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Full text

Executive Order on the placement on the market and sale of building components that come into contact with drinking water

Pursuant to sections 28(2), 30(2), 31(1) and 31 A(1) of the Danish Building Act (cf. Consolidating Act No 1185 of 14 October 2010, as amended by Act No 389 of 2 May 2012) and Act No 640 of 12 June 2013, section 1(3) of the Danish Public Administration Act (cf. Consolidating Act No 433 of 22 April 2014) and section 5(3) of Act No 606 of 12 June 2013 on access to public administration files, and following negotiations with the Minister for Justice, the following is hereby laid down in accordance with section 31 D(2) of the Danish Building Act:

Part 1

Scope and definitions

Scope

1.-(1) This Executive Order establishes regulations on the placement on the market and sale of commercially manufactured building components, which

- 1) are connected to the drinking-water supply, without which the supply would not be able to reach consumers;
- 2) are included in or connected to fixed water installations up to and including the draining point and which affect the quality of the drinking water; and
- 3) are used in connection with buildings that are covered by section 2(2) of the Danish Building Act.

(2) This Executive Order does not apply to

- 1) building components made of pure copper, electrogalvanized steel or hot-dip galvanized steel;
- 2) stainless steel alloy EN 1.4000-1.4999;
- 3) tap aerators that are designed as part of a mixer tap;
- 4) building components or components therein which are deemed to have only marginal contact with drinking water in terms of area or time, cf. section 8(4); or
- 5) cartridges.

Definitions

2. For the purposes of this Executive Order:

- 1) 'Accredited technical testing' means: Testing performed as an accredited service by a laboratory that is accredited for the testing in question by the Danish Accreditation and Metrology Fund (DANAK) or an equivalent accreditation body that is a signatory to the EA's (European Cooperation for Accreditation) or ILAC's (the International Laboratory Accreditation Cooperation) multilateral agreement on mutual recognition.
- 2) 'Accredited inspection' means: An inspection performed as an accredited service by an independent third party that is accredited for the inspection in question by the Danish Accreditation and Metrology Fund (DANAK) or an equivalent accreditation body that is a signatory to the EA's (European Cooperation for Accreditation) or ILAC's (the International Laboratory Accreditation Corporation) multilateral agreement on mutual recognition.

Part 2

Conditions for placement on the market and sales

3. In order for the building components covered by section 1(1) to be placed on the market or sold, it must be documented that the building component as a whole or the subassemblies in contact with water of which the building component consists:

- 1) are approved by the Secretariat for Approvals, cf. section 5(1) in this Executive Order;
- 2) are certified in Germany in accordance with the scheme that is applicable in Germany;
- 3) are approved in the Netherlands in accordance with the scheme that is applicable in the Netherlands; or
- 4) are type-approved in Sweden.

4. Companies that place on the market or sell building components, cf. section 3(1–4) must always be able to document that the building component satisfies the conditions in nos. (1)–(4). Documentation for this must be produced at the request of the Danish Transport and Construction Agency. The Danish Transport and Construction Agency publishes guidelines on their website concerning which documents will be considered adequate documentation.

Part 3

Administration of the approval scheme

5.-(1) Building components that are not covered by Section 3 nos. 2, 3 and 4 must be approved according to the regulations in Parts 3–6.

(2) Building components covered by section 1(2) nos. 2, 3, 4 and 5 and section 3 nos. 2, 3 and 4 can also be approved according to the regulations in Part 4.

(3) The same approval according to section 5(1) may only cover building components that have the same health-related properties, including as a result of the manufacturing process, and which are identical with respect to their purpose, design and material composition.

(4) Building components that are produced and placed on the market as combinations of different subassemblies can, however, be included under the same approval, provided that the individual subassemblies are tested separately.

(5) The Secretariat for Approvals, cf. section 7, makes a specific assessment of which building components may be covered by an application. The Secretariat for Approvals may also assess whether individual, small subassemblies covered by subsection (4) can be included in a building component, even if they deviate from subsection (3).

6.-(1) Building components that are approved in accordance with section 5(1), may be marked with 'Godkendt til drikkevand' (Approved for use with drinking water), cf. subsections (2)–(4), cf. however subsection (6) on digital marking.

