Impact of EU Commission Proposed Update to EU Plastics Regulation: Quality Amendment

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PLASTICS Industry Association

Basic EU Requirements for Plastics

- Plastic materials and articles must comply with the following:
  - **Framework Regulation (EU) No. 1935/2004**
    - Article 3 – must not transfer constituents to food that would endanger human health, change composition of food, or deteriorate organoleptic characteristics of food
  - **Good Manufacturing Practice Regulation (EC) No. 2023/2006**
    - Manufacture of starting substances excluded from GMP regulation (see Article 2)
  - **Plastics Regulation (EU) No. 10/2011**
    - Including 15th Amendment (EU Reg. No. 2020/1245) – DoC update for certain substances
    - Monomers and additives included on Union List (Annex I of 10/2011)
      - PPAs, Aids to Polymerization, Colorants, Solvents, Non-Intentionally Added Substances (NIAS), Coatings, as well as Printing Inks, Adhesives excluded from Positive List Requirement
    - Applicable SMLs and OMLs need to be evaluated
    - Non-intentionally added substances must be risk assessed
    - Specification/Limitations established for listed materials need to be met

18th Amendment to Plastics Regulation

- Deletes reference to the **Provisional List of Additives** (and makes surface biocides used in FCMs solely subject to the Biocidal Products Regulation)
- New labeling requirements
  - **Repeated use articles:** must provide information about their **maximum lifespan** to users and **instructions designed to slow down deterioration**
  - **FCMs intended for contact with food** *(but not yet in contact)*: Must be labelled with instructions for use directed at final user if they are subject to **food type, time/temperature or heating condition restrictions** in the Union List (column 10)
- Revises some requirements for migration testing. For example,
  - **Multi-material multi-layer FCMs** would need to comply with SMLs and OML in the Plastics Reg ***if*** the layer in **direct contact** with food is a plastic layer
  - Can no longer use default S/V ratio of **6 dm^2/kg food** for **small** packaging **(< 500 ml or grams)** – must use **real S/V ratio** in actual or foreseen use
- **Establishes new "high degree of purity" for substances used in manufacturing of plastic materials and articles**

Offcuts and Scraps

- Updates the rules for “re-processed plastics” (i.e., offcuts and scraps)
  - Must be collected in accordance with **GMP** (GMP Reg also updated)
  - Must originate from plastics meeting compositional requirements of the Plastics Regulation
  - Must ***not*** contain:
    - Substances that could exceed the migration limits applicable to plastic FCMs
    - Substances that impact compliance with Article 3 of Framework Regulation
    - Constituents originating from food, printing, coating, or adhesive (or substances used in processing the plastic, such as lubricants or cutting fluids) unless such constituents are **identified** and **risk assessed** under Article 19 of the Plastics Regulation

