

European Union Comments
CODEX COMMITTEE ON FOOD ADDITIVES
Forty-ninth Session
Macao SAR, China, 20-24 March 2017

AGENDA ITEM 5(a)

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): CCFA48 OUTSTANDING PROVISIONS; PROVISIONS FOR BENZOATES IN FC 14.1.4; PROVISIONS IN FC 5.0 AND 5.1; PROVISIONS ASSOCIATED WITH NOTE 22; PROVISIONS IN FC 01.1, 01.1.1, 01.1.3 AND 01.1.4 (REPORT OF THE EWG ON THE GSFA)

(CX/FA 17/49/7)

European Union Competence
European Union Vote

General comments

The European Union (EU) would like to thank the United States of America for chairing the electronic Working Group and preparing the paper CX/FA 17/49/7.

The EU comments are captured in the paper and the EU appreciates the possibility to discuss further the draft provisions on the General Standard for Food Additives.

Comments on Appendix 3: use of benzoates in category 14.1.4

The EU takes note of 3 Options recommended for consideration by the Committee. The EU supports **Option 1** (i.e. ML of 150 mg/kg).

The EU welcomes further discussion on the provision for the use of benzoates in food category 14.1.4. Lowering the maximum level (ML) to 250 mg/kg at the last CCFA meeting was a step in the right direction, however, a further reduction of the ML is needed to address the JECFA's recommendation related to the exceedance of the ADI.

The JECFA's exposure assessment was carried out using **the average typical reported use levels** from various countries **ranging between 83-209 mg/L** (maximum levels were reported between 173-627 mg/L) for beverages included in food category 14.1.4 for beverages included in food category 14.1.4¹.

Using the average typical reported use levels the exposure estimates indicated the exceedance of the ADI. Therefore, the EU cannot support Options 2 and 3 which recommend the ML of 200 mg/L (or 250 mg/L respectively) and 500 mg/L for beverages with a pH greater than 3.5.

The levels suggested in Option 2 and 3 are not in compliance with section 3.1 of the Preamble to the GSFA which states "*The inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources.*"

¹ WHO FOOD ADDITIVES SERIES: 71; Safety evaluation of certain food additives and contaminants / prepared by the Eightieth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), http://apps.who.int/iris/bitstream/10665/198360/1/9789240694897_eng.pdf?ua=1

Within the context of probable daily intake from all food sources the importance of the reduction of the ML in category 14.1.4 is underlined by the fact that according to JECFA non-alcoholic beverages provide the primary source of dietary exposure to benzoates. This finding is in line with EFSA which published the re-evaluation of benzoates in March 2016².

According to EFSA the usage of benzoates has highly increased in the products available on the EU market especially since 2013. The main food categories to which benzoates are added are soft drinks, table sauces and fish products. As regards the exposure the EFSA opinion used information on the actual use levels from industry (typical mean ranged between 50-150 mg/L) and the analytical results from the EU Member States (6.835 analytical results for flavoured drinks were reported to EFSA). The use levels of 100 mg/L (mean) or 150 mg/L (P95) respectively were used in the refined exposure scenarios for category 14.1.4 to calculate the overall exposure to benzoates that still exceeded the ADI in particular for toddlers and children consuming flavoured drinks.

The EU would like to offer some further arguments why it believes that the ML of 150 mg/L is appropriate for all beverages falling under category 14.1.4:

- A ML 150 mg/L is below the upper range of average typical use levels used by JECFA to calculate the exposure indicating an exceedance of the ADI
- A broad variety of products containing benzoates up to 150 mg/L is on the EU market. This level is sufficient and it allows achieving the intended technical effect. The EU is not aware of any issues related to microbiological stability and need for higher levels of benzoates.
- The need for higher levels cannot be explained by differences in climate – some EU Member States have regions having very hot summers (e.g. Spain, Greece and Italy). In addition, other Codex member from a tropical region replied to the first circular that similar level (160 mg/L) is satisfactory
- Considering the risks of exceedance of ADI for benzoates, it is appropriate to promote their use at the lowest level needed to achieve the intended technical effect. Best practices available among the Codex countries (e.g. use of the preservation methods based on physical processes – heat processing, carbonation, aseptic filling and an appropriate shelf-life) should thus be considered when assessing the appropriate use level of benzoates

² EFSA Journal 2016;14(4):4433 [110 pp.]; <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4433/epdf>