necessary for sensitive information to be sent to the Danish Transport, Construction and Housing Authority in order to process a case. For example, this could apply to ingredients that, according to the toxicological advisor's assessment, should be included in the test programme.

Such sensitive information can be subject to confidentiality requirements that are so strict that the information only can be released to

the external toxicological advisor by the manufacturer of the raw materials - and then only if a declaration of confidentiality is signed. In these cases, the toxicological advisor can send the information directly to the Danish Transport, Construction and Housing Authority.

Information that the Danish Transport, Construction and Housing Authority receives in connection to the processing of an application is exempted from access in accordance with section 30, no. 2 of the Access to Public Administration Files Act. Information is exempted if it relates to technical devices or processes, or operating or business procedures or the likes, provided it is of material economic importance for the person or enterprise to whom the information relates.

If it is necessary for the toxicological advisor to send confidential information concerning recipe ingredients, then please contact the Danish Transport, Construction and Housing Authority. If necessary, the toxicological advisor should be supplied with a written power of attorney to act on behalf of the applicant.

### **1.9 Responsibility for marking approved building components**

Only GDV approved building components can be marked "Godkendt til drikkevand" (the "drop mark"). It is, however, voluntary to use the mark. The mandatory marking with the GDV approval number must be placed on the building component or a label attached to the building component. If the building component is of a nature that makes it impossible, then the marking is to be placed on the packaging or in the enclosed documents.

The approval holder must ensure that the building component is provided with the correct marking when it is marketed and sold. All importers have an independent responsibility to ensure that building components marketed and sold by them are correctly marked. Similarly, all distributors have an independent responsibility to ensure that building components marketed and sold by them are correctly marked.

## **2. Building components covered by the scheme**

GDV approval can be applied for all factory-made building components in contact with drinking water for marketing and selling in Denmark. The approval comprises building components that are connected to the drinking water supply and therefore are included in the fixed installation for drinking water in the building from the property boundary to and including the tap (i.e. the point where the user releases the cold drinking water).

GDV approval can be applied if the building component meets the following, i.e. that the building component:

1. is connected to the drinking-water supply, and supply would not reach the consumers without the component,
2. is included in or is connected to fixed water installations up to and including the tap,
3. could affect the quality of the drinking water, and
4. is used in connection with buildings that are covered by section 2(2) of the Danish Building Act.

It is possible to voluntarily apply for approval of the following building components or components therein, which are not covered by requirements for approval under section 3(3) of the Executive Order (see also section 2.5):

1. Building components or components therein which are deemed to have only marginal contact with drinking water in terms of surface area or time.
2. Cartridges and tap aerators that are designed as part of a mixer tap.
3. Building components made of stainless steel alloy EN 1.4000-1.4999.

The Danish Transport, Construction and Housing Authority carries out a specific case-by-case assessment of whether a type of building component is covered by the Executive Order. This assessment depends on a concrete evaluation. The Authority provides guidance if needed.

### **2.1 Indicative list of building component groups**

An indicative list of the product groups of building components that are covered by the Executive Order, and groups of building components that are not covered or are exempted is available on [the web-site](#) of the Danish Transport, Construction and Housing Authority. Please note that the list is continuously updated.

Building components that are included on the list, and therefore theoretically can be included in a fixed installation for drinking water, but solely are placed on the market for other purposes than contact with drinking water, is not included in the Executive Order.

If in doubt as to whether a building component is covered by the Executive Order, please contact the Danish Transport, Construction and Housing Authority on [GDV@tbst.dk](mailto:GDV@tbst.dk) before submitting an application.

## **2.2 Part of a fixed installation**

A building component is part of a fixed installation when it is fixed directly onto or connected with the fixed pipework for drinking water from the property boundary up to the tap.

If a building component is connected with a non-permanent hose connection or a similar connection to the fixed pipework, then the building component is not part of the fixed installation, unless a shut-off valve is placed on the building component as the only shut-off possibility.

Tap valves installed for outdoor use must be mounted on the fixed pipework in order to be considered part of the fixed installation and thereby be included in the Executive Order. However, GDV approvals cannot be issued to building components mounted to the fixed pipework, but solely is marketed and sold for other purposes than use with drinking water e.g. "outdoor valves", taps for boiling water, taps for showers, when they are solely placed on the market or sold for other purposes (e.g. bidets, showers, tubs and boiling water).