(2) The 'Godkendt til drikkevand' marking must be designed in accordance with model no. 1 in Annex 2 and must be placed in such a way that it is clear, legible and durable. The 'Godkendt til drikkevand' marking is to be placed on the packaging, the building component or on a label affixed to the building component. If the component is of such a nature that this is not possible, the marking is to be placed in the accompanying documents.

(3) The 'Godkendt til drikkevand' marking must be accompanied by the name or identification mark of the manufacturer and the 'Godkendt til drikkevand' number.

(4) There must not be any other markings or labels on the building component that can be misleading with regard to the meaning or graphic design of the 'Godkendt til drikkevand' marking or which reduce the visibility or legibility of the 'Godkendt til drikkevand' marking.

(5) It is permissible to supplement the aforementioned marking requirements with a marking as shown in model 2 in Annex 2. This is provided that the marking requirements under subsections (2)–(4) are met.

(6) The marking may be designed electronically for the purposes of digital reading. The Danish Transport and Construction Agency will establish more detailed guidelines on this.

7.-(1) Administration of the voluntary approval scheme is carried out by a Secretariat for Approvals.

(2) Approvals in accordance with section 5 of this Executive Order are issued by the Secretariat for Approvals on behalf of the Danish Transport and Construction Agency.

(3) The Secretariat for Approvals is obliged to carry out the administration of the approval scheme according to the guidelines established by the Danish Transport and Construction Agency.

Part 4

Conditions for issuing approval

8.-(1) Building components must be such that drinking water, after coming into contact with them, still meets the requirements in the Executive Order on water quality and inspection of water supply systems. Building components that are covered by section 3, no.1, cf. section 5, of this Executive Order must be assessed and tested for migration of the substances specified in Annex 1 and for other substances hazardous to human health which may migrate from said products.

(2) Analyses carried out in connection with the testing of building components covered by subsection (1) must be in the form of accredited technical testing. In the absence of an accredited method for technical testing, other testing methods are acceptable if they provide a satisfactory level of protection and are thus deemed adequate by the Secretariat for Approvals.

(3) Prior to the issuance of an approval in accordance with section 5, the Secretariat for Approvals must perform an overall assessment of the health-related properties of the building components in order to ensure compliance

with subsections (1) and (2). As part of this assessment, the Secretariat for Approvals must assess whether there is documentation of compliance with the requirements in Annex 1, cf. however section 9(1).

(4) Building components or components therein which are deemed to have only marginal contact with drinking water in terms of area or time are not subject to the assessment and testing requirement.

9.-(1) A company that applies for a building component approval in accordance with section 5 must, as part of the application, submit documentation on the health-related properties of the building component, including the documentation in accordance with Annex 1, or documentation cf. section 3 nos. 2 and 3, which may replace the requirements in table 1 in Annex 1.

(2) The company must also submit documentation on the establishment of a self-check programme, including an incoming and finished goods inspection of the building component for which approval is sought.

(3) The company itself must provide the documentation under subsections (1) and (2) and pay the necessary expenses for this.

10. A condition for the issuance of an approval in accordance with section 5 is that the company applying for a building component approval arranges a self-check programme to ensure compliance with the requirements to obtain approval by the company during the approval period.

11.-(1) Prior to issuance of an approval according to section 5, an agreement on an annual inspection between the company and an accredited supervisory body must be in place, or a declaration of such an inspection. If an inspection declaration has been submitted, the final inspection agreement must be sent to the Secretariat for Approvals no later than two months prior to the first inspection. The inspection must be performed as an accredited inspection. The agreement must ensure that documentation can be presented to the Secretariat for Approvals which shows that building components placed on the market and sold under the issued approval have the health-related properties as assessed by the Secretariat for Approvals, cf. section 8(3) and that the company continues to meet the conditions on the arrangement of a self-check programme, cf. section 10.

(2) The supervisory body must be independent from the approval holder and the Secretariat for Approvals.

(3) The Secretariat for Approvals is obliged to assess that the agreement ensures that the conditions for issuing the approval according to section 5 are met by the company during the building component's approval period.

