POSITION PAPER on the Proposal for a revised Drinking Water Directive (DWD)\(^1\)

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Summary

The envisaged way forward as regards **materials in contact with drinking water** is totally inadequate. Instead of introducing a harmonised regulatory framework for such material based existing national schemes the Commission proposed to issue "*a standardisation mandate be under the Construction Products Regulation, to set requirements applicable to construction materials and products in contact with drinking water*". This disregards the fact that the CPR does not aim at harmonising performance requirements for construction products in Member States – its goal is to ensure performance declarations based on harmonised test methods, leaving it to national (building) regulations to determine the relevant protection levels.

Apart from that the Commission proposal ignores a long history of debate on this issue starting in the nineties. Among other, a proposal was developed by a "Regulators Group" in 2005 for an "EAS – The European acceptance scheme for construction products in contact with drinking water". Its basic assumptions and directions are still valid. After 6 years of work of this group the Commission discovered that the regulatory basis for the EAS was missing, i.e. that the Construction Products Directive (CPD, the predecessor of the CPR) was not an adequate basis for a harmonisation of rules.

It seems a mockery that after another 13 years the Commission arrived at the conclusion that now harmonisation can be achieved using the regulatory framework judged inadequate for this purpose at the time. Whilst standardisation is undoubtedly an excellent tool to provide test methods it is not the instrument to harmonise existing (or forthcoming) national legislation. It should be also noted that a previous mandate of the Commission (M/136) to provide harmonised specifications failed and had to be withdrawn.

Harmonisation of provisions for materials in contact with drinking water can only be achieved by harmonisation of the current national regulatory frameworks. One option is to include a provision in the revised DWD which obliges to Commission to elaborate regulatory provisions for the various materials in contact with drinking water to be inserted in Annexes to the DWD or to instruct the Commission to go for a separate piece of regulation following the example of materials in contact with food. In both cases a clear-cut time framework should be indicated (e.g. 2 years).

Whilst the Commission proposal includes a number of improvements regarding parameters covered and related thresholds, it is essential to point out that there may still be some gaps. Whilst stakeholders have indicated in the consultations the need to address so-called "emerging" pollutants or contaminants just a few substances have been added. It is suggested to instruct the Commission and Member States to conduct assessments specifically covering these substances (such as nanoparticles, pharmaceuticals or endocrine disrupters) and to take action where appropriate.
Materials in contact with drinking water (Article 10)

ANEC strongly disagrees with the proposed way forward regarding materials in contact with drinking water. It is suggested to delete the wording of the former article 10 of the Directive which placed an obligation on Member States to ensure that adequate materials are used ("to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive...").

Instead, provisions concerning a risk assessment "of the potential risks associated with the domestic distribution systems, and with the related products and materials" were introduced in Article 10. In addition, "the verification of whether the performance of construction products in contact with water intended for human consumption is adequate in relation to the essential characteristics linked to the basic requirement for construction works specified in point 3(e) of Annex I to Regulation (EU) No 305/2011²".

Finally, the Member States shall "take all necessary measures to ensure that the migration of substances or chemicals from construction products used in the preparation or distribution of water intended for human consumption does not, either directly or indirectly, endanger human health".

In fact, the new wording may be considered a more elaborate and refined version of the old one but does not really make any substantive difference. In both cases substantive performance requirements are missing – the Member States are in charge of taking all necessary measures at present and will be so in future.

In the "Explanatory Memorandum" to the proposal the Commission explains that evaluations, stakeholder consultations and impact assessments "found that Article 10 of the Directive concerning 'materials in contact with drinking water' leaves Member States too much flexibility in determining what 'necessary measures' are". In fact, in absence of harmonised regulatory provisions several Member States have in place (diverging) regulations in this area. It is further stated that "the need for harmonisation regarding materials and products in contact with drinking water was continuously pointed out by a range of stakeholders". ANEC was among the stakeholders making repeatedly the point that harmonised regulation (!) in this field is desperately needed. In fact, several stakeholders have called upon the Commission to come up with a

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² Construction Products Regulation (CPR)
regulatory framework in this area for decades! However, with the proposed changes the goal of harmonisation definitely cannot be achieved for the following reasons:

1) The CPR is not an adequate instrument to harmonise performance levels

The Commission further explains that "in parallel, a standardisation mandate be issued under the Construction Products Regulation, to set requirements applicable to construction materials and products in contact with drinking water". The Commission seems to believe that the preparation of harmonised standards will ensure that the harmonisation of current performance requirements in the MS. However, this is fundamentally wrong. Unlike other Directives or Regulations for products, the CPR does not aim to establish or to harmonise performance requirements for (construction) products. Member States retain their competence to set technical requirements for buildings and the associated performance of construction products. Such requirements shall be based on performance characteristics measured or calculated in accordance with harmonized European standards or European Assessment Documents ("harmonised technical specifications"), which provide a technical basis to assess the performance of construction products.

