


Food Contact Additives, a sector group of Cefic, and Plastics Europe support the implementation of Article 11 of Drinking Water Directive ((EU) 2020/2184) initiated by the European Commission. At the same time, we would like to ask the European Commission, ECHA and the Member States to consider the complexity of the issues, and legal certainty and enforceability of this Article 11 implementation package.


On the implementation regarding substances, we recommend:

1. Cost- and data-sharing mechanism in the application for EUPL




The envisaged timeline for adoption of the six legislative proposals appears very ambitious and challenging, given the complexity of establishing the EU Positive List ('EUPL') and the need for clarity on technical issues. We are particularly concerned that a hasty adoption of the current EUPL would lead to unintentional consequences and uncertainties for authorities and industry.

2. Coherence with other legislation on data requirements (One Substance, One Assessment)




We welcome the alignment of toxicological requirements with REACH Regulation, but also noted the divergence from the data set currently required for the food contact material legislation. In the spirit of the upcoming 'One Substance, One Assessment' approach, at this point of time, we request harmonised information requirements and make conference with the current data requirements of the FCM Legislations.

3. Additional mechanisms to improve toxicological requirements




We welcome the possibility of using Qualitative or Quantitative structure-activity relationship ((Q)SAR) and read-across approaches for non-intentionally added species. To complement this approach, we propose having those methods being accepted for substances in applications, as well as setting a specific mechanism where applicants have the option of discussing a testing proposal before starting with a given new toxicological study.

4. Clarity on the entries and the expiry dates in EUPL



We noted several duplicated entries on the EUPL and ask for clarification on the indicated conditions of use and expiry dates. We also request to amend the draft legal text to allow both competent authorities and economic operators to apply for for existing group entries on EUPL, provided that they can adequately justify that the toxicological profile of the group of substances is sufficiently similar to one another, consequently reducing the need for animal testing.

5. Safeguard measures and flexibility to the application process



It should be noted that there might be several cases in which applicants might not be able to provide the complete dataset requested by law in a short timeframe, due to the expected number of substances requiring additional testing and the anticipated limited capacity of the laboratories and testing houses. Therefore, we ask policy-makers to consider measures which can remedy this issue and give flexibility to the application process.

We would be happy to further contribute to discussions on the legislative proposals and offer our industry insights and expertise provided by member companies of FCA and Plastics Europe.

Please read our comprehensive proposals submitted to the public consultations in November 2023:

- https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13894-Drinking-water-methodologies-for-testing-accepting-substances-compositions-constituents-in-European-positive-lists/F3443679_en
- https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13896-Drinking-water-establishing-the-European-positive-lists-of-starting-substances-compositions-and-constituents/F3443681_en
- https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13712-Drinking-water-Adding-or-removing-starting-substances-compositions-or-constituents-from-the-European-positive-lists/F3443460_en