Optimization of the cumulative risk assessment of pesticides and biocides using computational techniques: Pilot project

This pilot project is intended as the first step in developing a computational strategy to assist in refining methods for higher tier cumulative and aggregate risk assessment of exposure to mixture of pesticides and biocides. For this purpose, physiologically based toxicokinetic (PBTK) models were developed for two compounds, tebuconazole and prochloraz, and a binary mixture of these compounds in two species, rat and human. PBTK models can be used to estimate the concentration levels (internal doses) of toxic substances and their metabolites in blood and tissue, by a collection of differential equations, and parameters describing species physiology and ADME (absorption, distribution, metabolism and elimination) characteristics of the chemicals. Sufficient data were found to determine the parameters needed for the PBTK model development. The PBTK models were validated on plasma and tissue concentration level data of tebuconazole in rabbit, and in most cases the predictions were seen to be within a factor of two compared to the experimental data. Also simple blood concentration measurements for both compounds from a mixture study in rat, and other data were used to validate and evaluate the models. Exposure scenarios were constructed based on findings of pesticide residues in food of ordinary consumers, and assessment of dermal exposure of professional workers. PBTK simulations were carried using these scenarios.
Artificial sweeteners: A brief review of their safety issues

Low-calorie sweeteners are authorised food additives in the European Union (EU). The safety of these sweeteners has been evaluated in accordance with internationally agreed principles for the safety evaluation of food additives. In the EU, the European Commission’s Scientific Committee for Food (SCF) was the scientific guarantor for the safety of food additives until March 2003. Since then this has been taken over by the European Food Safety Authority (EFSA), notably its Scientific Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel). Based on the large number of toxicological studies that are requested for the safety evaluation of food additives, a no observed adverse effect level (NOAEL) is identified for the most sensitive effect in the most sensitive animal species. A safety factor of 100 is normally applied to the NOAEL in order to establish an acceptable daily intake (ADI) for humans. The ADI is the amount of the food additive, expressed on a milligram per kilogram of body weight (bw) basis, that can be ingested daily over a lifetime without any appreciable health risk. The following low-calorie sweeteners have been allocated an ADI by either the SCF or EFSA: acesulfame K, aspartame, cyclamates, neotame, saccharin, steviol glycosides and sucralose.

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EFSA EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 304 (FGE.304): Five carboxamides from chemical group 30

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate five flavouring substances in the Flavouring Group Evaluation 304, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the three substances [FL-no: 16.117, 16.123 and 16.125] do not give rise to safety concerns at
their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining two candidate substances [FL-no: 16.118 and 16.124], no appropriate NOAEL was available and additional data are required. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. Specifications including complete purity criteria and identity for the materials of commerce have been provided for all five candidate substances.
EFSA Panel on Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 201Rev1: 2-Alkylated, alliphatic, acyclic alpha, beta-unsaturated aldehydes and precursors, with or without additional double-bonds, from chemical subgroup 1.1.2 of FGE.19

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider in this revision 1 of Flavouring Group Evaluation 201, the additional data on genotoxicity submitted by the Industry on two substances, 2-methylpent-2-enal [FL-no: 05.090] and 2-methylcrotonaldehyde [FL-no: 05.095], from subgroup 1.1.2 of FGE.19. First the Panel concluded that genotoxicity data on [FL-no: 05.095] can be representative for the substances [FL-no: 02.174, 05.033, 05.090, 05.105, 05.107 and 05.126], but not for [FL-no: 05.130, 05.178, 09.177 and 09.931], for which it was concluded in the previous version of this FGE that the available data were insufficient to evaluate their genotoxicity. Secondly, the Panel considers that the mutagenicity hazard could not be cleared by the endpoints evaluated in the in vivo micronucleus assay submitted. The Panel therefore concluded that further data are required in order to clarify the genotoxic potential of this subgroup. The Panel considers the Comet assay with [FL-no: 05.095] as test material and performed on liver, blood and first site of contact, as a preferred option to further investigate the genotoxicity in vivo.

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EFSA Panel on Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 222: Consideration of genotoxicity data on representatives for alpha, beta-unsaturated furyl derivatives with the α,β-unsaturation in the side chain from subgroup 4.6 of FGE.19 by EFSA

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate the genotoxic potential of six flavouring substances from subgroup 4.6 of FGE.19 in the Flavouring Group Evaluation 222. The Flavour Industry have provided additional genotoxicity studies for two representative substances, 3-(2-furyl)acrylaldehyde [FL-no: 13.034] and 4-(2-furyl)but-3-en-2-one [FL-no: 13.044], in FGE.222. Based on these new data the Panel could not rule out a clastogenic and aneugenic potential for the two substances and a in vivo Comet assay was requested for both substances, the one including a micronucleus assay.
EFSA Panel on Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 47, Revision 1: Bi- and tricyclic secondary, ketones and related esters from chemical groups 7 and 8

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate six flavouring substances in the Flavouring Group Evaluation 47, including an additional two substances in this Revision 1, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the six substances [FL-no: 02.119, 07.171, 07.196, 09.584, 09.848 and 09.888] do not give rise to safety concern at their levels of dietary intake, estimated on the basis of the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. Adequate specifications including complete purity criteria and identity of the materials of commerce have been provided for all six candidate substances.

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EFSA Panel on Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 51, Revision 1: Consideration of alicyclic ketones and secondary alcohols and related esters evaluated by the JECFA (59th meeting) structurally related to alicyclic ketones secondary alcohols and related esters in FGE.09Rev3 (2011)

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 20 alicyclic ketones and secondary alcohols and related esters evaluated by JECFA (59th meeting) in 2002. This revision is made due to inclusion of seven additional substances cleared for genotoxicity concern compared to the previous version. The substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel agrees with the application of the Procedure as performed by the JECFA for all 20 substances considered in this FGE and agrees with the JECFA conclusion, “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for all 20 substances, the information is adequate.

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EFSA Panel on Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 73, Revision 1: Consideration of alicyclic primary alcohols, aldehydes, acids and related esters evaluated by JECFA (59th meeting) structurally related to primary saturated or unsaturated alicyclic alcohol, aldehyde, and esters evaluated by EFSA in FGE.12Rev2 (2011)

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 16 alicyclic primary alcohols, aldehydes, acids and related esters evaluated by the JECFA at the 59th meeting in 2002. The revision is made due to consideration of one additional substance compared to the previous version. The substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel agrees with the application of the Procedure as performed by the JECFA for all 16 substances [FL-no: 02.114, 02.141, 05.098, 05.104, 05.112, 05.119, 05.123, 08.034, 08.060, 08.067, 09.028, 09.289, 09.488, 09.534, 09.536 and 09.615], considered in this FGE and agrees with the JECFA conclusion, "No safety concern at estimated levels of intake as flavouring substances" based on the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for all 16 substances, the information is adequate.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 08, Revision 4 (FGE.08Rev4): Aliphatic and alicyclic mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups from chemical groups 20 and 30

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 80 flavouring substances in the Flavouring Group Evaluation 08, Revision 4, using the Procedure in Commission Regulation (EC) No 1565/2000. Since the publication of the last revision of this FGE, the EFSA has been requested to evaluate 10 additional substances, which have been included in the present revision of FGE.08. For the substances methyl methanethiosulphonate [FL-no: 12.159], 2-methylbutane-2-thiol [FL-no: 12.172], 2-methylpropane-2-thiol [FL-no: 12.174], ethyl 2-mercaptop-2-methyl propanoate [FL-no: 12.304] and 2,4,4-trimethyl-1,3-oxathiane [FL-no: 16.057] there is an indication of a genotoxic potential in vitro. Therefore, in the absence of further genotoxicity data, the Panel concluded that the Procedure could not be applied to these five substances. For four substances, 3-mercaptooctanal [FL-no: 12.268], 3-mercaptopdecenal [FL-no: 12.269], methanediol diacetate [FL-no: 12.271] and 3,5-dimethyl-1,2-dithiolane-4-one [FL-no: 12.295] no data on use as flavouring substances in Europe are available. Therefore, no intakes in Europe can be estimated and accordingly the Panel concluded that the Procedure could not be applied to these four substances either. The remaining 71 substances were evaluated through a stepwise
approach that integrates information on the structure-activity relationships, intake from current uses, toxicological
threshold of concern, and available data on metabolism and toxicity. The Panel concluded that 57 substances do not give
rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining fourteen substances [FL-no: 12.093, 12.094, 12.097, 12.100, 12.112, 12.116, 12.120, 12.164, 12.167, 12.199, 15.007, 15.102 and 15.125 and 15.134], evaluated through the Procedure, no appropriate NOAEL was available and additional data are required. Besides the safety assessment of the flavouring substances, the specifications for the materials of commerce have also been considered and for 21 substances, evaluated through the Procedure, information on the stereoisomeric/positional composition and/or the specifications is lacking.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on
Flavouring Group Evaluation 08, Revision 5 (FGE.08Rev5): Aliphatic and alicyclic mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups from chemical groups 20 and 30
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 80 flavouring substances in the Flavouring Group Evaluation 08, Revision 4, using the Procedure in Commission Regulation (EC) No 1565/2000. Since the publication of the last revision of this FGE, the EFSA has been requested to evaluate additional toxicological data submitted for two flavouring substances, one on supporting substance 2,5-dihydroxy-2,5-dimethyl-1,4-dithiane [FL-no: 15.006], which support the evaluation of the candidate substance 2,5-dihydroxy-1,4-dithiane [FL-no: 15.134] and one on the candidate substance spiro(2,4-dithia-1-methyl-8-oxabicyclo[3.3.0]octane-3,3’-(1’-oxa-2’-methyl)-cyclopentane) and spiro(2,4-dithia-6-methyl-7-oxabicyclo[3.3.0]octane-3,3’-(1’-oxa-2’-methyl)-cyclopentane) [FL-no: 15.007], which have been included in the present revision of FGE.08. For the substances methyl methanethiosulphonate [FL-no: 12.159], 2-methylbutane-2-thiol [FL-no: 12.172], 2-methylpropane-2-thiol [FL-no: 12.174], ethyl-2-mercapto-2-methyl propanoate [FL-no: 12.304] and 2,4,4-trimethyl-1,3-oxathiane [FL-no: 16.057] there is an indication of a genotoxic potential in vitro. Therefore, in the absence of further genotoxicity data, the Panel concluded that the Procedure could not be applied to these five substances. For four substances, 3-mercaptopropanal [FL-no: 12.268], 3-mercaptopropanal [FL-no: 12.269], methanedithiol diacetate [FL-no: 12.271] and 3,5-dimethyl-1,2-dithiolane-4-one [FLno:12.295] no data on use as flavouring substances in Europe are available and no intake figures could be calculated, which is a preclude for evaluation of the four substances using the Procedure. The remaining 71 substances were evaluated through a stepwise approach that integrates information on the structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that 59 substances do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For 12 substances [FL-no: 12.093, 12.094, 12.097, 12.100, 12.112, 12.116, 12.120, 12.164, 12.167, 12.199, 15.102 and 15.125], evaluated through the Procedure, no appropriate NOAEL was available and additional data are required. Besides the safety assessment of the flavouring substances, the specifications for the materials of commerce have also been considered and for three substances, evaluated through the Procedure, information on the specifications is lacking.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 10, Revision 3 (FGE.10Rev3): Aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones from chemical groups 9, 13 and 30

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 63 flavouring substances in the Flavouring Group Evaluation 10, including additional two substances in this Revision 3, using the Procedure in Commission Regulation (EC) No 1565/2000. For one substance [FL-no: 10.170] a concern for genotoxicity could not be ruled out. The remaining 62 substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the 62 substances do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. For four substances evaluated through the Procedure, the stereoisomeric composition has not been specified sufficiently.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 205, (FGE.205): Consideration of genotoxicity data on representatives for 13 α,β-unsaturated aliphatic ketones with terminal double bonds and precursors from chemical subgroup 1.2.2 of FGE.19 by EFSA

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider in the Flavouring Group Evaluation 205, the additional data on genotoxicity submitted by the Industry on two representative substances, oct-1-en-3-one [FL-no: 07.081] and pent-1-en-3-one [FL-no: 07.102], from subgroup 1.2.2 of FGE.19. The Panel concluded that both substances were weakly genotoxic in bacteria with pent-1-en-3-one being the most potent (previously available data). In these assays the representative substances were highly cytotoxic with a steep toxicity curve, and with a very narrow concentration range resulting in mutagenicity. Both substances were also tested in mammalian cells for gene mutations at the hprt locus and for structural and numerical chromosomal aberrations in the micronucleus assay. Also in mammalian cells the test substances were highly cytotoxic. The Panel considered that the positive effects in the bacterial mutagenicity assays of the two representative substances cannot be overruled by the one negative and one equivocal gene mutation test in mammalian cells and the Panel recommend that an in vivo Comet assay on the first site of contact (e.g. the stomach) and on the liver is requested on the most potent of the representative substances, pent-1-en-3-one.
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 21, Revision 3 (FGE.21Rev3): Thiazoles, thiophenes, thiazoline and thienyl derivatives from chemical groups 29 and 30

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 59 flavouring substances in the Flavouring Group Evaluation 21, including an additional three substances in this Revision 3, using the Procedure in Commission Regulation (EC) No 1565/2000. Since the publication of the last revision of this FGE, the EFSA has been requested to evaluate three additional substances [FL-no: 15.057, 15.079 and 15.135], which have been included in the present revision of FGE.21. Seven of the substances [FL-no: 15.060, 15.086, 15.090, 15.114, 15.119 and 15.133] were considered to have genotoxic potential. The remaining 52 substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that 26 substances [FLno: 15.038, 15.039, 15.044, 15.050, 15.051, 15.052, 15.058, 15.061, 15.062, 15.063, 15.067, 15.068, 15.069, 15.071, 15.078, 15.080, 15.082, 15.084, 15.085, 15.087, 15.089, 15.098, 15.108, 15.115, 15.116 and 15.118] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining 26 candidate substances [FL-no: 15.037, 15.040, 15.042, 15.043, 15.045, 15.054, 15.055, 15.057, 15.064, 15.070, 15.072, 15.074, 15.076, 15.077, 15.079, 15.088, 15.091, 15.092, 15.093, 15.094, 15.096, 15.097, 15.106, 15.107, 15.129 and 15.135] evaluated through the Procedure, no appropriate NOAEL was available and additional data are required. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. For one substance [FL-no: 15.129], evaluated using the Procedure, an identity test is lacking and for four substances [FL-no: 15.042, 15.057, 15.079 and 15.135] the stereoisomeric composition has not been specified sufficiently.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 21, Revision 3 (FGE.21Rev3): Thiazoles, thiophenes, thiazoline and thienyl derivatives from chemical groups 29 and 30

