

Edvard Thomsens Vej 14 2300 København S Telefon 7221 8800 Fax 7262 6790 GDV@tbst.dk www.trafikstyrelsen.dk

Inspection guidelines version 3.2

13 August 2018

Content

1. Introduction and reading guide	2
1.1 Purpose of the inspection	2
1.2. The inspection period	2
1.3 Requirements for the inspection	3
1.4 Requirements for the inspection agreement	4
1.5 Examination of the inspection agreement by the Danish Transport	
1.6 Requirements for the supervisory body	5
1.7 Requirements for the inspection report	5
1.8 Examination of the inspection report and deadline for any follow-	
1.9 Consequences of failure to provide an agreement or undertake inspection	8
Annex A	9
Annex B1	0
	_



1. Introduction and reading guide

The inspection guidelines describe the requirements for performing inspections for building components that are approved for use with drinking water in the GDV scheme, including inspection of the approval holder's programme of self-checks. It is the responsibility of the approval holder to ensure that the inspection is conducted as stated in section 12 and 13 of the Executive Order.

The guideline is intended for both the approval holders and the accredited supervisory bodies (inspection bodies), which carry out the annual inspection and consists of the following:

- An introduction, with the general requirements for inspection, inspection agreement and inspection report etc.
- Annexes A, B and C, which contain the actual instructions for how the inspection should be carried out for different groups of building components.

The Inspection Guidelines has been updated to version 3.2 on August 2 2018 in which Annex C has been updated.

1.1 Purpose of the inspection

It is a condition for the approval of a building component that an annual inspection is carried out. This is to ensure that the building component is marketed under the same conditions that formed the basis for the approval. This means the building component has the same health-related properties that formed the basis of the approval throughout the entire approval period.

The purpose of the inspection is therefore to document the traceability from the inspection to the original approved building component. The inspection must be conducted with reference to the current Executive Order on market and sale of building components in contact with drinking water.

The approval holder must document that the produced building component has the same health-related properties as the approved, while the inspection body must verify that this documentation is adequate through gathering of objective evidence such as registrations, testimonies etc.

1.2. The inspection period

Annual inspection means that inspection is carried out once per calendar year on each place of production /place of inspection. The first inspection must be carried out no later than 11 months after the issue of the approval. During the approval period five inspections must be

carried out evenly distributed over the period. No calendar year must be skipped between two inspections.

The inspection report must be submitted to the Danish Transport, Construction and Housing Authority via e-mail: <u>GDV@tbst.dk</u> no later than two months after the inspection. However, the supervisory body must immediately report directly to the Danish Transport, Construction and Housing Authority if the inspection finds a lack of compliance with the provisions established in the agreement.

1.3 Requirements for the inspection

The inspection is carried out on the basis of the inspection agreement between the approval holder and the supervisory body and is carried out either at the place of production specified in the inspection agreement or at an importer's. The inspection can only take place at an importer's if the majority of the relevant processes can be documented in the form of procedures and records, and if all the building components for the Danish market go through the importer's warehouse/storage or if inspection is carried out on all the locations where the building components arrive in Denmark.

If another location than the one named in the inspection agreement is chosen, it must be justified and explained in the inspection report why this is more appropriate compared to carrying out the inspection at the place specified in the inspection agreement.

As a general rule the inspection is undertaken through document control of the approval holder's self-checks, including an Incoming & Finished Goods inspection. Based on the records it should be proven that the same materials are being used for the building component and that it still has the same construction as formed the basis of the approval.

The document control covers the records obtained by for example measuring, weighing and visual inspection as well as a control of the traceability from product to material certificate. Furthermore, the validity of possible underlying German and Dutch certificates must be checked. The document control can thus include transcripts or presentation of lists in the company's ERP system. The document control also covers the procedures that are written down to instruct those who carry out the self-checks.

Inspection of taps should include tests in accordance with Annex 1 of the Executive Order, which is specified in more detail in Annex B.

Inspection of sealants and linings must also include random sampling at the construction/production site, which is specified in more detail in Annex C.

