CFREP Comments on the proposed 18th Amendment of Regulation (EU) No 10/2011

Brussels, 15 April 2024

***EuPC** is the leading EU-level Trade Association, based in Brussels, representing European Plastics Converters. EuPC now totals about 51 European Plastics Converting national and European industry associations, it represents close to 50,000 companies, producing over 50 million tonnes of plastic products every year. The European plastics industry makes a significant contribution to the welfare in Europe by enabling innovation, creating quality of life to citizens and facilitating resource efficiency and climate protection. More than 1.6 million people are working in about 50,000 companies (mainly small and medium-sized companies in the converting sector) to create a turnover in excess of 280 billion € per year.*

***CFREP**, Contact Sensitive and Food Contact Plastics Regulatory Expert Panel, is a sector group of EuPC representing the food contact and contact sensitive plastics sector.*

The following comment is providing feedback on the 18th Amendments to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as regards recycled plastic and other matters related to quality control and manufacturing of plastic materials and articles intended to come into contact with food.

1. Disproportion of measures for food contact packaging made from different materials

We refer to ELIPSO's position and fully support it:

> *"It is problematic to continue specifying quality requirements for plastic packaging, further widening the gap in costs and time invested by plastic industry players in demonstrating safety, while other players do not have such a high level of detail to reach in order to meet the obligation introduced in the 1935/2004 framework regulation. We see this as a real distortion of competition which is not based on scientific grounds demonstrating that only plastics deserve such a high degree of quality."*

2. Amending the definition of 'additive' (Article 3)

The addition of *"including substances or materials in a solid state that become bonded to the polymer that constitute the plastic*" to the definition, without further precision, may suggest that all solid monomers and/or initial substances will be considered additives and must be listed accordingly. This interpretation extends beyond the legislative intent.

A revision of the wording, clarifying the precise meaning of "substances or materials," is necessary to ensure a clear interpretation and consistent implementation.

3. High degree of purity (Article 3a)

The introduction of the proposed Article 3a, which includes the concept of a "high degree of purity", raises significant concerns regarding practical compliance demonstration, in particular the requirements as laid down in Article 3a, point (iii) and (iv).

3.1. Clarification of the scope of Article 3a

To ensure that the demonstration of compliance with imposed requirements remains achievable, it is important to clarify that the provisions of the proposed Article 3a exclusively apply on the substances on the Union list as laid down in Article 5, point 2 together with those addressed in Article 6, point 3 (a) and (b) used at the manufacturing stage. Additionally, we ask to exclude substances used in coatings, inks and adhesives as proposed in section 2.3.

Further, the new article 3a refers to 'substances', 'constituents' and 'identity' without adding a definition of these terms in the regulation. To avoid potential ambiguities, it is advisable to provide clear definitions for these terms within this regulation. This includes clarifying that mechanically recycled plastics, such as mechanically recycled PET produced through technology compliant with Regulation (EU) No 2022/1616, should not be classified as substances subject to the new requirements.

3.2. Technical feasibility of demonstrating compliance with Article 3a, point (iii) and (iv)

From a scientific perspective, there is no consensus on the definition of purity levels that can be classified as 'high purity'. As small quantities of unidentified molecules are technically unavoidable in all substances for physico-chemical reasons, no substance can be considered as consisting of components of a solely identical nature.

The demonstration of the proposed conditions for minor contaminants and non-intentionally added substances, in particular point (iii) and (iv), lead automatically to applying the approach described in *EFSA Scientific Committee, 2018. Genotoxicity assessment of chemical mixtures. EFSA Journal 2019;17(1):5519* for every material or article introduced in the market. In addition to the extremely high cost implied by such requirements, it is questionable that it may be of any benefit insofar in-vitro genotoxicity test for mixtures do not show the sensitivity to detect genotoxic properties at such a low level, as demonstrated by the Migratox project (Research project "Migratox": safety assessment of food contact materials (ofi.at)) and relevant publications, such as Mutagenicity assessment of food contact material migrates with the Ames MPF assay: Food Additives & Contaminants: Part A: Vol 36 , No 9 - Get Access (tandfonline.com).