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 59 flavouring substances in the Flavouring Group Evaluation 21, including an additional three substances in this Revision 3, using the Procedure in Commission Regulation (EC) No 1565/2000. Since the publication of the last revision of this FGE, the EFSA has been requested to evaluate three additional substances [FL-no: 15.057, 15.079 and 15.135], which have been included in the present revision of FGE.21. Seven of the substances [FL-no: 15.060, 15.086, 15.090, 15.114, 15.119 and 15.133] were considered to have genotoxic potential. The remaining 52 substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that 26 substances [FLno: 15.038, 15.039, 15.044, 15.050, 15.051, 15.052, 15.058, 15.061, 15.062, 15.063, 15.067, 15.068, 15.069, 15.071, 15.078, 15.080, 15.082, 15.084, 15.085, 15.087, 15.089, 15.098, 15.108, 15.115, 15.116 and 15.118] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining 26 candidate substances [FL-no: 15.037, 15.040, 15.042, 15.043, 15.045, 15.054, 15.055, 15.057, 15.064, 15.070, 15.072, 15.074, 15.076, 15.077, 15.079, 15.088, 15.091, 15.092, 15.093, 15.094, 15.096, 15.097, 15.106, 15.107, 15.129 and 15.135] evaluated through the Procedure, no appropriate NOAEL was available and additional data are required. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. For one substance [FL-no: 15.129], evaluated using the Procedure, an identity test is lacking and for four substances [FL-no: 15.042, 15.057, 15.079 and 15.135] the stereoisomeric composition has not been specified sufficiently.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 226 (FGE.226): Consideration of genotoxicity data on one α,β-unsaturated aldehyde from chemical subgroup 1.1.1(b) of FGE.19 by EFSA

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate the genotoxic potential of one flavouring substance from subgroup 1.1.1(b) of FGE.19 in the Flavouring Group Evaluation 226. The Flavour Industry has provided additional genotoxicity studies for the substance [FL-no: 16.071] in FGE.226. Based on these new data the Panel concluded that 4,5-epoxydec-2(trans)-enal did not induce gene mutations in bacterial cells but was positive in an in vitro micronucleus assay, so, 4,5-epoxydec-2(trans)-enal is considered an in vitro genotoxic agent. The negative results obtained in an in vivo micronucleus assay cannot overrule the positive results of the in vitro micronucleus assay with and without S9-mix due to the lack of cytotoxicity in the bone marrow. On this basis, an in vivo Comet assay in rodents is recommended in order to verify possible genotoxic effects at the first site of contact (e.g., stomach/duodenum cells).

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 7, Revision 4 (FGE.07Rev4): Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 49 flavouring substances in the Flavouring Group Evaluation 07, including additional five substances in this Revision 4, using the Procedure in Commission Regulation (EC) No 1565/2000. Since the publication of the last revision of this FGE, the EFSA has been requested to evaluate five additional substances, 2,6-dimethylocta-1,5,7-trien-3-ol, octa-1,5-dien-3-ol, undeca-1,5-dien-3-ol, pseudo-ionone and 3,3,6-trimethylhepta-1,5-dien-4-one [FL-no: 02.145, 02.194, 02.211, 07.198 and 07.204], which have been included in the present revision of FGE.07. None of the 49 substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach that integrates information on the structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that all 49 substances do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. Besides the safety assessment of the flavouring substances, the specifications for the materials of commerce have also been considered. For three substances [FL-no: 02.194, 02.211 and 02.255] the stereoisomeric compositions have not been given and for one substance [FL-no: 07.156] information on the composition of the stereoisomeric mixture is lacking.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF): Scientific Opinion on Flavouring Group Evaluation 9, Revision 4 (FGE.09Rev4): Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical group 8 and 30, and an ester of a phenol derivative from chemical group 25

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 21 flavouring substances in the Flavouring Group Evaluation 9, Revision 4, using the Procedure in Commission Regulation (EC) No 1565/2000. The present revision of FGE.09 includes the assessment of four additional flavouring substances, p-menthan-3-one [FL-no: 07.059], 2,6,6-trimethylcyclohex-2-en-1-one [FL-no: 07.202], l-piperitone [FL-no: 07.255] and menthol 1-and 2-propylene glycol carbonate [FL-no: 09.843]. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the 20 substances [FL-no: 02.070, 02.075, 02.135, 02.167, 06.136, 07.059, 07.202, 07.203, 07.255, 09.154, 09.355, 09.520, 09.618, 09.619, 09.621, 09.843, 09.870, 09.929, 09.935 and 09.949] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining candidate substance [FL-no: 07.207], additional toxicity data are requested (further metabolism and/or toxicity studies). Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have been considered. Specifications including complete purity criteria and identity for the materials of commerce have been provided for all candidate substances.

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EFSA ; Scientific Opinion on Flavouring Group Evaluation 63, Revision 1 (FGE.63Rev1): Consideration of aliphatic secondary alcohols, ketones and related esters evaluated by JECFA (59th and 69th meetings) structurally related to saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids evaluated by EFSA in FGE.07Rev4 (2012)

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 19 aliphatic secondary alcohols, ketones and related esters evaluated by the JECFA at the 59th and 69th meetings in 2002 and 2008. This revision is made due to inclusion of six additional substances, 4,8-dimethyl-3,7-nonadien-2-ol, 6-methylhepta-3,5-dien-2-one, octa-1,5-dien-3-one, (E,E)-3,5-octadien-2-one, (3Z)-4,8-dimethyl-3,7-nonadiene-2-one and 4,8- dimethyl-3,7-nonadien-2-yl acetate [FL-no: 02.252, 07.099, 07.190, 07.247, 07.256 and 09.936] cleared for genotoxicity concern. The substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel agrees with the application of the Procedure as performed by the JECFA for all 19 substances considered in this FGE and agrees with the JECFA conclusion, “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach.

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 17 bicyclic secondary alcohols, ketones and related esters evaluated by the JECFA at the 63rd meeting in 2004. This revision of FGE.87 is made due to consideration of two additional substances [FL-no: 02.100 and 02.101] compared to previous version. Additionally, new information on EU production volume on two substances and information on stereoisomeric composition for 13 substances are also included. The substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel agrees with the application of the Procedure as performed by the JECFA for all 17 substances considered in this FGE and agrees with the JECFA conclusion, “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered for the substances evaluated through the Procedure and for two substances, [FL-no: 02.100 and 02.101], information on the stereoisomeric composition is lacking.

EFSA Scientific Opinion on Flavouring Group Evaluation 94, Revision 1 (FGE.94Rev1): Consideration of aliphatic amines and amides evaluated in an addendum to the group of aliphatic and aromatic amines and amides evaluated by the JECFA (68th meeting)

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert
Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 12 aliphatic amines and amides evaluated by the JECFA at the 68th meeting in 2007. This revision of the consideration is made due to additional toxicity data available for two substances, N-3,7-dimethyl-2,6-octadienyl cyclopropylcarboxamide [FL-no: 16.095] and N-[(ethoxycarbonyl)methyl]-p-menthane-3-carboxamide [FL-no: 16.111]. The substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern and available data on metabolism and toxicity. The Panel agrees with the application of the Procedure as performed by the JECFA for 11 of the substances considered in this FGE and agrees with the JECFA conclusion, “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach. For one substance [FL-no: 16.090] additional toxicity data are still needed before the evaluation can be finalised. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for one substance, [FL-no: 16.090], the composition of the stereoisomeric mixture has to be specified.

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Identification of Cumulative Assessment Groups of Pesticides
The present document has been produced and adopted by the bodies identified above as author(s). In accordance with Article 36 of Regulation (EC) No 178/2002, this task has been carried out exclusively by the author(s) in the context of a grant agreement between the European Food Safety Authority and the author(s). The present document is published complying with the transparency principle to which the European Food Safety Authority is subject. It may not be considered as an output adopted by EFSA. EFSA reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

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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 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 (diammonium 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 are classified into structural class I and two are classified into structural class III according to the decision tree approach presented by Cramer et al. (1978). The flavouring substance ammonia in the present group has been reported to occur naturally in a wide range of food items up to very high amounts. Hydrogen sulphide is also reported to occur naturally in a wide range of food items. 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 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/person/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). Although the genotoxicity data for the flavouring substances in this group are limited, the available data on genotoxicity do not preclude an evaluation of the candidate substances through the Procedure. 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 sulphide [FL-no: 16.002] would present no safety concern at the levels of intakes estimated on the basis of the MSDI approach.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 06, Revision 2 (FGE.06Rev2): Straight- and branched-chain aliphatic unsaturated primary alcohols, aldehydes, carboxylic acids, and esters from chemical groups 1 and 4

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 the 48 flavouring substances in this Flavouring Group Evaluation 06, Revision 2 (FGE.06Rev2), using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. These 48 flavouring substances belong to chemical groups 1 and 4, Annex I of the Commission Regulation (EC) No 1565/2000. The present Flavouring Group Evaluation deals with 48 straight- and branched-chain unsaturated primary alcohols, aldehydes, carboxylic acids and esters. Eight of the 48 flavouring substances possess a chiral centre [FL-no: 02.170, 02.175, 05.143, 09.341, 09.612, 09.871, 09.872 and 09.938]. Thirty-one of the 48 substances can exist as geometrical isomers [FL-no: 02.152, 02.195, 02.222, 02.234, 05.061, 05.082, 05.203, 05.217, 05.218, 05.220, 08.074, 08.102, 09.377, 09.567, 09.569, 09.572, 09.575, 09.638, 09.640, 09.643, 09.672, 09.673, 09.674, 09.831, 09.838, 09.855, 09.884, 09.885, 09.928, 09.937 and 09.939]. For 13 of these substances [FL-no: 02.152, 02.222, 05.061, 05.203, 05.218, 08.074, 08.102, 09.377, 09.640, 09.674, 09.831, 09.884, 09.885] no indication has been given that one of the possible isomers has preponderance in the commercial flavouring material. Forty-six candidate substances are classified into structural class I. Thirty-eight of the 46 candidate substances belong to structural class I and of the two candidate substances belonging to structural class II would result in a total intake of approximately 255 and 0.7 microgram/capita/day, respectively. These values are below the thresholds of concern for structural class I and class II substances of 1800 and
540 microgram/person/day, respectively. The total combined estimated intake of 65 of the 70 supporting substances for which European annual production data are available and of the 46 candidate substances from structural class I is approximately 6700 microgram/capita/day, which exceeds the threshold of concern for structural class I (1800 microgram/person/day). However, the substances are expected to be efficiently metabolised and are not expected to saturate the metabolic pathways. For the substances in this group the limited data available do not give rise to safety concern with respect to genotoxicity and carcinogenicity. Except for hex-3-etyl 2-ethylbutyrate [FL-no: 09.884] the candidate substances are expected to be metabolised to innocuous substances at the estimated levels of use as flavouring substances. One of the hydrolysis products of [FL-no: 09.884], 2-ethylbutyric acid, showed teratogenic potential in one mouse subcutaneous single-dose study, and is structurally related to valproic acid, which is a known teratogen. However, an additional study in which 2-ethylbutyric acid was given by gavage to pregnant rats showed a NOAEL of 200 mg/kg bw/day of 2-ethylbutyric acid. This dose is more than 4 x 107 times higher than the MSDI for 2-ethylbutyric acid arising from the intake of the candidate substance, [FL-no: 09.884]. Accordingly, the candidate substance [FL-no: 09.884] does not pose a safety concern with respect to teratogenicity when used at the level of intake as flavouring substance estimated on the basis of the MSDI approach. 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 these 48 candidate substances would not give rise to safety concern at the estimated levels of intake arising from their use as flavouring substances. When the estimated intakes were based on the mTAMDI approach they ranged from 36 to 40000 microgram/person/day for the 45 flavouring substances from structural class I for which data have been provided. Thus, the intakes were all above the threshold of concern for structural class I of 1800 microgram/person/day, except for nine flavouring substances [FL-no: 05.061, 05.174, 05.082, 05.203, 05.217, 05.218, 05.220, 09.937 and 09.939]. The estimated intakes of the two flavouring substances assigned to structural class II, based on the mTAMDI are 1600 and 3900 microgram/person/day, which is above the threshold of concern for structural class II of 540 microgram/person/day. The nine substances [FL-no: 05.061, 05.174, 05.082, 05.203, 05.217, 05.218, 05.220, 09.937 and 09.939], 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 38 of the 48 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. For one substance [FL-no: 09.647] no use levels were provided. Therefore, for these 39 substances 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. Subsequently, additional data might become necessary. In order to determine whether the conclusion for the 48 candidate substances can be applied to the material of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity for the materials of commerce have been provided for 46 of the 48 flavouring candidate substances. An ID test is missing for [FL-no: 09.938] and a boiling point is lacking for [FL-no: 09.674]. Otherwise the specifications are adequate for all 48 candidate substances, except that information on composition of stereoisomeric mixture has not been specified sufficiently for 13 of the substances [FL-no: 02.152, 02.222, 05.061, 05.203, 05.218, 08.074, 08.102, 09.377, 09.640, 09.674, 09.831, 09.884 and 09.885]. Thus, the final evaluation of the materials of commerce cannot be performed for 14 substances [FL-no: 02.152, 02.222, 05.061, 05.203, 05.218, 08.074, 08.102, 09.377, 09.640, 09.674, 09.831, 09.884, 09.885 and 09.938], pending further information. The remaining 34 substances [FL-no: 02.125, 02.138, 02.170, 02.175, 02.176, 02.195, 02.201, 02.234, 05.082, 05.143, 05.174, 05.217, 05.220, 08.100, 09.341, 09.368, 09.567, 09.569, 09.572, 09.575, 09.612, 09.638, 09.638, 09.672, 09.673, 09.838, 09.855, 09.871, 09.872, 09.897, 09.898, 09.928, 09.937 and 09.939] would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 06, Revision 3 (FGE.06Rev3): Straight- and branched-chain aliphatic unsaturated primary alcohols, aldehydes, carboxylic acids, and esters from chemical groups 1 and 4

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 50 flavouring substances in the Flavouring Group Evaluation 6, Revision 3, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the 50 substances [FL-no: 02.125, 02.138, 02.152, 02.170, 02.175, 02.176, 02.195, 02.201, 02.222, 02.234, 05.061, 05.082, 05.143, 05.174, 05.203, 05.217, 05.218, 05.220, 05.226, 08.074, 08.100, 08.102, 09.341, 09.368, 09.377, 09.567, 09.569, 09.572, 09.575, 09.612, 09.638, 09.640, 09.643, 09.672, 09.673, 09.674, 09.831, 09.838, 09.884, 09.885, 09.871, 09.872, 09.885, 09.896, 09.928, 09.937, 09.938, 09.939 and 09.950] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach.

Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. For one substance [FL-no: 09.938] an identity test is missing and for two substances [FL-no: 05.226 and 09.950] the range of the specific gravity is too wide. Additional, the stereoisomeric mixture has not been specified sufficiently for 12 substances [FL-no: 02.152

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 10, Revision 2 (FGE.10Rev2): Aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones from chemical groups 9, 13 and 30

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 61 flavouring substances in the Flavouring Group Evaluation 10, Revision 2, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the 61 substances do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. For four substances, information on composition of mixture and/or stereoisomerism has not been specified sufficiently.

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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 alpha-diketones or their corresponding alcohols or ketal [FL-no: 02.133, 06.134, 07.071, 07.152, 07.167, 07.168, 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 a wide range of food items. 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 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 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 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, 07.238, 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] 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 exist 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-nonadiene [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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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 12, Revision 2 (FGE.12Rev2): Primary saturated or unsaturated alicyclic alcohol, aldehyde, acid, and esters from chemical group 7
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 in 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 value 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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The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 21 flavouring substances in the Flavouring Group Evaluation 17, Revision 2, using the Procedure in Commission Regulation (EC) No 1565/2000. From the in vitro data available, genotoxic potential is indicated for the flavouring substances quinoxaline [FL-no: 14.147] and 2-methylquinoxaline [FL-no: 14.139]. Therefore, the Panel decided that the Procedure could not be applied to these two substances, so adequate genotoxicity data should be provided. For one substance [FL-no: 14.051] no intake data are available preventing it from being evaluated through the Procedure. The remaining 18 substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that 17 substances [FL-no: 14.081, 14.083, 14.084, 14.086, 14.087, 14.091, 14.097, 14.099, 14.101, 14.102, 14.108, 14.113, 14.122, 14.129, 14.148, and 14.161] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining substance [FL-no: 14.052] additional toxicity data are required.

Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for two substances information on specifications is lacking.
The Panel concluded that 28 substances [FL-no: 02.041, 02.052, 02.054, 02.120, 02.123, 02.129, 02.140, 02.144, 02.147, 02.149, 02.150, 02.168, 02.171, 02.181, 02.184, 02.197, 02.203, 02.206, 02.219, 02.226, 02.230, 02.253, 09.171, 09.356, 09.614, 09.617, 09.671 and 09.808] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining four substances [FL-no: 02.146, 02.185, 02.191 and 09.669] no appropriate NOAEL was available and additional data are required. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for six substances information is lacking.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 206 (FGE.206): Consideration of genotoxicity data on representatives for 12 alpha,beta-unsaturated ketones and precursors from chemical subgroup 1.2.3 of FGE.19 by EFSA

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 209 (FGE.209): Consideration of genotoxicity data on one alpha,beta-unsaturated aldehyde from chemical subgroup 2.3 of FGE.19 by EFSA

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 20, Revision 3 (FGE.20Rev3): Benzyl alcohols, benzaldehydes, a related acetal, benzoic acids, and related esters from chemical groups 23 and 30
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider in this revision 3 of Flavouring Group Evaluation 20, the SCF Opinion on benzoic acid. Furthermore information on stereoisomeric composition for two substances [FL-no: 06.104 and 09.570] and new information to support the re-allocation of the structural class for the candidate substance piperonyl alcohol [FL-no: 02.205] has been submitted. The 41 flavouring substances in Flavouring Group Evaluation 20 were evaluated using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on
metabolism and toxicity. The Panel concluded that all the substances do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach.

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**EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 211 (FGE.211): Consideration of genotoxicity data on representatives for one alpha, beta-unsaturated ketone and three precursors from chemical subgroup 2.5 of FGE.19 by EFSA**

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**EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 212 Rev1 (FGE.212 Rev1):alpha,beta-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.6 of FGE.19**

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 218, Revision 1 (FGE.218Rev1): alpha,beta-Unsaturated aldehydes and precursors from subgroup 4.2 of FGE.19: Furfural derivatives

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 flavouring substances using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. In the present revision of FGE.218, FGE.218Rev1, there has been a reassessment of one candidate substance, 5-methylfurfural [FL-no: 13.001], for which there was a request for genotoxicity data in FGE.218. Flavouring Group Evaluation 218 (FGE.218) consists of furfural [FL-no: 13.018] and seven substances structurally related to furfural, 5-methylfurfural [FL-no: 13.001], furfuryl alcohol [FL-no: 13.019] and five esters of furfuryl alcohol and aliphatic saturated carboxylic acids [FL-no: 13.057, 13.062, 13.067, 13.068 and 13.128]. In the previous version of this Opinion, FGE.218, the Panel had expressed the following view. The five furfuryl esters are anticipated to be hydrolysed to furfuryl alcohol (and carboxylic acids). Furfuryl alcohol is expected to be oxidised to the alpha,beta-unsaturated aldehyde furfural. However, based on the data then available the Panel concluded that furfural is not of concern with respect to genotoxicity.

Furthermore, the Panel concluded that not only furfural but also the structurally related furfuryl alcohol and the five furfuryl esters are not of concern with respect to genotoxicity. Accordingly these seven substances can be evaluated through the Procedure in FGE.66. In the FGE.218 Opinion of 2008 the Panel also expressed its view on 5-hydroxymethylfurfural and 5-methylfurfural. It is anticipated that 5-methylfurfural [FL-no: 13.001] can be oxidised to the primary alcohol 5-hydroxymethylfurfural [FL-no: 13.139]. 5-Hydroxymethylfurfural has been evaluated by EFSA in FGE.13 dealing with furfuryl and furan derivatives. In the latter Opinion, it was concluded that since 5-hydroxymethylfurfural may be metabolised to 5-[(sulphoxy)methyl)furfural which shows genotoxic potential in vitro, 5-hydroxymethylfurfural could not be evaluated through the Procedure. Accordingly, the Panel concluded that 5-methylfurfural could not be evaluated through the Procedure either. Industry has submitted additional data on the 5-hydroxymethylfurfural including metabolism, genotoxicity and carcinogenicity data. Based on these data and further genotoxicity studies identified by EFSA, the Panel concluded that, notwithstanding the indications of in vitro genotoxicity in conditions that favour the formation of 5-[(sulphoxy)methyl]furfural and the limited in vivo genotoxicity study, the essentially negative results of the carcinogenicity study in rats and mice indicate that 5-hydroxymethylfurfural is of no concern under the conditions of intended use. This conclusion is also applicable to 5-methylfurfural, a candidate substance in the current FGE.218Rev1, because this substance may be metabolised to 5-hydroxymethylfurfural. Accordingly, both 5-hydroxymethylfurfural [FL no: 13.001] and 5-methylfurfural [FL-no: 13.139] can be evaluated through the Procedure.
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 56 flavouring substances in the Flavouring Group Evaluation 21, Revision 2, using the Procedure in Commission Regulation (EC) No 1565/2000. Seven of the substances (Fl-no: 15.060, 15.086, 15.090, 15.099, 15.114, 15.119 and 15.133) were considered to have genotoxic potential. The remaining 49 substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that 26 substances (Fl-no: 15.038, 15.039, 15.044, 15.050, 15.051, 15.052, 15.058, 15.061, 15.062, 15.063, 15.067, 15.068, 15.069, 15.071, 15.078, 15.080, 15.082, 15.084, 15.085, 15.087, 15.089, 15.098, 15.108, 15.115, 15.116 and 15.118) do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining 23 candidate substances (Fl-no: 15.037, 15.040, 15.042, 15.043, 15.045, 15.054, 15.055, 15.064, 15.070, 15.072, 15.074, 15.076, 15.077, 15.088, 15.091, 15.092, 15.093, 15.094, 15.096, 15.097, 15.106, 15.107 and 15.129), of the 49 substances evaluated through the Procedure, no appropriate NOAEL was available and additional data are required. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. For two substances are an identity test lacking and for one has the stereoisomeric composition to be specified.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 220, Revision 1 (FGE.220Rev1): alpha,beta-Unsaturated ketones and precursors from chemical subgroup 4.4 of FGE.19: 3(2H)-Furanones. 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 asked to evaluate flavouring substances using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. The present revision of FGE.220, FGE.220Rev1, concerns the evaluation of additional data submitted by Industry in response to the requested genotoxicity data in FGE.220 on the representative substance for subgroup 4.4b, 4-hydroxy-2,5-dimethylfuran-3(2H)-one (Fl-no: 13.010). Flavouring Group Evaluation 220 (FGE.220) concerns 10 substances, corresponding to subgroup 4.4 of FGE.19. The 10 substances are alpha,beta-unsaturated 3(2H)-furanones [Fl-no: 13.010, 13.084, 13.085, 13.089, 13.099, 13.117, 13.119, 13.157, 13.175 and 13.176]. The substances were further subdivided into two subgroups as five of the 10 substances can only exist as alpha,beta-unsaturated ketones (subgroup 4.4a) while in the other five substances the alpha,beta double bond can be involved in keto-enol tautomerism (subgroup 4.4b). For the substances in subgroup 4.4a [Fl-no: 13.089, 13.117, 13.119, 13.157 and 13.175], the previous conclusions of the Panel in FGE.220 were that the available data on genotoxicity were too limited to evaluate these substances through the Procedure. Additional studies were needed as outlined in the Genotoxicity Test Strategy for Substances belonging to Subgroups of FGE.19 (EFSA, 2008bb). For the substances in subgroup 4.4b [Fl-no: 13.010, 13.084, 13.085, 13.099 and 13.176], the Panel had in FGE.220 expressed the view that evidence for genotoxicity was available both in vitro and in vivo. Evidence from in vitro studies indicated that the genotoxicity of the candidate substances in this subgroup may be caused by indirect (thresholded) mechanisms of action (in particular generation of reactive oxygen species). The concern for carcinogenicity was alleviated, since one of the substances, for which positive genotoxicity data in mice were obtained, was not carcinogenic in a valid chronic assay in rats. Therefore, no further
genotoxicity tests in somatic cells were required. However, some evidence was also available that this substance might elicit genotoxic effects in germ cells, which theoretically may result in reduced reproductive capacity or in inheritable genetic damage. Reduced reproductive capacity and inheritable genetic damage are toxicological endpoints which differ from carcinogenicity and therefore, the negative results for the carcinogenicity study could not be used to overrule this concern. It is not clear if (and if so to what extent) the thresholded mechanism mentioned above would be relevant for genotoxic effects in the germ cells. Therefore, the Panel conclusions of the previous evaluation in FGE.220 were that these five substances could not be evaluated through the Procedure. The Panel recognised that the studies which provided indications for germ cell genotoxicity were of limited validity. For this reason a robust GLP-controlled cytogenetic investigation in mouse spermatocytes according to the OECD guideline 483 was requested. In March 2009 the Flavouring Industry submitted new data in reply to the above requested data for subgroup 4.4b of FGE.220. These data have now been examined by the Panel which has concluded the following. The results of a valid rat fertility and dominant lethal study have shown that the representative substance for subgroup 4.4b, 4-hydroxy-2,5-dimethylfuran-3(2H)-one [FL-no: 13.010], is unable to induce adverse effects both on male rat reproductive capacity and dominant lethality. On this basis, the Panel concludes that there is no concern for this substance to induce heritable genetic damage or adverse effects on male reproductive capacity. Accordingly the substances in subgroup 4.4b of FGE.19 [FL-no: 13.010, 13.084, 13.085, 13.099 and 13.176] can be evaluated using the Procedure. Since no data were submitted to further evaluate the genotoxic potential of the substances in subgroup 4.4a, the Panel maintains its position that for this subgroup additional data on genotoxicity are needed. © European Food Safety Authority, 2011

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 22, Revision 1 (FGE.22Rev1): Ring substituted phenolic substances from chemical groups 21 and 25
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 28 flavouring substances in the Flavouring Group Evaluation 22, Revision 1, using the Procedure in Commission Regulation (EC) No 1565/2000. The substance 3,4-methylenedioxyphenol [FL-no: 04.080] was reported to have a genotoxic potential in vitro, while in vivo studies were not available. Therefore, the Panel concluded that the Procedure could not be applied to this substance until adequate genotoxicity data become available. The remaining 27 substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that these 27 candidate substances do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. Adequate specifications for the materials of commerce are available for all 27 flavouring substances evaluated through the Procedure.