1.4 Requirements for the inspection agreement

The approval holder must enter an agreement on an annual inspection with an accredited supervisory body. The requirement that an inspection agreement must be in place can also be considered fulfilled if the applicant, at the time of application, have entered into a mutual agreement with a supervisory body on accredited inspection provided that the building component is approved. In that case, the applicant must solemn declare that the final agreement with the inspection body will be submitted to the authority within the specified timeframe (see below).

The inspection agreement or the signed agreement must be submitted with the application. However, the documentation can also consist of a solemn declaration to an inspection agreement. In any case, the final inspection agreement must be submitted to the authority no later than 2 months before the first inspection.

The inspection agreement should meet the following form and content requirements if it is to be used as a basis for an approval of the building component:

- The agreement must ensure that an annual inspection is carried out according to the Executive Order and this guideline and that the supervisory body has access to the relevant production and storage facilities throughout the approval period.
- The inspection agreement must state a unique identification of which building components are included by stating product name, type, model number, item/serial number or similar, or by referring to the product/version list attached to the application.
- The final inspection agreement must state the GDV-approval number of the building component covered by the agreement.
 If the inspection agreement covers several GDV-approvals, all GDV-approval numbers must be specified.
- The inspection agreement must clearly specify the place of inspection.
- The accreditation of the supervisory body must be clearly stated in the inspection agreement, including that the inspection body is accredited to conduct inspections according to the current Executive Order on market and sale of building components in contact with drinking water.
- The inspection agreement must be signed and dated by the supervisory body and the applicant/approval holder.

1.5 Examination of the inspection agreement by the Danish Transport, Construction and Housing Authority

The Danish Transport, Construction and Housing Authority examines any simultaneous submitted inspection agreement as a part of the processing of the application, and verifies that the agreement complies with the requirements regarding the agreement.

If the approval holder fails to submit the final inspection agreement latest 2 months before the first inspection is to be carried out, the GDV approval will be recalled and consequently, the building component may no longer be placed on the market with the GDV approval number. The approval can also be recalled if the final inspection agreement does not meet the listed requirements for an inspection agreement.

1.6 Requirements for the supervisory body

The inspection should take place as an accredited inspection. This means that the supervisory body (inspection body) must be accredited in accordance with DS/EN ISO/IEC 17020 to carry out inspections and must also at the same time be accredited to carry out inspections in accordance with the Executive Order. This must be stated in the accreditation of the supervisory body.

The accreditation body that has issued the accreditation of the inspection body holds information on what the accreditation covers. In Denmark the national accreditation body, DANAK, has information on accredited supervisory bodies on its website. For foreign supervisory bodies the information on the accreditation can be obtained from the national accreditation body that has accredited the supervisory body.

The supervisory body must be impartial in relation to the approval holder.

In connection with the annual inspection of the self-checks, the supervisory body should ensure that the building component continues to have the same health properties that formed the basis of the approval. During the inspection, the supervisory body therefore ensures that a programme of self-checks is in place, and that this has been used in relation to the approval of the building component, when necessary. Furthermore, for taps random samples for testing must be taken.

1.7 Requirements for the inspection report

The inspection body's report of the annual inspection should be prepared in accordance with the inspection body's accreditation so that the Danish Transport, Construction and Housing Authority as a minimum is able to read the following from the report:

- 1. Conclusion where the inspection body notes if the approved building component, according to the inspection: A) continues or does not continue to comply with the conditions for approval. (If for example the inspection body finds that other materials than the materials approved are being used) or B) if the yearly inspection cannot ensure that the requirements of the Executive Order are met (ex. if the inspection cannot establish traceability from certificates of materials to the building component). The inspection body must also conclude and assess if the approval holder should submit additional documentation and if so which, for example by inspection, sampling, migration testing and weighing. This should be followed by an assessment with an estimate of when the approval holder can have required the additional required information for the inspection body and when a follow up report will be sent to the authority (see section 1.8 for more). The conclusion must contain a recommendation for the authority in regards to initiatives, such as requests for the approval holder of mandatory follow-up initiatives. The conclusion must be placed on the first page of the report.
- 2. Any other specific comments from the inspection body, resulting from the inspection carried out, for example, that minor deviations would be followed up with strict supervision of these during the next inspection. On this basis, the Danish Transport, Construction and Housing Authority must for example be able to assess, if it is necessary to emphasize to the approval holder that the duty of information to the authority as well as to the inspection body concerning any alterations must be complied with.
- 3. If the inspection is carried out at one or more locations other than specified in the inspection agreement: The inspection body's reason for carrying out the inspection in other places and justification for that this is carried out in accordance with the rules of inspection.

