Short term leaching test for products in contact with drinking water – proposal of revised Pb leaching criteria for NKB test method

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Sammendrag

Utlekkingstest for produkter i kontakt med drikkevann – forslag til revidert grenseverdi for Pb i NKB testmetode.

Verdens helsorganisasjon (WHO) har publisert retningsgivende verdier for drikkevannskvalitet siden 1958. Siden den gang har den anbefalte maksimale konsentrasjonen i drikkevannet blitt redusert fra 100 µg/L til 10 µg/L. Det generelle anbefalingen fra WHO i dag er å holde konsentrasjonen av Pb så lav som mulig.

I Norge benyttes NKB produktregler for å bestemme utlekkingen av Pb fra metalliske produkter. Utlekkingskravet for Pb på 20 µg i NKB 4 ble publisert i 1986 og er basert på daværende helsekriterier og retningsgivende verdier. Det vil derfor være riktig å benytte et revidert utlekkingskrav på 5 µg for NKB 4, noe som allerede er innført i Sverige og Danmark. Den reviderte verdien for Pb kan også benyttes for NKB 9, NKB 13 og NKB 18 ved å benytte faktorer som tar hensyn til produktdimensjonen.

Abstract

The World Health Organization (WHO) has published guidelines for drinking water qualities through a number of publications since 1958. The guideline value for Pb has been decreased from 100 µg/L to 10 µg/L during this period. Today the general advice by WHO is to keep the Pb concentration in drinking water as low as possible.

In Norway, the hygienic performance of metallic products is usually tested according to NKB product rules (i.e. leaching performance). The health-based leaching limits (product performance criteria) for Pb (20 µg) in NKB 4 was published in 1986 and was based on the standards and guideline values issued in that period. It is therefore appropriate to use a revised leaching limit of 5 µg, when products are tested according to NKB 4. For products falling under the other NKB rules, the limit of 5 µg may be used as a basis along with size-based conversion factors. The suggested criterion for Pb is already implemented in Sweden and Denmark.

Introduction

Nordic product rules no 4 (NKB 4) is covering sanitary taps for hot and cold water supply systems. Regarding the assessment of hygienic properties, the development of a leaching test method started already in 1974 (Nielsen, 1974), and the NKB 4 rules was published in July 1986 by the Nordic committee on Building regulations. The hygienic performance (leaching performance) of the product is assessed by measuring the leaching of lead (Pb) and cadmium (Cd) according to a fixed sampling

scheme. The leaching limits (product performance criteria) are given in absolute quantites, i.e. the raw concentration measured in the leachate, given in µg/L, is multiplied with the volume of the product (exposure volume). In NKB 4 the criteria for Pb and Cd are 20 µg and 2 µg, respectively.

The Pb limit was based on the guideline value for drinking water quality of 50 µg/L (WHO, 1984) and on the provisional tolerable weekly intake (PTWI) limit of 3000 µg/person, equivalent to 50 µg/kg of body weight (WHO, 1972). The PTWI was originally established for adults and was not applicable for children and infants.

The present study shows how the existing NKB 4 leaching criterion is derived for Pb and the basis for the proposed revised limit.

Basis for the World Health Organisation (WHO) guideline value for Pb

The World Health Organization (WHO) has published guidelines for drinking water qualities through a number of publications since 1958. These guidelines can be summarised as follows:

- 1958: WHO International standards for drinking water first edition
- 1963: WHO International standards for drinking water second edition
- 1971: WHO International standards for drinking water third edition
- 1983-1984: Guidelines for drinking-water quality (first edition)
- 1993–1997: Guidelines for drinking-water quality (second edition)
- 1998-2002: Addenda to second edition
- 2004: Guidelines for drinking-water quality third edition
- 2008: Guidelines for drinking-water quality third edition (incorporating 1st and 2nd Addenda)
- 2011: Guidelines for drinking-water quality fourth edition

In 1986, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a provisional tolerable weekly intake (PTWI) of 25 µg/kg body weight (equivalent to 3.5 µg/kg of body weight per day) for infants and children. It was taken into account that Pb is a cumulative toxicant and that any increase in the body burden of Pb should be avoided (WHO, 1987). This PTWI was reconfirmed by JECFA in 1993 and extended to all age groups (WHO, 1993).