Building components that are part of production processes, e.g. brewing of beer, production of soft drinks, etc., is not included in the Executive Order. The building components could however be subject to documentation requirements in accordance with the Danish Veterinary and Food Administration's regulations for food contact material.

In the case of building components as, for example, connecting hoses, that will be marketed both as building components for use in fixed drinking water installations and as food contact materials in non-permanent drinking water installations both sets of regulations must be complied with.

## **2.3 Ensuring drinking water quality**

Building components in contact with drinking water are governed by section 8.4.1(6) of the Building Regulations. This conforms with the objective of the Building Act; to ensure that buildings are constructed and designed to provide satisfactory levels of safety in relation to health.

The concern for health issues also forms the basis of the objective of the Executive Order, which is to ensure drinking water quality. This can be achieved through the requirements for GDV approval of building components and the obligations of the approval holder to subsequently have an annual inspection of the approved building component.

The annual inspection ensures that the building component does not change health-related properties, for example, after changes in production methods, construction or choice of materials.

A GDV approval can be issued if it is documented in the application that the building component does not have an influence on drinking water quality. The basis of requirements is stated in the Executive Order. Before a building component can be approved, all the necessary documentation for the health-related properties and relevant health-related testing must be available. A toxicological assessment that the building component does not have an influence on drinking water quality cannot replace an approval.

#### **2.4 Building components, which cannot be approved**

Certain building components are not included in the Executive Order and cannot be GDV approved. These are building components made of:

- pure copper
- electrogalvanized steel
- hot-dip galvanized steel

GDV approval presupposes that the building component can be used throughout Denmark regardless of the type of water. However, building components made of pure copper, electrogalvanized steel or hot-dip galvanized steel are not usable in all parts of Denmark due to differences in the Danish drinking water. Therefore, these building components are not included in the Executive Order.

In practice, such building components are considered the same as installations for water for technical use, see 8.4.2.1(9) in the Building Regulations, according to which such building components must be marketed in such a way that incorrect use can be avoided.

Use of building components, e.g. pipes, made of electrogalvanized and hot-dip galvanized steel/galvanized steel and of pure copper requires careful consideration on the basis of knowledge about the specific, local conditions, e.g. water quality and consumption patterns (see the standards for water installations, DS 439 Code of practice for domestic water supply installations).

In this connection, note that the building owner is responsible to the municipality as building authority for ensuring that the design of drinking water installations provides satisfactory safety in a health context, see section 1 of the Building Act. The individual fitter is also responsible separately for performing tasks professionally and correctly.

In some places in Denmark, it is still possible to use building components made of electrogalvanized and hot-dip galvanized steel/galvanized steel and pure copper for drinking water installations, even though the relevant building component has not been approved for drinking water, see the Executive Order.

Building components with individual components made of pure copper, e.g. mixer taps with inflow pipes/connecting pipes made of pure copper or fittings/end pieces made of pure copper, are covered by the approval requirement of the Executive Order.

Components made of pure copper, electrogalvanized steel or hot-dip galvanized steel, which are part of a GDV approved building component will, however, not be able to obtain an independent approval. Although, it will be possible to market inflow pipes, connecting pipes, fittings and end pieces made of pure copper as spare parts specifically for the relevant approved mixer taps in which individual components are included and thus have already been tested.

## **2.5 Building components exempt from approval requirements, which can obtain voluntary approval**

The following building components are exempted from approval in the Executive Order, but can be applied for a voluntary approval:

- Cartridges that are designed as part of a mixer tap.
- Tap aerators that are designed as part of a mixer tap.
- Building components or components therein which are deemed to have only marginal contact with drinking water in terms of area or time.
- Building components made of stainless steel alloy EN 1.4000-1.4999.

These building components or subassemblies can therefore be marketed and sold in Denmark without GDV approval or German/Dutch/Swedish approval. Furthermore, they can be included in other building components and are not subjected to requirements for testing.

The Danish Transport, Construction and Housing Authority assesses whether a building component or a subassembly therein only has marginal contact with drinking water in terms of surface area or time based on a concrete evaluation. The assessment is based on the extent of contact with water when the building component or subassembly is in use.