In other words, the CPR aims to make available performance declarations using harmonised test methods allowing MS to choose the performance levels deemed adequate (for specific purposes). Consequently, the CE mark does not indicate a specific performance level – it just indicates that all essential characteristics of the construction product laid down in harmonised technical specification have been determined and declared. This may also include performance classes or thresholds (minimum requirements acceptable throughout Europe). However, the main aim is to provide information needed to judge whether the product meets all relevant regulatory provisions in any Member State. Consequently, a manufacturer does not need to declare e.g. the content or emissions of chemicals if there is no national legislation, which sets requirements for these substances. In such cases, the manufacturer may make use of the so-called “No Performance Determined” (NPD) option, unless a declaration is required based on a decision of the Commission by means of delegated acts in accordance with Article 3(3) of the CPR.

In this context it should be noted that the Commission is currently preparing a classification system of performance of construction products in relation to their emissions of dangerous substances into indoor air. Also in this case, the idea is not to have a harmonisation of the performance requirements throughout Europe. Rather it is to allow Member States (who wish to have rules for this) to choose from the offered classes. Hence, the classification is supposed to reflect current EU Member States rules (where they exist). Also, here the so-called "harmonisation" does NOT prevent market fragmentation. Apart from that it should be noted that most Member States do not have regulations for indoor emission. For them this future classification scheme will be highly irrelevant unless any organisation wishes to voluntarily make use of the information provided. It does not provide any additional protection for European citizens living in
countries other than the ones which have regulation in place. It is amazing to see which enormous efforts are being made to develop such a system of extremely limited use.

2) Previous efforts to establish a European Acceptance Scheme for materials in contact with drinking water were ignored

Already in 1999 (after several years of debate), a "Regulators Group" for Construction Products in contact with drinking water (RG-CPDW) was established by the European Commission with the task of developing a common European approach to the assessment and certification of CPDW. Their work resulted in the publication of the “EAS – The European acceptance scheme for construction products in contact with drinking water” in 2005\(^3\) based on already existing approval systems for such products in several Member States (i.e. in France, Germany, Netherlands and United Kingdom). It was envisaged that this EAS would replace these existing national regulatory schemes.

However, although the EAS proposal received broad support from various stakeholders (authorities, industry, drinking water service operators) the Commission did not pursue the case further. After around 10 years (!) of discussion, and 6 years of work of the Regulators Group the Commission discovered that the regulatory basis for the EAS was missing, i.e. that the Construction Products Directive (CPD, the predecessor of the CPR) was not an adequate basis for a harmonisation of rules. In addition, the Commission claimed that the necessary resources for making the system operational were not available. Consequently, the Commission withdrew its support for the EAS.

It is an unprecedented mockery that after another 13 years the Commission has arrived at the conclusion that the ball should be played back to the construction sector regulation – found to be an entirely inadequate framework for this purpose in the past!

It may be of interest that the EAS proposal itself made suggestions on how to overcome the impasse. It was suggested to amend the DWD Article 10 in the following way:

- "Add a paragraph to Article 10 (Quality assurance of treatment, equipment and materials) stating the requirement for Member States to use materials and products in new installations that confirm with the requirements (acceptance levels) set out in a new Annex IV to the DWD related to the migration of substances into water intended for human consumption (the EAS Positive List, the EAS Composition List and the EAS approved Constituents List) and enhancement of microbial growth.
- Add a paragraph to Article 10 to make it possible to issue Community guidelines for the testing regime (to be drawn in accordance with the committee procedure laid down in Article 12 of the Directive).
- Add a paragraph to Article 11 of the Directive (Review of Annexes) with the obligation for the Commission to adapt Annex IV to scientific and technical

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progress and to requests to add new substances, compositions and/or constituents to the lists. Such changes shall be adopted in accordance with the committee procedure laid down in Article 12. The scientific input could be delivered by national toxicologists under the umbrella of the Scientific Committee on Health and Environment Risks”.

These ideas may need some further elaboration and adaptation but are still valid in principle. Article 10 (or another article) could simply contain a provision that the Commission shall establish an approval system for materials in contact with drinking water based on the systems already available in some Member States.

It should be also noted that efforts are being made to harmonise the existing systems (“4-MS initiative”), i.e. that the Commission could build on systems which have at least partially been harmonised between the most relevant Member States.

Finally, it needs to be stressed that not all materials used in the context of drinking water supply are construction products, so the scope needs to be broader than the scope of the CPR. This needs further investigation and discussion.

As an alternative one could envisage, of course, a separate piece of legislation for this type of materials in analogy to the regulatory framework for materials in contact with food. In such case ANEC considers it essential that the DWD contains a clear-cut instruction for the Commission to come up with a legislative proposal within 2 years!