Furthermore, the inspection report must note the relevant building component's GDV approval number on the first page.

If the inspection report covers more than one approval, then it must be clear in the report, which comments refer to the individual GDV approval numbers.

The inspection report must be submitted to the Danish Transport, Construction and Housing Authority in either English or Danish via e-mail: GDV@tbst.dk within two months after the inspection has been conducted.

The inspection report is "negative" if the requirements of the Executive Order has not been met. The supervisory body must react with a negative inspection report:

- if the approval holder's programme of self-checks is inoperative, or it is otherwise obvious to the supervisory body that the approval holder fails to provide the necessary remedial action if the programme of self-checks shows that the building component does not meet the conditions of the approval.
- if through records as mentioned in Annex A-C and other objective evidence, the supervisory body is unable to demonstrate traceability from the approved building component to the originally approved building component.

The report (positive or negative) should be sent to the approval holder, who forwards it to the Danish Transport, Construction and Housing Authority. However, the approval holder may authorize in writing the inspection body to submit the inspection report directly to the Danish Transport, Construction and Housing Authority. In such cases, the report must also be sent to the approval holder at the same time at latest.

If the inspection reveals that the conditions and provisions set out in the inspection agreement have not been met (a negative report), then the inspection body must immediately report this directly to the Danish Transport, Construction and Housing Authority. This is in cases where the inspection body cannot ensure that the building component complies with the conditions of approval and the requirements from the Executive Order, meaning that the authority should assess if the approval holder for example is required to provide additional documentation.

Based on the conclusions, the Danish Transport, Construction and Housing Authority will evaluate any additional steps potentially in cooperation with the inspection body and will inform the approval holder as well as the inspection body on any proceedings. If necessary, the Danish Transport, Construction and Housing Authority will revoke the GDV approval based on a negative inspection report if additional documentation is not sufficient.

1.8 Examination of the inspection report and deadline for any follow-up

From the conclusion of the inspection report, the Danish Transport, Construction and Housing Authority will assess if there exist sufficient documentation proving that the building component fulfil the requirements for continued approval. If the inspection report shows that, the requirements for inspection and the Executive Order are met, the report will be used as basis for a continuation of the approval.

If the Danish Transport, Construction and Housing Authority assess that additional documentation for the inspection is needed, then the authority may order the approval holder to submit additional documentation, for example from inspection, sampling, migration testing and weighing. The authority will inform the approval holder as well as the inspection body of any additional request for documentation.

In these cases, the approval holder will be given 2 weeks to document the necessary conditions to the inspection body. In some cases, the deadline can be extended, if procurement of the additional information requires more time. The inspection body will assess if any additional documentation is satisfactory and note the evaluation in a follow-up report sent to the authority. The follow-up report must be submitted to the Danish Transport, Construction and Housing Authority within two months after the deadline set by the authority and the approval holder must require the needed documentation for the inspection body.

1.9 Consequences of failure to provide an agreement or undertake inspection

The applicant/approval holder is responsible for ensuring that the inspection agreement is entered into and meets the conditions for the annual inspection. The approval holder covers any costs related to the inspection. The approval holder must also ensure that the supervisory body on a regular basis is informed of any amendments to the approval, which could have an influence on the annual inspection and maintenance of the approval. This is to ensure that the inspection at all times can document that the building component has the health properties that formed the basis of the approval. Likewise, the approval holder must inform the Danish Transport, Construction and Housing Authority immediately if the inspection agreement is terminated.

If the agreement is breached by the approval holder or the inspection body will, in the worst case, lead to the revocation of the GDV approval. The consequence of a withdrawal is that the approval holder must ensure that the building component concerned is withdrawn from the market.

Annex A

Specific requirements for inspection for hoses, pipes, fittings, valves, machinery, devices and other building components

The inspection should be carried out in compliance with the general section above, and the specific requirements below.

