23 June 2023

FCA and PlasticsEurope's comments on the draft acts implementing of Article 11 Drinking Water Directive

Food Contact Additives (FCA), a sector group of Cefic, and PlasticsEurope, welcome the opportunity to provide written comments to the European Commission Expert Group under the Drinking Water Directive (DWD). Since we focus on substances to be used in materials coming into contact with drinking water, our comments primarily address the legislative proposals concerning starting substances, i.e., 1. Implementing Act (IA), 2. IA and 3 Delegated Act (DA)[1].

We support the implementation of Article 11 on the establishment of an EU harmonised positive list for starting substances, compositions or constituents to be authorised for use in the manufacture of materials or products which come into contact with water intended for human consumption and would like to provide out thoughts and suggestions below to make the implementation workable.

Table of contents and summary:

[1] https://circabc.europa.eu/ui/group/65764c73-4a57-45dc-8199-473014cf65bf/library/b38d7ed3-0efa-441a-b992-7386959d6196

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- Definitions
  Among the legal texts, we found ambiguous definitions and inconsistencies with one another, as well as with other legislation, which can potentially lead to legal uncertainty. We propose clearly defining the concepts once, the first time they are used to avoid duplication and avoid repeating definitions already present in the Drinking Water Directive.

- Closing remarks

Timeline for adoption of the legislative proposals

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. Particularly, the intended adoption of the EUPL in 2. IA by January 2024, preponed by one year from the originally planned January 2025, is considered too early. In our view, there are still many uncertainties and open questions on the EUPL draft, given that the draft list is still to be cleaned up and verified, and that several of the elements will be clarified in the upcoming implementation guidelines and this study on the establishment of the first EUPL, which are still to be developed.

We are aware of the European Commission's intention to set all the relevant implementing acts and delegated acts for the same date for easier and more practical implementation. We do however believe that an hasty adoption of the current EUPL will lead to unintentional consequences and uncertainties for authorities and industry.

Comments on the contents of the legislative proposal

(1) Coherence with other legislation on the assessment of substances

The draft acts require different data package requirements for substances used in the production of materials coming into contact with drinking water, compared to the current requirements requested by the European Food Safety Authority (EFSA) for the assessment of substances to be used in food

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contact materials (FCM)[2]. This will lead to different application dossiers to be submitted to European Chemicals Agency (ECHA) for drinking water (DW) substances compared to the ones to be submitted to EFSA for FCM substances. We would like to highlight that such approach is not in line with the EU Commission's intention to implement the 'One Substance, One Assessment' concept[3], which is currently under preparation by the Commission's services.

(2) <u>EUPL and procedures of assessment of EUPL</u>

The following are our findings of the draft EUPL in 2. IA Annex and our comments on them.

(i) Expiry dates in the draft EUPL (2. IA Annex)

- There is a significant number of substances to be re-evaluated in short periods. We wonder if there is enough capacity in authorities, such as Member States and ECHA Committee for Risk Assessment (RAC), testing laboratories and applicants. Depending on the number of new tests needed, arising e.g. from the additional data package requirements compared to the current EFSA requirements, 3 years seems to be a very short timeframe. There could also be a situation that testing laboratories are overloaded and are not able to carry out services in a timely manner. In addition to that, it should be considered that arising from the expiry date of current 'group entries', multiple individual applications might need to be submitted and assessed one by one.

- Currently there are data and studies available from the requirements under e.g. the REACH Regulation or the Food Contact Materials legislation. However, not all the requested data required for all the substances listed up in the draft EUPL may be readily available. This could result in increased burden on applicants, testing laboratories and the competent authorities. Thus, our assumption is that, if a toxicological test is accepted in accordance with REACH requirements, it would be acceptable for re-assessment for drinking water; for example, toxicology tests under OECD Guidelines have been found valid under the REACH regime.

