

**Position paper to  
Food safety – plastic food contact materials (FCMs) (update to quality control rules)**

The Regulation aims to increase quality control under Regulation (EU) No 10/2011 on plastic in terms of recycled plastic food contact materials FCMs.

*Eurocolour, the umbrella association for manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe, welcomes the possibility of consultation to identify appropriate measures to ensure the safety of plastic food contact materials (FCM).*

**Our key messages:**

- ❖ Contradiction summary and draft regulation ! New rules “of high degree purity” for substances made from waste and natural materials, as announced since 2022 and communicated in 2023, not unexpectedly extended to all substances !
- ❖ No purity requirements with migration limits that are not feasible in practice (0.15 ppb and 50 ppb).
- ❖ Requirements that lead to a purity level for raw materials of >99.99999 % do not make sense in practice.
- ❖ New rules for a high degree of purity are not required for colorants and fillers. Studies have shown that there is no migration from the inside of a plastic matrix.

**Conclusion:**

- ❖ We reject the new limits. Purity requirements that go beyond the requirements of Regulations (EU) No. 1333/2008 and (EU) No. 1334/2008 for food additives are not feasible in practice.
- ❖ We propose pragmatic approaches for colorants, such as upper limits for PAA, PAH and metals.
- ❖ The rules for purity are incorrectly positioned in (EU) No 10/2011, these rules should be included in the Framework Regulation for FCM (EU) No 1935/2004 or in regulation (EU) No 2023/2006 good manufacturing praxis.

**Contradiction summary and regulation!**

The summary “*introducing purity requirements for substances obtained from waste and natural materials*” this does not reflect the proposed draft regulation of Article 8 and 3a. “*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.*”

New rules for substances made from waste and natural materials, as announced since 2022 and communicated in 2023, not unexpectedly extended to all substances !

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**Requirement not feasible in practice**

The definition of purity requirements above migration limits of 0.15 ppb and 50 ppb cannot be met with available raw materials as well as colorants and fillers. This unexpected extension of the purity requirement of waste materials and natural raw materials to all raw materials used, including colorants and fillers, is not feasible in practice.

**Raw materials with the required degree of purity not available**

Sample calculations by Keller & Heckman, presented at the public web conference on March 21, 2024, show that only impurity of 0.1 ppm would be permissible, i.e. raw materials for FCM would have to have a purity level >99.99999%, [March 2024-Impact of Quality Amendment Slides.pdf \(khlaw.com\)](#). Such raw materials are not available in the market as they are impossible to produce.

**"High purity" rules not required for colorants and fillers**

Studies have shown that there is no migration from the inside of a plastic matrix. colorants and fillers cannot migrate from the food contact material into food. Particle migration can be excluded for particles larger than 2 or 3 nm. The "SCHEER - Scientific Opinion on the safety of titanium dioxide in toys" of 27.07.2023 also states that no migration from a solid plastic matrix is possible, [SCHEER - Scientific Opinion on the safety of titanium dioxide in toys - European Commission \(europa.eu\)](#)

**Findings from the following studies:**

- ❖ No migration of organic and inorganic pigments and fillers
- ❖ No migration of printing inks with pigments (organic and inorganic) and filler
- ❖ No migration of carbon black

**1) Migration of nanoparticles from plastic packaging materials containing carbon black into foodstuffs**

Johannes Bott, Angela Störmer, Roland Franz, *Food Addit Contam Part A Chem Anal Control Expo Risk Assess.* **2014**, 31(10),1769-82, <https://doi.org/10.1080/19440049.2014.952786>

**2) Investigations into the Potential Abrasive Release of Nanomaterials due to Material Stress Conditions-Part A: Carbon Black Nano-Particulates in Plastic and Rubber Composites**

Johannes Bott and Roland Franz, Department of Product Safety and Analytics, Fraunhofer Institute for Process Engineering and Packaging (IVV), 85354 Freising, Germany <https://doi.org/10.3390/app9020214> ; <https://www.mdpi.com/2076-3417/9/2/214>

**3) Nanoscale pigment particles: Analysis of the migration behaviour form printing ink layers of printed food packaging into food**

Dr. Matthias Henker Flint Group Germany GmbH, Dr Sarah-Lisa Theisen Siegwerk Druckfarben AG & Co. KGaA, Dr Michael Becker ECKART GmbH, Dr Marting Schieß, German Paint and Printing Ink Association (VdL) [DLR nanoscale pigment particles.pdf \(eupia.org\)](#);

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**4) Nanoscale pigment particles: Investigation on the migration of nanoscale pigment particles from printing ink layers to food during transient direct contact**

Dr. Matthias Henker, Martin Schleiß, Frank Lange, Inga Buschauer, Christof Walter, Dirk Lange und Lutz Becker [2020-02-DLR- Nanoscale pigment particles.pdf \(eupia.org\)](#)

**5) VdMi research project „Investigations into the release and and transfer of nanomaterials used as pigments and fillers from can coatings into food“**

Food Packaging and Shelf Life 16 (2018), 112–121, Johannes Bott, Angela Störmer, Peter Albers, Fraunhofer Freising [Investigation into the release of nanomaterials from can coatings into food – ScienceDirect](#)

**6) A model study into the migration potential of nanoparticles from plastics nanocomposites for food contact**

Angela Störmer, Johannes Bott & Roland Franz, *Food Packaging and Shelf Life* 2(2) 73-80 FCM Substance No 87 (= Silicon dioxide, silanated) [A model study into the migration potential of nanoparticles from plastics nanocomposites for food contact - ScienceDirect](#)

**7) Critical review of the migration potential of nanoparticles in food contact plastics**

A. Störmer, J. Bott, D. Kemmer, R. Franz, *Trends in Food Science & Technology* [Critical review of the migration potential of nanoparticles in food contact plastics - ScienceDirect](#)

**Conclusion:**

We reject the new limits. Purity requirements for FCM that go beyond the requirements of Regulations (EU) No. 1333/2008 and (EU) No. 1334/2008 for food additives are not feasible in practice.

We propose pragmatic approaches for colorants, such as upper limits for PAA, PAH and metals.

The rules for purity are incorrectly positioned in (EU) No. 10/2011, these regulations should be included in the Framework Regulation for FCM (EU) No. 1935/2004 or in (EU) No. 2023/2006 Good Manufacturing Practice (GMP) for FCM.

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**About Eurocolour:**

*Eurocolour e. V. is the umbrella association for manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe.*

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