Therefore, assessment by evaluation of functional groups, or by ToxTree, or on the basis of data available on the ECHA website, should also be allowed for substances for which it is not yet known that they are genotoxic. Further, point (iii) refers to a presence limit of 0.05 mg/kg, whereas we recommend aligning the limit with the European Food Safety Agency's 'Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (2019)' for similar types of substances, i.e. 0.09 mg/kg.

Regarding Article 3a, point (iv) clarification is needed on how to handle substances that are identified at a generic level (e.g. "saturated hydrocarbon") but the precise molecular identity is not known. We request a modification of the concept to rule out genotoxicity for generically identified substances based on the identified chemical groups. A migration limit of 0.15 µg/kg food is appropriate for substances known to be genotoxic, but is disproportionate at the risk management stage for substances not known to be genotoxic. Based on the current de facto limit of 0.01 mg/kg food, setting now a 67-fold lower value for substances not known to be genotoxic is not reasonable.

Additionally, legal requirements have to be proportionate to the risks: Sorbitan monolaurate (FCM No. 414; PM Ref. 87600), which happens to be a dual use additive – it is authorised as a direct food additive under No. E 493. The food additive authorisation states that E 493 must have a purity level of ≥ 95% ("content not less than 95 % of a mixture of sorbitol, sorbitan, and isosorbide esters", 2 % could be water, the remaining 3 % is not identified) when added directly to food. According to the current Regulation (EU) No 10/2011, good technical quality is sufficient for use in plastic FCMs, as also explained in the Commission's guidance document. To ensure that the requirements of the new Article 3a, point (iv) are met for addition to plastic FCMs, the purity level would have to be much higher than for direct addition to food.

In summary, these requirements charges manufacturers and regulatory bodies with a burden for which no compliance tools are currently available. Demonstrating compliance with such stringent thresholds for unknown contaminants and substances presents an insurmountable technical challenge, and it shows particularly inapplicable when considering the inherent variability in materials and manufacturing processes. At this stage, it is not even known whether the essential substances would be available in the proposed quality, in the quantity and at a cost level required by our industry.

We urge a thorough technical and regulatory assessment on the feasibility and practicality of the requirements as proposed in Article 3a, in particular paragraph (iii) and (iv), in light of current scientific understanding and industry capabilities. It is crucial that regulations strike a balance between ensuring safety and feasibility for manufacturers to comply effectively.

3.3. Purity requirements for pigments, colorants and fillers

The Commission Implementing Decision C(2024)238 is laying down rules for the application of Directive (EU) 2020/2184 (Drinking Water Directive). In Annex I, chapter 4.6, table 8, purity requirements for pigments, colorants and fillers are defined. To ensure coherence, we propose to follow the similar approach as proposed in the drinking water regulation for the purity requirements of pigments, colorants and fillers by adding the following paragraph to the proposed Article 3a in Regulation (EU) No 10/2011:

> "*By derogation from paragraph 1, as regards to purity, and 2 the requirements of Commission Implementing Decision C (2024) 238 Annex 1, 4.6, table 8, shall apply to pigments, colorants and fillers*."

4. Placing on the market of plastic materials and articles (Article 4)

Recycled plastics intended for contact with food do not fall within the scope of application of Regulation (EU) No 10/2011. For this reason, recalling compliance with Regulation (EU) No 2022/1616 in Article 4 (f) may seem superfluous.

5. Biocides: Reference to Regulation (EU) No 528/2012 (Article 6)

With regard to the use of biocidal products, the reference to Regulation (EU) No 528/2012 has raised the question of selecting of the most suitable product-type:

Article 6, point 5, is referring to biocidal products authorized under Regulation (EU) No 528/2012 for product-type 4. However, product-type 4 relates to disinfectants used in food contact materials and articles for the purpose of cleaning and disinfecting these materials.
There may be other effects that are desired in the manufacture of intermediate materials (e.g. keeping microbial contaminants away from the production of plastic pellets or preservation of plastic surfaces), for example preserving the said food contact materials and articles from being contaminated by microbiological agents. In this case the use of biocides classified as "preservatives" is more appropriate, such as listed in product-type 6 or 7. For raw material, which has been treated with biocide to preserve them from contamination, product-type 9 is considered most appropriate.