- Thus, we would like to ask the Commission to include a provision in the main text of 2. IA and/or 3. DA to ensure that in case of such situation, the substance to be re-assessed is maintained on the list on an interim basis until the assessment has been completed. We would suggest that possible solutions be drawn from other relevant and similar legislations, where also a review/ assessment and inclusion of certain substances in an EU positive list was required within a very short timeframe. For example, Article 6 (5) of Food Contact Materials Regulation for Plastics Implementation Measures (PIM) (Regulation (EU) 10/2011) and

[2] Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials | EFSA (europa.eu)

[3] EFSA-ECHA-position-paper-OSOA.pdf (europa.eu)

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preamble (28) of Flavouring Substances Regulation (EU) 872/2012 could be good examples to solve the said issue.

- At the same time, an outreach and notification system targeted at potential applicants, should be envisaged, in order to inform relevant stakeholders when the validity of a substance is reaching the end of the expiry date in the legal text.

- It is unclear how long the substance is permitted to stay in the positive list after a positive re-assessment by ECHA's RAC and the Commission, and we would welcome further clarification.

(ii) Timeline of procedures in 2. IA and 3. DA

- The accordance check (Article 5, 3. DA) provides a very short period of time to bring an application into accordance, considering that additional tests might be necessary and lack of capacity of test houses might delay this process. We therefore propose inserting a provision to address the issue of an applicant not being able to bring the application into accordance in time through no fault of his own. This could be solved by obliging the applicant to inform ECHA of the reasons for the delay and to bring the application into accordance without undue delay.

- From experience with the current legislation at the national level, 'formulation review' (3. DA, and 4. IA Annex) of information over impurities for all substances used during the manufacture is very challenging and time consuming.

- Contents of the application are very detailed (3. DA Annex) and practice has shown that the requested information for the assessment is driven by the manufacturing technologies and synthesis of a substance of different producers. This could result in the authorisation being restrictive only to a specific applicant in the market. In addition, in some cases, the authorised levels mentioned in the draft EUPL are very low, which would increase the uncertainty in the application and implementation of the Directive.

- Ongoing studies regarding Arvin 8 have not been taken into account in 2. IA Annex IV, Table 4. We would request that once results and conclusions are ready the values in Table 4 are automatically updated.

- For some of the substances, calibrants, analytical methods, etc. might not be readily available and will require time to develop them.

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(iii) Inconsistence with the WHO guidelines[4]

- In our view, the allocations factor (specific migration limit (SML) vs maximum tolerable concentration (MTC)) used to derive the migration limit should be aligned with the one suggested by World Health Organization (WHO). The 4 MSi[5] and the former European Acceptance Scheme (EAS) derive the MTC values on the basis of the SML divided by 20 from the positive list of Food Contact Materials PIM Regulation. The WHO estimates the normal allocation of the total daily intake of drinking water to be 20%. The previous allocation factor of 20 was found to be too conservative (confirmed in the latest edition[6]) and the MTC values should be derived by dividing the SML by 10. Therefore, we would like to suggest that substances with a fixed SML (in the EU or national regulations) should be divided by a factor of 10 for inclusion in the EUPL for materials in contact with drinking water. As can be seen in the latest edition of the WHO guidelines, the 10% allocation factor is already outdated according to the latest scientific developments.

- Table 1 on Annex V of the Drinking Water Directive, the MTCtap is defined as "*MTCtap: Maximum tolerable concentration at the tap (either derived from the opinion of ECHA for the purposes of inclusion of the substance in the European positive list, or based on a specific migration limit set in Commission Regulation (EU) No 10/2011 and considering a 10 % allocation factor and water consumption of 2 litres per day*", hence it is understood that the MTCtap could be derived from ECHA's RAC opinion for the purpose of inclusion of the substance in the EUPL, **or** based on SML set in Reg. 10/2011 and considering the 10% allocation factor. This is understood as the 10% figure is only to be applied in combination with the SML considerations.