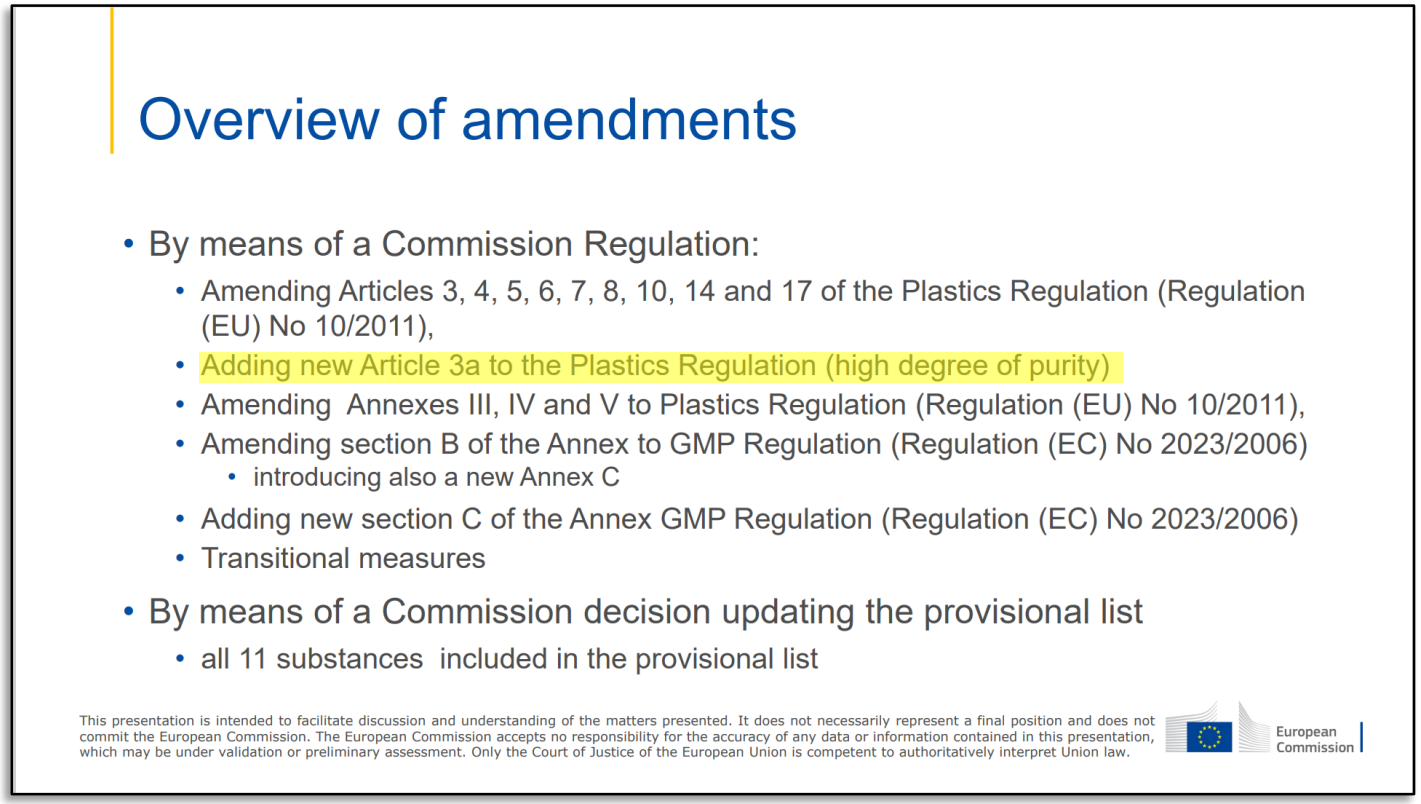
History of Proposed Quality Amendment Text

- First mentioned in 2022 at DG Sante working group (WG) meeting
  - Concern expressed about purity when starting materials recovered from waste
  - “Precise wording still being developed”
- DG Sante (Schupp) presented at industry conference
  - Claimed that “contaminants (from waste) ≠ impurities (from manufacture)!”
    - Thus, not NIAS, and not subject to Article 19 of the Plastics Regulation
- Proposal further refined in early 2023
  - Starting materials (from waste, natural materials) “high degree of purity”
  - Assumption of “full migration into food” first discussed
  - Permitted migration limits for various categories of impurities discussed

DG Sante Slides from Jan. 2024 WG Meeting

Approach to Quality Amendment Revised (*somewhat*)

- Purity requirements moved to Article 3a
- Article 8 imposed “high degree of purity” to starting substances, including substances of natural origin and substances originating from waste
- Draft text published on March 13, 2024



Overview of amendments

- By means of a Commission Regulation:
  - Amending Articles 3, 4, 5, 6, 7, 8, 10, 14 and 17 of the Plastics Regulation (Regulation (EU) No 10/2011),
  - Adding new Article 3a to the Plastics Regulation (high degree of purity)
  - Amending Annexes III, IV and V to Plastics Regulation (Regulation (EU) No 10/2011),
  - Amending section B of the Annex to GMP Regulation (Regulation (EC) No 2023/2006)
    - introducing also a new Annex C
  - Adding new section C of the Annex GMP Regulation (Regulation (EC) No 2023/2006)
  - Transitional measures
- By means of a Commission decision updating the provisional list
  - all 11 substances included in the provisional list

Proposed Text has Broad Application

In preparation

Draft act

Feedback period

13 March 2024 - 10 April 2024

FEEDBACK: OPEN

UPCOMING

Commission adoption

Planned for

Second quarter 2023

About this initiative

Summary

This Regulation aims to increase quality control under Regulation (EU) No 10/2011 on plastic FCMs by:

- ensuring alignment with Regulation (EU) 2022/1616 on recycled plastics and Regulation (EU) No 528/2012 on biocidal products;
- introducing purity requirements for substances obtained from waste and natural materials; and
- adapting migration testing of multi-layer materials and repeat testing.

It also adds quality control rules to Regulation (EC) No 2023/2006 on good manufacturing practice.