Therefore, we would propose to extend the scope to further product-types with the additional requirement that these need to be petitioned for food contact use.

6. General requirements on substances (Article 8)

In addition to our comment on the feasibility of demonstration the "high degree of purity" as proposed in Article 3a applying to substances used in manufacturing plastic materials and articles, including those manufactured from waste, the following paragraph poses challenges in its implementation:

> "*Manufacturers of plastic materials and articles and of products from intermediate stages of their manufacturing shall know the composition of the substance and make it available to the competent authorities on request.*"

Requiring manufacturers at all stages to know and share the composition could impose significant burdens and inefficiencies. For example, a final manufacturer might receive an extensive list of substances without clear guidance on the relevance or necessity for testing. Many components may not be present in the final product due to processes like polymerization or evaporation, rendering their quantities irrelevant. Additionally, the requirement to disclose the origin and amounts of substances pose challenges related to trade secrets.

The requirement for end-users to assess compliance for every listed substance could result in redundant testing for the same product and application and increased costs for all parties involved, contradicting the goal of efficiency and cost-effectiveness.

We therefore propose the following wording:

> "*Manufacturers of **substances** ~~plastic materials and articles and of products from intermediate stages of their manufacturing~~ shall know the composition of the substance **used in his manufacturing operation** and make it available to the competent authorities on request.*"
>
> *Manufacturers of plastic materials and articles and of products from intermediate stages of their manufacturing shall know **substance manufacturers contact** ~~the composition of the substance~~ and make it available to the competent authorities on request.*"

This will ensure maintaining the concept of performing compliance work as early as possible in the supply chain to avoid double costs, as stated in the "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain" on principles for sharing compliance work throughout the production chain (page 7).

In Article 8, point 2, it is our understanding that high purity requirements do not apply to substances originating from natural origin, making it impossible to meet these requirements on high degree of purity for intermediate materials if natural-origin substances are used.

Regarding Article 8, point 3, we ask to add clarification that the supporting information required in this context is only that which relates to the business operator's own use of single substances in his manufacturing operation.

Further, the Article 8, point 4, requires that manufacturers of food contact materials and articles shall ensure that competent authorities can take samples to verify the level of purity and composition, including that of the substances and materials used for their manufacture. The requirement is rather unclear: **the manufacturer of a finished product can at the best retain a sample of the purchased material or substances, by no means it can be expected to obtain samples from its supplier of the relevant starting material or substance used for the production of the supplied products.** In addition to that, there are instances where the monomers pose physical hazards, making their shipment and storage challenging for conventional companies. Also, there should be a limit for the time which that material or substance is retained (6 months? 12 months?) to avoid accumulation of samples.

Additionally, the wording of Article 8 does not inherently address the inclusion of mechanically recycled PET acquired through an approved process within a suitable technology as outlined in Regulation (EU) No 2022/1616. However, due to the requirement in Article 4(2) of Regulation (EU) No 2022/1616, which mandates that recycled plastic materials and articles adhere to specific chapters of (EU) No 10/2011, including Article 8, it is necessary to explicitly state the exemption of mechanically recycled PET from this Article.

7. General restrictions and requirements concerning the composition of plastic materials and articles (Article 10)

In Article 10, clarification is needed whether the requirement also applies to intermediate materials. Furthermore, clarification is needed on Article 10, point 2, letter (d): In this part the reference of substances in food is mentioned. In our opinion these substances are those considered as dual use.

There is a discrepancy with the introduction to point 3 of Article 10, which does not allow for increased migration even if it meets the safety requirements of the regulations. We propose, when designed for repeated use in contact with food, the composition of plastic materials and articles must ensure that there is no increase in migration beyond the authorized limits specified in Regulation (EU) No 10/2011 for the constituents of the material or article into the food during their maximum lifespan when subjected to subsequent use cycles.

8. Labelling of repeated use materials and articles (Article 14a)

We support the objective of educating consumers on the safe use of plastic food contact articles; however, we have several concerns regarding the practicability of the proposed new Article 14a.

