FCA and PlasticsEurope position on EU positive list for materials in contact with drinking water

Food Contact Additives (FCA), a Cefic Sector group, and PlasticsEurope welcome the adoption of the revised Drinking Water Directive (DWD). In particular, we support the Article 11 provisions 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 in contact with water intended for human consumption.

FCA/PlasticsEurope call for an EU positive list for substances used in the manufacture of materials in contact with drinking water (DW) to be developed on the basis of:

- *Substances authorised for used in food contact materials (FCM) according the Regulation (EU) 10/2011*
- *The 4MSi list*
- *EU national lists*

A system for the inclusion of future petitioned substances in the positive list for materials in contact with DW should also be established.

Development of EU positive list

Transposition of entries from FCM into DW positive list - allocation factor (SML vs MTC)

According to the 4MSi provisions, the Maximum Tolerable Concentration (MTC) values are defined on the basis of the Specific Migration Limit (SML) from the positive list of Regulation (EU) 10/2011, divided by a factor of 20. This factor assumes a person consumes two litres of potable water every day. Further, the water is in contact with a given material and 10% of the total exposure to the substances comes from materials in contact with DW[1].

[1] Directive (EU) 2020/2184 on the quality of water intended for human consumption (recast)

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According to the World Health Organization[2], the normal allocation of the total daily intake of drinking water is 20%, which reflects a reasonable level of exposure while still being protective[3].

This value was updated as the previous allocation factor of 10% was found to be excessively conservative, leading to MTC values being derived by dividing the SML by 10.

Therefore, for inclusion in the EU positive list for materials in contact with DW, substances with a fixed SML (arising from EU or national regulations) should be divided by a factor 10.

Default detection limit of 0.1 ppb – alignment with Regulation (EU) 10/2011

For substances subject to a restriction of "non-detectable" (ND) (listed substances with SML = ND or non-listed, non-CMR classified substances present above 0.02% in the end product) a detection limit of 0.1 ppb is referenced. This limit is extremely low and presents an analytical challenge for certifying laboratories (in particular – but not limited to – non-listed substances where no analytical method is available).

If no suitable analytical method with a "limit of detection" (LOD) of 0.1 ppb is available, it is proposed to align with the default detection limit of 10 ppb in line with Regulation (EU) 10/2011. A lower limit could only be applied in those cases where analytical methods would exist and allow reaching a lower detection limit**.**

The same principle and provision should be applied for substances exempted from positive listing, such as NIAS, APs and PPAs.

Migration Modelling

In the analysis of articles and materials in contact with drinking water, the given limits for the migration of substances are very low. In practice, industry must prove migration is below 0.1 µg/L; however, experience with test houses show that for most substances, there are no analytical methods with a detection limit of 0.1 µg/L or there is great variation in the results. There is a clear need for migration modelling, which is already established in relevant food contact legislation[4], where insufficient analytical methods are available, or to reduce time and cost for analytical work.

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[2] Guidelines for drinking-water quality (4th Edition), WHO 2012, page 176.

[3] Krishnan K, Carrier R (2013). The use of exposure source allocation factor in the risk assessment of drinking-water contaminants. *Journal of Toxicology and Environmental Health. Part B. Critical Reviews*, 16(1).

[4] Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

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Several experts are developing migration models around food contact and drinking water (e.g., JRC working groups, Fabes[5] [6] [7] and UBA). Valid mathematic models exist but require discussion and decision by authorities to be applied in drinking water. As such, we recommend DG ENV and ECHA lead in validating these mathematical models for materials and articles in contact with drinking water. The use of these models should be accepted by authorities for demonstrating compliance with the DWD.

We welcome the work carried out by the JRC working group and are ready to provide technical input to support further developments.

Substances exempted from positive listing

Non-Intentionally Added Substances (NIAS)

Regulation (EU) 10/2011 introduces "Non intentionally added substances" (NIAS). These are defined as "*either impurities in the substances used or reaction intermediates formed during the polymerisation process or decomposition or reaction products which can occur in the final product*". NIAS are exempted from authorisation and inclusion in the plastic FCM EU list. For the EU positive list of materials in contact with DW we recommend that:

1. Under Regulation (EU) 10/2011 NIAS are covered by the authorisation of the substance intentionally used and should not require separate positive listing in a future EU list of materials in contact with DW. Furthermore, these types of substances, if needed, could be covered via a specification or restriction in the corresponding entry for the intentionally added substance in the EU list for materials in contact with DW.

2. In line with the UBA Evaluation Criteria Document for plastics and organic materials[8], NIAS not classified under Regulation (EC) 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, and which are present in the end-product/finished article in an individual concentration level below 0.02 weight% and total sum below 0.1 weight% (or for which the migration is <0.1 ppb) should be permitted without further specific evaluation. Compliance with the 0.1 ppb migration limit can be demonstrated based on predicted low solubility in water (software), "worst case calculation", migration modelling or migration testing.