Furthermore, in 1993 the guideline value for Pb in drinking water was decreased from 50 µg/L to 10 µg/L (WHO, 1996). This value was derived from the assumption of a 50% allocation of the PTWI (25 µg/kg) to drinking-water for a 5 kg bottle-fed infant consuming 0.75 L of drinking water per day. As infants were considered to be the most sensitive subgroup of the population, this guideline value was thought to also be protective for other age groups.

However, based on dose–response analyses, JEFCA estimated that a PTWI of 25 µg/kg is associated with a decrease in at least 3 IQ points in children and an increase in systolic blood pressure in adults. JECFA therefore concluded that the PTWI could no longer be considered health protective, and it was withdrawn (WHO, 2011a; WHO, 2011b).

Because Pb exposure arises from a range of sources, of which water is frequently a minor one, and as it sometimes is difficult to achieve a concentration lower than 10 µg/L by central conditioning, such as phosphate dosing, the guideline value is maintained at 10 µg/L. Hence, the guideline value is designated as provisional on the basis of treatment performance and analytical achievability (WHO, 2011c). It can also be noted that it seems difficult to establish a threshold limit for Pb that ensures no negative effect on the intellectual and cognitive development of children. Thus, it is not possible to set a tolerable daily or weekly intake. The current advice is to lower the exposure to a minimum.

The Pb limit in the Drinking Water Directive (DWD) in Europe is 10 µg/L, as the parameters and parametric values in Annex I of the DWD are generally based on the WHO guidelines for drinking water quality. This was adopted by the EU and laid down in the revised DWD in 1998 (effective from 25 December 2013).

The limit for Pb in drinking water in Norway is 10 µg/L and is based on the implementation of DWD in Norwegian regulation (drikkevannsforskriften). This limit also applies for drinking water in the other Nordic countries due to their EU membership.

NKB product rules and the background for the leaching criteria

Product performance criteria and drinking water limit

The NKB leaching criteria are given in absolute quantities (µg). To compare with other leaching tests that operate in concentrations (e.g. µg/L) it is important to realise how the raw concentrations are re-calculated and converted (normalised). Moreover, it is important to distinguish between a product performance criteria (e.g. 20 µg for Pb in NKB 4) and the DWD criteria (e.g. 10 µg/L for Pb). The former is placed directly on the product by a fixed test method and the latter is serving as a function based criteria for the building, i.e. the building or the work shall deliver drinking water safe for the health and the water consumed from its delivery points should be in compliance with DWD.

However, all performance criteria in leaching tests for hygienic purposes are normally derived from this function based criteria. The challenge is that the derivation and normalisation are conducted differently in different test procedures (e.g. NSF 61 - section 4, AS/NZS 4020 etc.) due to different assumptions applied in the methods based on the dump and fill principle (batch test). The main reasons for different assumptions are that the Pb concentration measured at the consumers tap are caused by sources like the raw water, treatment processes and the product surfaces that come in water contact. In addition, the various products used in the water supply and in the internal distribution (domestic installation and service line) have different surface areas in contact with the water and obviously contribute differently to the leached amount. A product compliance leaching test needs to address these aspects, both by the test principle and by the consecutive normalisation process. From a scientific view, this may not be possible to achieve for all products by one single test method.

Relation between product performance and the performance criteria

The different NKB product rules are specified in table 1, including the respective criteria.