Smaller components or subassemblies (such as O-rings and gaskets), which are designed to ensure a tight seal between two parts and which, when the two parts are screwed together, do not have or only

have marginal contact with the drinking water in terms of surface area, are in general not covered by the requirement of the Executive Order for testing and approval.

A building component or a subassembly with a water surface area of less than 4 cm<sup>2</sup>, will generally be considered marginal contact with drinking water.

Similarly, no testing and approval is required for building components or subassemblies, which do not have significant contact with drinking water in terms of time. In practice, significant contact time is anything over 30 minutes at a time.

## **2.6 Building components in the same application**

GDV approval is issued on the basis of the test version and can only cover building components that have the same health-related properties and are identical in terms of purpose, design, manufacturing process and material composition. If, subsequently, relevant changes are made to any of these, then a new application must be submitted for approval of the changed building component.

The assessment of what is covered by a single approval must be based on a general understanding of the term "building component", which is that one and the same building component may consist of one or more components and can be manufactured in different dimensions and thus in different versions. Generally, all versions of a building component under application must be made of the same composition of materials.

However, building components produced and placed on the market as combinations of different subassemblies can be included under the same approval, provided that the individual subassemblies are tested separately.

These could be, for example, a hose set which as a building component is sold with enclosed fittings made of different materials. These may also be building components such as mixer taps, which are sold with several different types of spouts.

With regard to building components made of stainless steel alloys (EN 1.4000-1.4999) with no testing requirements, several alloys may be included in the same application following a concrete assessment from the Danish Transport, Construction and Housing Authority.

For the individual application, the Danish Transport, Construction and Housing Authority makes a specific assessment of which building components may be covered by the application. This assessment will be based on a concrete evaluation.

The Danish Transport, Construction and Housing Authority may also assess whether individual, small subassemblies can be included in a building component, even if they deviate in design, manufacturing process and material composition. This may, for example, be a small subassembly in a building component under the application, which is made of another material, e.g. another alloy than in the other versions. In such cases, the applicant must provide more details about the deviations in the application.

The Danish Transport, Construction and Housing Authority can be contacted for guidance as to whether building components or versions thereof may be included in the same application.

### **2.7 On-demand production**

“On-demand” production of a building component can be requested under the same approval within a given range. The requested product range must be indicated in the application such as dimensions (length/diameter), flexure angles etc. The declaration concerning on-demand production is included in the schedule of materials for the building component (see the Application guidelines for more information).

With regard to on-demand production, the building component is delivered upon special requests from a specific customer ordering an exact version of the building component in terms of design, manufacturing process and materials, but in a version with special dimensions that are not included in the version list. On-demand production may be within a range of products that are described in more detail in the approval but normally not produced and therefore not specified as specific versions in the version list.

### **2.8 Building components that are marketed as independent spare parts**

A building component that constitutes a subassembly of an approved building component, for example a spout that is part of an approved mixer tap, may be placed on the market as an independent spare part with the same approval number. However, this assumes that the subassembly has been tested and fulfill all documentation requirements of the approval of the complete building component.

### **2.9 Building components that consist of individual components**

Building components that consist entirely of individual components that all meet the requirements of the Executive Order can be marketed and sold without a separate approval. However, the building

component must bear all the approval numbers for the individual components concerned.

If the building component contains some individual components that come into contact with drinking water that are not already approved, then the entire building component must be approved with either a Danish GDV approval or covered by specific German, Dutch or Swedish certificates/approvals. A GDV approval requires that all individual components are approved in the GDV scheme.

For building components where all the individual components have been approved in advance and the only individual components that are "new" are external (for example, metal grids, etc.) and therefore do not influence the drinking water quality, no GDV approval is required. However, the building component should bear all the approval numbers for the individual components in contact with drinking water.

### **3. Application procedure**

Applications are sent to the Danish Transport, Construction and Housing Authority via the electronic application form on [Virk/Indberet](#). Information and documentation indicated in the Application guidelines and the Schedule(s) of materials applicable to the building component must be submitted with the application.

Each application receives a specific case number, which identifies the unique application.

Before submitting the application, please read the Application guidelines, the relevant Schedule(s) of materials, the Testing requirement form and the Inspection guidelines carefully. These guidelines are all found on the website of the Authority [here](#).