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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 19 flavouring substances in the Flavouring Group Evaluation 23, Revision 2 (FGE.23Rev2), using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. These 19 flavouring substances belong to chemical groups 15, 16, 22, 26 and 30, Annex I of the Commission Regulation (EC) No 1565/2000. The present Flavouring Group Evaluation deals with 19 candidate substances, which are aliphatic, alicyclic and aromatic ethers including anisole derivatives. Four of the candidate substances are aliphatic ethers, one is an alicyclic ether, three are alicyclic hydrocarbons with an ether side chain, two are ethers containing a benzene moiety, eight are phenol ethers and one is a napthol ether. Five of the 19 candidate substances possess one or more chiral centres and three can exist as geometrical isomers. For one substance [FL-no: 03.022] Industry has informed that it occurs as a mixture of E- & Z-isomers, however, the composition of the mixture has to be specified. Two of the flavouring substances are classified into structural class I, seven are classified into structural class II and 10 are classified into structural class III. Ten of the substances in the present group have been reported to occur naturally in a wide range of food items. 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 19 flavouring substances in this group have intakes in Europe from 0.011 to 49 micrograms/capita/day, which are below the threshold of concern value for structural class I of 1800 micrograms/person/day, for structural class II of 540 micrograms/person/day and for structural class III of 90 micrograms/person/day. On the basis of the reported annual production in Europe (MSDI approach), the combined intake of the two candidate substances belonging to structural class I, seven candidate substances belonging to structural class II and of the 10 candidate substances belonging to structural class III, would result in combined intakes of approximately 1.2, 52 and 26 micrograms/capita/day, respectively. These values are lower than the thresholds of concern for structural class I, II or III substances. The estimated total combined intakes of the candidate and supporting substances (in Europe) are approximately 2800, 1300 and 130 micrograms/capita/day for structural class I, II and III substances, respectively. The combined daily per capita intake of 2800 micrograms exceeds the threshold of concern of 1800 micrograms/person/day for structural class I substances. The supporting substances were evaluated at the 51st JECFA meeting, where it was noted that although the combined intake exceeds the threshold for structural class I the substances are expected to be efficiently metabolised and would not saturate the metabolic pathways. The Panel agreed with this view and concluded that the combined intake of about 1.2 micrograms/capita/day for the candidate substances in structural class I is negligible compared to the combined intake of 2800 micrograms/capita/day of the supporting substances. Likewise the total combined intake of the seven candidate substances and ten supporting substances from structural class II is approximately 1300 micrograms/capita/day, which exceeds the threshold of concern for a compound belonging to structural class II of 540 micrograms/person/day. The supporting substances in structural class II were evaluated at the 61st JECFA meeting, where it was noted that although the combined intake exceeds the threshold, the substances are expected to be efficiently metabolised and would not saturate the metabolic pathways. The Panel agreed with this view and concluded that the combined intake of about 52 micrograms/capita/day for the candidate substances in structural class II is negligible compared to the combined intake of 1250 micrograms/capita/day of the supporting substances. The total combined intake of candidate and supporting substances of structural class III is 130 micrograms/capita/day, which is above the threshold of concern for structural class III of 90 micrograms/capita/day. The supporting substances were evaluated by the JECFA at the 59th and 61st meetings, where it was noted that although the combined intake exceeds the threshold for the
structural class, the substances are expected to be efficiently metabolised and would not saturate the metabolic pathways. The Panel agreed with this view and concluded that the combined intake of about 26 micrograms/capita/day for the candidate substances in structural class III is minor compared to the combined intake of 100 micrograms/capita/day of the supporting substances. For the substances in this group, the available data on genotoxicity do not give rise to safety concern. According to the available data on supporting substances, it is expected that all 19 candidate substances in this group [FL-no: 02.247, 02.248, 03.008, 03.011, 03.012, 03.015, 03.016, 03.020, 03.022, 03.024, 04.059, 04.067, 04.068, 04.069, 04.075, 04.079, 04.084, 08.127 and 09.687] would be metabolised to innocuous products at the reported levels of intake as flavouring substances. It was noted that no repeated dose toxicity studies have been provided for any of the candidate substances and only a few studies were available on supporting substances. However, these toxicological data were consistent with the conclusions in the present Flavouring Group Evaluation using the Procedure. It was concluded that on the basis of the default MSDI approach the 19 candidate substances would not give rise to safety concerns at estimated levels of intake arising from their use as flavouring substances. When the estimated intakes were based on the mTAMDI approach they were 3200 micrograms/person/day for the two flavouring substances belonging to structural class I and for six of the seven flavouring substances belonging to structural class II, for the remaining flavouring substance from class II it is 14000 micrograms/person/day. These intakes are above the threshold of concern for structural class I of 1800 micrograms/person/day and for structural class II of 540 micrograms/person/day. For eight of the ten candidate substances belonging to structural class III the mTAMDI are 3200 or 3900 micrograms/person/day, which are above the threshold of concern of 90 microgram/person/day. For one substance from structural class III the mTAMDI of 58 micrograms/person/day is below the threshold. This substance is also expected to be metabolised to innocuous products.

For one substance the mTAMDI could not be estimated as no use levels have been provided. Thus, for 17 of the 19 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 substances have been assigned. Therefore, for these 17 substances, and for [FL-no: 02.248] for which use levels are missing, 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. In order to determine whether the conclusion for the 19 candidate substances can be applied to the materials of commerce, it is necessary to consider the available specifications. Specifications including purity criteria and identity for the materials of commerce have been provided for all 19 flavouring substances. Information on the stereoisomeric composition is missing for one of the substances [FLNo: 03.022], as Industry has informed that it occurs as a mixture of E- & Z-isomers, however, the composition of the mixture has to be specified. Thus, the final evaluation of the materials of commerce cannot be performed for this substance, pending further information. The remaining 18 substances [FL-no: 02.247, 02.248, 03.008, 03.011, 03.012, 03.015, 03.016, 03.020, 03.024, 04.059, 04.067, 04.068, 04.069, 04.075, 04.079, 04.084, 08.127 and 09.687] would present no safety concern at the estimated levels of intake based on the MSDI approach.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 23, Revision 3 (FGE.23Rev3): Aliphatic, alicyclic and aromatic ethers including anisole derivatives from chemical groups 15, 16, 22, 26 and 30
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 20 flavouring substances in the Flavouring Group Evaluation 23, Revision 3, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that all 20 substances [FL-no: 02.247, 02.248, 03.008, 03.011, 03.012, 03.015, 03.016, 03.020, 03.022, 03.024, 04.059, 04.067, 04.068, 04.069, 04.075, 04.079, 04.084, 08.127, 09.687 and
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 25, Revision 2 (FGE.25Rev2): Aliphatic and aromatic hydrocarbons from chemical group 31

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 37 flavoured substances in the Flavouring Group Evaluation 25, Revision 2, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the ten substances [FL-no: 01.001, 01.027, 01.028, 01.033, 01.034, 01.038, 01.039, 01.046, 01.054 and 01.057] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining 27 candidate substances [FL-no: 01.021, 01.022, 01.023, 01.030, 01.031, 01.032, 01.035, 01.036, 01.037, 01.042, 01.043, 01.044, 01.047, 01.050, 01.051, 01.052, 01.053, 01.055, 01.056, 01.058, 01.059, 01.060, 01.064, 01.066, 01.067, 01.070 and 10.078] no appropriate NOAEL was available and additional data are required. Besides the safety assessment of these flavoured substances, the specifications for the materials of commerce have also been considered. For five substances, the composition of the stereoisomeric mixture has to be specified further.
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 300 (FGE.300): One cyclo-aliphatic amide from chemical group 33

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate a flavouring substance in the Flavouring Group Evaluation 300 using the Procedure in Commission Regulation (EC) No 1565/2000. The substance was not considered to have genotoxic potential. The substance was evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that for the substance [FL-no: 16.115] evaluated through the Procedure, no appropriate NOAEL was available and additional data are required. Besides the safety assessment of this flavouring substance, the specifications for the materials of commerce have also been considered. The composition of the stereoisomeric mixture has to be specified.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 301 (FGE.301): A sulphur substituted pyrimidin-derivative and its hydrochloride salt

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate two flavouring substances, 4-amino-5,6-dimethylthieno[2,3-d]pyrimidin-2(1H)-one [FL-no: 16.116] and 4-amino-5,6-dimethylthieno[2,3-d]pyrimidin-2(1H)-one hydrochloride [FL-no: 16.120] in the Flavouring Group Evaluation 301, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the two substances [FL-no: 16.116 and 16.120] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach.

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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 one flavouring substance in the Flavouring Group Evaluation 303, using the Procedure as referred to in the Commission Regulation (EC) No 1565/2000. The flavouring substance belongs to chemical group 30, Annex I of the Commission Regulation (EC) No 1565/2000. The candidate substance spilanthol [FL-no: 16.121] is a branched chain unsaturated aliphatic amide from chemical group 30. The substance has been presented with specification of the stereoisomeric composition. The candidate substance was assigned to structural class III, according to the decision tree approach presented by Cramer et al., 1978. According to the Flavour Industry spilanthol has been identified in the plant Spilanthes oleracea, which is used in some countries as a spice. 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. Genotoxicity data are not available for the candidate substance spilanthol [FL-no: 16.121]. However, the Panel considers that the lack of genotoxicity data do not preclude the evaluation of this aliphatic amide by using the Procedure. The candidate substance cannot be anticipated to be metabolised to innocuous products. According to the default MSDI approach, the candidate substance in this group has an intake in Europe of 24 micrograms/capita/day [FL-no: 16.121]. For the candidate substance, this is below the threshold of concern value for structural class III (90 micrograms/person/day). When the estimated intake was based on the mTAMDI approach it is 830 micrograms/person/day for the candidate substance from structural class III, which is above the threshold of concern for structural III of 90 micrograms/person/day. Therefore more reliable exposure data are required. On the basis of such additional data, the flavouring substance should be reconsidered using the Procedure. Subsequently, additional data might become necessary. No relevant data on toxicity are available for the candidate substance or the three supporting substances. The only toxicity data available is a 28-day study which is not considered sufficient to evaluate chronic effects of the substance. Accordingly, additional data are required for the candidate substance. According to the practice of the Panel, a minimum requirement to provide an adequate NOAEL for flavourings in the Procedure is a 90-day study. In order to determine whether the conclusion for the candidate substance can be applied to the material of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity for the material of commerce have been provided for the flavouring substance. In conclusion, for the candidate substance spilanthol [FL-no: 16.121] additional data on chemical defined material are required as a 28 day study is not considered sufficient to deriving a NOAEL.
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 308 (FGE.308): Glucose Pentaacetate and Sucrose Octaacetate

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 309 (FGE.309): Sodium Diacetate
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate sodium diacetate [FL-no: 16.073] in the Flavouring Group Evaluation 309, using the Procedure in Commission Regulation (EC) No 1565/2000. However, although in principle it would be possible to evaluate sodium diacetate via the Procedure, the Panel considered that this is not necessary, since the substance and its dissociation products are covered by the group ADI for acetic acid and sodium acetate, including sodium diacetate, derived by the Scientific Committee on Food. Based on this group ADI, the use as sodium diacetate as a flavouring substance at the current levels of dietary intake raises no safety concern.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 30, Revision 1 (FGE.30Rev1): 4-Prop-1-enylphenol and 2-methoxy-4-(prop-1enyl)phenyl 3-methylbutyrate from chemical group 17
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate two flavouring substances in the Flavouring Group Evaluation 30, Revision 1, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The two substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and
toxicity. The Panel concluded that the two substances [FL-no: 04.097, 09.894] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered. For [FL-no: 09.894] the composition of the stereoisomeric mixture needs to be specified.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 310 (FGE.310): Rebaudioside A from chemical group 30
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate rebaudioside A [FL-no: 16.113], a steviol glycoside. The substance was not considered to have genotoxic potential. Since a comprehensive and adequate toxicological database, including human studies, is available for steviol glycosides, the Panel based its evaluation of rebaudioside A on a comparison of the ADI of 4 mg/kg bw, expressed as steviol, established by EFSA, with the estimated dietary exposure figures based on the MSDI and mTAMDI approaches. The Panel concluded that rebaudioside A [FL-no: 16.113] would not give rise to safety concerns at the estimated level of intake arising from its use as flavouring substance.
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate one flavouring substance, acetaldehyde ethyl isopropyl acetal [FL-no: 06.137], structurally related to the 58 flavouring substances in the Flavouring Group Evaluation 03, in a Revision 2, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The new substance was along with the remaining 58 substances evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded as for the other already evaluated substances that the substance [FL-no: 06.137] do not give rise to safety concern at its level of dietary intake, estimated on the basis of the MSDI approach. Besides the safety assessment of this flavouring substance, the specifications for the materials of commerce have also been considered, and since the publication of FGE.03Rev1 additional information on chirality on 30 substances is made available and has been incorporated into the present Revision 2 of FGE.03.

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The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 50, Revision 1 (FGE.50Rev1): Consideration of pyrazine derivatives evaluated by JECFA (57th meeting) structurally related to pyrazine derivatives evaluated by EFSA in FGE.17Rev2 (2010)
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. Since the previous version of FGE.50, new in vitro and in vivo genotoxicity data on 5-methylquinoxaline [FL-no: 14.028] have been provided. The Panel concluded that these data allowed to rule out genotoxicity concerns for the substance. 5-Methylquinoxaline was then evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the substance do not give rise to safety concerns at the levels of dietary intake, estimated on the basis of the MSDI approach. So in total, for all the 41 JECFA evaluated pyrazines derivatives [FL-no: 14.005, 14.006, 14.015, 14.017, 14.018, 14.019, 14.020, 14.021, 14.022, 14.024, 14.025, 14.026, 14.027, 14.028, 14.031, 14.032, 14.034, 14.035, 14.037, 14.043, 14.044, 14.049, 14.050, 14.053, 14.054, 14.055, 14.056, 14.062, 14.067, 14.069, 14.077, 14.082, 14.095, 14.096, 14.098, 14.100, 14.114, 14.121, 14.123, 14.142 and 14.144] evaluated in FGE.50, the Panel agrees with the JECFA conclusion, "No safety concern at estimated levels of intake as flavouring substances" based on the MSDI approach. Adequate specifications for the materials of commerce are available for all 41 flavouring substances.

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EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF); Scientific Opinion on Flavouring Group Evaluation 74, Revision 1 (FGE.74Rev1): Consideration of Simple Aliphatic Sulphides and Thiols evaluated by the JECFA (53rd and 61st meeting) Structurally related to Aliphatic and Alicyclic Mono-, Di-, Tri-, and Polysulphides with or without Additional Oxygenated Functional Groups from Chemical Group 20 evaluated by EFSA in FGE.08Rev1 (2009)

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 consider the Joint FAO/WHO Expert Committee on Food Additives (the JECFA) evaluations of flavouring substances assessed since 2000, and to decide whether no further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. These flavouring substances are listed in the Register, which was adopted by Commission Decision 1999/217/EC and its consecutive amendments. The JECFA has evaluated a group of 12 simple aliphatic sulphides and thiols at the 61st meeting and seven trisulphides in a group of simple aliphatic and aromatic sulphones and thiols at the 53rd meeting. One of the substances evaluated by the JECFA at its 61st meeting is not in the Register (spiro[2,4-dithia-1-methyl-8-oxabicyclo(3.3.0)octane-3,3’-(1’-oxa-2’-methyl)-cyclopentane], JECFA-no: 1296). Accordingly this consideration will deal with 18 JECFA evaluated substances. The Panel concluded that the 18 substances in the JECFA flavouring group of simple aliphatic sulphides and thiols are structurally related to the group of 66 aliphatic and alicyclic mono-, di-, and polysulphides with or without additional oxygenated functional groups evaluated by EFSA in the Flavouring Group Evaluation 08, Revision 1(FGE.08Rev1). The Panel agrees with the outcome of the application of the Procedure performed by the JECFA for eight of the 18 aliphatic sulphides and thiols [FL-no: 12.179, 12.198, 12.212, 12.238, 12.239, 12.255 and 12.291]. For two tertiary thiols, 2-methyl-4-oxopentane-2-thiol [FL-no: 12.169] and 2-mercapto-2-methylpentan-1-ol [FL-no: 12.241], the Panel concluded that they should not be evaluated through the Procedure, as they are structurally related to three tertiary thiols evaluated in FGE.08Rev1 which could not be evaluated through the Procedure due to concern with respect to genotoxicity in vitro. For the eight tri- and polysulphides [FL-no: 12.009, 12.013, 12.020, 12.023, 12.045, 12.074, 12.155 and 12.280] the Panel did not agree with the JECFA that appropriate studies were available for deriving NOAELs, and accordingly additional data are required for these eight substances. For two substances [FL-no: 12.045 and 12.155] the JECFA evaluation is only based on MSDI values derived from production figures from the USA. EU production figures are needed in order to finalise the evaluation of these substances. For one substance use levels have been provided by the Industry. For the remaining 17 substances use levels must be provided. These are needed to calculate the mTAMDIs in order to identify those flavouring substances that need more refined exposure assessment and to finalise the evaluation. In order to determine whether the conclusion for the 18 JECFA evaluated substances can be applied to the materials of commerce, it is necessary to consider the available specifications. Adequate specifications including complete purity criteria and identity are available for 10 of the 18 JECFA evaluated substances. For seven substances [FL-no: 12.009, 12.020, 12.045, 12.169, 12.238, 12.239 and 12.291] information on secondary components and/or composition of mixture is requested. For six substances [FL-no: 12.009, 12.020, 12.023, 12.045, 12.074 and 12.155] no solubility in ethanol and/or solubility in water is available. Finally, the European production volumes are not available for [FL-no: 12.045 and 12.155]. Thus, for 10 substances [FL-no: 12.009, 12.020, 12.023, 12.045, 12.074, 12.155 and 12.280] additional toxicity data are required. For the remaining five of the 18 JECFA evaluated simple aliphatic sulphides and thiols [FL-no: 12.179, 12.198, 12.212, 12.255 and 12.257] the Panel agrees with JECFA conclusion “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 8, Revision 3 (FGE.08Rev3): Aliphatic and alicyclic mono-, di-, tri- and polysulphides with or without additional oxygenated functional groups from chemical groups 20 and 30