3. In line with the UBA Evaluation Criteria Document for plastics and organic materials, APs and PPAs which are not listed and not classified under Regulation (EC) 1272/2008 as

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[5] P.V. Mercea, A. Kalisch, M. Ulrich, H. Benz, O.G. Piringer, V. Toşa, R. Schuster, S. Aranyi, P. Sejersen, Polymer Testing, Volume 65, 2018, Pages 176-188, https://doi.org/10.1016/j.polymertesting.2017.11.025
[6] P.V. Mercea, A. Kalisch, M. Ulrich, H. Benz, O.G. Piringer, V. Toşa, R. Schuster, P. Sejersen, Volume 76, 2019, Pages 420-432, https://doi.org/10.1016/j.polymertesting.2019.03.023
[7] P.V. Mercea, C. Losher, H. Benz, M. Petrasch, C. Costa, V.W. Stone, V. Toşa, Polymer Testing, Volume 104, 2021, 107385, https://doi.org/10.1016/j.polymertesting.2021.107385
[8] Part 5.2.2 (a) "low use" and part 5.2.2 (b) "no migration".

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Category 1A or 1B carcinogenic, mutagenic[9] or toxic to reproduction, can be used under the following conditions:

1. Their individual concentration level in the end product is below 0.02 weight% and total sum below 0.1 weight (or for which the migration is below 0.1 ppb)
2. Their migration is below 0.1 ppb which can be demonstrated by measured or predicted low solubility in water, worst case calculation, migration modelling or migration testing

Aids to Polymerisation (APs) & Polymer Production Aids (PPAs)

Regulation (EU) 10/2011 references two types of substances: "Aids to polymerisation" (AP) and "Polymer Production Aids" (PPA).

- PPAs are "*substances used to provide a suitable medium for polymer or plastic manufacturing. They may be present, but neither are they intended to be present in the finished materials nor do they have a physical or chemical effect in the final material*".

- APs are "*substances which initiate the polymerisation reaction and/or control the formation of the macromolecular structure. They are not intended to be incorporated[10] in the final polymer and do not have a function in the final plastic*".

While APs and PPAs are derogated from positive listing under Regulation (EU) 10/2011, some substances might be listed, hence for the EU positive list of materials in contact with the DW we would recommend that:

- APs and PPAs which are evaluated and authorised at EU national level (e.g., in the Dutch Warenwet Chapter I and German BfR) for plastic FCMs should be included in the EU positive list.

- Food Contact SML (as fixed in Regulation (EU) 10/2011 or in national regulations) should be divided by a factor 10 (see section on MTC/SML above).

- APs and PPAs with a Molecular Weight (MW) higher than 1000 Daltons are not considered to present a toxicological risk.[11] Gaseous APs and PPAs are considered intrinsically safe due to negligible migration and should be exempted from positive listing.

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[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

[10] Incorporated in this context means reacted onto or becoming a part of the chemical structure of the polymer

[11] Note for Guidance For the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials

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In line with the UBA Evaluation Criteria Document for plastics and organic materials[12], APs and PPAs which are not listed nor classified under Regulation (EC) 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, and which are present in the end product can be used under the following conditions:

- Presence in the end product in individual concentration level is below 0.02 weight% and total sum below 0.1 weight (or for which the migration is below 0.1 ppb)
- Migration is below 0.1 ppb which can be demonstrated by measured or predicted low solubility in water, worst case calculation, migration modelling or migration testing

Solvents

Under the provisions of Regulation (EU) 10/2011, solvents fall under the definition of PPAs.

As such, solvents should similarly be considered and managed in the EU list of materials in contact with DW.

Solvents have multiple functionalities - while some may be listed as "solvent", others may be listed under a different functionality (such as a monomer or other starting substance). Solvents which have been evaluated by EFSA, or by a national food safety authority, and are authorised for food contact (as Swiss/German Printing Ink Ordinance) should be included in the EU list of materials in contact with DW subject to SML/10.

Due to their high volatility, solvents generally disappear from the product and are present in the end product in very small quantities. As shown in the corresponding entries for hydrocarbon solvent in the 4MSi combined list, solvents are authorised if the production process temperature is above the boiling point.

Non-listed solvents which are not classified under Regulation (EC) No. 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction or as substances in nanoform, and which are present in the end product in concentration levels of <0.02% or for which migration is <0.1 ppb can considered safe and are exempt from listing[13] (as in UBA document , point 5.2.2 " low use " and " no migration "[14]). Compliance with the 0.1 ppb migration limit can be demonstrated based on predicted low solubility in water (software), worst case calculation, migration modelling or migration testing (requires availability of analytical method with LOD = 0.1 ppb).

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[12] Part 5.2.2 (a) "low use" and part 5.2.2 (b) "no migration".