We understand that the labelling requirements shall apply to final articles not yet in contact with food at the moment that they are supplied to the final consumer; however, the current wording includes "material", which could also refer to intermediate materials such as plastic pellets. Given that various operating steps during the converting process, such as mixing pellets with other materials or heat treatment steps can change the permissible use conditions, a manufacturer of materials may not be able to adequately inform consumers. Additionally, intermediate material producer might not always be informed that the masterbatch/compound will be used in repeated applications. Ultimately, only the manufacturer of the final food contact article can determine the permissible use conditions.

We therefore propose to include only articles, and not materials, in the labelling requirements:

> *"1. The manufacturer or other operator responsible for placing on the market a ~~material or~~ article **not yet in contact with food at the moment that they are supplied to the final consumer** to inform consumers on its safe use; intended for repeated use shall provide information about its the maximum life span to its users by means of labelling or instructions, […]"*

Furthermore, the labelling and instruction requirements must be practical considering the size of different articles. Detailed information on the maximum life span and safe use requires sufficient space on the item. **Therefore, manufacturers of articles should be allowed to inform their customers via a leaflet or, to avoid unnecessary packaging, via their website.**

Finally, we have serious concerns on the obligation for manufacturers of articles for repeated use to describe observable changes in the articles which may compromise the function or the safety of the article. Misuse cannot be predicted, and the obligation opens to liability of the manufacturers for any possible unforeseeable misuse that consumers can make. We therefore strongly reject that obligation.

Manufacturers can inform on the intended use and possible limitations of the articles introduced in the market, but other than that it should be consumers responsibility to follow the instructions.

9. Labelling (Article 14)

The new wording of article 14 foresees the application of Article 11 and 12 to multilayer multi-material and articles. We think that it is necessary to evaluate the implication of this engagement for the producers to comply with Article 11 and 12.

10. Removal of derogation for containers with volume less than 500 ml (Article 17(2))

The derogation of containers with volume less than 500ml from the calculation of migration results using the actual S/V ration was introduced in order to compensate for the gross overestimation made by assuming that consumers eat food packaged in small containers in a quantity equal to 1 kg per day, all containing the same migrating substances. The entire construction of the food contact regulation is based on the accumulation of worst-case scenarios and exposure overestimation, removing that derogation represents a big impact, which is not supported by any justification or evidence of safety problems.
It is not acceptable that many articles perfectly compliant with the current legislation are set out of the law without any evidence that they represent a problem. **We strongly reject this amendment, and we call for maintaining the current text.**

EuPC fully supports the Flexible Packaging Europe position:

> *"The phrasing 'underestimation of the real migration of substances into food' is fundamentally wrong and misleading – the S/V ratio does not serve to underestimate or overestimate the "real migration", it serves to turn the analytical finding into the legally required parameter that needs to be compared with the migration limit to decide on compliance or non-compliance. […] Requiring this now for all food pack sizes below 500g is a very significant change affecting a majority of all flexible packaging formats and creating significant costs and bottlenecks and uncertainty in the business continuity for the FCM converters and the food industry alike. Such a far-reaching change should not be undertaken without an in-depth impact assessment and a clear demonstration of the need for this change from the point of view of consumer safety."*

11. Amendments to Annex IV of Regulation (EU) No 10/2011

In Annex IV, point 6 would require full disclosure of NIAS that may be present in the plastic formulation. We believe that this measure is highly disproportionate, especially with respect to the requirements placed on other non-plastic food contact materials and articles, forcing manufacturers of intermediate and finished materials and articles to disclose information that shall normally be provided only to Control Authorities.

Regarding Annex IV, point 8, as already pointed out, determining the life span of a consumer article is not possible. The frequency of use can vary dramatically (a glass lunch box with a plastic lid can be used every day or once a month), and the conditions of use are very variable. It must be consumers responsibility to determine when an article is damaged and discontinue its use accordingly. For multi-component articles this may be different for each component, e.g. for the glass lunch box with a plastic lid. We would also point out that any criteria to determine the life span are missing, and therefore the requested report cannot be created. **We therefore call for withdrawal of this obligation.**

12. Compliance Testing (Annex V of Reg. (EU) 10/2011)

While we appreciate the effort to provide clarity on the technical requirements of the analytical method for testing compliance of migration from plastic food contact materials and articles, we believe that such technical specifications would be more appropriately housed in the *"Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food",* preventing Annex V from becoming overly burdensome with specific technical details.