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 70 flavouring substances in the Flavouring Group Evaluation 08, Revision 3, using the Procedure in Commission Regulation (EC) No 1565/2000. For the substances 2-methylpropane-2-thiol [FL-no: 12.174], methyl methanethiosulphonate [FL-no: 12.159], 2-methylbutane-2-thiol [FL-no: 12.172] and 2,4,4-trimethyl-1,3-oxathiane [FL-no: 16.057] there is an indication of a genotoxic potential in vitro. Therefore, in the absence of further genotoxicity data, the Panel concluded that the Procedure could not be applied to these four substances. For four substances, 3-mercaptooctanal [FL-no: 12.268], 3-mercaptodecanal [FL-no: 12.269], methanedithiol diacetate [FL-no: 12.271] and 3,5-dimethyl-1,2-dithiolane-4-one [FL-no: 12.295] no data on use as flavouring substances in Europe are available. Therefore, no intakes in Europe can be estimated and accordingly the Panel concluded that the Procedure could not be applied to these four substances either. The remaining 62 substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that 48 substances do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining fourteen substances [FL-no: 12.120, 12.093, 12.094, 12.097, 12.100, 12.112, 12.116, 12.164, 12.167, 12.199, 15.007, 15.102 and 15.125 and 15.134] evaluated through the Procedure, no appropriate NOAEL was available and additional data are required. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for eighteen substances information on specifications is lacking.

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accordingly the substances could not be considered by EFSA using the evaluation Procedure. Industry has now provided production volumes for these substances. Based on these newly provided production figures, MSDI values for EU have been calculated and based on these MSDI values the substances have been re-considered by the stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. In the FGEs in question, genotoxicity of the substances considered in FGE.96 has already been addressed. For none of the substances a concern for genotoxicity was identified. The Panel concluded that 87 of the substances do not give rise to safety concerns at the levels of dietary intake, estimated on the basis of the MSDI approach. However, for the substance 2-acetyl-1-ethylpyrrole [FL-no: 14.045], the Panel could not identify an appropriate NOAEL and accordingly additional data are required. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for eight stereoisomeric substances [FL-no: 06.040, 08.073, 09.371, 09.780, 10.050, 13.060, 13.161 and 16.039], the stereoisomeric composition has to be specified further.

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
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Research output: Book/Report › Report – Annual report year: 2011 › Research › peer-review

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 9, Revision 3 (FGE.09Rev3): Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical group 8 and 30, and an ester of a phenol derivative from chemical group 25
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 17 flavouring substances in the Flavouring Group Evaluation 9, Revision 3, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the 16 substances [FL-no: 02.070, 02.075, 02.135, 02.167, 06.136, 07.203, 09.154, 09.355, 09.520, 09.618, 09.619, 09.621, 09.870, 09.929, 09.935 and 09.949] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining candidate substance [FL-no: 07.207] additional toxicity data are requested (further metabolism and/or toxicity studies). Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been provided for all 17 candidate substances.

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DOIs:
EFSA ; Scientific Opinion on Flavouring Group Evaluation 59, Revision 1 (FGE.59Rev1): Consideration of aliphatic and aromatic ethers evaluated by JECFA (61st meeting and 63rd meeting) structurally related to aliphatic, alicyclic and aromatic ethers including anisole derivatives evaluated by EFSA in FGE.23 Rev2 (2010)
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 30 flavouring substances consisting of aliphatic and aromatic ethers evaluated by the JECFA. The substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel agrees with the application of the Procedure as performed by the JECFA for the 30 substances considered in this FGE and agrees with the JECFA conclusion, “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for two substances, are information on the composition of stereoisomeric mixture lacking.

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Contributors: EFSA Publication
Number of pages: 32
Publication date: 2011

EFSA ; Scientific Opinion on Flavouring Group Evaluation 66, Revision 1 (FGE.66Rev1): Consideration of Furfuryl Alcohol and Related Flavouring Substances Evaluated by JECFA (55th meeting)
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 14 flavouring substances in the Revision 1 of Flavouring Group Evaluation 66, using the Procedure in Commission Regulation (EC) No 1565/2000. None of the substances were considered to have genotoxic potential. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that the 14 substances [FL-no: 13.001, 13.002, 13.003, 13.005, 13.018, 13.019, 13.025, 13.038, 13.057, 13.062, 13.067, 13.068, 13.073 and 13.128] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach.

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 44
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EFSA Scientific Opinion on Flavouring Group Evaluation 67, Revision 1 (FGE.67Rev1): Consideration of 40 furan-substituted aliphatic hydrocarbons, alcohols, aldehydes, ketones, carboxylic acids and related esters, sulfides, disulfides and ethers evaluated by JECFA at the 65th meeting (JECFA, 2006b) and re-evaluated at the 69th meeting (JECFA, 2009c)

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 33 furan-substituted aliphatic hydrocarbons, alcohols, aldehydes, ketones, carboxylic acids and related esters, sulfides, disulfides and ethers evaluated by the JECFA. In the present version of FGE.67 eight additional substances have been included. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. For twenty-two substances [FL-no: 13.029, 13.030, 13.045, 13.052, 13.054, 13.059, 13.061, 13.066, 13.069, 13.070, 13.083, 13.101, 13.103, 13.105, 13.106, 13.107, 13.123, 13.138, 13.148, 13.163 and 13.191] a concern for genotoxicity was raised and therefore these were not evaluated using the Procedure. The Panel concluded that 8 substances [FL-no: 13.006, 13.021, 13.022, 13.023, 13.024, 13.116 and 13.190] do not give rise to safety concerns at the levels of dietary intake, estimated on the basis of the MSDI approach. For one substance [FL-no: 13.058] additional toxicity data are requested. Besides the safety assessment of these substances, the specifications for the materials of commerce have been considered. For three substances [FL-no: 13.031, 13.045 and 13.047] data on specifications / stereoisomerism are missing.

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EFSA Scientific Opinion on Flavouring Group Evaluation 78, Revision 1 (FGE.78Rev1): Consideration of aliphatic and alicyclic and aromatic hydrocarbons evaluated by JECFA (63rd meeting) structurally related to aliphatic and aromatic hydrocarbons evaluated by EFSA in FGE.25Rev2

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 24 aliphatic, alicyclic and aromatic hydrocarbons evaluated by the JECFA (65th meeting). In the previous version of FGE.78, the Panel concluded...
that for 13 substances no applicable NOAEL was available for the substance itself or on a structurally related compound and therefore further data were required. Additional data (long term study of toxicity, mutagenicity studies and new tonnage figure) have now become available for beta-myrcene [FL-no: 01.008] and the present revision of FGE.78, FGE.78Rev1, includes the evaluation of these data. The substances were evaluated through a stepwise approach (the Procedure) that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. Two substances [FL-no: 01.011 and 01.013] are genotoxic in vitro and potentially carcinogenic, and are therefore not evaluated using the Procedure. The Panel concluded that the nine substances [FL-no: 01.002, 01.005, 01.006, 01.010, 01.016, 01.019, 01.020, 01.045 and 01.077] do not give rise to safety concerns at the levels of dietary intake, estimated on the basis of the MSDI approach. For 13 substances [FL-no: 01.003, 01.004, 01.007, 01.008, 01.009, 01.014, 01.017, 01.018, 01.024, 01.026, 01.029, 01.040 and 01.061] additional toxicity data are requested. For one substance [FL-no: 01.024] EU production figure is needed to finalise the evaluation. Besides the safety assessment of these substances, the specifications for the materials of commerce have been considered. For two substances [FL-no: 01.018 and 01.061] the isomeric composition is lacking. For 14 substances [FL-no: 01.004, 01.007, 01.008, 01.009, 01.017, 01.018, 01.019, 01.020, 01.024, 01.026, 01.029, 01.040, 01.045 and 01.061] further information on the composition of mixture is requested.

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EFSA ; Scientific Opinion on Flavouring Group Evaluation 86, Revision 1 (FGE.86Rev1): Consideration of aliphatic and aromatic amines and amides evaluated by JECFA (65th meeting)

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Research output: Book/Report › Report – Annual report year: 2011 › Research › peer-review
EFSA ; Scientific Opinion on Flavouring Group Evaluation 91, Revision 1 (FGE.91Rev1): Consideration of simple aliphatic and aromatic sulphides and thiols evaluated by JECFA (53rd and 68th meetings) structurally related to aliphatic and alicyclic mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups evaluated by EFSA in FGE.08Rev3 (2011)

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of 47 simple aliphatic and aromatic sulphides and thiols evaluated by the JECFA at the 53rd meeting in 1999 and the 68th meeting in 2007. The revision is made due to consideration of two additional substances compared to previous version. The substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel agrees with the application of the Procedure as performed by the JECFA for 34 substances considered in this FGE and agrees with the JECFA conclusion, “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach. Contrary to the JECFA, the Panel concluded for three substances [FL-no: 12.077, 12.108 and 12.162], which has been cleared by the JECFA at step B5 (the MSDI <1.5 μg person per day), that adequate NOAELs exist and accordingly concluded at step B4 no safety concern at the estimated level of intake. Furthermore, for the trisulphides [FL-no: 12.114 and 12.256], contrary to the JECFA, the Panel concluded that no adequate NOAEL exists and that additional toxicity data are required. For eight substances [FL-no: 12.038, 12.085, 12.137, 12.138, 12.145, 12.252, 12.259 and 12.272] the Panel decided, also contrary to the JECFA, that the Procedure could not be applied due to concern for genotoxicity. So, the Panel concluded that 37 substances do not give rise to safety concern at their levels of dietary intake, estimated on the basis of the MSDI approach. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered for the substances evaluated through the Procedure and for three substances, [FL-no: 12.274, 12.284 and 15.049], information on the composition of stereoisomeric mixture is lacking.

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Contributors: EFSA Publication
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Publication date: 2011

EFSA ; Scientific Opinion on Flavouring Group Evaluation 98 (FGE.98): Consideration of three ring-unsaturated delta-lactones

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to consider evaluations of flavouring substances assessed since 2000 by the Joint FAO/WHO Expert Committee on Food Additives (the JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present consideration concerns a group of three unsaturated delta-lactones [FL-no: 10.031, 10.037 and 10.044] previously evaluated by the JECFA at their 49th meeting in 1997. The JECFA considered that further information on the metabolism of these three substances was required and that they should be evaluated together with other substances containing alpha,beta-unsaturation and that, therefore, their evaluation should be deferred. However, the EFSA Panel has considered that these three JECFA evaluated aliphatic lactones can be hydrolysed and metabolised to innocuous products in line with the aliphatic lactones evaluated by EFSA in FGE.10Rev2. The substances were evaluated through a stepwise approach that integrates information on structure-activity relationships, intake from current uses, toxicological threshold of concern, and available data on metabolism and toxicity. The Panel concluded that all three substances do not give rise to safety concern at their levels of dietary intake, estimated on the basis of the MSDI approach.

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Estimation of dietary intake of PCB and organochlorine pesticides for children and adults

Levels of organochlorine substances, including a number of organochlorine pesticides and PCB, are monitored in food, including meat, fish and dairy products. The substances are slowly degradable and therefore persist for long periods in the environment, where they accumulate in the fatty tissues of animals and humans. They are included, because of the potential health-hazardous effect of these compounds on humans. The highest average contents are found in cod liver and fatty fish. The Danish population’s average daily intake has been estimated at between 0.03 and 0.3 μg/day for organochlorine pesticides and 0.9 μg/day for the indicator PCB-sum. People with a relatively high intake of these substances (the 95th percentile) are estimated to consume approximately twice as much. In general, the highest contributions to the intake of the organochlorine environmental contaminants are from fish, meat and dairy products. However, children have a relatively higher intake from milk and milk products and a lower intake from fish compared to adults.
**EuroFIR eBASIS: application for health claims submissions and evaluations**

**Background:** The European Food Information Resource (EuroFIR) network has established the eBASIS (Bioactive Substances in Food Information System) online food composition and biological effects database for plant-derived bioactive compounds (phytochemicals). On the basis of submitted evidence, the European Food Safety Authority (EFSA) expert panel on Dietetic Products, Nutrition and Allergies assesses whether claims made under articles 13.1, 13.5 or 14 of the Regulation (EC) 1924/2006, which governs the use of nutrition and health claims on foods, are scientifically justified. This report evaluates the eBASIS biological effects database in the preparation and evaluation of health claims dossiers.