[13] 4MSi Common Approach Part C (see here) Solvents which are not classified as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B, in accordance with CLP Regulation No. 1272/2008, and are completely removed during the manufacturing process as confirmed with testing if required, taking into account boiling point, temperature of manufacturing process and use of the product.

[14] UBA document - point 5.2.2 (https://www.umweltbundesamt.de/sites/default/files/medien/5620/dokumente/anlage_1_ktw-bwgl_allgemein_0.pdf) Solvents are needed as production aids for the manufacture of organic materials. Due to their high volatility, they generally disappear from the product at process temperatures above boiling point and are present in the end product in only very small quantities. There is no need to determine migration in this case.

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Assessment of substances excluded from positive listing

Under Regulation (EU) 10/2011, substances excluded from positive listing "*shall be assessed in accordance with internationally recognised scientific principles on risk assessment*." In the absence of guidance, FCA[15], PlasticsEurope[16] and further associations in the FCM value chain have developed industry-specific guidelines which aim to provide recommendations on scientific risk assessment principles to manufacturers and downstream users of substances used in FCM.

To ensure alignment with Regulation (EU) 10/2011, the upcoming legislative measure setting up an EU harmonised positive list for material in contact with DW should include an equivalent provision for these types of substances.

Purity criteria for starting substances

Consideration on suitable purity criteria for starting substances is covered by the petition process and is reflected in the corresponding entry in the positive list, if needed. Requesting a horizontal 99,9% purity criteria by default for all entries in the positive list is not possible in practice. The purity of the different substances is dependent on a variety of factors such as synthesis method, type, and origin of raw materials. This is especially important for raw materials from a natural origin.

To align with FCM legislation, and for substances used for materials in contact with DW, the purity should comply with Article 8 of FCM legislation. This could be combined with the information provided in the SDS in accordance with the chemical legislation.

SMLs for metals from plastics- alignment with Regulation (EU) 10/2011

The MTCs for metals in the 4MSi list are based on the parametric value in the DWD divided by a factor 10 (with the exception of cobalt and lithium). FCA/PlasticsEurope recommends aligning with the SMLs for metals in Annex II of the 15th amendment of Regulation (EU) 10/2011 divided by a factor 10.

For metals with a ND restriction, we recommend to keep the current MTCs (see table below):

[15] FCA – Guidelines – Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under the requirements of Article 3 of the Framework Regulation (EC) 1935/2004

[16] PlasticsEurope – Risk Assessment of non-listed substances (NLS) and non-intentionally substances (NIAS) under Article 19 of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with wood

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Metal	Parametric value in DWD Part B (ppb)	Current MTC 4MS part C Annex D (ppb)	SML annex II 10/2011 (ppb)	Proposed MTC (SML/10) (ppb)
Al	200	20	1000	100
Sb	5 *(new 10)*	0.5 (new 1)	40	4
As	10	1	ND (LOD = 10 ppb)	ND
Ba	700 (WHO guideline)	70	1000	100
B	1000 *(new 1500)*	100 (new 150)	-	
Cd	5	0.5	ND (LOD= 2 ppb)	ND
Cr	50 *(new 25)*	5 (new 2.5)	ND (LOD = 10 ppb)	ND
Co	-	2.5	50	5
Cu	2000	200	5000	500
Fe	200	20	48000	4800
Pb	10 *(new 5)*	1 (new 0.5)	ND (LOD = 10 ppb)	ND
Li	-	30	600	60
Mn	50	5	600	60
Hg	1	0.1	ND (LOD= 10 ppb)	ND
Ni	20	2	20[17]	10
Se	10 *(new 20)*	1 (new 2)	-	1
Zn	2500 (WHO guideline)	250	5000	500

[17] The SML for Nickel in Regulation EU 10/2011, was set by the Commission on the basis of the 2015 EFSA Scientific Opinion on nickel and chronic Tolerable Daily Intake (2,8 µg/Ni per kg b.w. per day). However, in 2020 EFSA updated its Scientific Opinion, deriving a higher chronic TDI (13 µg/kg bw). The SML for nickel from plastic was not yet updated in Regulation EU 10/2011.

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Other types of substances

Provisions for pigments, fibre reinforced plastic, should be aligned with BfR recommendation IX and point 5.4.3 of KTW-BWGL.

Provisions for fillers, substances in nano form or additives used in glass fibre sizing for glass should be aligned with Regulation (EU) 10/2011.

Re-evaluation of substance /expiry date

The DWD will include an expiry date and require a re-evaluation for positive listed substances. FCA/PlasticsEurope recommend the evaluation of substances should be done according to a risk-based approach considering the intrinsic properties of a given substance together with exposure to the consumer.

Applying such approach should allow to further refine and expand the expiry dates to enable a smooth re-evaluation programme.FCA/PlasticsEurope questions the need for re-evaluation of substances which already have the most stringent restriction SML = ND.

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April 2023