

EFCC reply to EC consultation on Drinking water – Adding or removing starting substances, compositions or constituents from the European positive lists

Brussels, 10 November 2023

Directive (EU) No 2020/2184 on the quality of water intended for human consumption (DWD) includes minimum hygiene requirements for materials that come into contact with water intended for human consumption.

On 16 October the European Commission launched a consultation on the delegated act that supplements the Directive and that lays down the procedure for amending the European positive list ('EUPL') of starting substances, compositions or constituents to be used in the manufacture of materials or products intended to be in contact with drinking water.

EFCC is actively involved in supporting the establishment of the European positive lists of starting substances, compositions and constituents via the study launched by ECHA in April 2023.

In its reply to this public consultation, EFCC would like to take the opportunity to share its comments and concerns related to the establishment of the positive lists based on the experiences and exchanges triggered by the above-mentioned study, as well as the experience gained from the application of European national and non-European drinking water regulations.

EFCC is concerned that

- ***the increased data collection and analytical requirements needed for the positive listing will put a significant burden on the manufacturers. Consequently, downstream user formulators fear that the number of applicants will be very limited which leads to a lack of substances available for drinking water materials leading to a significant reduction of construction products available for drinking water installations;***
- ***neither the DWD nor the implementing act provide sufficient protection for the shared data and confidential business information for downstream user formulators;***
- ***the positive listing of polymers under the DWD will be introduced before the revised REACH will have defined the rules on polymers creating legal uncertainty for the construction chemicals industry and other market players;***

EFCC requests the European Commission to consider the above listed concerns before adopting the delegated act and reduce the requirements that put significant burden on applicants, refrain from the positive listing of polymers under the DWD before the revised REACH will have defined the rules on polymers, as well as limit the publicly available information linked to the positive listing to protect the intellectual property of the European economic operators.

Background

The revised Drinking Water Directive requires starting substances, compositions or constituents that are used to manufacture a material that comes into contact with drinking water between the water source and the tap to be included in one of four European positive lists.

In accordance with the requirements set in the DWD (see recital 22), for the inclusion of a starting substance, composition or constituent in the European positive lists, a risk assessment of the starting substance, composition or constituent itself, as well as relevant impurities and foreseeable reaction and degradation products in the intended use, should be required to be submitted to ECHA. The risk assessment to be carried out by the applicant should cover health risks arising from the potential migration under worst foreseeable conditions of use and from the toxicity.

Concerns

Increased data collection and analytical requirements

For the positive listing the dossier submitters have to carry out a risk assessment of the starting substance, composition or constituent itself, as well as relevant impurities and foreseeable reaction and degradation products in the intended use, migration tests under worst foreseeable conditions of use and from the toxicity.

The collection of the necessary data and to carry out the required analytical requirements for a complex product takes time and is costly. Therefore, puts a significant burden on the applicants, including downstream users who provide the information on the migration testing. Estimated based on the recommendations in the guidance document, merely the analytical data collection requirement can easily reach costs of over 100.000€ for the applicant.

Considering the high costs for the positive listing and that the market for materials in contact with drinking water is a niche market, downstream user formulators expect that the number of applicants will be very limited which leads to a lack of substances available for drinking water materials after 2025. Consequently, this would lead to a reduction of construction products available for drinking water installations which could put the distribution of the drinking water to European consumers via the pipe systems at risk.

To decrease the burden of the dossier submitters, we suggest requiring them to provide only analytical data and to assess only hazardous migrating constituents (> 0,1%) that had an impact on the final classification and labelling of the substance according to CLP and REACH, and the reference substances of the migrating constituents are stable and could be isolated. In addition to that, the testing requirements should not only depend on the migration rate, but also on the marketed volumes.

Confidentiality

Article 10 of the delegated regulation specifies what kind of information submitted to ECHA shall be considered as confidential and may not be made publicly available.

EFCC is concerned that almost the full set of information that has to be submitted will be publicly available and no study and study results can be kept confidential.

As formulators, we are particularly concerned about disclosing the submitted information on polymers, as the publication of some specific information would indirectly lead to the disclosure of our recipes that are confidential business information.

Polymers used as concrete admixtures

In recital 6 and Article 3 (4) of the delegated act it is stated that *"in the case of a polymer with a high molecular weight which is used as an additive in an organic material, the application should be on the monomer, since the monomer is expected to be more reactive and thus more relevant for human health. Furthermore, assessing each and every polymer manufactured from such monomer would not be proportionate. ...In the case of an admixture for cementitious material, the application should be for the polymer since the polymer may be composed of multiple monomers whose interaction can only be assessed if the application is for the polymer."*

The polymers mentioned above have been used for more than 30 years in admixtures in cementitious materials as mortars and concretes in contact with drinking water and without putting consumers' safety at risk.

EFCC thinks that the safe use of these polymers is already ensured by the provisions of DWD and its implementing and delegating acts by the assessment of the monomers. Therefore, EFCC considers that it would not be proportionate to assess each polymer or each and every polymer used as an additive. EFCC suggests that polymers used in admixtures should be assessed by their monomers.

The positive listing of polymers under the DWD would prejudice the still ongoing discussions on registration of polymers under REACH and set a precedent, where REACH should be the leading regulation. Therefore, listing of monomers should remain the only requirement on polymers at least until polymer registration requirements under REACH has been defined.

Recommendations

Based on the concerns described above, EFCC requests the European Commission to reduce the increased data collection and analytical requirements that are expected to be required for the positive listing and that put significant burden on applicants. EFCC suggests focussing only on the hazardous migrating constituents.

EFCC strongly recommends that the positive listing of polymers under the DWD should be introduced only after the revised REACH has already defined the rules on polymers to avoid creating legal uncertainty for the construction chemicals industry and other market players.

EFCC considers that neither the DWD nor this implementing act provide sufficient protection for the shared data and confidential business information. Therefore, EFCC

invites the Commission to limit the publicly available information linked to the positive listing to protect the intellectual property of the European economic operators.

EFCC believes that if the currently planned requirements are not reduced, the number of applicants will be very limited which would lead to a lack of substances available for drinking water materials after 2025. Consequently, this would lead to a significant reduction of construction products available for drinking water installations.

EFCC, based in Brussels, is the European Federation for Construction Chemicals and is the European Association representing over 70% of the companies and national federations working in the Construction Chemicals Industry in Europe. The European construction chemicals market was valued at €15 billion in 2020. Construction chemicals are mainly used for speeding up the work in construction projects that are under development or in new projects to improve the overall sustainability of the building or construction.

Construction Chemicals are all those chemicals that are used in the construction industry, from admixtures for concrete to mortar systems, flooring applications, sealants & adhesives, waterproofing systems, anticorrosion agents and many other additives & solutions aimed at improving performance, durability, energy efficiency and the overall sustainability of construction and buildings.

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