The European Food Safety Authority (EFSA) asked the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (the Panel) 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 nine flavouring substances in the Flavouring Group Evaluation 12, Revision 2 (FGE.12Rev2), using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. These nine flavouring substances belong to chemical group 7, Annex I of the Commission Regulation (EC) No 1565/2000. FGE.12Rev2 includes the assessment of two additional flavouring substances compared to FGE.12Rev1. The present FGE.12Rev2 deals in total with nine primary saturated or unsaturated alicyclic alcohol, aldehyde, acid, and esters belonging to chemical group 7. Seven of the nine flavouring substances possess one or more chiral centres and additionally, and due to the presence of a double bond, one of these substances can exist as geometric isomer. For two of these substances, the stereoisomeric composition has not been specified. The nine flavouring substances are classified into structural class I. Three of the flavouring substances in the present group have been reported to occur in essential oils. In its evaluation, the Panel as a default used the “Maximised Survey-derived Daily Intake” (MSDI) approach to estimate the per capita intakes of the flavouring substances in Europe. However, when the Panel examined the information provided by the European Flavouring Industry on the use levels in various foods, it appeared obvious that the MSDI approach in a number of cases would grossly underestimate the intake by regular consumers of products flavoured at the use level reported by the Industry, especially in those cases where the annual production values were reported to be small. In consequence, the Panel had reservations about the data on use and use levels provided and the intake estimates obtained by the MSDI approach. In the absence of more precise information that would enable the Panel to make a more realistic estimate of the intakes of the flavouring substances, the Panel has decided 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 nine flavouring substances in this group have intakes in Europe from 0.011 to 43 micrograms/capita/day, which are below the threshold of concern for structural class I (1800 micrograms/person/day) substances. The flavouring substances are expected to be metabolised to innocuous products at the estimated levels of intake as flavouring substances. The genotoxic potential of this group of flavouring substances cannot be assessed since information on the flavouring substances or on structurally related substances is missing. However, this does not preclude evaluation of the flavouring substances in the present group using the Procedure (SCF, 1999a). It is considered that on the basis of the default MSDI approach these nine 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 they ranged from 1600 to 5000 micrograms/person/day for the nine flavouring substances from structural class I. For six of the substances the intakes were above the threshold of concern for structural class I of 1800 micrograms/person/day. Thus, for these six of the nine flavouring substances considered in this Opinion the intakes, estimated on the basis of the mTAMDI, exceed the relevant threshold for their structural class, to which the flavouring substance has been assigned. Therefore, for these six substances [FL-no: 02.134, 02.186, 08.135, 09.342, 09.670 and 09.829] more reliable exposure data are required. On the basis of such additional data, these flavouring substances should be reconsidered along the steps of the Procedure. Following this procedure additional toxicological data might become necessary. The three substances which have mTAMDI intake estimates below the threshold of concern for structural class I, are also expected to be metabolised to innocuous products. In order to determine whether this evaluation could be applied to the material of commerce, it is necessary to consider the available specifications. Specifications including complete purity criteria and identity for the materials of commerce have been provided for the nine flavouring substances. Information on the stereoisomeric composition for four of these substances [FL-no: 02.186, 05.157, 05.198 and 09.670] has not been specified sufficiently, as the Flavour Industry has informed that these substances consists of a “mixture of isomers”. However, the isomeric composition of the mixtures have to be provided. Thus, the final evaluation of the materials of commerce cannot be performed for these four substances, pending further information. The five remaining substances [FL-no: 02.134, 05.183, 08.135, 09.342 and 09.829] would present no safety concern at the estimated levels of intake based on the MSDI approach.

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