Records

Requirements for records when inspection is carried out on the place of production

The approval holder should be able to document traceability for the approved building component in relation to:

- Record of product name, date of production and order number.
- GDV approval number.
- Record of number of GDV approved building components delivered to the approval holder.
- Traceability from the GDV approved building component to material type or raw material certificate for the parts of the building component that come into contact with drinking water.

The approval holder is responsible for ensuring that accessible, written instructions and procedures concerning the programme of self-checks are available. These should be in a language that is relevant to the place of production.

Requirements for records when inspection is carried out in storage facilities in Denmark

The following are the minimum requirements for the records that should be available for each consignment/batch:

- Record of number of received building components.
- Record of product name, order number and date of receipt.
- Record and verification of materials by use of certificates or other traceability to the materials that are part of the building product according to the approval issued.
- Verification of whether there is a current approval for the building component with an associated "Approved for use with drinking water" number.
- Verification of whether any individual components which come into contact with drinking water are approved as part of the building component or with an independent approval, which is still valid at the time of carrying out the inspection.
- Verification of whether the approved building component is correctly marked with the GDV approval number.
- Other records resulting from measurement, weighing or visual inspection of the building component.

Annex B

Specific requirements for inspection for taps

The inspection should be carried out in compliance with the general section above, and the specific requirements below.

Specific inspection requirements for taps

For taps it is required that once a year a random sampling is taken for migration testing in accordance with Annex 1 of the Executive Order.

Records

Requirements for records when inspection is carried out on the place of production

The approval holder should be able to document the following for the approved building component:

- Record of product name, date of production and order number.
- GDV approval number.
- Record of number of GDV approved building components delivered to the approval holder.
- Traceability from the GDV approved building component to material type and raw material certificate for the parts of the building component that come into contact with drinking water.

The approval holder is responsible for ensuring that accessible, written instructions and procedures concerning the programme of self-checks are available. These should be in a language that is relevant to the place of production.

Requirements for records when inspection is carried out in storage facilities in Denmark

The following are the minimum requirements for the records that should be available for each consignment/batch:

- Record of number of received building components.
- Record of product name, order number and date of receipt.
- Verification of whether there is a current approval for the building component with an associated "Approved for use with drinking water" number.
- Records and verification of materials by use of certificates or other traceability to the materials that are part of the building product according to the approval issued.
- Verification of whether any individual components, which come into contact with drinking water are approved as part of the

13 August 2018

- building component or with an independent approval, which is still valid at the time of carrying out the inspection.
- Verification of whether the approved building component is correctly marked with the GDV approval number.
- Record of the weight of the taps and comparison with the previous consignment.
- Other records resulting from measurement or visual inspection of the received building components.

Random Sampling

As far as possible, random samples are to be taken during the inspection. The supervisory body should take a random sampling of a representative section of the product range for test.

Holders of one approval are required to have that approval tested every year. Holders of several approvals can rotate between the approvals if they are produced at the same production facility and under the same circumstances, in a way where each GDV approval have been subject to minimum one migration test during the approval period. It is the responsibility of the approval holder in collaboration with the inspection body to ensure that taps representing every GDV approval has been migration tested during the approval period.

The requirements for the random samples should reflect what has been defined in Annex 1 of the Executive Order. This shows sample sizes of three for the nickel test and one for the lead/cadmium test. Different taps are taken at each annual inspection as far as is practically possible. The purpose of the migration test is to check the production facilities and the company's self-check programme.

Requirements for test reports

Testing and test documentation should as a general rule, be carried out at the annual sampling according to the test methods specified in Annex1, table 2, of the Executive Order, i.e. for lead, cadmium and nickel.

Annex C

Specific inspection requirements for coating materials and linings

The inspection shall be carried out in accordance with the general sections above and the supplementary specific requirements below. For sealants and coating materials, the inspection shall be carried out both at the approval holder's once a year as document control and inspection carried out by the supervisory body. Furthermore, the inspection will be conducted as continuous "project inspection" before the coated drinking water installations is taken into use at all construction sites where the building component is used and where water samples are taken for migration test.

It is a condition for the approval that during the entire approval period the approval holder markets and sells both the building component and the actual renovation in bulk and as described in the application for approval and with the same executing parties, e.g. a particular sub-contractor certified for the renovation according to ISO 9001 or equivalent.