**Methods:** The eBASIS biological effects database is a compilation of expert-evaluated data extracted from the literature, prioritising human intervention studies to investigate health effects of phytochemicals. Currently included are 4750 records from 445 studies providing data on 56 validated biomarkers, mainly relating to cardio-metabolic and bone health outcomes. The data cover 144 bioactive compounds from 17 compound classes. Using the EFSA Register of Questions and the database of general function health claims, we identified claims relating to phytochemicals made under articles 13.1, 13.5 and 14 and compared them with the eBASIS database to identify overlap between them. Results: The EFSA online health claims database contains 4240 submissions under article 13.1, of which 2157 pertain to plants or plant-based bioactive compounds; 496 of these relate to plants or bioactive compounds included in the eBASIS biological effects database. Out of the 18 current 13.5 'new function' claims on EFSA's register of questions, 7 are for plants or plant-based bioactive compounds, of which 6 are included in eBASIS. Of the 222 defined article 14 claims, 21 pertain to plants or plant-based bioactive compounds, of which 19 are in eBASIS.

**Conclusions:** There is extensive overlap between eBASIS and the submitted health claims that relate to plant-based bioactive compounds. EuroFIR eBASIS is a useful tool for regulators to independently check completeness of health claims applications relating to phytochemicals and is a potentially valuable resource to assist claimants in the compilation of dossiers on functional foods and health claims.


**Risk assessment of mixtures of pesticides. Current approaches and future strategies**

The risk assessment of pesticide residues in food is based on toxicological evaluation of the single compounds and no internationally accepted procedure exists for evaluation of cumulative exposure to multiple residues of pesticides in crops, except for a few groups of pesticides sharing a group ADI. However, several attempts have been suggested during the last decade. This paper gives an overview of the various approaches. It is of paramount importance to consider whether there will be either no interaction or interaction between the compounds in the mixture. When there are no interactions several approaches are available for the risk assessment of mixtures of pesticides. However, no single simple approach is available to judge upon potential interactions at the low doses that humans are exposed to from pesticide residues in food. In these cases, PBTK models could be useful as tools to assess combined tissue doses and to help predict potential interactions including thresholds for such effects. This would improve the quality of the risk assessment.
Scientific Opinion on Flavouring Group Evaluation 01, Revision 2 (FGE.01Rev2): Branched-chain aliphatic saturated aldehydes, carboxylic acids and related esters of primary alcohols and branched-chain carboxylic acids from chemical groups 1 and 2: EFSA-Q-2009-00566


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Scientific Opinion on Flavouring Group Evaluation 72 (FGE.72): Consideration of aliphatic, branched-chain saturated and unsaturated: EFSA-Q-2008-056

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Scientific Opinion on Flavouring Group Evaluation 81 (FGE.81): Consideration of hydroxypropenylbenzenes evaluated by JECFA (61st meeting) structurally related to 2-methoxy-4-(prop-1-enyl)phenyl 3-methylbutyrate from chemical group 17 evaluated by EFSA in FGE.30: EFSA-Q-2008-065

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Scientific Opinion on Flavouring Group Evaluation 83, Revision 1 (FGE.83Rev1): Consideration of ethyl maltol and two 6-keto-1,4-dioxane derivatives substances evaluated by JECFA (65th meeting): EFSA-Q-2008-00909

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Original language: English
DOI: 10.2903/j.efsa.2010.1409

Scientific Opinion on Flavouring Group Evaluation 8, Revision 1 (FGE.08Rev1): Aliphatic and alicyclic mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups from chemical groups 20 and 30: EFSA-Q-2009-00479

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Publication information
Publisher: European Food Safety Authority
Original language: English
DOI: 10.2903/j.efsa.2010.1021
Scientific Opinion on Flavouring Group Evaluation 90 (FGE.90): Consideration of aliphatic, acyclic and alicyclic terpenoid tertiary alcohols and structurally related substances evaluated by JECFA (68th meeting) structurally related to aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters evaluated by EFSA in FGE.18Rev1 (2009): Question No EFSA-Q-2009-00561

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Scientific Opinion on Flavouring Group Evaluation 94: Consideration of aliphatic amines and amides evaluated in addendum to the JECFA group aliphatic and aromatic amines and amides by JECFA: EFSA-Q-2009-00560

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Scientific Opinion on Flavouring Group Evaluation 95 (FGE.95): Consideration of aliphatic, linear or branched-chain saturated and unsaturated alcohols, aldehydes, acids and related esters evaluated by JECFA (69th meeting) structurally related to esters of branched- and straight-chain aliphatic saturated primary alcohols and of one secondary alcohol, and branched- and straight-chain unsaturated carboxylic acids evaluated by EFSA in FGE.05Rev1 (2008): EFSA-Q-2009-00714

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Publication date: 2010

Scientific Opinion on Flavouring Group Evaluation 9, Revision 2 (FGE.09Rev2): Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical group 8 and 30, and an ester of a phenol derivative from chemical group 25: EFSA-Q-2009-00562

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Publication date: 2010
Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on calcium L-methionate, magnesium L-methionate and zinc mono-L-methionine sulphate as sources for calcium, magnesium and zinc added for nutritional purposes to food supplements: Question No EFSA-Q-2005-138, EFSA-Q-2005-143, EFSA-Q-2005-076

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Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on magnesium ascorbate, zinc ascorbate and calcium ascorbate added for nutritional purposes in food supplements: Question number EFSA-Q-2005-087, EFSA-Q-2005-104, EFSA-Q-2006-229

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Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on selenious acid added for nutritional purposes to food supplements: Question No EFSA-Q-2006-278

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Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review
Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on calcium caprylate and magnesium caprylate as a source of calcium and magnesium added for nutritional purposes to food supplements, following a request from the European Commission: Questions No EFSA-Q-2008-017, EFSA-Q-2008-018

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on calcium phosphinate as a source of calcium added for nutritional purposes to food supplements following a request from the European Commission: Question No EFSA-Q-2006-279

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on calcium silicate, silicon dioxide and silicic acid gel added for nutritional purposes to food supplements following a request from the European Commission: Questions No EFSA-Q-2005-140, EFSA-Q-2006-220, EFSA-Q-2005-098,
Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on choline-stabilised orthosilicic acid added for nutritional purposes to food supplements following a request from the European Commission: Question No EFSA-Q-2006-189

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Publication status: Published
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Contributors: EFSA Publication
Publication date: 2009

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on chromium(III)-, iron(II)- and selenium- humic acid/fulvic acid chelate and supplemented humifulvate added for nutritional purposes to food supplements following a request from the European Commission: Questions No EFSA-Q-2006-191, EFSA-Q-2006-192, EFSA-Q-2006-193, EFSA-Q-2006-194

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2009

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on chromium(III) lactate trihydrate as a source of chromium added for nutritional purposes to food supplements, following a request from the European Commission: Question No EFSA-Q-2006-307

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on chromium nitrate as a source of chromium added for nutritional purposes to food supplements following a request from the European Commission: Question No EFSA-Q-2005-216

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2009

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on chromium picolinate, zinc picolinate and zinc picolinate dihydrate added for nutritional purposes in food supplements following a request from the European Commission: Questions No EFSA-Q-2005-077, EFSA-Q-2006-231, EFSA-Q-

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Publication status: Published
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Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on inositol hexanicotinate (inositol hexaniacinate) as a source for niacin (vitamin B3) added for nutritional purposes in food supplements following a request from the European Commission: Question No EFSA-Q-2005-213, EFSA-Q-2006-199

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Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on iron (II) taurate, magnesium taurate and magnesium acetyl taurate as sources for iron or magnesium to be added as a nutritional substance in food supplements following a request from the European Commission: Question number EFSA-Q-2005-217, EFSA-Q-2005-178, EFSA-Q-2006-187, EFSA-Q-2006-288

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Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on manganese ascorbate, manganese aspartate, manganese bisglycinate and manganese pidolate as sources of manganese added for nutritional purposes to food supplements following a request from the European Commission: Question number: EFSA-Q-2008-226; EFSA-Q-2008-302; EFSA-Q-2005-144; EFSA-Q-2005-037; EFSA-Q-2005-160; EFSA-Q-2008-322

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2009

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on potassium molybdate as a source of molybdenum added for nutritional purposes to food supplements following a request from the European Commission: Question number EFSA-Q-2005-157

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2009

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on Se-Methyl-L-Selenocysteine as a source of selenium added for nutritional purposes to food supplements following a request from the European Commission: Question No: EFSA-Q-2005-170, EFSA-Q-2006-306, EFSA-Q-2006-308

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 60 (FGE.60). Consideration of furfuryl alcohol and related flavouring substances evaluated by JECFA (55th meeting) structurally related to Furfuryl and furan derivatives with and without additional side chain substituents and heteroatoms evaluated by EFSA in FGE.13 (2005): Question No EFSA-Q-2008-032R

Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 64 (FGE.64): Consideration of aliphatic acyclic diols, triols, and related substances evaluated by JECFA (57th meeting) structurally related to aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones from chemical groups 9, 13 and 30 evaluated by EFSA in FGE.10Rev1: Question No EFSA-Q-2008-032P

Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 74 (FGE.74). Consideration of Simple Aliphatic Sulphides and Thiols evaluated by JECFA (61st meeting) Structurally related to Aliphatic and Alicyclic Mono-, Di-, Tri-, and Polysulphides
Scientific Opinion of the Panel on Food Contact Material, Enzymes, Flavourings & Processing Aids on a request from the Commission on Flavouring Group Evaluation 217: alpha,beta-Unsaturated ketones and precursors from chemical subgroup 4.1 of FGE.19: Lactones: Question No EFSA-Q-2008-762

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
Contributors: EFSA Publication
Publication date: 2009

Scientific Opinion of the Panel on Food Contact Material, Enzymes, Flavourings & Processing Aids on a request from the Commission on Flavouring Group Evaluation 57: Consideration of two structurally related pulegone metabolites and one ester thereof evaluated by JECFA (55th meeting): Question No EFSA-Q-2008-032H

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Contact Material, Enzymes, Flavourings and Processing Aids on a request from the European Commission on Flavourings Group Evaluation 43 (FGE43): Question No EFSA-Q-2008-047

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
Contributors: EFSA Publication
Publication date: 2009
Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF): Question No EFSA-Q-2009-00482

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Contributors: EFSA Publication
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Contributors: EFSA Publication
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Source-ID: 255753
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Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on a request from the European Commission on Flavouring Group Evaluation 61 revision 1 (FGE.61rev1): Question No EFSA-Q-2009-00484

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Research output: Book/Report → Report – Annual report year: 2009 → Research → peer-review

Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on Flavouring Group Evaluation 89 (FGE.89): Consideration of phenyl-substituted aliphatic tertiary alcohols and related aldehydes and esters evaluated by JECFA (63rd and 68th meetings) structurally related to aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters evaluated by EFSA in FGE.18Rev1 (2009): Question No EFSA-Q-2008-309

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Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on Flavouring Group Evaluation 89 (FGE.89): Consideration of phenyl-substituted aliphatic tertiary alcohols and related aldehydes and esters evaluated by JECFA (63rd and 68th meetings) structurally related to aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters evaluated by EFSA in FGE.18Rev1 (2009): Question No EFSA-Q-2008-309

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
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Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on Flavouring Group Evaluation 89 (FGE.89): Consideration of phenyl-substituted aliphatic tertiary alcohols and related aldehydes and esters evaluated by JECFA (63rd and 68th meetings) structurally related to aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters evaluated by EFSA in FGE.18Rev1 (2009): Question No EFSA-Q-2008-309

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Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on Flavouring Group Evaluation 89 (FGE.89): Consideration of phenyl-substituted aliphatic tertiary alcohols and related aldehydes and esters evaluated by JECFA (63rd and 68th meetings) structurally related to aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters evaluated by EFSA in FGE.18Rev1 (2009): Question No EFSA-Q-2008-309

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Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on Flavouring Group Evaluation 89 (FGE.89): Consideration of phenyl-substituted aliphatic tertiary alcohols and related aldehydes and esters evaluated by JECFA (63rd and 68th meetings) structurally related to aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters evaluated by EFSA in FGE.18Rev1 (2009): Question No EFSA-Q-2008-309

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Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on Flavouring Group Evaluation 89 (FGE.89): Consideration of phenyl-substituted aliphatic tertiary alcohols and related aldehydes and esters evaluated by JECFA (63rd and 68th meetings) structurally related to aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters evaluated by EFSA in FGE.18Rev1 (2009): Question No EFSA-Q-2008-309

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Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on Flavouring Group Evaluation 89 (FGE.89): Consideration of phenyl-substituted aliphatic tertiary alcohols and related aldehydes and esters evaluated by JECFA (63rd and 68th meetings) structurally related to aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters evaluated by EFSA in FGE.18Rev1 (2009): Question No EFSA-Q-2008-309

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
Contributors: EFSA Publication
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Source: orbit
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Research output: Book/Report → Report – Annual report year: 2009 → Research → peer-review
Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids on a request from the Commission on FGE54rev1 Consideration of benzyl derivatives evaluated by JECFA (57th meeting) structurally related to benzyl alcohols, benzaldehydes, a related acetal, benzoic acids and related esters evaluated by EFSA in FGE.20Rev1 (2009): Question No EFSA-Q-2009-00483

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
Contributors: EFSA Publication
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Contributors: EFSA Publication, Binderup, M.
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Contributors: EFSA Publication
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Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

Scientific Opinion on the re-evaluation of Allura Red AC (E 129) as a food additive on request from the European Commission: Question No EFSA-Q-2008-230

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

Scientific Opinion on the re-evaluation of Azorubine/Carmoisine (E 122) as a food additive on request the European Commission: Question number: EFSA-Q-2008-226

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Source: orbit
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Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review
Scientific Opinion on the re-evaluation Tartrazine (E 102) on request from the European Commission: Question No EFSA-Q-2008-222

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Contributors: EFSA Publication
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Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

Scientific Opinion on the use of high viscosity white mineral oils as a food additive on request from the European Commission: Question No EFSA-Q-2008-003

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Original language: English
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DOIs:
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URLs:
Source: orbit
Source-ID: 255469
Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

Scientific Opinion on the use of natamycin (E 235) as a food additive: Question No EFSA-Q-2007-072

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review
Scientific Opinion on the use of Polyglycitol Syrup as a food additive. Question No EFSA-Q-2007-072

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Publication status: Published
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Contributors: EFSA Publication
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Publisher: European Food Safety Authority
Original language: English
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URLs:
Source: orbit
Source-ID: 255430
Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

Updated Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the European Commission related to the 2nd ERF carcinogenicity study on aspartame taking into consideration study data submitted by the Ramazzini Foundation in February 2009: EFSA-Q-2009-00474

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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URLs:
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Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

Flavouring Group Evaluation 5, Revision 1 (FGE.05Rev1): Esters of branched- and straight-chain aliphatic saturated primary alcohols and of one secondary alcohol, and branched- and straight-chain unsaturated carboxylic acids from chemical groups 1, 2, and 5: Question No EFSA-Q-2003-148B