Although there are different rules, the same leaching method are used for all. Details of the leaching method are described elsewhere (Engelsen and Slåttsveen, 2010). For leaching tests in general, the raw concentrations (measured directly in the leachate) need to be converted into a value (product performance) assessable against certain criteria. The conversion of the raw concentration to a specific value for the product performance is the same for all NKB rules and is conducted according to Eq. 1:

$$C_{leached} = C_{raw} \times V_{product} \quad (1)$$

where,

$C_{leached}$ = product performance (i.e. leaching performance) representing the total quantity of metal leached (µg)

C_{raw} = raw concentration measured in the leaching water (µg/L)

$V_{product}$ = volume of product filled to its capacity (L)

$C_{leached}$ represents the leaching performance of a product, which is compared with the leaching criteria given in the NKB method. Note that for fittings and valves the leaching criteria are dependent on the product diameter as shown in table 1 and will be discussed in the following.

As mentioned earlier, different concepts or methods exist for converting the raw concentrations into specific performance values that can be compared with existing criteria. Note that the raw concentration values are never compared directly with the parametric criteria in DWD.

The existing product performance criteria for Pb in the NKB rules in Norway (table 1) are based on a PTWI of 3000 µg/person, i.e. a tolerable daily intake of 430 µg per person for which 450 µg per person was used. Furthermore, 10%

Test method	Published	Product groups	Diameter (mm)	Pb (µg)
NKB 4	1986	Sanitary taps	n.r.	20[1]
NKB 9	1989	Non-return valves	15	10
			20	15
			25	20
			32	100
			40	200
			50	500
NKB 13	1989	Shut-off valves	10	5
			15	10
			20	15
			25	20
			32	100
			40	200
			50	500
NKB 18	1990	Metallic fittings for PB and PEX tubes	15	5
			18	10
			22	15
			28	20
			35	50
			42	100
			54	200
			63	500

[1] For water fittings to hygienic use (bath, bidet and shower), 200 µg applies

Table 1. Existing product performance limits for Pb in NKB product rules. The products shall comply with the limits for water collected at day 9 and 10.

of this dose was assumed originating from the drinking water installation. Hence, 45 µg is the maximum contribution from the installation. The WHO guideline value for Pb was 50 µg/L in 1986 and is equivalent to a daily dose of 125 µg for a person consuming 2.5 L water per day. Given the fact that several potential sources will contribute to Pb in drinking water, 45 µg released from the drinking water installation was chosen as a collective limit. From this we can deduce that the NKB product limits are based on health criteria. Furthermore, this total amount (45 µg) needed to be shared by 3 groups, thus each allowed to release 15 µg:

1. Taps
2. Stop valves, check valves etc.
3. Pipes, fittings, water meters etc

Since sanitary taps are endpoint devices (located at the draw off point), only one limit can be used for this group of products. The final limit was increased from 15 µg to 20 µg. Hence, the performance value $C_{leached}$ in NKB 4 is

compared with the product performance criteria of 20 µg for Pb.

For valves and fittings the health based criteria of 15 µg was used as the starting point. This criteria was further normalised assuming the number of draw off points and the number of products used according to Eq. 2:

$$C_{limit\ product} = 15 \times n/a \quad (2)$$

where,

$C_{limit\ product}$ = the leached limit the product needs to comply with (µg), i.e. product performance criteria

n = number of draw off points the product distribute the water to

a = number of products upstream the draw off point

The values for n were calculated on the basis of the assumed pressure drop in the pipe depending on the diameter with an average flow per draw off point of 0.2 L/s. The values for a were calculated assuming that minimum one stop valve was present at the entrance of the installation and that one stop valve was installed after each change in dimension. In addition, the proportionality between the exposed surface area and the leached amount was also applied.

Revised NKB product performance criteria for Pb in Denmark and Sweden

Denmark

The building regulation in Denmark (byggeloven, 2010) states that the water supply shall be in compliance with the regulations for water supply and environmental protection. Furthermore, in the regulation on the water quality and the inspection of water supply, the drinking water quality parameters are specified (BEK 802, 2016).