Finally, it should be highlighted that the WHO Regional Office for Europe in its Commission funded project supporting the revision of the DWD (see below) supported "ongoing efforts towards introducing an EU-wide approval scheme for materials in contact with drinking-water". Unfortunately, this recommendation was ignored by the Commission.

3) Standards are no suitable instruments for an approval system

Undoubtedly standards are an important instrument e.g. to provide test methods complementing legal provisions. However, they are not the best instrument on which a harmonised European framework for drinking water materials can be based. First, standards cannot make existing national regulations redundant. Second, they are no substitutes for missing harmonised European regulations. Third, this holds true in particular, where approval systems including positive lists of materials and/or ingredients are necessary. The European standardisation system does not have the authority for such approvals which are typically based on judgement of data provided by industry by independent scientific committees or bodies.

As an example, materials in contact with food made of plastics need an authorisation of ingredients (such as monomers or additives) based on an opinion by an EFSA scientific
committee. In fact, for a European approval system for materials in contact with drinking water a similar system is needed.

Finally, it must be stated that previous efforts develop European harmonised standards in this area failed with the consequence that a Mandate by the Commission adopted in 2010 (M136) was withdrawn.

As National Regulations will always take precedence over Standards, individual member states will still have the discretion to finalise arrangements at National level which might present an obstacle to the internal market due to multiple testing and approval at the national level.

It is quite obvious that it would mean to put the cart before the horse to launch a standardisation request to the European Standardisation Bodies in absence of a regulatory harmonisation.

**Conclusion on materials in contact with drinking water**

The revision of the DWD is an opportunity to harmonise rules for materials in contact with drinking water. This cannot be achieved on the basis of a standardisation request to prepare harmonised standards. It can only be achieved by harmonisation of the current national regulatory frameworks. One option is to include a provision in the revised DWD which obliges to Commission to elaborate regulatory provisions for the various materials in contact with drinking water to be inserted in Annexes to the DWD or to instruct the Commission to go for a separate piece of regulation following the example of materials in contact with food. In both cases a clear-cut time framework should be indicated (e.g. 2 years).

**Emerging pollutants (Articles 8, 10, 18, Annex I)**

The explanatory memorandum states "The consultations clearly supported updating and revising the list of parameters. The public consultation overwhelmingly favoured the list including endocrine disrupting compounds, substances used in consumer products and pharmaceuticals, whereas many technical experts disagreed". It is acknowledged that the DWD parameter list is based on the most recent WHO Guidelines for drinking-water quality and a special project commissioned to the WHO Regional Office for Europe in support to the revision of Annex I of the DWD ("Drinking Water Parameter Cooperation Project", September 2017\(^5\)). In the latter the following key massage can be found: "Several emerging contaminants and groups of contaminants were considered but not recommended for inclusion in Annex I Part B because the data show that concern for health is highly unlikely. Contaminants considered were: asbestos, glass fibres,

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nanoparticles, chlorophenols, N-nitrosodimethylamine, thallium, calcium/magnesium, personal care products, pharmaceuticals and endocrine disrupting compounds (EDCs)”. ANEC trusts that the assessments by WHO have been thoroughly made and concludes that indeed there is no need to include thresholds for these substances at present. However, we also believe that this issue cannot be ticked off until the next revision of the Directive which may occur in 20 years from now (just as the current revision comes 20 years after adoption of the previous version). Whilst the Commission is obliged at least every five years to review Annex I in the light of scientific and technical progress (Article 18) and is entitled to change the Annexes of the Directive using Delegated Acts (previously this was based on a Comitology procedure) it gives a large room for manoeuvre for the Commission does not necessarily mean that changes will be made.

It may be useful to give the Commission some instructions on how these reviews should be made and what needs to be included. For instance, one could require that the Commission presents a report every 5 years addressing, in particular, emerging pollutants such as relevant pharmaceuticals, nanoparticles, endocrine disrupters, etc. including measured concentrations from across Europe and relevant health thresholds demonstrating that action is - or is not - required.

From this follows that the obligation to look at emerging pollutants should be extended to Member States when conducting hazard assessments of bodies of water used for the abstraction of water intended for human consumption (Article 8) or performing a domestic distribution risk assessment (Article 10).

**Improved water quality for consumer trust**

In addition to the above there is clearly a need to discourage plastics use whilst improving the quality of tap water. As long as high level of safety cannot be ensured, consumers cannot be pushed to drink tap water rather than bottled, (fewer bottles saves energy too), especially in countries or locations where drinking tap water has traditionally been inadvisable or discouraged, if consumers perceive the taste or odour to be unpleasant.

ANEC believes the scope of the Directive should be broadened to cover quality of tap water including also organoleptic parameters (taste, odour, colour).

It is thus imperative that the revision brings about a real improvement for drinking water quality that also allows consumers to safely reduce their consumption of bottled water.

ENDS.
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About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 34 countries.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.

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