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Publisher: European Food Safety Authority
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Source-ID: 235657
Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review

Legal and Illegal Colours
Food additives are evaluated by the European Food Safety Authority's (EFSA) Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (the AFC Panel). The AFC Panel is supported by its standing working group on food additives (WG ADD), which prepares draft opinions on food additives, including colours,
and on the bioavailability and safety of nutrient sources. The WG ADD consists of several members from the AFC Panel together with selected external experts. The draft opinions go forward to the AFC Panel for discussion and final adoption. The adopted opinions are published on the EFSA web site. During its first 5 years of existence the AFC Panel has experienced the highest workload of all EFSA Panels, of which evaluations of food additives have been a substantial part. Although the AFC Panel has issued many opinions on food additives, some of which have been widely debated, such as opinions on aspartame [EFSA. (2006). Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) related to a new long-term carcinogenicity study on aspartame. Opinion expressed on 03/05/2006. Available at http://www.efsa.europa.eu/EFSA/efsalocale-1178620753812_1178620765743.htm. Accessed 12.05.08.] and parabens [EFSA. (2004). Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) related to para hydroxybenzoates (214e219). Opinion expressed on 13/07/2004. Available at http://www.efsa.europa.eu/EFSA/efsalocale-1178620753812_1178620761956.htm. Accessed 12.05.08.] this paper only deals with some of the major issues that the Panel has faced in relation to the use of food colours. The three topics to be dealt with are (1) evaluation of illegal colours in food in the EU (EFSA, 2005), (2) re-evaluation of the authorised food colours in the EU (ongoing, but one opinion on Red 2G has been published; EFSA, 2007), and (3) evaluation of ‘the Southampton study’ on hyperactivity in children after intake of food colours (and sodium benzoate) (ongoing at the time of this presentation, but an opinion has now been published; EFSA, 2008). All rights reserved, Elsevier.
Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 63 (FGE.63), Consideration of aliphatic secondary alcohols, ketones and related esters evaluated by JECFA (59th meeting) structurally related to saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids evaluated by EFSA in FGE.07: Question No EFSA-Q-2008-0320

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 35
Publication date: 2008

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request related to Flavouring Group Evaluation 3, Revision 1 (FGE.03Rev1): Acetals of branched- and straight-chain aliphatic saturated primary alcohols and branched- and straight-chain saturated or unsaturated aldehydes, an ester of a hemiacetal and an orthoester of formic acid, from chemical groups 1, 2 & 4: Question No EFSA-Q-2003-146B

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 68
Publication date: 2008

Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 18th list of substances for food contact materials

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Polycyclic Aromatic Hydrocarbons in Food: Question N° EFSA-Q-2007-136

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food (ANS) on a request from the Commission on a mixture of chromium di- and tri-nicotinate as a source of chromium: Question No EFSA-Q-2005-079

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food (ANS) on a request from the Commission on benfotiamine, thiamine monophosphate chloride and thiamine pyrophosphate chloride, as sources of vitamin B1

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Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to food (ANS) on a request from the Commission on calcium L-threonate as a source for calcium added for nutritional purposes in food supplements: Question No EFSA Q-2005-158
Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food (ANS) on a request from the Commission on pantethine as a source for pantothenic acid added as a nutritional substance in food supplements: Question No EFSA-Q-2006-227

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on adenosylcobalamin and methylcobalamin as sources for Vitamin B12

Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on Calcium fluoride as a source of fluoride added for nutritional purposes to food supplements: Question No EFSA-Q-2005-088
Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on Calcium sulphate for use as a source of calcium in food supplements: Question No EFSA-Q-2005-075

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food on a request from the Commission on disodium fluorophosphate added for nutritional purposes to food supplements

General information
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC) on a request from the Commission on the results of the study by McCann et al. (2007) on the effect of some colours and sodium benzoate on children’s behaviour: Question No EFSA-Q-2007-171

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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission Flavouring Group Evaluation 1, Revision 1 (FGE.01Rev 1): Branched-chain aliphatic saturated aldehydes, carboxylic acids and related esters of primary alcohols and branched-chain carboxylic acids from chemical groups 1 and 2: Question No EFSA-Q-2008-033

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission Flavouring Group Evaluation 2, Revision 1 (FGE.02Rev 1): Branched- and straight-chain aliphatic saturated primary alcohols and related esters of primary alcohols and straight-chain carboxylic acids and one straight-chain aldehyde from chemical groups 1 and 2: EFSA-Q-2008-034

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission Flavouring Group Evaluation 6, Revision 1 (FGE.06Rev 1): Flavouring Group Evaluation 6, Revision 1 (FGE.06Rev 1): Straight- and branched-chain aliphatic unsaturated primary alcohols, aldehydes, carboxylic acids, and esters from chemical groups 1 and 4: Question No EFSA-Q-2003-149B

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Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission Flavouring Group Evaluation 7, Revision 1 (FGE.07Rev1): Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5: Question No EFSA-Q-2003-150B

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Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission on Camphor in flavourings and other food ingredients with flavouring properties: Question No EFSA-Q-2003-144

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Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission on Flavouring Group Evaluation 36, (FGE.36) Two triterpene glycosides from the priority list: EFSA-Q-2003-172C

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission on magnesium aspartate, potassium aspartate, magnesium potassium aspartate, calcium aspartate, zinc aspartate, and copper aspartate added for nutritional purposes to food supplements
Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission on Selenium-enriched yeast as source for selenium

Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC) on a request from the Commission on the toxicokinetics of Bisphenol A: Question No EFSA-Q-2008-382

Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the European Commission on Flavouring Group Evaluation 4: 2-Ethylhexyl derivatives from chemical group 2: Question No EFSA-Q-2003-147
Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on substances in food contact materials, 19th list: Question NO EFSA-Q-2003-197, EFSA-Q-2007-014

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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) Primary saturated or unsaturated alicyclic alcohol, aldehyde, and esters from chemical group 7: Question No EFSA-Q-2003-155B

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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC): Pyridine, pyrrole, indole and quinoline derivatives from chemical group 28 Flavouring Group Evaluation 24, Revision 1: Question No EFSA-Q-2003-167B

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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on FGE.85 Consideration of miscellaneous nitrogen-containing substances evaluated by JECFA: Question No EFSA-Q-2008-069

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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 09 Rev1, (FGE.09 Rev1) Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical groups 8 and 30, and an ester of a phenol carboxylic acid from chemical group 25: Question No EFSA-Q-2003-152B

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 31, (FGE.31) One Epoxide from Chemical Group 32: Question No EFSA-Q-2008-035

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 56 (FGE.56) Consideration of monocyclic and alcohols, ketones and related esters evaluated by JECFA (63rd meeting) structurally related to secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols and an ester of a phenol carboxylic acid evaluated by EFSA in FGE.09Rev1 (2008): Question EFSA-Q-2008-032G

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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 69, (FGE.69) Aromatic substituted secondary alcohols, ketones and related esters: EFSA-Q-2008-053

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 73, (FGE.73) alicyclic primary alcohols, aldehydes, acids and related esters: EFSA-Q-2008-057

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 76, (FGE.76) sulphur-containing heterocyclic compounds evaluated by JECFA (59th meeting): EFSA-Q-2008-080

Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 80 (FGE.80) consideration of alicyclic, alicyclic-fused and aromatic-fused ring lactones evaluated by JECFA (61st meeting) structurally related to a aromatic lactone evaluated by EFSA in FGE.27: Question No EFSA-Q-2008-064

Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 83, (FGE.83) Consideration of 6-keto-1,4-dioxane derivatives substances evaluated by JECFA (65th meeting): EFSA-Q-2008-067
Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 84, (FGE.84) Anthranilate derivatives: EFSA-Q-2008-068

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Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 86, (FGE.86) Consideration of aliphatic and aromatic amines and amides evaluated by JECFA: Question No EFSA-Q-2008-070

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from Commission on Flavouring Group Evaluation 87, (FGE.87) bicyclic secondary alcohols, ketones and related esters: EFSA-Q-2008-071

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Publication status: Published
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission on certain bisglycinates and glycinate nicotinate as sources for copper, zinc, calcium, magnesium and chromium

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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission on magnesin L-lysinate, Calcium L-lysinate, Zinc L-lysinate as sources for magnesium, calcium and zinc subject

General information
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Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission on mixed tocopherols, tocotrienol tocopherol and tocotrienols as sources for vitamin E

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission on the safety in use of lycopene as a food colour

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Contributors: EFSA Publication
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Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission on the use of rosemary extracts as a food additive: Question No EFSA-Q-2003-140


Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the European Commission on Coumarin in flavourings and other food Ingredients with flavouring properties: Question No EFSA-Q-2008-677
Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods (AFC) on a request from the Commission on Pyridoxal-5’-phosphate as a source for vitamin B6 added for nutritional purposes in food supplements

General information
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Flavouring Group Evaluation 5, Revision 1 (FGE.05Rev1): Esters of branched- and straight-chain aliphatic saturated primary alcohols and of one secondary alcohol, and branched- and straight-chain unsaturated carboxylic acids from chemical groups 1, 2, and 5: Question No EFSA-Q-2003-164A

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OPINION OF THE SCIENTIFIC PANEL ON CONTAMINANTS IN THE FOOD CHAIN ON A REQUEST FROM THE COMMISSION RELATED TO THE POTENTIAL INCREASE OF CONSUMER HEALTH RISK BY A POSSIBLE INCREASE OF THE EXISTING MAXIMUM LEVELS FOR AFLATOXINS IN ALMONDS, HAZELNUTS AND PISTACHIOS AND DERIVED PRODUCTS: Question No EFSA-Q-2006-174

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 14th list of substances for food contact materials

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Contributors: EFSA Publication
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Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 15th list of substances for food contact materials

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Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 17th list of substances for food contact materials

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Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials In Contact with Food on a request from the Commission related to an application on the use of ethyl lauroyl arginate as a food additive: Question No EFSA-Q-2006-035

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to an application on the use of partially depolymerised guar gum as a food additive: Question No EFSA-Q-2006-122

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Calcium ascorbate with a content of threonate for use as a source of vitamin C in food supplements: Question No EFSA-Q-2005-044

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 10
Publication date: 2007

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Calcium, iron, magnesium, potassium and zinc L-pidolate as sources for calcium, iron, magnesium, potassium and zinc added for nutritional purposes to food supplements and to foods intended for particular nutritional uses

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Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to D-alpha-tocopheryl polyethylene glycol 1000 succinate (TPGS) in use for food for particular nutritional purposes: Question No EFSA Q-2003-126

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Publication date: 2007

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on the food colour Red 2G (E128) based on a request from the Commission related to the re-evaluation of all permitted food additives: Question No EFSA-Q-2007-126

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Contributors: EFSA Publication
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Risk Assessment of malachite green and leucomalachite green found in farmed fish

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Contributors: Olesen, P. T., Larsen, J. C., Schnipper, A.
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Risk assessment of malachite green and leucomalechite green found in farmed fish
Risk Assessment of Malachite Green in Food

Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with food (AFC) on a request from the Commission on Calcium citrate malate as source for calcium intended for use in foods for Particular Nutritional Uses (PARNUTS) and in foods for the general population (including food supplements)

Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC) on a request from the Commission on the safety in use of beeswax: Question No EFSA-Q-2006-021
A safe strategy for addition of vitamins and minerals to foods
Addition of vitamins and minerals to foods must be done without health risk to any consumer group. International expert groups have aimed at establishing tolerable upper intake levels (ULs) for vitamins and minerals although lack of solid data on their safety is a major obstacle to this work. In this paper, we summarize the existing ULs and suggest the use of guidance levels (GLs) set by others and temporary guidance levels (TGLs) proposed here, whenever no consensus UL has been established for adults. We suggest the use of body surface area ratios to establish similar levels for younger age groups. The levels are applied in a model for calculation of safe fortification levels for all ages. We have estimated the upper 95th percentile intake of vitamins and minerals from food in various Danish age and gender groups and suggest that a daily multivitamin mineral pill is included in the calculation of total dietary intake levels of all vitamins and minerals. By subtracting this dietary intake level from the UL, GL or TGL, we calculate the amount that can be safely used for fortification. Since safety must be assured for all age groups, the smallest difference relative to energy intake calculated for any age group is proposed as the maximal allowance (MA) for fortification with each nutrient. We suggest that the MA should be expressed in weight units per energy unit in order to distribute it equally between potentially fortifiable food groups according to their usual contribution to total energy intakes.
Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 24: Pyridine, pyrrole, indole and quinoline derivatives from chemical group 28: Question No EFSA-Q-2003-167

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Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 26: Amino acids from chemical group 34: Question No EFSA-Q-2003-169

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2,2-BIS(4-HYDROXYPHENYL)PROPANE (Bisphenol A): Question No EFSA-Q-2005-100

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Publication information
Publisher: European Food Safety Authority
The polychlorinated dibenzo-p-dioxins (PCDD), polychlorinated dibenzofurans (PCDF), and dioxin-like polychlorinated biphenyls (dioxin-like PCB) are ubiquitous in food of animal origin and accumulate in fatty tissues of animals and humans. The most toxic congener is 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). The toxic responses include dermal toxicity, immunotoxicity, carcinogenicity, and reproductive and developmental toxicity. Toxic equivalency factors have been established for the other PCDD, PCDF and dioxin-like PCB relative to TCDD, and the combined toxicity of a sample can be expressed as toxic equivalent (WHO-TEQ). The EC Scientific Committee for Food evaluated these compounds in 2001. The assessment used the most sensitive adverse toxicological end-points of TCDD in experimental animals. These were developmental and reproductive effects in the male offspring of rats administered TCDD during pregnancy. Because of the large difference between rats and humans in the biological half-life of TCDD, the assessment used a body burden approach to compare across species and derived a tolerable weekly intake of 14 pg TCDD/kg of body weight (bw), which was extended to include all the 2,3,7,8-substituted PCDD and PCDF, and the dioxin-like PCB, and expressed as a group tolerable weekly intake of 14 pg WHC-TEQ/kg bw. The FAO/WHO Joint Expert Committee on Food Additives (JECFA)
performed a similar assessment whereas the US Environmental Protection Agency (US EPA) has paid more attention to human data on carcinogenicity.
Ochratoxin A: Previous risk assessments and issues arising