Regarding products in contact with drinking water, the building regulation states that these products are subject to approval (BR15, 2015). A new regulation has recently come into force regarding approval and certification of the hygienic properties of products in contact with drinking water (BEK 1007, 2016). For marketing and sale of these products, BEK 1007 requires documentation and one of the following options may be accepted; the Danish GDV (Godkendt til Drikkevand) approval, the Swedish type approval, certificate according to the German scheme or approval according to the Dutch scheme.

In the Danish GDV, the main product performance criteria regarding Pb leaching is 5 µg when the product made of metallic materials is tested according to the NKB 4 method (GDV, (BEK 1007, 2016; GDV, 2015). The regulation applies to factory-made building products used in the internal distribution system. From this it follows that 5 µg also applies to products that in principle are covered by other NKB rules than NKB 4 shown in Table 1. Hence, a conversion of the 5 µg criterion is conducted for products falling under NKB 9, NKB 13 and NKB 18 based on the diameter, as indicated in BEK 1007. These new size-based criteria are shown in table 2. It can be noted that the new regulation also contain criteria for Ni and Cd of 80 µg and 2 µg, respectively.

Sweden

The National Board of Housing, Building and Planning (Boverket) publishes the Swedish building code (BBR, 2011a). It contains the mandatory provisions and general recommendations pursuant to the Planning and Building Act (2010:900) and the Planning and Building Ordinance (2011:338). Furthermore, the drinking water quality is given in the regulation issued by National Food Agency, Sweden (Livsmedelsverket, 2015).

In the Swedish building code of 2011 (BBR, 2011b) no product performance criteria was given with respect to leaching of Pb from products in contact with drinking water. However, through voluntary type approvals, NKB rules have been applied for Pb and Cd leaching and the product performance criteria of 20 µg and 2 µg have been used for Pb and Cd, respectively.

Already in 2012, a proposal for incorporation of a Pb leaching criteria in the general recommendations of the BBR was drafted. The

Product diameter (mm)	Product performance criteria (µg)
Fittings, distribution pipes etc.	
15	5.0
18	5.0
22	5.0
28	5.0
35	6.3
42	7.5
54	9.6
63	11.3
Valves etc.	
10	5
15	5
20	5
25	5
32	6.4
40	8
50	10
65	13
80	16
90	18
100	20

Table 2. Product performance criteria for fittings, distribution pipes and valves regarding leaching of Pb (GDV, 2015).

intention was to have the new criteria effective from 1st of July 2013 with a transition time of 3 years, i.e. 1st of July 2016. The chosen implementation time was also roughly in line with the transition in Denmark at that time. However, for various reasons the new criteria for Pb became effective from 2014. The new Pb leaching criteria was 5 µg tested according to NKB 4 or 5 µg/L tested according to SS-EN 15664 and it was incorporated in the general recommendation of the BBR 21. It is important to emphasise that the former method is a product test, whereas the latter is a test performed on the metallic material used in the product. In addition, the general recommendation also opens for other test methods as long as it fulfils the given leaching criteria. The new criteria becomes effective from 1st of July 2017 and is covering drinking water taps (devices used at draw off points).

The purpose of the new criteria is to reduce the risk of neurotoxicity for infants, children and pregnant women. According to the European Food Safety Agency and the Scientific Committee on Health and Environmental Risks, this vulnerable groups may be subjected to increased health risk at levels even lower than 10 µg/L of Pb in the drinking water (DWD limit) (Boverket, 2014).

Furthermore, the reasons for recommending NKB 4 and the criterion of 5 µg were based on the previous market surveillance in Sweden where around 66 % of the tested products (n =

Product diameter (DN) (mm)	Conversion factor	Product performance criteria (µg)
Fittings	DN_x/DN_{28}	
15	0.54	2.7
18	0.64	3.2
22	0.78	3.9
28	1.0	5.0
Valves	DN_x/DN_{25}	
10	0.4	2.0
15	0.6	3.0
20	0.8	4.0
25	1.0	5.0

Table 3. Product performance criteria for fittings and valves regarding leaching of Pb (SP Certifering, 2016).