Note that an application will not be considered submitted until the Danish Transport, Construction and Housing Authority has received the electronic application form from [virk.dk](#). The Danish Transport, Construction and Housing Authority will subsequently assess if the documentation is adequate. Inadequate applications will be rejected.

### **4. Testing**

Building components submitted for approval must be assessed and tested according to Annex 1 of the Executive Order.

Table 1 in Annex 1 of the Executive Order shows a gross list for types of materials that are not metal. Tests should only be carried out with

regard to the relevant harmful substances, which based on a professional assessment by the applicant or the applicant's toxicological advisor, are suspected of migration from the building component under application.

It is therefore a requirement that it is technically possible to demonstrate whether a building component contains the harmful substance in question.

Table 2 in Annex 1 of the Executive Order shows a gross list for materials made from metal. Three types of metals are subjected to the requirements of testing. Testing for nickel is only relevant if the building component is chrome-plated/nickel-plated.

For more information, please read the Application guidelines, the relevant Schedule(s) of materials as well as the Overview of testing requirements for various types of building components approved for use with drinking water. These documents are found [here](#).

#### **4.1 Accredited testing**

Analyses of the building components for which approval is applied, must be carried out as accredited technical testing. The laboratory, which carries out the testing, must therefore be accredited for the relevant testing.

In the absence of an accredited method for technical testing, other testing methods are accepted if they provide a satisfactory level of protection and are thus deemed adequate by the Danish Transport, Construction and Housing Authority.

Through accredited technical testing, the Danish Transport, Construction and Housing Authority only ensures that the test result complies with the requirements in the Executive Order, as the quality of the analysis is ensured by DANAK or a corresponding foreign accreditation body as part of the inspection with the laboratory's accreditation. For non-accredited technical testing, the Danish Transport, Construction and Housing Authority will assess whether the quality of the analysis can be deemed adequate.

If the toxicological advisor does not believe that there are accredited test possibilities for an ingredient, then the non-accredited testing must be carried out by an accredited test laboratory that uses a quality control system developed according to EN ISO/IEC 17025:2005, or a laboratory that follows a quality manual complying with EN ISO/IEC 17025:2005. The method that the laboratory uses should be described by the laboratory in accordance with their practice and quality control, and it should be shown in the test report. The description and the test report must contain specifications of the detection limit. The

test report must state that the test has been carried out as a non-accredited test, and the toxicological advisor's explanation as to why the test has been carried out non-accredited must be submitted.

#### **4.2 The test version of the building component ("worst-case")**

The test version must be one of the versions covered by the application for the building component, and it must be a version of the building component that is representative for all the versions under application. It must be the version, which, under testing, constitutes a worst-case in relation to risk of migration of harmful substances into drinking water.

The test version can be the version of the building component that has the largest water surface area, i.e. where the area-to-volume ratio is greatest (typically fittings, hoses, pipes), or the version of the building component that has the greatest volume (typically mixer taps).

Other factors could also contribute to defining which version of the building component will constitute the test version. For example, there can be cases where it is necessary to test an item with a larger dimension because the item with the smallest dimension is too small for it to be practicable to get enough water for the test. In these cases, documentation for the test programme must be attached, including the toxicological advisor's assessment of why it was necessary to test in the dimension that was used.

The specific schedule(s) of materials for specific building component groups describe which test version of the building component or individual component that should be used. In certain cases, the toxicological advisor should define the test version.

The Danish Transport, Construction and Housing Authority can offer advice to applicants or toxicological advisors on which test version to use in cases of doubt.

#### **4.3 Testing of building components made of metal**

For building components made of metal, Table 2 in Annex 1 of the Executive Order specifies three metals, which are subject to testing requirements. Testing of nickel is only relevant if the building component is chrome-plated/nickel-plated.

Quality requirements for the analysis of lead, cadmium and nickel are considered complied with when carried out by an accredited laboratory and implemented as either NKB4, NKB9, NKB13 and NKB18 or other relevant NKB test, which the laboratory is accredited to carry out.

For stainless steel alloys, EN 1.4000-1.4999 there is no requirement of testing. In such cases, it is sufficient if the applicant can document the composition of materials through a declaration in the schedule of materials.