- While recognising that the current DWD had been adopted before the update of the said WHO guidelines, we would suggest that one potential solution be amending Annex V of the DWD which refers to the older version of the WHO guidelines at a sooner stage. We are rather concerned with inconsistences between the EU standard and the international standard suggested by WHO. We are aware that Article 20 of DWD obliges the Commission to review Annexes I and II at least every 5 years in light of scientific and technical progress and submit a legislative proposal to amend the Directive where appropriate. We also assume that the Commission may wish to combine the potential correction of the WHO guidelines reference together with such mandatory review exercise, as this would be in line with the intention of the legislators to keep the Directive up to date with the latest scientific developments.

[4] Guidelines for drinking-water quality: Fourth edition incorporating the first and second addenda, World Health Organization (WHO) 03/2022 https://www.who.int/publications/i/item/9789240045064

[5] The four Member States (MS) Germany, France, the Netherlands and the United Kingdom of Great Britain and Northern Ireland in 2011, who agreed on collaboration in the harmonisation of tests for the hygienic suitability of products in contact with drinking-water. It is called '4MS-Initiative' (4MSI).

[6] Guideline for drinking-water quality, WHO 03/2022, p. 176

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- However, if the amendment to the allocation factor comes at a later stage, and on the basis of the proposed expiry dates in the draft EUPL (January 2028 – January 2037), one could assume that there would be inconsistent treatment of re-assessment of the substances over this period. That may trigger concerns about unfair and discriminatory treatment among those substances. Consequently, in our view, this issue should be addressed rather sooner than later to avoid such a scenario.

(3) Test methods

1. IA Annexes and 4. IA Annex provide testing requirements and methodologies for substances and final materials. Our initial finding is that many of the requested testing parameters are not referenced in the European standards (CEN). In addition, test methods – especially those which are new to the industry – would need robin tests to ensure harmonised testing across the EU accredited laboratories.

To ensure the legal certainty, optional testing methods are better to be avoided. For example, for enhancement of microbial growth (EMG) testing for 'unexpected substances' and 'Analysis of migration water', the legal text proposal reads '*standard EN 16421:2015 – method 1 or 2 shall be used*[7]'. This would need to be considered in the corresponding guidelines currently under development.

We would like to stress the importance of differentiating between products intended for use in chlorinated water and standard drinking water products. We also would like to highlight that many parts of Europe only use non-chlorinated water, requiring all products to be tested with chlorinated water is not proportionate.

1.IA Annex 4 requests Good Laboratory Practices (GLP) or ISO 17025 certified laboratories for migration modelling in petitioning. Petitions in the past have shown that analytical methods to achieve a detection limit of 0.1 µg/l are not available and cannot be developed. In order to be able to demonstrate migration below that level, migration modelling would be needed. Using a validated method or software is sufficiently reliable if the applicant can demonstrate that the used data are coming from certified test houses/-reports. Only assigning GLP/ISO 17025 certified laboratories would limit the availability of test houses and migration modelling experts.

Migration modelling in applications requires a Good Laboratory Practices (GLP) or ISO 17025 certified laboratory. Applications in the past has shown that in many cases an analytical method to achieve a detection limit of 0.1 µg/l is not available and cannot be developed. That is the case where migration modelling is needed. Only using GLP/ISO 17025 certified laboratories for that would limit the availability of test houses and migration modelling experts. Using a validated method or software is sufficiently reliable if the applicant can demonstrate that the used data is coming from certified test houses/-reports.

[7] Annex to 4. IA

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Last but not the least, testing bodies may need time to prepare capacity and accreditation to receive and implement requests from applications throughout the EU.

(4) Definitions

Among the six legal texts (main and annexes), we found ambiguous definitions and inconsistencies with one another, as well as with other legislation, which can potentially lead to legal uncertainty. We propose clearly defining the concepts once, the first time they are used to avoid duplication and avoid repeating definitions already present in the Drinking Water Directive. The following table shows some examples of inconsistency and ambiguity.