120) complied with the new criteria and the fact that the same criteria has been incorporated in the Danish regulation shown above.

According to the Swedish certification bodies, they will apply the criteria for products used in the whole internal distribution system (Fredriksson, 2016). Furthermore, a conversion of the 5 µg limit is conducted for valves and fittings with different diameters. The size-based new criteria for these types of products are shown in table 3. The conversion factor is calculated by simply considering the ratio between the product diameters (DN_x/DN_{28} and DN_x/DN_{25}), as calculated in Table 3. This factor is multiplied with 5 µg.

Recommendation for Norway

Existing regulation and practice

The technical regulation in Norway (Byggteknisk forskrift 2010 – TEK 10) is laid down by the Ministry of Local Government and Regional Development on 23 March 2010 pursuant to the Act of 27 June 2008 No. 71 relating to planning and the processing of building applications (Planning and Building Act). The provisions implement Directive 89/106/EEC (Construction Products Directive (CPD)), Directive 95/16/EC (Lifts Directive) and Directive 2006/42/EC (Machinery Directive). From 1 July 2013, CPD was replaced with Construction Products Regulation (CPR) (Regulation 305/2011/EU). Under the provisions of CPR, it become mandatory for manufacturers to apply for CE marking to any of their products which are covered by a harmonised technical specification.

The Norwegian regulation on conditions for the marketing of construction products (Forskrift om omsetning og dokumentasjon av produkter til byggverk – DOK) has been effective from 1 January 2014, and is part of the implementation of the CPR in Norwegian law. The regulation requires assessment and verification of product performance which is relevant for the basic work requirements of construction works. It follows from DOK that it is mandatory to provide product documentation that ensures that the product fulfils the CPR basic work requirements, even for products that are not going to be CE-marked.

The Norwegian building code (TEK 10) does not provide product performance criteria for Pb leaching. The advisory part of the regulation refers to NKB 4 as an example of product documentation that can be used. Thus, in Norway the Pb and Cd leaching criteria of 20 µg and 2 µg, respectively, are applied in the approval and certification for marketing and actual use of the products falling under these rules.

Proposal for revised leaching criteria

The original criteria in the NKB rules are health-based as shown above. However, the basis for the Pb criteria are a guideline value of 50 µg/L and a PTWI of 50 µg/kg. It was also shown above that JEFCA and WHO in the period of 1986-1993 recommended the PTWI and the drinking water limit for Pb to be 25 µg/kg and 10 µg/L, respectively. Furthermore, the PTWI was later considered not to be health protective and was withdrawn. The WHO guideline value has been kept at 10 µg/L but is designated as provisional.

Hence, it is relevant to revise the product performance criteria given in Table 1. This has recently been conducted in Sweden and Denmark and the product performance criteria of 5 µg of leached Pb is applied when the NKB test is used. These changes have been incorporated into their building regulations.

It is therefore recommended that when the NKB test method is used, the product performance criterion of 5 µg released Pb is applied to products falling under NKB 4 without conversion factor. It is further recommended that the same criterion is valid for products falling under the other NKB rules and other related products made of brass (e.g. threaded fittings) that are used in the internal distribution (including service line and the domestic installation). The conversion factors used in Sweden may be applied.

Furthermore, if reference to NKB is to be given in the Norwegian building regulation, it is recommended that the proposed criterion is incorporated in the guideline by specifying the maximum leaching of 5 µg Pb.