Registrations at the general annual inspection at the approval holder

The following requirements are the minimum requirements for the registrations that shall be available for each consignment/batch at the annual inspection at the approval holder:

- That a sub-contractor, if any, carrying out renovations is not replaced during the approval period.
- Registration of the number of construction sites and identification of these with belonging migration tests in the year in question related to the continuous reports to the supervisory body.
- Registration of received materials.
- Control of whether there is compliance between the material received and the material originally approved.
- Documentation for traceability to:
 - o Product name, production date and order number
 - GDV approval number
 - o Batch number
 - Raw material type and raw material certificate (issued by a third party organ)

The supervisory body shall be particularly aware of the following:

Control of approval and marking with the GDV approval number

13 August 2018

- Documentation for unchanged or new composition of materials
- Going through written procedures and directions for use
- The producer's internal responsibility relations
- Mixing process, mixture proportions, weighing
- Traceability to originally approved materials
- Hardening process and hardening time
- Competences of the employees
- That the sub-contractor is the same as the one stated in the GDV approval
- Complaints of the product and the handing of complaints in the self-check program
- Registrations
- Sampling

Inspection with the renovation projects

In order to maintain a GDV approval, the approval holder shall continuously report to the supervisory body about oncoming projects with carrying out sealing and pipe lining. This includes information on where and when a project is expected to take place, when water samples can be conducted, and when the analysis of the test results are expected to be available.

With the continuous reports of the approval holder to the supervisory body, it is possible for the supervisory body in cooperation with the approval holder to plan the "project inspection" at the actual construction sites and to take water samples to analysis at each individual coated installation. It might for example be at the tap in each individual building covered by the renovation. The analysis results from an accredited laboratory are then submitted to both the approval holder and the supervisory body.

This makes it possible that the approval holder and the supervisory body have received the analysis result approximately 3 weeks after the water sample was taken. If the result is positive (where the limit values are observed), the GDV approval holder may thus be certain that the building component meets the conditions in the GDV approval, and that the renovation of the building in question is evaluated to be in accordance with the conditions in the approval. The GDV approval holder can then report the drinking water installation ready for use to the owner of the building. In large projects, water samples may be taken and analysed continuously so that the individual drinking water installations can be taken into use continuously.

Random sampling at the individual construction site (the individual project)

The GDV approval holder is responsible for making an agreement with an accredited laboratory on taking water samples and making analysis. The accredited laboratory shall ensure that the water sample is taken by an impartial expert and shall ensure that the water sample is then submitted directly to be analysed by an accredited laboratory. The accredited laboratory shall evaluate which water samples shall be taken in order to ensure that all individual drinking water installations are covered by the analysis. It shall be concluded in the sample report whether the limit values are exceeded and thus whether the renovation of the drinking water installation meets the conditions for the GDV approval. The water sampling shall be conducted accredited in accordance with the ISO 5667-5 standard.

The water samples at the construction site shall be taken after the coating process has been fully completed, i.e. after the material is mixed, led into the drinking water system and hardened for 7-10 days, and the system has then been flushed. The water sample shall be taken from the tap for each individual, renovated drinking water installation in the building. In an apartment building, one water sample for each of the renovated stairways is normally sufficient.

A water sample of 24 hours stagnated water shall be taken for analysis. Before taking water samples, the tap shall shortly be opened so that the water that has been in the mixer tap is flushed. In this way, water samples will be taken from water of the renovated pipes. At least a 2 litres sample of the 24 hours stagnated water shall be taken.

The further process after taking water samples

As mentioned, the accredited laboratory ensures that the result in the form of a testing report for one or more water samples is submitted to the approval holder and the supervisory body. The testing report must contain relevant information such as approval number, the actual construction site (building), flat number or such, date for taking samples etc. in order to ensure traceability. The approval holder is responsible to take action on the basis of the results and conclusions of the testing report.

Furthermore, the supervisory body is also obliged to evaluate the conclusion in the testing report. In case of exceeding of limit values, where the construction component is <u>not</u> evaluated to meet the conditions for the GDV approval, the supervisory body shall immediately inform the approval holder and the Danish Transport, Construction and Housing Authority to the conclusions of the testing report. This is in

addition to the direct communication between the accredited laboratory and the approval holder and the approval holder's duty to take action.