Part 5

Inspection carried out during the approval period

12.-(1) In order to ensure that the requirements to obtain an approval under this Executive Order are met by the approval holder during the approval period of the building component, an annual inspection agreement between the approval holder and an accredited inspection body must be in place, cf. section 11 of this Executive Order.

- (2)** The inspection requirement applies to all building components approved under this Executive Order.
- (3)** Inspection is carried out in accordance with the inspection agreement that has been approved by the Secretariat for Approvals, cf. section 11 of this Executive Order. The annual inspection is performed by the supervisory body as a documentary check, which consists of a review of the approval holder's self-checks, including the established incoming and finished goods inspection.
- (4)** If the annual review does not provide sufficient assurance that the building components meet the requirements of this Executive Order, the Secretariat for Approvals may require the approval holder to submit additional documentation in accordance with this Executive Order. This documentation may comprise:
- 1) inspection,
 - 2) sampling,
 - 3) migration testing, and
 - 4) weighing.
- (5)** Inspection for mixer taps must include testing in accordance with Annex 1 to this Executive Order.
- 13.** Following inspection, the supervisory body prepares a report that the approval holder then submits to the Secretariat for Approvals. The report contains an assessment of whether the provisions established in the agreement between the supervisory body and the approval holder have been complied with.
- 14.** The supervisory body is obligated to immediately report directly to the Secretariat for Approvals if the inspection finds a lack of compliance with the provisions established in the agreement between the supervisory body and the approval holder.

Part 6

Issuance, renewal, revision and revocation of approvals

- 15.-(1)** Application for approval according to section 5 must be sent to the Secretariat for Approvals.
- (2)** The Secretariat for Approvals will publish the procedures for application and the expected case-processing time.
- 16.-(1)** It is the responsibility of the approval holder to notify the secretariat of approvals of matters that may impact compliance of an approved building component with the conditions of this Executive Order.
- (2)** If the Secretariat for Approvals is thereby or otherwise made aware of such matters, it is the responsibility of the Secretariat for Approvals to notify the approval holder that the approval is revoked, cancelled or must be revised, if:
- 1) supplemental provisions are established or provisions for the area concerned are amended or repealed;

2) the building component approved is altered and the alteration is of significance to matters covered by the approval;

3) an inspection finds – or it comes to light in another manner – that the approved building component no longer meets the conditions that have been stipulated; or

4) use of the approved building component has unacceptable effects on the building component or its surroundings.

(3) Approvals issued in accordance with section 5 can also be revised or revoked by the Secretariat for Approvals if the approval holder does not satisfy the conditions established for creation of the approval, e.g. concerning self-checks, cf. section 9(2).

17.-(1) Approvals are issued for five-year periods, but only until the period of validity of supporting certificates or other documentation expires.

(2) The approvals may be reissued for a new period prior to expiry if the approval holder provides documentation that the building component continues to meet the conditions for approval under this Executive Order.

Part 7

Supervision of the Secretariat for Approvals

18.-(1) The Secretariat for Approvals must be accredited to issue approvals in accordance with section 5 of this Executive Order and in accordance with international standards for conformity assessment of requirements for certification bodies that certify products, processes and services by the Danish Accreditation and Metrology Fund (DANAK) or an equivalent accreditation body that is a signatory to the EA's (European Cooperation for Accreditation) or IAF's (International Accreditation Forum) multilateral agreement on mutual recognition.

(2) The Secretariat for Approvals must annually inform the Danish Transport and Construction Agency about the results of the accreditation body's supervision of the Secretariat for Approvals' activities.

(3) The accreditation body must immediately inform the Danish Transport and Construction Agency if the supervision process finds that the Secretariat for Approvals cannot maintain the accreditation.

(4) The Danish Transport and Construction Agency supervises the Secretariat for Approvals for compliance with the rules in this Executive Order.

Part 8

Administrative provisions

19. The rules of the Danish Public Administration Act and the Danish Access to Public Administration Files Act apply to cases in which a decision is made by the Secretariat for Approvals pursuant to this Executive Order.

20.-(1) Appeals against decisions made by the Secretariat for Approvals under this Executive Order may be lodged with the Danish Transport and Construction Agency.