Quotation from the (draft) legal text = *italic*

Subject	Comparison with other IAs/DAs and other legislation, and comments
Art. 2. (1) 1. IA: *'Agency' means the European Chemicals Agency set up pursuant to 75(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.*	In recital 22 of Drinking Water Directive, it is described as *European Chemicals Agency set up under Regulation (EC) No 1907/2006 of the European Parliament and of the Council ('ECHA').*
Art. 2 (2) 1. IA: *European positive list described in in 1. IA and 3. DA as one of the lists of starting substances, compositions or organic cementitious constituents established by Decision [Article 11(2)(b) Commission Implementing Decision]*	Art. 2 (4) 4. IA: *'European positive lists' means the lists referred to in Article 11(2)(b) of Directive (EU) 2020/2184 and are lists of starting substances, compositions or constituents, depending on the type of materials, namely organic, cementitious, metallic, enamels and ceramic or other inorganic materials, authorised for use in the manufacture of materials or products intended to come in contact with water intended for human consumption. Those lists include, where appropriate, conditions for their use and migration limits.*
Art. 2 (3) 1. IA: *'organic cementitious constituent' means an organic substance intentionally used in the manufacture of cementitious materials.*	Art. 1 (9) 2. IA: *'organic cementitious constituent' means an organic substance that used in the manufacture of cementitious materials.*
Art. 2 (7) 1. IA: *'relevant substance' for the purpose of toxicological testing and risk assessment and acceptance, a substance identified in accordance with Section 3 of Annex 4 to this Decision.*	Art. 2 (19) 4. IA: *'relevant substance' means a substance to be analysed in the migration or contact water in accordance with the requirements set out in the relevant Annexes of this Decision.*

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	It is important to differentiate between relevant substance for toxicological testing and risk assessment and acceptance and relevant substance for migration testing with clear terminology because it is not the same concept.
Annex 1 1.2 of 1. IA: *For the purpose of this Annex, a starting substance and an organic cementitious constituent are substances defined as follows: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.* This definition repeats Art. 3 of REACH Regulation . But the definition found in Annex 1 of 1. IA covers both starting substances and organic cementitious constituents. We question why the definition covers both concepts and why it is defined in the annex.	Not coherent with Art. 2 (1) of 4. IA where starting substance is defined as: *a substance that has been intentionally added in the production of organic materials or of admixtures for cementitious materials.* And not coherent with Art. 2 (3) of 4. IA where constituent is described as: *i. a substance that has been intentionally used to manufacture a cementitious material; or* These articles expressly mention that starting substances and constituents of cementitious materials are only those that were intentionally used, which would exclude impurities contrary to what is defined in the Annex of 1. IA.
Art. 1 (2) 2. IA: *'material' is prepared from starting substances or organic cementitious constituents and used in the manufacturing process of a product intended to come in contact with water intended for human consumption*;	Art. 2 (5) 4. IA: *'material' is prepared from a combination of substances and used in the manufacturing process of a product intended to come in contact with water intended for human consumption.*
Art. 1 (3) 2. IA: *'monomer' means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process*; This is the same definition as in Art. 3 (6) REACH Regulation.	Monomer or other starting substance is defined as follows in Art. 3 (6) Food Contact Materials PIM Regulation. *(a) a substance undergoing any type of polymerisation process to manufacture polymers; or* *(b) a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or* *(c) a substance used to modify existing natural or synthetic macromolecules;*

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Art. 1 (4) 2. IA: *'organic material' means a material that mainly consist of carbon-based substances*	Art. 2 (6) 4. IA: *'organic material' means a material, as defined under this Article, that mainly consist of carbon-based substances and that falls under material categories such as plastics, rubbers, coatings, adhesives, lubricants and silicones.*
Art. 1 (6) 2. IA: *'polymer' means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:* *(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;* *(b) less than a simple weight majority of molecules of the same molecular weight.* *In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer.* This is the same definition as in Art. 3 (5) REACH Regulation ((EC) 1907/2006).	According to Art. 3 (3) of Food Contact Material PIM Regulation, 'Polymer' means *any macromolecular substance obtained by:* *(a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or* *(b) chemical modification of natural or synthetic macromolecules; or* *(c) microbial fermentation;*"
Art. 1 (14) 2. IA: *'ceramic materials' means inorganic poly- or single crystalline, non-metallic solid materials subjected to high temperature in manufacture.*	Art. 2 (10) 4. IA: *'ceramic materials' means inorganic poly- or single crystalline, non-metallic solid materials subjected to high temperature in manufacture or use.*
Art. 1 (15) 2. IA: *'enamel' means a vitreous material obtained by melting at temperatures above 1200 °C, and fritting of a mixture of inorganic substances. The fritted material may be applied to a metal substrate by melting at a temperature above 480 °C.*	Art. 2 (9) 4. IA: *'enamel' means a material, as defined under this Article, that is a vitreous material obtained by melting at temperatures higher than 1200 °C and fritting of a mixture of inorganic substances. The fritted material may be applied to a metal substrate by melting at a temperature above 480 °C.*