#### **4.4 Testing of building components made of plastic/elastomers or made of both metal and plastic/elastomers**

For building components or individual components made of plastic/elastomers, it is necessary to carry out a toxicological assessment and prepare special test programmes as a basis for the testing (see section 4.5).

Only building components or individual subcomponents made of plastic/elastomers where the component has more than marginal contact with drinking water in terms of surface area or time must be tested for the relevant "other substances" of Table 1 in Annex 1 of the Executive Order.

Mixer taps and other building components made of both metal and plastic/elastomers must be tested several times, so that migration of plastic/elastomers and metal is tested correctly.

If the mixer tap contains plastic subassemblies, e.g. plastic hoses, these must be tested in a separate test, but can be included in the same approval. Plastic hoses in mixer taps, which are screwed on with a screw thread or similar and which can be removed easily must therefore be tested separately.

In cases where e.g. a plastic hose cannot be removed, the tap body and the plastic hose may, as an exception, be tested together, although still several times, so that migration of plastic/elastomers and metal is tested correctly.

#### **4.5 Toxicological assessment and test programme**

The schedules of materials specify when the toxicological advisor should carry out a toxicological assessment and prepare a test programme for the building component. In such cases, the toxicological advisor must subsequently carry out an assessment of the test results from the testing.

A toxicological adviser can be advantageous to use if in doubt of the conditions concerning assessment and testing of the building component.

The toxicological advisor must base the toxicological assessment of the chemical substances, which migrate from the building component on a human-toxicological foundation that ensures that consumers are

not exposed to a health risk even with a lifelong intake of drinking water at a concentration of the relevant chemical substances corresponding to the acceptance limit values used by the toxicological advisor.

Therefore, the toxicological assessment includes an initial overall assessment of the building component, including an assessment of the substances that can migrate into the drinking water, and therefore are relevant for testing. This assessment must be carried out based on knowledge of the composition of materials as well as on the materials' contact with drinking water in terms of surface area and time. The assessment must justify why the individual substances are deemed relevant for testing. The assessment must also take into account any migration of substances from adhesives under plastic surfaces etc., which are in considerable contact with the drinking water. In addition to the toxicological assessment, a test programme should be prepared for the laboratory selected to carry out tests and analyses.

When testing for substances (e.g. organic substances) where no limit values are stipulated in the Executive Order on Drinking Water, it is especially important that the toxicological advisor carefully considers detection limits as part of the test programme. This is to ensure that the test results satisfactorily document that the building component does not release harmful substances to the drinking water in an amount that is unacceptable in terms of health. The toxicological advisor's assessment concerning the detection limits must be included as documentation in the application.

It is particularly important that the toxicological advisor give special attention to the method of analysis with regard to suitability, capacity, selectivity and robustness when testing substances that are problematic to health. This includes whether the detection limits of the analysis methods are sufficient to ensure a satisfactory level of protection, in situations where it is not possible to use accredited testing of substances.

A very low detection limit should be used for very harmful substances, while the detection limit for less toxic substances can be higher. The detection limit should be set as one-tenth of the maximum level that may be released into the water. It is therefore important that the toxicological advisor define the requirements that are to be stipulated for the detection limit for the laboratory's analysis method when preparing a test programme based on the toxicity test profile of the substance (health-related properties).

Furthermore, the toxicological advisor must submit a reasoned memorandum for the acceptance limit values used (i.e. limit values for the level that can be accepted as the highest amount/concentration) for substances where no testing requirements have been stipulated in the

Executive Order. The toxicological assessment must be based on this reasoned memorandum, including potential confidential substances.

When determining acceptance limit values for organic substances not covered by the Executive Order on Drinking Water, the toxicological advisor must ensure that the sum of acceptance limit values does not result in infringement of the testing requirement for TOC (VOC + NVOC) stipulated in the Executive Order.

Moreover, the toxicological advisor (or the relevant laboratory) must make a technical assessment of the extractions to be used to measure turbidity, taste and smell as well TOC, including a human-toxicological reason for this if other extractions than the 3rd extraction are used.

The Danish Transport, Construction and Housing Authority may advise the toxicological advisor on drawing up documentation.

Reference can be made to the Danish EPA report: Status assessment concerning migration of organic substances from PE pipes to drinking water, Environmental Project no. 1443, 2012, as inspiration to carrying out toxicological assessments and test programmes.

