16th amendment

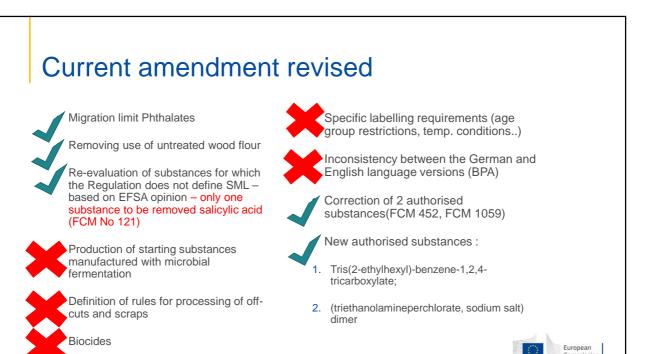


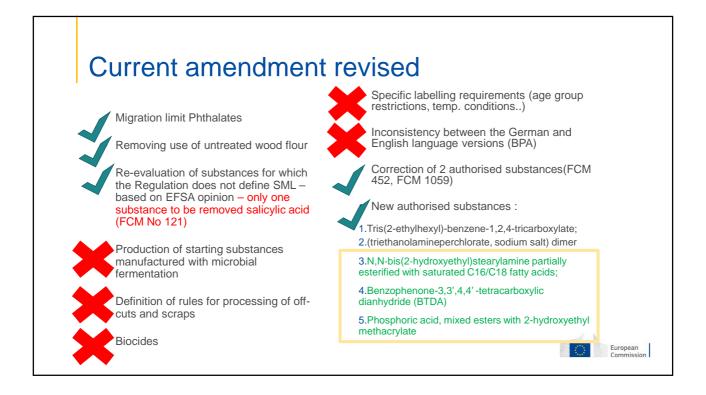
Points previously discussed

- · 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:
- Tris(2-ethylhexyl)-benzene-1,2,4tricarboxylate;
- (triethanolamineperchlorate, sodium salt)
 dimer







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
- <u>EFSA Conclusion</u>: 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 μ g/kg for the majority of the foods, but up to 230 μ g/kg was reported."
- (...) "Migration ranged from <1 μ g/kg to 200 μ g/kg or μ g/L, although in the majority of the foods (77%), it was below 10 μ g/kg, and in 26% of the foods, it was below 1 μ g/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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