

# 16<sup>th</sup> amendment









## Points previously discussed





- Migration limit Phthalates
- Removing use of untreated wood flour
- Re-evaluation of substances for which the Regulation does not define SML – based on EFSA opinion
- Production of starting substances manufactured with microbial fermentation
- Definition of rules for processing of off-cuts and scraps
- Biocides
- Specific labelling requirements (age group restrictions, temp. conditions..)
- Inconsistency between the German and English language versions (BPA)
- Correction of 2 authorised substances (FCM 452, FCM 1059)
- New authorised substances :
  1. Tris(2-ethylhexyl)-benzene-1,2,4-tricarboxylate;
  2. (triethanolamineperchlorate, sodium salt) dimer



## Current amendment revised




-  Migration limit Phthalates
-  Removing use of untreated wood flour
-  Re-evaluation of substances for which the Regulation does not define SML – based on EFSA opinion – **only one substance to be removed salicylic acid (FCM No 121)**




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  1. Tris(2-ethylhexyl)-benzene-1,2,4-tricarboxylate;
  2. (triethanolamineperchlorate, sodium salt) dimer
  3. N,N-bis(2-hydroxyethyl)stearylamine partially esterified with saturated C16/C18 fatty acids;
  4. Benzophenone-3,3',4,4' -tetracarboxylic dianhydride (BTDA)
  5. Phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate



## New authorised substances

[N,N-bis\(2-hydroxyethyl\)stearylamine partially esterified with saturated C16/C18 fatty acids](#)

*EFSA opinion 2020;18(3):6047*

- Favourable scientific opinion on the use of the substance N, N-bis(2-hydroxyethyl)stearylamine partially esterified with saturated C16/C18 fatty acids (FCM No 1081)
- Additive intended for production of plastic FCM
- **EFSA Conclusion** : Not of safety concern for the consumer when **used at up to 2% (w/w) in all polymers** only intended for contact **with dry foods** for up to **6 months** at room temperature.
  - Dry foods → foods for which table 2 of Annex III assigns simulant E.
- Migration of the sum of N,N-bis(2-hydroxyethyl)stearylamine and its mono- and di-ester, should not exceed **1.2 mg/kg food**.



## New authorised substances

[Benzophenone-3,3',4,4' -tetracarboxylic dianhydride \(BTDA\)](#)

*EFSA opinion 2020;18(7):6183*

- Favourable scientific opinion on the use of the substance benzophenone-3,3',4,4'-tetracarboxylic dianhydride (BTDA) (FCM substance No 1083)
- BTDA can be used at **up to 43% as a co-monomer** in the production of polyimides for **repeated use** contact **with acidic or fatty foods** at temperatures **up to 250°C**.
- **Migration of BTDA should not exceed 50 µg/kg**



## New authorised substances

Phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate

*EFSA opinion 2020;18(5):6120*

- Favourable scientific opinion on the use of the substance phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (FCM substance No 1082)
- Used for the production of kitchen countertops and sinks. These composite articles are intended **for repeated contact with all food types**. The contact time is not expected to exceed several hours at room temperature or a short time at high temperature (1 h at 70°C).
- **Used as a co-monomer at up to 0.35% to manufacture polymethylmethacrylate-based composites**
- Migration should not exceed **0.05 mg/kg food** expressed as the sum of the mono-, di- and triesters of phosphoric acid and the mono-, di-, tri- and tetraesters of diphosphoric acid.



## Next steps

After the WG, the draft proposal will be provided to MS for comments.

Intended to be presented at the next PAFF Meeting : 28 February (if possible) or 21 April 2022 or specific PAFF together with plastic recycling



# Styrene



## Context

**Major significance** (estimate 20% of the market of plastic FCM) used to produce common plastics such as polystyrene (PS), expanded polystyrene (EPS), high impact polystyrene (HIPS), styrene butadiene rubber (SBR)

- **Styrene is authorised** to be used as a monomer or starting substance under Annex I (FCM No 193) of Regulation (EU) No 10/2011 **without a specific migration limit or additional restrictions**.
- **April 2020**, EFSA opinion on prioritization of the re-evaluation of the already authorized substances from Annex I to Regulation (EU) No 10/2011 (*EFSA Journal 2020;18(6):6124*)

→ includes Styrene (high-priority)



## Context

**EFSA Opinion adopted 9 September 2020** (*EFSA Journal* 2020;18(10):6247) re-evaluating the safety of styrene.

*(...) based on the data provided in the IARC Monograph and by the industry, a concern for genotoxicity associated with oral exposure to styrene cannot be excluded. The migration of styrene into foods packed in styrenic plastics is below **10 µg/kg for the majority of the foods**, but up to 230 µg/kg was reported."*

*(...) "Migration ranged from <1µg/kg to 200 µg/kg or µg/L, **although in the majority of the foods (77%), it was below 10 µg/kg**, and in 26% of the foods, it was below 1 µg/kg."*

→ **Inconclusive - Lack of data to conclude on genotoxicity**

More data is necessary to be provided to EFSA by the industry.

**Temporary SML of 10ppb achievable for majority of plastics analysed**



## Context

**Migration tests : are migration testing approaches representative for real styrene migration into food?**

- Issue raised by industry : the testing into simulants are too severe and not representative of the real migration of styrene into foods.

**Data?**

→ **Launch of a survey to collect data on migration (simulant vs food)**

→ **Analysis of data from tests carried out by MS**

Establish **temporary SML of 10ppb** and ensure that the tests are representative of the actual migration of styrene into the food



# Thank you



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