Following a request from the European Commission, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) was requested to deliver a scientific opinion on the safety assessment of the flavouring substances caffeine [FL-no: 16.016] and theobromine [FL-no: 16.032] in the Flavouring Group Evaluation 49, Revision 1. Consequent to the 2015 scientific opinion from the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the safety of caffeine from all dietary sources, the CEF Panel considered it inappropriate to evaluate the two substances through the Procedure. For caffeine, the Panel based its assessment on the safety threshold of 5.7 mg/kg body weight (bw) per day for adults, except pregnant/lactating women, and 3 mg/kg bw per day for children, adolescents, pregnant and lactating women, as established by the NDA Panel. The safety evaluation of theobromine takes into account that approximately 11% of an oral dose of caffeine is metabolised to theobromine and that both substances have a similar pharmacological profile. For the exposure assessment, a brand loyalty model was chosen. In this model, it was assumed that a consumer is exposed on a long-term basis to a specific category of food (i.e. non-alcoholic beverages), containing caffeine or theobromine at their respective maximum use levels. For the rest of the categories, normal use levels applied. Daily dietary exposure to caffeine and theobromine (excluding systemic exposure) added as a chemically defined flavouring substance ranged 0–2.3 and 0–0.4 mg/kg bw, respectively, across all population groups.

The Panel concluded that caffeine [FL-no: 16.016] and theobromine [FL-no: 16.032] would not be expected to present safety concern based on their estimated levels of intake from their use as flavouring substances.