Additionally, we would ask for standardized methods to be defined as it was already started in a Guidance document, which was never published.

13. Reprocessing of by-products

Furthermore, we would like to highlight inconsistencies in the current wording regarding the reprocessing of plastic by-products, as outlined in the draft proposal.

In recital (5) of the amendments, by-products are defined as follows:

> *"By-products are not considered waste if they can be used directly in the manufacturing of plastics without any further processing."*

However, the proposed definition of reprocessing under Regulation (EU) No 10/2011 includes certain processing steps:

> *"'(20) 'reprocessing of plastic' means remelting, mixing, reacting or otherwise combining plastic materials resulting as a by-product from an intermediate or final manufacturing stage to use them again in the manufacture of plastic materials and articles alone or combined with material originating from earlier manufacturing stages."*

<u>On one hand, this definition of "reprocessing" does not adequately consider common industrial practices for re-processing at the manufacturing stage, such as shredding, re-grinding, or granulating, on the other hand, the reuse of by-products cannot be done if they are not "reprocessed"</u>. Also, we do not understand whether the use of by-products can be distinguished in "direct" and "indirect", and hypothetical "indirect" use should be prevented. **We suggest amending the text as follows:**

> (5) *"By-products are not considered waste if they can be used ~~directly~~ in the manufacturing of plastics ~~without any further processing~~";*

Further, the following sentence "... *to use them again in the manufacture of plastic materials and articles alone or combined with material originating from earlier manufacturing stages*" of the proposed definition of "reprocessing of plastic" under Article 3 could reduce the use of by-products. Processing scraps, intended as by-products that maintain the same suitability characteristics as the raw materials from which they come and can be used in the same production process or in other converting plants. **The mixing of by-products must therefore not be limited only to materials that come from the same production process from which they originated.** Based on these premises, the definition be corrected as follows:

> (20) *" 'Reprocessing of plastic' means **shredding, regrinding, granulating**, remelting, mixing, reacting or otherwise combining plastic materials resulting as a by-product from an intermediate or final manufacturing stage to use them again in the manufacture of plastic materials and articles alone or combined with ~~material originating from earlier manufacturing stages~~ **other materials compliant to Reg. (EU) 10/2011.***"

14. Amendment of Regulation 2023/2006 (Annex II (3))

Annex II (3) of the amendments to Regulation (EC) No 2023/2006 prohibits the mixing of plastic materials with plastic of another composition.

> *"4. At any stage of production or reprocessing operations, operators shall ensure that the quality assurance system **prevents that materials intended for reprocessing are mixed with batches of plastic of another composition, other materials, or with waste materials**.'"*

It is obvious that plastic by-products with a certain composition cannot be mixed with plastics with a composition with which physical-chemical incompatibility takes place, but it is equally obvious that a plastic by-product may be incorporated, e.g., in a blend with different composition, and it is not understandable how this may represent a problem. For reasons of availability and demand, it is common practice to interchangeably use alternative raw materials, sometimes together, in the manufacture of plastic FCM. **We request the removal of the requirement that plastics of a different composition cannot be mixed.**

This prohibition of mixing batches of plastic of another composition or other materials during reprocessing operations raises inconsistencies with the proposed definition of reprocessing in the Regulation (EU) No 10/2011. We therefore recommend revising as follows:

> *"4. At any stage of production or reprocessing operations, operators shall ensure that the quality assurance system prevents that materials intended for reprocessing are mixed with ~~batches of plastic of another composition, other materials, or with waste materials.'~~ **materials not in compliance with Reg. (EU) 10/2011.**"*

Additionally, clarification is needed on the definition of "same quality" as referred to in the definition of 'batch' in Article 2, point (20) of Regulation (EU) No 2022/1616:

> "*3. Such bins, bags or containers may be transferred for reprocessing individually or be grouped in secondary packaging. The resulting unit shall be considered as a batch of material intended for reprocessing. The definition of 'batch' in Article 2, point (20) of Regulation (EU) 2022/1616 shall apply*."

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