Topic Food safety

Type of act Regulation

Committee C20408

- Implication that the proposal only applies to “substances of natural origin” and “substances manufactured from waste” is incorrect:
  - Proposed amendment to Article 8 applies “high degree of purity” to all substances used in the manufacture of plastic materials and articles

Article 3a

High degree of purity

A substance used in the manufacture of plastic materials and articles shall be considered as having a high degree of purity where all of its constituents form part of its identity, and it otherwise contains only a minor amount of contaminants and non-intentionally added substances that fulfil one of the following conditions:

(i) they comply with the specifications or restrictions specified in the authorisation of the substance in table 1 of Annex I, if any;

(ii) they have been subject to a risk assessment in accordance with Article 19 and considered compliant;

(iii) they have been subject to an individual toxicological assessment which concludes that genotoxicity is ruled out, in accordance with the relevant guidance adopted by the Authority, and they are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to an individual migration of any of them resulting in their presence in food exceeding 0.05 mg/kg;

(iv) they are unknown or have not been subject to an assessment specified in points (ii) or (iii), but are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to individual migration into food of any of them resulting in their presence in food exceeding 0.00015 mg/kg.

Problematic Text: “full migration to food…”

- For unknown or unidentified contaminants

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Article 8

General requirements on substances

1. Substances used in the manufacture of plastic materials and articles, including those manufactured from waste, shall be of a high degree of purity and shall be of a technical quality suitable for the intended and foreseeable use of the materials or articles.

   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.

2. By derogation from paragraph 1, as regards purity, the following requirements shall apply to substances of natural origin:

   (v) if the substance is identified by a name in this Regulation that refers to a natural multi constituent material where the source is biological, that substance may be used as obtained from its natural origin, provided it has been entirely separated from other natural materials from which the substance was obtained and that are not forming part of its identity, or,

   (vi) if the substance is identified by a name in this Regulation that refers to a natural multi constituent material where the source is mineral, that substance may be used as obtained from its natural origin, provided it has been entirely separated from the other natural matter that is not forming part of its identity of the substance.

   Any additional specifications or requirements applicable to a substance or material of natural origin set out in Table 1 of Annex I, applicable to the substance or material, shall apply.

3. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that documentation showing compliance with paragraphs 1 to 2 is part of the documentation referred to in Article 16.

4. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that competent authorities can take samples to verify their degree of purity and their composition, including that of the substances and materials used for their manufacture.

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Article 8

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   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.

3. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that documentation showing compliance with paragraphs 1 to 2 is part of the documentation referred to in Article 16.

4. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that competent authorities can take samples to verify their degree of purity and their composition, including that of the substances and materials used for their manufacture.

Purity as a Specification of Starting Material

- Proposed amendments to Articles 3a and 8 impose new specification on starting materials
  - Cannot avoid impact by passing identity and concentration of substance along value chain (with Declaration of Compliance)
  - If starting material does not meet “high degree of purity” cannot be used in plastic food-contact material or article
  - Requirement is not limited to Annex I listed materials
    - Would also apply to all “substances used in the manufacture of…”
    - Purity specification also applies to colorants, PPAs, aids to polymerization, solvents, etc.
- Applies to virgin materials, as well as products of natural origin and materials produced from waste

Key Takeaway

Amendment does not tell you what to do with already identified impurities, but rather establishes detection limit for assessing purity of starting substances!

Impact on Purity of Typical Monomer

- Example: consider impurity in **dimethyl terephthalate** (DMT):
  - Assume manufacturer has identified all impurities in monomer, down to 10 ppm
  - Recall: definition of “high degree of purity”

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(iv) they are unknown or have not been subject to an assessment specified in points (ii) or (iii), but are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to individual migration into food of any of them resulting in their presence in food exceeding 0.00015 mg/kg.

Impact on Purity of Typical Monomer

- Example: consider impurity in **dimethyl terephthalate** (DMT):
  - What is calculated migration of unknown impurity present at 1 ppm in DMT, "assuming full migration to food"
    - Specification is migration cannot exceed 0.00015 mg/kg
  - To assess "total mass transfer" (for impurities 100-250 g/mole), JRC indicates that layer thickness of 40 µm-PET should be used:

$$\langle M \rangle = 1 \times 10^{-6} \text{ g-imp/g-DMT} \times 0.65 \text{ g-DMT/g-PET} \times 1.4 \text{ g-PET/cm}^3 \times 40 \text{ µm-PET} \times 1 \text{ cm/10,000 µm} \times 600 \text{ cm}^2\text{/kg-food} \times 1000 \text{ mg/g}$$

$$= 0.002 \text{ mg/kg-food, or ~10 times too high}$$

- Bottom line – DMT monomer producer must ensure that an unknown impurity is not present in DMT at more than 0.1 ppm (or ensure DMT is 99.99999% pure)

