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Section *Novel Food and Toxicological Safety of the Food Chain*
(subsection of Phytopharmaceuticals-Legislation Committee meeting)
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CIRCABC Link: <https://circabc.europa.eu/w/browse/be316299-65bf-4c7b-9da0-97bfe17fd8d>

SUMMARY REPORT

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the extension of the use citric acid (E 330) in cocoa and chocolate products.

Citric acid (E 330) is a food additive authorised in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.

The Commission received an application for the modification of the conditions of use of citric acid (E 330) contained in food category 05.1 ‘Cocoa and Chocolate products as covered by Directive 2000/36/EC’, by increasing its maximum level of use to 10 000 mg/kg for milk chocolate.

Citric acid (E 330), when used as a stabiliser in cocoa mass containing high levels of polyphenols, lowers pH and reacts with a part of polyphenols intensifying cocoa mass colour into characteristic pink shades accompanied by a berry-fruit sour taste which is achievable with the maximum level of 10 000 mg/kg.

The safety of citric acid (E 330) was evaluated by the Scientific Committee for Food, which established its acceptable daily intake as ‘not specified’. The term ‘not specified’ is used when, on the basis of the available toxicological, biochemical and clinical data, the total daily intake of the substance, arising from its natural occurrence and its present use or uses in food at the levels necessary to achieve the desired technological effect, will not present a hazard to health.

Therefore, it is appropriate to authorise the use of citric acid (E 330) in milk chocolate at 10 000 mg/kg.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annex II to Regulation (EC) No 1333/2008 as a follow-up to an application.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the extension of the use of polysorbates (E 432-436) in beverages.

Polysorbates (E 432-436) are substances authorised for use as food additives in a wide variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.

The Commission received an application for the authorisation of the use of polysorbate 65 (E 436) as an anti-foaming agent in several types of beverages.

The European Food Safety Authority re-evaluated the safety of polysorbates (E 432-436) and concluded that the exposure estimates did not exceed the acceptable daily intake (ADI) of 25 mg/kg body weight/day in the refined non-brand-loyal scenario for all age groups.

The impact on the overall exposure from the extended use of polysorbate 65 (E 436) at the maximum level of 10 mg/kg in the food categories 14.1.4 'Flavoured drinks', 14.2.3 'Cider and perry', 14.2.4 'Fruit wine and made wine' and 14.2.8 'Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol' in Part E of Annex II to Regulation (EC) No 1333/2008 is negligible.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annex II to Regulation (EC) No 1333/2008 as a follow-up to an application.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of the use of soybean hemicellulose (E 426).

Soybean hemicellulose (E 426) is a food additive authorised in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.

The Commission received an application for the extension of use of soybean hemicellulose (E 426) as a stabiliser in flavoured fermented milk products and flavoured drinks to prevent an agglomeration and precipitation of proteins and phase separation under acidic conditions.

The European Food Safety Authority re-evaluated the safety of soybean hemicellulose (E 426) and concluded that it is very unlikely that there is a safety concern from the current use of soybean hemicellulose (E 426) as a food additive, and that there is no need for a numerical acceptable daily intake (ADI). Such conclusion is used for substances of a very low safety concern and only if there is reliable information for both exposure and toxicity and there is a low probability of adverse health effects in humans at doses that do not induce nutritional imbalance in animals.

Therefore, it is appropriate to include soybean hemicellulose (E 426) in Group I of Part C of Annex II to Regulation (EC) No 1333/2008 that also covers the requested extension of use.

The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annexes II to Regulation (EC) No 1333/2008 as a follow-up to an application.

One Member State stressed the importance of ensuring that an adequate information about the presence of potentially allergenic proteins in soybean hemicellulose (E 426) is provided to the consumer as outlined in the EFSA opinion on the re-evaluation of soybean hemicellulose (E426) as a food additive.

The Commission clarified that soybeans and products thereof are listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council among substances or products causing allergies or intolerances whose indication, with the exception of certain specified products, shall be mandatory. This obligation also applies to soybean hemicellulose (E 426).

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sorbic acid (E 200) in liquid colour preparations for the decorative colouring of egg shells.

The Commission received an application for the modification of the conditions of use of sorbic acid (E 200) in liquid colour preparations for sale to the final consumer for the decorative colouring of egg shells. Pursuant to Part 2 of Annex III to Regulation (EC) No 1333/2008, sorbic acid (E 200) is an already authorised food additive in colour preparations at a maximum level of 1 500 mg/kg in the preparation. The application shows that a higher level of sorbic acid (E 200) (2 500 mg/kg in the preparation) is needed to consistently ensure appropriate preservation, and consequently microbiological safety, of these specific liquid colour preparations.

EFSA recently established a new group ADI for sorbic acid (E 200) and potassium sorbate (E 202) of 11 mg sorbic acid/kg bw per day, and concluded that the currently authorised uses of sorbic acid (E 200) and potassium sorbate (E 202) do not lead to an exceedance of the ADI. It results from the tests carried out by the applicant that the migration of sorbic acid (E 200) from the egg shell to the edible part of the egg is below the level of detection. Consequently, the requested higher level of sorbic acid (E 200) would not lead to an increase of the exposure of consumers to sorbic acid (E 200) and is not of safety concern.

Therefore, it is appropriate to authorise the use of sorbic acid (E 200) as a preservative in liquid colour preparations for the sale to the final consumer for the decorative colouring of egg shells at the maximum level of 2 500 mg/kg in the preparation.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) in liquid vegetable oil emulsions.

The Commission received an application for the authorisation of the use of polyglycerol polyricinoleate (PGPR, E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less.

PGPR (E 476) is a water-in-oil emulsifier capable of forming very stable oil emulsions with high water content. In studies carried out by the applicant, comparing the effectiveness of different emulsifiers for the production of liquid vegetable oil emulsions with reduced fat content, PGPR (E 476) gave the best results both in terms of physical as well as organoleptic properties of the obtained product. The emulsion can be used in the same way as vegetable oils for the preparation of cold and hot dishes. However, the emulsion has a lower fat content (70 % or less), and therefore a lower caloric content than the vegetable oil used for its production. The level of use of PGPR (E 476) needed to achieve the intended technological function was 4 000 mg/kg.

In 2017 EFSA re-evaluated the safety of PGPR (E 476) and concluded that the authorised uses would not lead to an exceedance of the ADI. The applicant has shown that the requested new use of PGPR (E 476) does not lead to an exceedance of the ADI and it is therefore of safety concern.

Therefore, it is appropriate to authorise the use of PGPR (E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70 % or less (food category 02.2.2).

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) 1881/2006 as regards maximum levels of perchlorate in certain foods.

Given the delay incurred in the adoption procedure it was agreed to change the date of application from 1 April 2020 to 1 July 2020.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) correcting certain language versions of Regulation (EC) No 124/2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed (language versions to be corrected: BG, LT and HR).

Vote taken: Favourable opinion.