#### **4.6 Test reports and assessment**

The following test documentation must be submitted with the application:

- Test reports from the laboratory where the building component was tested.

If toxicological advice was a requirement, the applicant must also submit:

- Toxicological assessment and test programme for the building component from the toxicological advisor.
- The toxicological advisor's assessment of the test results and conclusions based on the test reports. The assessment should include a conclusion as to whether the test results for the individual substances are within the limit values stipulated.

The test documentation should contain the following:

- Unique identification of the test specimen in the form of a product name, which specifies type and model number, serial number or similar, and perhaps a photo of the item tested. The test specimen must be the test version of the building component defined in accordance with the instructions in the schedule of materials.
- The detection limit and percentage deviation for the test analyses carried out.

- Unique identification of substances that are specified anonymously in the test report, for example, information about CAS registry numbers. This information can also be sent directly to the Authority by the toxicological advisor, as described in section 1.10.
- In relation to the test report, information should be provided concerning the accreditation of the laboratory to carry out the relevant testing.

Previously prepared test documentation can be submitted as basis for an application, but it must be an accurate representation of the present application. If there is any doubt to whether the documentation can be traced to the current building component, the Danish Transport, Construction and Housing Authority can involve the supervisory body in order to validate the connection between the building component and the documentation.

The measurement results must state the specific substances for which testing has been carried out. If the specific test programme includes substances where no requirements are stipulated in Annex 1 of the Executive Order, the toxicological assessment of the test result must include a technical assessment of whether the levels found affect the quality of drinking water. The Danish Transport, Construction and Housing Authority carries out an overall assessment of the health-related properties of the building component based on the toxicological assessment and the test results submitted with the application.

#### **4.7 Foreign test documentation**

Foreign test documentation can only be used as a basis for an application for approval to the extent that it meets the requirements for accredited technical testing as described in section 4.1. This entails that testing must be carried out in accordance with the standards for migration tests and methods of analysis stipulated in Annex 1 of the Executive Order, and that testing must be carried out as accredited technical testing by a laboratory accredited for the relevant test.

German DVGW and KTW certificates as well as the Dutch ATA approvals/The Kiwa Water Mark can be submitted as documentation and fulfil the requirements for assessment and testing of plastic and elastomers without any further testing. Only certificates/approvals for specified building components or individual component may be submitted. Certificates for materials cannot be used as documentation. For more information, see the Application guidelines.

To maintain the full five year approval period, the Danish Transport, Construction and Housing Authority requires that the approval holder

continuously document the validity of foreign certificates/approvals used as documentation for the approval.

Documentation must be written in English or Danish. If not, a translation into either English or Danish must be attached if the documentation is to be included in the processing of the application. The applicant is responsible for any translations required.

## **5. Self-check programme**

It is a condition for GDV approval that a self-check programme is organized. This includes checking of goods received and finished products for the building component (Incoming & Finished Goods Inspection), in order to ensure that the conditions for approval are met throughout the entire approval period.

The purpose of the self-check programme is therefore to ensure that the building component is still being manufactured in conformity with the originally approved building component. This should be documented in the form of procedures and records. In the review of documentation at the annual inspection of the self-check programme, it should be possible to demonstrate that the same construction and the same materials are being used for the building component as what formed the basis of the approval.

Should the self-check show that an approved building component does not comply with the requirements for approval, the approval holder must have procedures that ensures immediate implementation of the necessary corrective actions. The corrective actions must ensure that the building components comply with the originally documented requirements and that any defective products are not placed on the market, respectively are withdrawn from the market.

In the application a solemn declaration is therefore submitted to state that the applicant will ensure the establishment of a self-check programme for the approved building component before it is marketed and sold in Denmark.

## **6. Inspection agreement**

It is a condition for the approval that the applicant enter an agreement on an annual inspection with an accredited supervisory body. See the Inspection guidelines and the Application guidelines [here](#), where the requirements for the agreement and documentation of this are described in detail.

## **7. Case Processing**

The Danish Transport, Construction and Housing Authority will first examine the application in order to verify that all data has been provided and that it is accompanied by the relevant documentation. In case documentation is missing, the applicant will be asked to submit the missing information. The application will be rejected if the requested documentation is not submitted within a given timeframe.

