Joint Expert Groups 2024

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FCMJEG

1.172 The COT considered risk assessments prepared by the Joint Expert Group on Food Contact Materials (FCMJEG) regarding the following regulated product applications:

- on the safety of the use of phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (HEMAP) as a component in the manufacture of kitchen countertops and sinks. This assessment was for HEMAP only, and not the final reaction mixture used in the manufacture. The final assessment was published in July 2024.
- On the safety of the use of Calcium tert-butylphosphonate as an additive used in the manufacture of plastic materials and articles intended to come into contact with food. The final assessment is expected to be published early 2025.

On the safety of the recycling processes:

- Document on the evaluation of the recycled poly(ethylene terephthalate) decontamination process operated by LINPAC for use in the manufacture of articles in contact with food.
- on the recycled poly(ethylene terephthalate) decontamination process operated by Wellman Neufchâteau Recyclage (subsidiary of Indorama Ventures) for use in the manufacture of materials and articles in contact with food.

- on the evaluation of the safety of the process for the recycling of post-consumer poly(ethylene terephthalate) into food contact materials.

1.173 These items are currently reserved as the Committee Advice Papers are not currently published.

Committee Advice Document on the safety of 2-hydroxyethyl methacrylate phosphate as a monomer for use in the manufacture of plastic food contact materials and articles

1.174 The COT considered a Committee Advice Document (CAD) prepared by the Joint Expert Group on Food Contact Materials (FCMJEG) regarding an application for 2-hydroxyethyl methacrylate phosphate (HEMA) as a monomer in a commercial product for use in the manufacture of kitchen countertops and sinks that are intended for contact with all types of food (RP1190).

1.175 All components of the commercial product are listed in assimilated Regulation EU No. 10/2011 on plastic materials and articles intended to come into contact with food. The application and the following assessment are for HEMA only, not the commercial product.

1.176 Satisfactory information regarding the identity of substance, physical and chemical properties, intended application of substance, data on migration of substance and toxicological data were submitted.

1.177 The toxicological information that formed the basis of the risk assessment was a bacterial reverse mutation test (Ames test), which was conducted in accordance with OECD No. 471, and an *in vitro* mammalian micronucleus test, in accordance with OECD No.487, on the commercial product. Results of the Ames

test and *in vitro* micronucleus (MN) test showed no mutagenic, clastogenic or aneugenic potential for the commercial product under the experimental conditions described.

1.178 The specific migration of the sum of HEMAP plus its phosphate and diphosphate esters under the worst foreseeable conditions of use was 24.8 µg/6 dm2 (assumed that this is equivalent to contact with 1 kg food).Taking into account that the specific migration of the sum of HEMA plus its phosphate and diphosphate esters is not expected to exceed 50 µg/kg food and the negative results in the Ames and *in vitro* micronucleus tests, the FCMJEG proposed a specific migration limit (SML) of 0.05 mg/kg food for HEMA.

1.179 Overall, the COT considered the information and data provided in the FCMJEG CAD sufficient to conclude that there was no concern for a risk to human health from the use of HEMA in the specific final commercial mixture in the manufacture of kitchen countertops and sinks up to a maximum percentage in formulation of 0.35%.

1.180 The full FCM JEG CAD: FCMJEG Applications | Committee on Toxicity

Committee Advice Document on Calcium *tert*-butylphosphonate as an additive for use in the manufacture of plastic food contact materials and articles

1.181 The COT considered a Committee Advice Document (CAD) prepared by the Joint Expert Group on Food Contact Materials (FCMJEG) regarding an application for calcium *tert*- butylphosphonate as an additive used in the manufacture of plastic materials and articles intended to come into contact with food (RP1702).

1.182 The information on the identity of the substance, the physical and chemical properties and intended application were considered satisfactory.

1.183 Results from the overall and specific migration tests demonstrated the migration of calcium *tert*-butylphosphonate to be close to or below the limit of detection (up to 10 µg/kg).

1.184 Owing to the low migration of calcium tert-butylphosphonate as an additive under the conditions of use specified in the application, limited toxicology testing was required. Results of the Ames test and *in vitro* micronucleus (MN) test

showed no mutagenic, clastogenic or aneugenic potential for the commercial product under the experimental conditions described.

1.185 The available toxicology data showed calcium *tert*-butylphosphonate to be negative in the *in vitro* Ames test and *in vitro* micronucleus (MN) assay and therefore unlikely to be of concern for potential genotoxicity, especially based on low exposure to humans.

1.186 Overall, there is unlikely to be a genotoxicity risk to health from the use of calcium *tert*-butylphosphonate as an additive in the manufacture of plastic materials and articles intended to be in food contact with food. However, a potential health risk to infants <16 weeks via feeding bottles could not be assessed because infants <16 weeks are expected to be exclusively fed on breast milk and/or infant formula. There is a lack of data including exposure data for these circumstances having regard to the sensitive nature of the age group.

1.187 Calcium *tert*-butylphosphonate was therefore recommended for approval for use as an additive as outlined in the application and specified above.

1.188 The full FCM JEG CAD is due to be published shortly: FCMJEG Applications | Committee on Toxicity.

AEJEG assessments

1.189 The COT considered Risk Assessments prepared by the Joint Expert Group on Additives, Enzymes and other Regulated Products (AEJEG) regarding the following regulated product applications:

- Committee Advice on the safety of the Application to modify the conditions of use of E401 (sodium alginate) for use as a surface treatment in entire fruits and vegetables.
- Extension of use of nisin (E 234) to a new food category “egg analogues”
- Application for a change in the steviol glycoside specification in the United Kingdom to include a new manufacturing method for Steviol Glycosides including Rebaudioside D.
- Authorisation of new food additive substance Glycolipids.

1.190 All items are currently reserved as they cover draft AEJEG Committee Advice Papers not currently published.

1.191 AEJEG Committee Advice Papers will be published in 2025.