(2) Appeals against decisions made by the Secretariat for Approvals are submitted to the Secretariat for Approvals, which must assess and give notice within four weeks as to whether or not the appeal gives rise to a revision of the decision. If the Secretariat for Approvals cannot reply within said timeframe, the appellant must be given a reason for this. Such notification must specify when a reply can be expected.

21. Upon approval issuance, renewal or revocation, the Secretariat for Approvals collects a fee in accordance with the Executive Order on payment for processing approval applications for building components that come into contact with drinking water.

Part 9

Penalties

22. Infringement of the provisions in sections 3 and 4 is punishable by a fine.

23. Companies etc. (legal persons) may incur criminal liability according to the regulations in Part 5 of the Criminal Code, cf. section 30(5) of the Danish Building Act.

Part 10

Entry into force

24.-(1) This Executive Order enters into force on 1 July 2016.

(2) Executive Order No 666 of 20 May 2015 on the issuing of approvals for building components that come into contact with drinking water is repealed, cf. however subsection (5).

(3) Building components that are placed on the market and sold in accordance with this Executive Order, but for which a "VA" (*vand- og afløbsinstallationer* — water and drainage installations) approval was issued prior to 1 April 2013, which covers the health-related properties, are not covered by the compliance requirement of this Executive Order before the expiry of the VA approval on 1 July 2017.

(4) Circular No 89 of 20 August 1986 on approval schemes for materials and designs etc. for construction and equipment etc. for water and drainage installations continues to apply to building components that have a VA approval under said circular, cf. subsection (3).

(5) Building components that must be approved under section 5 of this Executive Order, but for which a VA approval was issued prior to entry into force of this Executive Order, which include the health-related properties,

cf. subsection (3), must however continue to be marked in accordance with section 23(3), cf. section 7 of Executive Order No 666 of 20 May 2015 until the expiry of the VA approval on 1 July 2017.

The Danish Transport and Construction Agency, 29 June 2016

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/ Janni Torp Kjærgaard

Annex 1

Gross requirement list for obtaining and retaining approval under this Executive Order, cf. section 3, no. 1

Table 1: Testing requirements for building components and subassemblies that consist of materials other than metal ¹⁾

Parameter	Analysis method	Testing requirements ^{2) 3) 4)}	Comment
Colour		No changes in relation to blind test	Testing is required only if the building component is coloured or has additives that can release colour into the drinking water.
Turbidity		No changes in relation to blind test	
Flavour and odour	EN 1622	No significant change in relation to blind test	
TOC (VOC + NVOC)		0.3 mg/l or 1 mg/m ² /day	For installations with a length of over 2 m.
TOC (VOC + NVOC)		1.5 mg/l or 15 mg/m ² /day	For installations no more than 2 metres long, and small components.
Silver		10 µg/l	May be relevant for filters, such as ion exchange filters, osmosis systems, and carbon filters.
Phenols	DS 281:1975 or DS/EN/ISO 14402	No measured phenols. ⁵⁾	Quality requirements for the analysis method: Detection limit 2 µg/l.
Other substances ⁶⁾		< 10% of the difference between the quality requirement for drinking water at entry point into property and taps. ⁷⁾	
Bacterial count at 22°C	DS/EN ISO 6222	Bacterial count in the treated water is less than five times the content of the inlet water. ⁸⁾ There must be no selection of bacterial count towards	May be relevant for water treatment systems, including filters such as

		pure cultures at the end of the test period.	ion exchange filters, osmosis systems, and carbon filters.
Bacterial count at 37°C	DS/EN ISO 6222	Bacterial count in the treated water is less than five times the content of the inlet water. ⁹⁾ The bacterial count must not increase systematically and gradually over the test period. There must not be any selection in bacterial flora towards pure cultures at the end of the test period.	May be relevant for water treatment systems, including filters such as ion exchange filters, osmosis systems, and carbon filters.