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Art. 4 paragraph 1 3. DA mentions competent authority as defined in REACH Art.3, 19 as the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation.	Art. 4 (3) 3 3. DA mentions a public authority, while Recital (2) 1. IA mentions relevant authority. Using the same terminology can avoid confusion or additional definitions are needed to clearly define the differences.
Art. 2 (16) 4. IA: *'multilayer product' means a product intended to come in contact with water intended for human consumption that consist of two or more layers of final materials bonded together and cannot be non-destructively disassembled for the testing.*	Better definition is needed to differentiate between hot water building application and infrastructural cold water application, so that testing of cold water pipes at 60°C is avoided.
Art. 4, 4. IA on *Identification of relevant substances and relevant other parameters* *I. Final organic materials* *1) For products intended to come in contact with water intended for human consumption …*	Art. 4, 4. IA: *III. Final cementitious material* *1) For products that come into contact with water intended for human consumption …* We question if this means that there is a difference between products that come in contact with water intended for human consumption and those intended to come in contact with water intended for human consumption.
Article 7, 4. IA *Exceptions for assessment of materials used in minor and assembled components* *Under specific conditions that are set out in the Annexes of this Decision, materials used in minor components and components of assembled products may be subject to reduced testing.*	Minor components were not defined in the delegated or implementing acts. Additionally, there is no need to use this concept here, since minor components and components are both subject to reduced testing.
Art. 1 (5) 5. DA: *'component' means an identifiable part of an assembled product and that is intended to come in contact with water intended for human consumption.*	Art. 2 (15) 4. IA: *'component' means an identifiable part of an assembled product and that is intended to come in contact with water intended for human consumption. A component of an assembled product can itself be considered as a product.*

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Among the above, we are of the opinion that the definitions of 'monomer' and 'relevant substances' particularly should be defined leaving no legal uncertainty. Additionally, it is needed to clearly define and delineate 'non-intentionally added substances' (NIAS) from 'unexpected substances.' We also would propose the term 'migrating substance' as it better captures the meaning of the concept.

Closing remarks

Our comments above summarise the key findings from the DW groups of FCA and PlasticsEurope, and we understand that other stakeholders involved in the relevant drinking water operations and businesses provided their own thoughts and suggestions. At the same time, while our comments focus on only 1. IA, 2. IA and 3. DA, we already see, that certain aspects of the 4. IA may have relevance to applications and assessments of substances conducted under the said three legislative proposals on substances. Together with feedback from other stakeholders on the final materials and products, we are hoping for harmonised legislation, operation and enforcement of the whole package of implementation of Article 11 of Drinking Water Directive.

As the final note, we would like to ask the European Commission, ECHA and the Member States to further consider the complexity of the issues, and legal certainty and enforceability of this Article 11 implementation package. If further explanation is needed, we would be happy to provide additional information or details, including industry's practice. Last but not the least, we thank you again for this opportunity to provide written feedback to the legislative proposals.

Contact

We remain at your disposal for your questions and further discussion on this paper as well as on our joint position paper in April 2023[8].

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[8] https://fca.cefic.org/wp-content/uploads/2023/04/FCA-PlasticsEurope-Updated-position-paper-on-positive-list-for-DW-materials-FINAL_April2023.pdf
https://plasticseurope.org/knowledge-hub/fca-and-plasticseurope-position-on-eu-positive-list-for-materials-incontact-with-drinking-water/