The Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (the Panel) was asked to provide scientific advice to the Commission on the implications for human health of chemically defined flavouring substances used in or on foodstuffs in the Member States. In particular, the Panel was requested to evaluate four flavouring substances in the Flavouring Group Evaluation 46, Revision 1 (FGE.46Rev1), using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. These four flavouring substances belong to chemical group 30, Annex I of the Commission Regulation (EC) No 1565/2000. The present Flavouring Group Evaluation deals with ammonia [FL-no: 16.009], and three ammonia salts (diamination sulphide [FL-no: 16.002], ammonium chloride [FL-no: 16.048] and ammonium hydrogen sulphide [FL-no: 16.059]). The flavouring substances cannot exist as geometrical or optical isomers. Two of the flavouring substances belong to structural class I and two are classified into structural class III.

The Panel concluded also to perform an estimate of the daily intakes per person using a "modified Theoretical Added Maximum Daily Intake" (mTAMDI) approach based on the normal use levels reported by Industry. In those cases where the mTAMDI approach indicated that the intake of a flavouring substance might exceed its corresponding threshold of concern, the Panel decided not to carry out a formal safety assessment using the Procedure. In these cases the Panel requires more precise data on use and use levels. According to the default MSDI approach, the two flavouring substances [FL-no: 16.009 and 16.048] belonging to structural class I have estimated intakes in Europe of 34 and 140 microgram/capita/day, respectively, which are below the threshold of concern for structural class I substances (1800 microgram/person/day). The two substances belonging to structural class III have estimated intake in Europe of 62 and 5.6 microgram/capita/day, respectively, which is below the threshold of concern for structural class III substances (90 microgram/person/day). The estimated intakes were based on the mTAMDI approach based on the normal use levels reported by Industry. For the candidate substance ammonium chloride [FL-no: 16.048] there is a well-performed carcinogenicity study available, which indicates that the substance does not induce tumours. Ammonia is a substance that is readily absorbed in the gut. It is produced endogenously in amounts that far exceed those that are to be ingested as flavourings. The three ammonium salts are expected to give rise to ammonium ion and chloride or hydrogen sulphide. Ammonia is expected to be transported by the portal circulation to the liver and metabolised to urea by the Krebs urea cycle and subsequently excreted by the kidneys. Hydrogen sulphide is a substance that is produced endogenously. The major pathway for sulphide metabolism is oxidation to sulphate and excretion by the kidney. The major oxidation product of sulphide is thiosulphate which is then converted to sulphate. The primary location for these reactions is the liver. All four substances are accordingly expected to be metabolised to innocuous substances at the anticipated levels of intake as flavouring substances. It was noted that where toxicity data were available they were consistent with the conclusions in the present flavouring group evaluation using the Procedure. On the basis of the default MSDI approach the Panel concluded that the flavouring substances would not give rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances. When the estimated intakes were based on the mTAMDI approach the values for the two substances from structural class I, ammonia and ammonium chloride [FL-no: 16.009 and 16.048], are 110000 microgram/person/day and 220000 microgram/person/day, respectively. These values are above the threshold of concern for structural class I of 1800 microgram/person/day. For one of the substances from structural class III, ammonium hydrogen sulphide [FL-no: 16.059], the mTAMDI value is 220 microgram/person/day. This value is above the threshold for structural class III of 90 microgram/person/day. For the other substance from structural class III no data are available on use and use levels. Thus, intake estimates based on the mTAMDI approach exceed the threshold of concern for the three flavouring substances in this flavouring group, and more reliable exposure data are requested for all four substances. On the basis of such additional data, these flavouring substances should be reconsidered using the Procedure. Subsequently, additional data might become necessary. In order to determine whether this evaluation could be applied to the materials of commerce, it is necessary to consider the available specifications. Specifications including complete purity criteria for the materials of commerce have been provided for the four flavouring substances. Identity tests is missing for one of the flavouring substances, ammonium hydrogen sulphide [FL-no: 16.059]. Thus, the final evaluation of the materials of commerce cannot be performed for this substance, pending further information. The remaining three flavouring substances, ammonia [FL-no: 16.009], ammonium chloride [FL-no: 16.048] and diammonium sulfide [FL-no: 16.002] would present no safety concern at the levels of intakes estimated on the basis of the MSDI approach.