- 1) includes, for example, hoses, pipes, fittings, water treatment systems, cartridges, large O-rings, gaskets, etc.
- 2) Migration test performed according to DS/EN 12873-1. For the flavour and odour parameters, the migration test is performed according to DS/EN 1420. Other migration tests are acceptable if they provide an equivalent level of protection and are thus deemed adequate by the scheme's Secretariat for Approvals.
- 3) For migration tests performed in accordance with DS/EN 12873-1 and DS/EN 1420, the individual parameters are measured from the third extraction. Measurements of turbidity, flavour and odour, and TOC may use up to the ninth extraction.
- 4) In cases where testing requirements are exceeded by minor and negligible amounts, the Secretariat for Approvals may base its approval on a toxicological assessment enclosed with the application, if it is probable that the requirements on drinking water at the tap will not be exceeded.
- 5) With respect to specific phenols, the requirements listed under 'Other substances' apply.
- 6) 'Other substances' means the substances for which quality requirements are set out in the Executive Order on water quality and inspection of water supply systems and which are not specifically mentioned in Annex 1. Assessment and testing, cf. section 8(1) is also required for other substances hazardous to human health that are not specifically mentioned in this Annex 1 or in the Executive Order on water quality and inspection of water supply systems, but which may be in and migrate from building components.
- 7) The quality requirements for drinking water can be found in Annexes 1 a–1 d of the Executive Order on water quality and inspection of water supply systems.
- 8) A value in the treated water of ten-times the content of the inlet water immediately after both seedings can be accepted.
- 9) A value in the treated water of ten-times the content of the inlet water immediately after both seedings can be accepted.

Table 2: Testing requirements for metal building components and subassemblies ¹⁰⁾

Parameter	Migration method	Testing requirement	Comment
Lead	NKB4 ¹¹⁾	5 µg	
Cadmium	NKB4 ¹¹⁾	2 µg	
Nickel ¹²⁾	NKB4 ¹¹⁾	80 µg	The requirement applies to the average total quantity calculated for at least three products.
	DS/EN 16058	20 µg	The requirement applies to the average total quantity calculated for at least three products.

10) Including e.g. mixer taps, fittings, valves, hose ends, end caps for branch pipes, etc.

11) Nordic Building Regulations Committee, product rule 4 — NKB4, or similar. Depending on the type of product, testing can also be carried out according to NKB9, NKB13, NKB18, or other relevant NKB testing method.

12) When testing fixtures for nickel migration, either of the two methods specified may be used.

Annex 2

Approved for use with drinking water marking

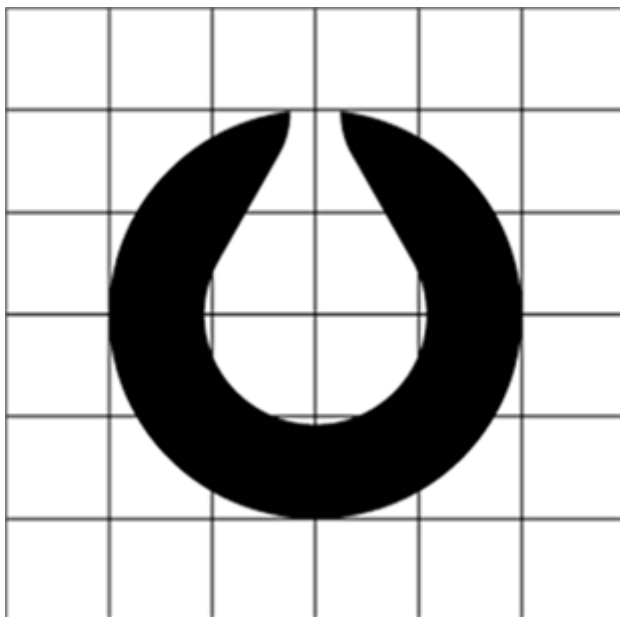
The 'Godkendt til drikkevand' marking consists of the following design with 'Godkendt til drikkevand' to the right of the marking (symbol) as shown in model 1. Model 1 is the mandatory logo. Model 2 shows the marking without the text and can be used as an optional, additional marking engraved directly on the building component.

If the marking is scaled up or down, the proportions shown below must be retained. The mandatory logo (Model 1) must be at least 8 mm high. If the optional, additional symbol is used (Model 2), it must be at least 5 mm high.

Model 1:



Model 2:



Additional markings:

The 'Godkendt til drikkevand' marking is accompanied by the name or identification mark of the manufacturer and the 'Godkendt til drikkevand' number.

The marking may be designed electronically for the purposes of digital reading. A digital marking must be immediately accessible and readable so it appears just as in print.