The Danish Transport, Construction and Housing Authority may withdraw the GDV approval if the test requirements are exceeded. If the water sample shows that value limits are exceeded, the drinking water installation in question cannot meet the conditions for the GDV approval and is therefore not legal to use. Thus, there may be cases where it turns out that the drinking water installation in one or more stairways in an apartment building does not meet the requirements and cannot be taken into use.

Test program and analysis

The toxicological advisor shall prepare the test program for the migration test at the time of application.

The analysis shall be made at an accredited test laboratory in accordance with Annex 1 of the Executive Order. As mentioned, the analysis are carried out according to the test program for construction sites on which the GDV approval was based and which was prepared by the applicant's toxicological advisor.

In any case, the water samples shall as a minimum be analysed for the following parameters:

- NVOC
- Smell and taste
- Other substances evaluated relevant on the basis of the material in question, e.g. formaldehyde. As regards the material epoxy coating, analysis for at least bisphenol A and formaldehyde shall, however, be carried out.

The water samples shall meet the requirements for the GDV scheme.

Requirements to reporting of time schedules and the annual inspection reports

As regards the individual renovation projects, the GDV approval holder is as mentioned responsible for continuously reporting to the supervisory body when water samples are taken at the construction sites so that the supervisory body can be ready also to evaluate the conclusions of the test reports. The report on time schedules shall be made timely so that the supervisory body can be expected to attend.

Basically a water sample is taken as soon as the coating is fully hardened (typically 7 – 10 days after the coating), and analysis are completed within approximately 3 weeks by an accredited laboratory after which both the approval holder and the supervisory body are notified of the result.

The supervisory body will typically use approximately 5 working days to evaluate the test reports and, if relevant, notify both the GDV approval holder and the Danish Transport, Construction and Housing Authority if limit values are exceeded. Therefore, the GDV approval holder will principally have to expect that use of a specific drinking water installation in e.g. a building cannot be used until around 3 weeks after completed hardening and sample taking. It may be agreed between the approval holder and an accredited laboratory and with the supervisory body that water samples are taken along with the completion of the renovation of the individual buildings. In that situation, individual apartments can be taken into use in an ongoing process approximately 3 weeks after taking the specific water samples.

Responsibility

The approval holder is responsible towards the Danish Transport, Construction and Housing Authority to ensure that the conditions in the GDV approval are being met.

Reporting on renovation projects in the annual inspection report from the supervisory body

Once a year the supervisory body shall submit an inspection report to the Danish Transport, Construction and Housing Authority on the annual inspection at the approval holder's containing a summary of all water sample results from the construction sites since the last inspection report. As part of the annual inspection at the approval holder's, the supervisory body shall compare the information on renovation projects of the self-check programme with results of analysis of water samples in order to check whether samples have been taken at all relevant individual drinking water installations and at all construction sites and that all limit values are met. Therefore, it must be possible for the supervisory body to compare information on water samples with the list of relevant drinking water installation prepared by the accredited laboratory. This shall be included in the annual inspection report. In this way the Danish Transport, Construction and Housing Authority will get a general view of how and when coating of drinking water installations have been made in Denmark and whether the conditions in the GDV approval are met.

The requirements for submitting the annual inspection reports are the same as for other GDV approved building components.

Sanctions in case the requirements are not met

If the Danish Transport, Construction and Housing Authority does not receive an annual inspection report from the supervisory body as required, the conditions for maintaining the GDV approval are regarded as not being met.

The conditions for maintaining the GDV approval is regarded as not being met in cases where:

- the value limits are exceeded or
- the required water samples are not taken at the construction site or
- the renovated drinking water installation in the building is taken into use before the relevant analysis results are available or
- the installation is taken into use in spite of the limit values being exceeded.

Furthermore, if limit values are exceeded the approval holder shall be under the obligation without unnecessary delay to notify the building authority (municipality) in question of this including information on the actions taken by the approval holder to ensure that the drinking water installation is not taken into use.

If the approval holder does not comply with the obligation to notify, the conditions for maintaining the GDV approval are regarded as not being met. The approval holder is responsible towards the Danish Transport, Construction and Housing Authority for documenting that the local building authority (the municipality) has been notified in due time if any limit value has been exceeded.