## **8. Approval and payment**

Only applications where an approval is issued is subjected to payment of the fee. This means that there is no fee for case processing in the event that an application is rejected.

If the building component can be approved, the applicant will receive a letter of commitment of approval and an invoice for payment of the approval fee follows. The fee is stipulated in the Payment Executive Order and is found on the website of the Authority [here](#).

By accepting the payment of the invoice, the applicant warrants the health-related documentation and that the conditions for approval will be met. When the Danish Transport, Construction and Housing Authority has registered the payment of the approval fee, the final written approval and the certificate in Danish and English will be issued. Thereafter, the building component can be marketed and sold in Denmark with the GDV approval number and the "Godkendt til drikkevand" mark. The certificate will be published on the website of the Authority [here](#).

## **9. Changes in the rules and guidelines**

Applicants and approval holders must keep up to date with the guidelines and any changes to the rules that could affect the GDV approval, for example by following the website of the Danish Transport, Construction and Housing Authority [here](#).

## **14. Application for renewal of approval**

Approvals are issued for a period of five years. An approval can be renewed for another period if the approval holder applies for renewal at least three months before the approval expires.

The guideline to renewal of GDV approvals is found [here](#).

## **Annex 1: Additional material**

*The application guidelines for building components approved for use with drinking water:* The application guidelines provide a practical review of the application procedure when applying for approval of a building component and the documentation to be enclosed with the application.

*Overview of testing requirements for various types of building component approved for use with drinking water:* The testing requirements guide provides an overview of the testing requirements in Annex 1 of the Executive Order applicable for different types of building components. Note that the overview is not an exhaustive list of the testing requirements.

*Schedule of materials for different types of building components:* The schedule of materials is a combination of further guidelines on testing requirements and the test version for the relevant type of building component, as well as an auxiliary form, which must be completed and submitted with the application. In the schedule of materials, more detailed information regarding the composition of materials in the building component and the test version, is specified. It is also possible to note if the application covers any on-demand production.

A schedule of materials is available for the following types of building components:

- Metal pipes
- Pipes and hoses made of plastic/elastomers
- Fittings, manifolds, valves etc. made of metal and plastic/elastomers
- Taps
- Devices
- Sealants and linings

*Inspection guidelines for building components approved for use with drinking water:* The inspection guidelines are separate guidelines on the requirements for the inspection agreement and the annual inspection of approved building components.

*Guidelines on renewal:* The renewal guideline describes how to apply for a renewal of existing the GDV approval for a new period of 5 years.

All guidelines, the testing requirements guide and the schedules of materials are available at the authority [here](#).

Frequently asked questions (FAQ) about the scheme are also found on the website.

**Annex 2: List of terms**

*Contractual basis for the application:* The contractual basis between the Danish Transport, Construction and Housing Authority and the applicant, which shall apply to the application, and which is the basis for certification and approval. In the application form, the applicant must declare full accept of the contractual basis for the application.

*Accreditation:* The GDV scheme includes requirements for accreditation of laboratories to perform accredited technical testing and supervisory bodies to perform annual inspections. The Danish Accreditation and Metrology Fund (DANAK) or an equivalent accreditation body that is a signatory to the EA's (European co-operation for Accreditation) or ILAC's (the International Laboratory Accreditation Cooperation) multi-lateral agreement on mutual recognition must perform such accreditations.

*Analysis method:* The standards for testing specified in Annex 1 of the Executive Order.

*Applicant:* Manufacturer (or the established representative of a manufacturer in Denmark), an importer or a distributor. The application can be submitted on behalf of the company by a contact person, for example an employee of the company or an external toxicological advisor with the necessary power of attorney, etc.

*Building components that come into contact with drinking water:* Factory-made building components covered by section 1 of the Executive Order.

*Certification:* Approval and certification take place at the same time. The approval has a certificate enclosed stating that the building component is approved for use with drinking water.

*Distributor:* The company selling the building component in Denmark.

*Drinking water:* Cold drinking water, i.e. water from the drinking water supply transported via the cold water pipes in fixed water installations in buildings.

*Self-check programme:* A control programme, including an on-receipt and finished-product control (Incoming & Finished Goods Inspection) of the building component that the approval holder must establish in order to ensure that the requirements for obtaining approval of the building component are met throughout the entire approval period.

