EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 11, Revision 2 (FGE.11Rev2): Aliphatic dialcohols, diketones, and hydroxyketones from chemical groups 8 and 10 - DTU Orbit (16/01/2019)

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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 12 flavouring substances in the Flavouring Group Evaluation 11, Revision 2 (FGE.11Rev2), using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. These 12 flavouring substances belong to chemical group 10, Annex I of the Commission Regulation (EC) No 1565/2000. The present flavouring group includes 12 candidate substances; nine alphan-diketones or their corresponding alcohols or ketals [FL-no: 02.133, 06.134, 07.071, 07.152, 07.168, 07.238, 07.248 and 07.260], and three beta-diketones or their corresponding hydroxyketones [of which one is a tertiary alcohol] [FL-no: 07.097, 07.165 and 07.184] all belonging to chemical groups 8 and 10. One of the 12 candidate substances possesses four chiral centres [FL-no: 06.134] two possesses two chiral centres [FL-no: 02.133 and 07.168] and four substances possesses one chiral centre [FL-no: 07.097, 07.167, 07.184 and 07.238]. One of the substances [FL-no: 07.260] is a mixture of four isomers. Five of the candidate substances are classified into structural class I, six are classified into structural class II and one is classified into structural class III. Eight of the 12 candidate substances in the present group have been reported to occur naturally in food. In the current evaluation, the Panel has 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 Flavour 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 12 candidate substances have European daily per capita intakes ranging from 0.0012 to 15 microgram, which are below the thresholds of concern for structural class I, II and III (1800, 540 and 90 microgram/person/day, respectively). The candidate substance 3-methyl-2,4-nonadione [FL-no: 07.184] contains a structural 2,4-dione element similar to pentan-2,4-dione. The only genotoxicity data available for this substance was a valid unpublished GLP study in S. typhimurium and E. coli which were both negative. Similar negative result was obtained for pentan-2,4-dione in a valid GLP study in Salmonella, however, positive genotoxicity results were obtained in other studies both in vitro and in vivo. Due to this anticipated structural alert for genotoxicity (the 2,4-dione structure) the Procedure was not applied for 3-methyl-2,4-nonadione [FL-no: 07.184] and accordingly additional data on genotoxicity are required. For the remaining candidate substances, genotoxicity data are only available for a limited number of substances, and the genotoxicity could not be assessed adequately. However, the genotoxicity data available on these remaining 11 candidate substances do not preclude evaluation using the Procedure. Ten of the 11 flavouring substances evaluated through the Procedure are expected to be metabolised to innocuous products. For the remaining candidate substance evaluated through the Procedure, diacetyl-trimer [FL-no: 06.134] the data available do not allow to anticipate hydrolysis to innocuous products. No No Observed Adverse Effect Level (NOAEL) exists for the substance or a structurally related substance to provide an adequate margin of safety under the conditions of intended use and accordingly additional data are required. It was noted that where toxicity data were available they were consistent with the conclusions in the present flavouring group evaluation using the Procedure. It is considered that on the basis of the default MSDI approach the ten of the 11 candidate substances evaluated through the Procedure [FL-no: 02.133, 07.071, 07.097, 07.152, 07.165, 07.167, 07.168, 07.184, 07.248 and 07.260] 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 3900 microgram/person/day for the five candidate substances from structural class I. For one of these candidate substances [FL-no: 02.133] the estimated intake is above the threshold of concern of 1800 microgram/person/day for structural class I. For the six candidate substances, which are assigned to structural class II, the estimated intake based on the mTAMDI range from 1500 to 5400 microgram/ person/day, which is above the threshold of concern for structural class II of 540 microgram/person/day. For the one candidate substance [FL-no: 07.168] from structural class III the mTAMDI value is 1600 microgram/person/day, which exceeds the threshold of concern for structural class III of 90 microgram/person/day. The four candidate substances [FL-no: 07.097, 07.165, 07.167, 07.238] which have mTAMDI intake estimates below the threshold of concern for structural class I are also expected to be metabolised to innocuous products. Thus, for seven of the 11 candidate substances evaluated through the Procedure [FL-no: 02.133, 06.134, 07.071, 07.152, 07.168, 07.248 and 07.260] the intakes, estimated on the basis of the mTAMDI exceed the threshold for the structural class, to which the flavouring substances have been assigned. Therefore, more reliable exposure data are required. On the basis of such additional data, the substances should be reconsidered along the steps of the Procedure. Following this procedure additional toxicological data might become necessary. In order to determine whether the conclusion for the candidate
substances can be applied to the materials of commerce, it is necessary to consider the available specifications. The stereoisomeric compositions have not been specified for three of the substances [FL-no: 06.134, 07.184 and 07.260]. One of the substances [FL-no: 07.260] is a mixture of four isomers (three positional isomers, where one of these can exists as two stereoisomers) and the composition of mixture is not specified. Furthermore, for [FL-no: 07.097] the minimum assay is too low, so information on secondary components of [FL-no: 07.097] is missing. Thus, the final evaluation of the materials of commerce cannot be performed for four substances [FL-no: 06.134, 07.097, 07.184 and 07.260], pending further information. For the candidate substance diacetyl-trimer [FL-no: 06.134] additional metabolism/toxicity data are required, and for 3-methyl-2,4-nonadione [FL-no: 07.184] data on genotoxicity are required before it can be evaluated through the Procedure. The remaining eight substances [FL-no: 02.133, 07.071, 07.152, 07.165, 07.167, 07.168, 07.238 and 07.248] would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

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