Impact and transition period

It is expected that approximately 10-20 % of the existing products tested in Norway according to NKB method would not comply with the criteria of 5 µg for Pb. According to the previous market surveillance conducted by Boverket in Sweden, around 66% of the tested products complied with the new criteria (Boverket, 2014). It can also be noted that the same products are to a large extent placed on the Nordic market. This indicate that the manufacturers, sales distributors etc. operating on the Norwegian market, already have started the process for having the products approved according to the new criteria since the majority also operate on the market in Sweden and Denmark. It can further be noted that the transition periods, in both Denmark and Sweden, have been prolonged due to the time consuming measures necessary to be taken in the manufacturing process.

Conclusion

The World Health Organization (WHO) has published guidelines for drinking water qualities through a number of publications since 1958. The guideline value for Pb has been decreased from 100 µg/L to 10 µg/L. Today the general advice by WHO is to keep the Pb concentration in drinking water as low as possible.

In NKB product rules the health-based main leaching criteria have been derived on old standards and guideline values. It is therefore appropriate to use a revised product performance criterion of 5 µg for Pb, when products are tested according to NKB 4. For products falling under the other NKB rules, the same limit of 5 µg may be used along with size-based conversion factor.

References

BBR, 2011a. BFS 2011:6 ändrad t.o.m. BFS 2015:3. The National Board of Housing, Building and Planning (Boverket).

BBR, 2011b. BFS 2011:6. BBR 18: 27. April 2011. The National Board of Housing, Building and Planning (Boverket).

BEK, 1007. Executive Order No. 1007 on the placement on the market and sale of building components that come into contact with drinking water. Danish Transport and Construction Agency.

BEK 802, 2016. Bekendtgørelse om vandkvalitet og tilsyn med vandforsyningsanlæg. Ministry of Environment and Food of Denmark.

Boverket, 2014. Konsekvensutredning BBR 2014 - Ändring av Boverkets byggeregler (BBR). Boverket 20 Juni 2014.

BR15, 2015. Executive Order on the Publication of the Danish Building Regulations 2015. Danish Transport and Construction Agency.

Byggeloven, 2010. LBK 1185 af 14/10/2010 Bekendtgørelse af byggeloven. Danish Transport and Construction Agency.

Engelsen, C.J. and Slåttsveen T., 2010. Påvirkning av metalliske materialer på drikkevannet. Vann 02:2010.
Fredriksson, J., 2016. Skarp tolkning om bly i blandare. VVS-Forum Nr. 1 januari 2016.

GDV, 2015. Materialspecifikation – vejledning og skema om komponenter og materialer. Byggevarer: Fittings, fordelerrør, ventiler, o.l. af metal og plast/elastomere. Godkendt til drikkevand 22. maj 2015.

Livsmedelsverket, 2015. Livsmedelsverkets föreskrifter om dricksvatten (SLVFS 2001:30), 18. november 2015.

Nielsen, K., 1974. Drikkevandsoptagelse af cadmium og bly fra armaturer. SBI-Notat 36 (1974), Statens Byggforskningsinstitut (Danish Building Research Institute).

SP Certifering, 2016. Krav för typgodkännande av produkter i kontakt med dricksvatten. SP Sveriges Tekniska Forskningsinstitut, SP Certifering, Ver. 2016-03-17.

WHO, 1972. Evaluation of certain food additives and the contaminants mercury, lead and cadmium. Report no 505, Report series 501.

WHO, 1984. Guidelines for Drinking Water Quality, volume 1-2.

WHO, 1987. Evaluation of certain food additives and contaminants (Thirtieth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 751, 1987.

WHO, 1993. Evaluation of certain food additives and contaminants. (Forty-first report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 837, 1993.

WHO, 1996. Lead in Drinking-water. Background document for development of WHO Guidelines for Drinking-water Quality.

WHO, 2011a. Evaluation of certain food additives and contaminants. WHO Technical Report Series, No. 960.

WHO, 2011b. Safety evaluation of certain food additives and contaminants. WHO Food Additives Series, No. 64.

WHO, 2011c. Lead in Drinking-water Background document for development of WHO Guidelines for Drinking-water Quality.