*Subassemblies:* The individual components that a building component may be composed of, for example, tap body, spout etc.

*Declaration on establishment of self-check programme:* As part of the application, the applicant solemnly declares an intent to establish a

self-check programme for the approved building component before this is placed on the market and sold in Denmark.

*Declaration on an agreement on annual inspection:* Instead of submitting an agreement on annual inspections with an accredited supervisory body, the applicant may choose to attach a solemn declaration to the application stating that such agreement has been made and that the final inspection agreement will be submitted later.

*Manufacturer:* The company that has produced the given building component or an established representative of the company in Denmark.

*Factory-made building component:* A building component manufactured in factory production and not in a workshop.

*Fixed installations for drinking water:* The fixed pipework for drinking water in a building from the property boundary to the draining point. Temporarily connected appliances and other devices, for example, coolers for drinking water connected with a non-permanent hose connection, do not form part of the fixed pipework.

*GDV:* Abbreviation for the approval scheme for building components that come into contact with drinking water.

*Approval:* Approval issued by the Danish Transport, Construction and Housing Authority according to the Executive Order.

*Approval holder:* The entity (manufacturer, importer or distributor) which upon application is granted approval for the building component concerned.

*Approval period:* The period is 5 years from the date of the approval of the building component.

*Importer:* The company placing the building component on the Danish market.

*Ingredients:* Substances included in the composition of a material type.

*Materials:* Are divided into primary material groups: plastics, elastomers, metals, ceramics and others. The individual material groups include different material types, for example, brass, gunmetal, stainless steel, EDPM rubber, nitrile rubber, silicone, PEX, etc.

*Schedule of materials:* Guidelines and forms concerning the building component and its individual components (subassemblies). The schedule of materials for the type of building component under application must be completed and enclosed with the application form. The forms must include information concerning test version, types of materials and any on-demand production.

*Product list:* Also called version list. List of all the versions of the building component covered by the application. The product list must be attached to the application and must include overall information about the building component, as well as information clearly designating and identifying all the versions of the building component covered by the application.

*Product name:* Unique identification of the building component, which specifies the brand/label and the product name used to market the building component, as well as any type and model number, serial number or similar.

*Draining point:* The place where drinking water can be tapped with an expectation that the water is drinkable, for example, taps at washbasins or tap valves that are part of a fixed water installation. The draining point can also be a drinking water cooler, but only if it is permanently mounted as part of a fixed water installation.

*Testing requirements:* Requirements concerning the limit values for substances stipulated in Annex 1 of the Executive Order that must be fulfilled in connection with testing.

*Testing requirements guide:* Overview of the general testing requirements laid down for various types of building components and materials.

*Test laboratory:* A laboratory that is accredited to carry out accredited technical testing for an ingredient that is relevant for the building component concerned. The accreditation must be in compliance with section 8(2), in the Executive Order.

*Test report:* Report on the technical testing carried out by the accredited laboratory where the building component was tested.

*Test version:* The version of a building component manufactured in several different dimensions that is tested for the greatest migration of substances into drinking water ("worst-case"). The test version may be defined in the schedule of materials. If there is only one version of the building component, then that is the test version.

*Inspection agreement:* Agreement between the approval holder and an accredited supervisory body on an annual inspection during the approval period.

*Supervisory body:* Independent third party body that is accredited to carry out accredited inspection.

*Inspection report:* Report prepared by the supervisory body concerning the annual inspection.

*Toxicological advisor:* A technical specialist who has the necessary toxicological expertise to advise applicants about assessment and

testing of building components that come into contact with drinking water. This includes the preparation of test programmes and subsequent assessment of test results, based on a human-toxicological foundation. The toxicological advisor can be an external advisor or an internal employee. There are no requirements for accreditation of toxicological advisors.

*On-demand production:* On-demand production of the building component where, after a specific order, the building component is delivered in specific dimensions within a range of products, described in more detail in the approval, but not typically produced. In the application, the applicant specifies the range of products for any on-demand production in the schedule of materials attached for the relevant type of building component.

*Version list:* Also called product list, see above.

*Annual inspection:* Accredited inspection carried out annually by an accredited supervisory body as agreed with the approval holder to ensure that the requirements for the approval are complied with in the approval period of the building component.