Results for Other Starting Materials

- Volatile monomer (ethylene) used in manufacture of polyolefin:
  - 1 ppm impurity results in migration of ~0.12 mg/kg assuming full migration to food, or ~1000 times too high
  - Producer must identify all impurities down to 1 ppb (purity = 99.9999999%)

- Antioxidant
  - If you assume use at 0.5% use level, and assume full migration to food, 1 ppm impurity results in migration of 0.0004 mg/kg for polypropylene, or ~3 times too high
  - Producer must identify all impurities down to 0.3 ppm (purity = 99.99997%)

Somewhat Favorable Change from Proposal

they are unknown or have not been subject to an assessment specified in points (ii) or (iii), but are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to individual migration into food of any of them resulting in their presence in food exceeding 0.00015 mg/kg.

- Change may indicate a recognition that some losses of impurities could occur during polymerization or manufacture of material/article
- Not clear how a raw material producer will know extent of loss, and change may have no ACTUAL impact on what must be done

Declarations of Compliance

- Amendment also proposes to update DoC requirement
  - **Annex I listed substances** (subject to restrictions or specifications) must *also* be disclosed
  - This includes impurities, reaction intermediates formed during production process, decomposition or reaction products

ANNEX IV
Declaration of compliance

The written declaration referred to in Article 15 shall contain the following information:

…

6) adequate information relative to the substances used, **including impurities in the substances used, reaction intermediates formed during the production process, decomposition or reaction products, in particular ~~or products of degradation thereof~~** for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,

- that are subject to restrictions **and/or specifications in Annex I and/or** in Annex II, or
- for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to **~~a migration from the final material~~ individual migration into food from the final plastic material or article** exceeding 0,00015 mg/kg food or food simulant;

Alternate (Likely Incorrect) Interpretations

- Some have suggested suppliers can use “risk assessment” or “diffusion modeling” or other assumptions regarding loss of impurities when producing final material or article to limit impact of proposed change
  - If identity of substance is unknown – **must not migrate** at levels exceeding 0.00015 mg/kg food, **assuming full migration to food**
    - If impurity identity unknown, cannot conduct an Article 19 risk assessment
    - If impurity identity unknown, cannot rule out genotoxicity
    - Diffusion modeling is not “full migration to food”
    - Considering reduction of impurity from further processing (polymerization, etc.) potential option, but may limit to certain manufacturing processes, products, or uses
- BOTTOM LINE: Most starting material producers do not identify all impurities down to 0.1 ppm (or lower) level
  - Starting material cannot be considered to have “high degree of purity” under proposed text
  - Proposal will require impurity assessment that may not be commercially achievable

Inconsistent with Focus on Final Articles

- Commission has indicated that revision to food contact legislation will shift focus from clearing starting materials to establishing requirements on finished materials and articles
  - Increasing purity requirements for starting materials inconsistent with that approach

- The proposed approach does not appear to be proportional to risk
- The proposed approach appears to impose higher standard on plastic materials and articles (as compared to starting substances for other materials)

DG Sante Proposed Timeline to Adoption

- Discussed at Food Contact Materials Working Group – January 2024
- Open for Public Consultation: 13 March 2024 – 10 April 2024
- Vote by Standing Committee (Plants, Animals, Food and Feed, PAFF) – 24 April 2024
- Would need to be translated and would then undergo scrutiny of the European Parliament (EP) and the Council
- EP elections in June 2024 (election recess until 10 July 2024)
- Adoption – (late) 2024 (?)

Potential Comments

- Pause proposal to allow additional discussions with starting material producers to assess feasibility
- Rework proposal to permit considerations of intended uses of starting materials and finished articles
  - To permit losses of impurities during processing
  - To consider diffusion or other modeling of finished article use
- Move requirement to Framework Regulation (?) and/or GMP Regulation
  - Would require starting substances for all materials to meet same purity requirements (should not be directed at just plastics)
  - Other materials also could potentially have impurities introduced from waste stream, and not proportional to assess only plastic starting materials

More Potential Comments

- Joint Research Committee (JRC) document that discusses article thickness when considering total mass transfer was never finalized, and is no longer publicly available
- DoC requirement for impurities redundant if required to assume “full migration to food”
- Seek confirmation that mechanically recycled plastics complying with Reg. No. 2022/1616 are not within the scope of the “high degree of purity” requirement for “substances … manufactured from waste”

For More Information

- Send an email to existing Keller and Heckman contact(s), or
- Email: quality_amendment@khlaw.com
- Let us know:
  - Are you interested in receiving more information about this amendment?
  - How will this amendment impact you?
  - Can we prepare comments to the commission for you to submit?

Thank You

Any questions?

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