Ochratoxin A (OTA) causes nephropathy in all species tested with large sex and species differences in potency, pigs being most sensitive. It has been linked to Balkan endemic nephropathy (BEN) in humans. Embryotoxicity, teratogenicity, and immunotoxicity occur only at doses higher than those causing nephrotoxicity. OTA has long serum half-lives in various species including humans. OTA produced renal tumours in mice and rats. The male rat was most sensitive, renal carcinomas occurring after 70 μg/kg bw per day but not 21 μg/kg bw per day. OTA was not mutagenic in most studies in bacteria and mammalian cells, but produced DNA damage and chromosomal aberrations in mammalian cells in vitro, and in mice in vivo. DNA adducts found in the kidneys of mice and rats dosed with OTA, did not contain fragments of OTA. OTA in food has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and by the EC Scientific Committee on Food (SCF). JECFA established a provisional tolerable weekly intake (PTWI) of 100 ng/kg bw based on the LOEL for renal effects in pigs. Conversely, SCF recommended reducing exposure to OTA as much as possible, e.g. below 5 ng/kg bw per day. Both committees recommended further studies to clarify the mechanism by which OTA induces nephrotoxicity and carcinogenicity.
Opinion of the Scientific Panel on Contaminants in Food Chain on a request from the Commission related to ergot as undesirable substance in animal feed: Question No EFSA-Q-2003-38

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Contributors: EFSA Publication
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Opinion of the Scientific Panel on Contaminants in Food Chain on a request from the Commission related to fumonisins as undesirable substances in animal feed: Request No EFSA-Q-2003-040

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 32
Publication date: 2005

OPINION OF THE SCIENTIFIC PANEL ON CONTAMINANTS IN THE FOOD CHAIN ON A REQUEST FROM THE COMMISSION RELATED TO THE PRESENCE OF NON DIOXIN-LIKE POLYCHLORINATED BIPHENYLS (PCB) IN FEED AND FOOD: Question No EFSA-Q-2003-114

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 137
Publication date: 2005
Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 5: Esters of 23 branched- and straight-chain aliphatic saturated primary alcohols and of one secondary alcohol, and 24 branched- and straight-chain unsaturated carboxylic acids from chemical groups 1, 2, and 5: Question No EFSA-Q-2003-148

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 74
Publication date: 2005

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 204).
Source: orbit
Source-ID: 238960

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 10: Aliphatic primary and secondary saturated and unsaturated alcohols, aldehydes, acetals, carboxylic acids and esters containing an additional oxygenated functional group and lactones from chemical groups 9, 13 and 30: Question No EFSA-Q-2003-153

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 110
Publication date: 2005

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 246).
Source: orbit
Source-ID: 238969

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 12: Primary saturated or unsaturated alicyclic alcohol, aldehyde, and esters from chemical group 7

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 38
Publication date: 2005

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 208).
Source: orbit
Source-ID: 238982
Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 13: Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms from chemical group 14: Question No EFSA-Q-2003-156

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 73
Publication date: 2005

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 215).
Source: orbit
Source-ID: 238983
Research output: Book/Report › Report – Annual report year: 2005 › Research › peer-review

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 14 (FGE.14): Phenethyl alcohol, aldehyde, esters, and related phenylacetic acid esters, From chemical group 15

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 48
Publication date: 2005

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 216).
Source: orbit
Source-ID: 238984
Research output: Book/Report › Report – Annual report year: 2005 › Research › peer-review

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 15 (FGE.15): Aryl-substituted saturated and unsaturated primary alcohol/aldehyde/acid/ester derivatives from chemical group 22

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 45
Publication date: 2005

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 247).
Source: orbit
Source-ID: 238989
Research output: Book/Report › Report – Annual report year: 2005 › Research › peer-review

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 17: Pyrazine derivatives from chemical group 24: Question No EFSA-Q-2003-160

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Opinion of the Scientific Panel on Food Additives, Flavours, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 20: Benzyl alcohols, benzoaldehydes, a related acetal, benzoic acids, and related esters from chemical group 23: Question No EFSA-Q-2003-163

Principper for sundhedsmæssig vurdering af kemiske stoffer med henblik på fastsættelse af kvalitetskriterier for luft, jord og vand: Miljøprojekt 9742005

Risk of adverse health effects from intake of contaminants in traditional Greenland diet.
Opinion of the Scientific Panel on Contaminants in Food Chain on a request from the Commission related to ochratoxin A (OTA) as undesirable substance in animal feed: Request No EFSA-Q-2003-039

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 36
Publication date: 2004

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 101).
Source: orbit
Source-ID: 239310
Research output: Book/Report › Report – Annual report year: 2004 › Research › peer-review

Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to Aflatoxin B1 as undesirable substance in animal feed: Request No EFSA-Q-2003-035

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Publication date: 2004

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Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 39).
Source: orbit
Source-ID: 239315
Research output: Book/Report › Report – Annual report year: 2004 › Research › peer-review

Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to Deoxynivalenol (DON) as undesirable substance in animal feed: Question No EFSA-Q-2003-036

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 42
Publication date: 2004

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 73).
Source: orbit
Source-ID: 239313
Research output: Book/Report › Report – Annual report year: 2004 › Research › peer-review

Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to Zearalenone as undesirable substance in animal feed: Question No EFSA-Q-2003-037

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
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Publication date: 2004

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 44
Publication date: 2004

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 3 (FGE.03): Acetals of branched- and straight-chain aliphatic saturated primary alcohols and branched- and straight-chain saturated aldehydes, and an orthoester of formic acid, from chemical groups 1 and 2: Question number EFSA-Q-2003-146

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 59
Publication date: 2004

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 6 (FGE.06): Straight- and branched-chain aliphatic unsaturated primary alcohols, aldehydes, carboxylic acids, and esters from chemical groups 1 and 4: Question No EFSA-Q-2003-149

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 69
Publication date: 2004
Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 7 (FGE.07): Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 63
Publication date: 2004

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 164).
Source: orbit
Source-ID: 238965
Research output: Book/Report › Report – Annual report year: 2004 › Research › peer-review

Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) on a request from the Commission, Flavouring Group Evaluation 9 (FGE.09): Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical group 8 and an ester of a phenol carboxylic acid from chemical group 25: EFSA-Q-2003-152

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 51
Publication date: 2004

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 165).
Source: orbit
Source-ID: 238967
Research output: Book/Report › Report – Annual report year: 2004 › Research › peer-review

Workshop on trichothecenes with a focus on DON: summary report
A number of mycotoxins of the class of trichothecenes are produced by a variety of Fusarium fungi commonly found on cereals. Unfavourable weather conditions may lead to a high level of Fusarium infections in crops such as wheat and correspondingly high trichothecene contents. The ILSI Europe Natural Toxin Task Force therefore organised a workshop on trichothecenes with a special focus on deoxynivalenol (DON). A number of experts reviewed the current knowledge on trichothecenes with respect to occurrence, including aspects of mould growth, toxin formation, storage and effects of processing; prevention; analytical methodologies, including sampling; surveillance and exposure assessments; and toxicology and risk assessment. A number of recommendations were given under the headings: prevention, sampling and analytical methods, exposure assessment, and toxicology. Gaps in knowledge were also identified.

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Larsen, J. C., Hunt, J., Perrin, I., Ruckenbauer, P.
Pages: 1-22
Publication date: 2004
Peer-reviewed: Yes

Publication information
Journal: Toxicology Letters
Volume: 153
Applicability of the CALUX bioassay for screening of dioxin levels in human milk samples

The CALUX (chemically activated luciferase expression) bioassay based on rat hepatoma (H4IIE) cells is a sensitive assay for the detection of Ah receptor agonists like 2,3,7,8-substituted chlorinated dibenzo-p-dioxins and dibenzofurans and related PCBs. In this paper, the assay was optimized and applied for monitoring levels of dioxins in human milk samples. Combination effects of dioxin-like compounds were evaluated by testing potential mechanisms of interaction between seven of the major dioxin-like compounds in human milk using the isobole method. Results showed that the compounds acted additively, indicating that the usual assumption of additivity in the risk assessment process is valid. In general the relative potencies (REPs) of the single agents were in accordance with their TEFs assigned by the World Health Organisation, except for the mono-ortho-substituted PCB118 that had a 40-fold lower REP in CALUX. The total dioxin-like activity was determined in 16 Danish human milk samples and was in the range 20.5-55.8 pg TEQ g(-1) fat. These values were compared with TEQs obtained from GC/MS analysis (range 14.8-43.6 pg TEQ-g(-1) fat) that overall were a little lower than CALUX TEQs. The results obtained with the bioassay when testing milk extracts fractionated into dioxins/furans, non-ortho PCB and mono/di-ortho PCB fractions indicated that the correlation between the bioassay and the chemical analyses depends primarily on the A receptor activity observed in the mono/di-ortho PCB fraction.
Opinion of the Scientific Committee on Food on chemically defined flavouring substances listed in the EU register, Flavouring Group Evaluation 1 (FGE.01): Branched-chain aliphatic saturated aldehydes, carboxylic acids and related esters of primary alcohols and branched-chain carboxylic acids from chemical groups 1 and 2

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2003

Opinion of the Scientific Committee on Food on chemically defined flavouring substances listed in the EU register, Flavouring Group Evaluation 2 (FGE.02): Branched- and straight-chain aliphatic saturated primary alcohols, aldehydes and related esters of primary alcohols and straight-chain carboxylic acids from chemical groups 1 and 2

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2003

Children and the unborn child, Exposure and susceptibility to chemical substances – an evaluation: Report to the Danish Environmental Protection Agency

Children are at risk of exposure to a lot of high-production-volume synthetic chemical substances which have been introduced into the market within the past 50 years; these chemical substances are used widely in consumer products and are dispersed in the environment. Children as well as the unborn child have in some cases appeared to be uniquely vulnerable to chemical toxicants because of their biological growth and development. Furthermore, children may be more heavily exposed than adults to certain chemicals and pollutants in the environment. This report summarises and discusses the current knowledge about the biological susceptibility and exposure of chemical substances to children during the embryonic, foetal, and postnatal periods.

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Number of pages: 117
Publication date: 2001

Children and the unborn child, Exposure and susceptibility to chemical substances – an evaluation: Report to the Danish Environmental Protection Agency

Children are at risk of exposure to a lot of high-production-volume synthetic chemical substances which have been introduced into the market within the past 50 years; these chemical substances are used widely in consumer products and are dispersed in the environment. Children as well as the unborn child have in some cases appeared to be uniquely vulnerable to chemical toxicants because of their biological growth and development. Furthermore, children may be more heavily exposed than adults to certain chemicals and pollutants in the environment. This report summarises and discusses the current knowledge about the biological susceptibility and exposure of chemical substances to children during the embryonic, foetal, and postnatal periods.

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Number of pages: 117
Publication date: 2001
Combinatory effects of common food additives and contaminants

General information
Publication status: Published
Organisations: Secretariat, Division of Virology, National Veterinary Institute, Division of Toxicology and Risk Assessment, National Food Institute, Technical University of Denmark
Contributors: Nielsen, T. K., Larsen, J. C., Leffers, H., Breinholt, V.
Pages: 166-166
Publication date: 2001
Peer-reviewed: Yes

Publication information
Journal: Toxicology
Volume: 164
Issue number: 1-3
ISSN (Print): 0300-483X
Ratings:
Scopus rating (2001): SJR 0.565 SNIP 0.731
Web of Science (2001): Indexed yes
Original language: English
DOIs: 10.1016/S0300-483X(01)00386-9
Source: orbit
Source-ID: 230667
Research output: Contribution to journal › Conference abstract in journal – Annual report year: 2001 › Research › peer-review

Exposure levels of endocrine disruptors in Nordic Countries - Discussion

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Department of Management Engineering
Pages: S461-S462
Publication date: 2001
Peer-reviewed: Yes

Publication information
Journal: APMIS
Volume: 109
Issue number: Suppl. 103
ISSN (Print): 0903-4641
Ratings:
Web of Science (2001): Indexed yes
Original language: English
Source: orbit
Source-ID: 230681
Research output: Contribution to journal › Journal article – Annual report year: 2001 › Research › peer-review

Using the CALUX bioassay for screening and determination of dioxin-like compounds in human milk

General information
Publication status: Published
Organisations: Division of Food Chemistry, National Food Institute, Division of Toxicology and Risk Assessment
Contributors: Laier, P., Cederberg, T. L., Vinggaard, A., Larsen, J. C.
Publication date: 2001
Environmental polycyclic aromatic hydrocarbons affect androgen receptor activation in vitro

Nine structurally different polycyclic aromatic hydrocarbons (PAHs) were tested for their ability to either agonize or antagonize the human androgen receptor (hAR) in a sensitive reporter gene assay based on CHO cells transiently cotransfected with a hAR vector and an MMTV-LUC vector. Benz[a]anthracene (B[a]A), benzo[a]pyrene (B[a]P), fluoranthene, chrysene and 7,12-dimethylbenz[a]anthracene (DMBA) were acting as antiandrogens in vitro, resulting in IC50 values of 3.2, 3.9, 4.6, 10.3 and 10.4 μM, respectively. Only at the highest concentration tested (10 μM), a slight inhibitory effect by pyrene: phenanthrene, and anthracene was observed. In contrast, dibenzo[a,h]anthracene (DB[a,h]A) gave rise to an agonistic effect, which was added upon the effect of the androgen receptor agonist R1881 (0.1 nM). The antiandrogenic responses by PAHs (10 μM) were found to be fully reversible, determined in the presence of increasing concentrations of R1881. No cytotoxic effects of the tested compounds were observed as determined either by metabolic reduction using AlamarBlue (up to 20 μM) or determined in cells transfected with a constitutively active hAR up to 10 μM. The well-known ability of certain PAHs to activate the Ah receptor was assessed in H4IIE liver cancer cells, stably transfected with a luciferase reporter gene system. The positive control 2,3,7,8-tetrachlorodibenzo-dioxidin (TCDD) caused a 13-14-fold induction of luciferase activity reaching maximum activity at 0.1 nM. DB[a,h]A, B[a]P, Chrysene, B[a]A and DMBA gave rise to a 4.5-fold induction of luciferase activity at 0.03, 0.4, 0.89, 3.06, and 9.27 μM, respectively, whereas fluoranthene, pyrene, phenanthrene and anthracene were without effect. In conclusion, no clear correlation between the antiandrogenic effects and the Ah receptor activation in vitro was seen. However, the Ah receptor agonists containing four or five aromatic rings (i.e. B[a]A, B[a]P, chrysene, DMBA) appeared to be the most potent antiandrogens (with the exception of DB[a,h]A), whereas those not able to activate the Ah receptor containing three or four aromatic rings (i.e. pyrene, phenanthrene, anthracene) displayed either very weak or no antiandrogenic effect at concentrations up to 10 μM (with the exception of fluoranthene which blocked the hAR at lower concentrations, but did not activate the Ah receptor).

Lack of oestrogenic effects of food preservatives (parabens) in uterotrophic assays

The oestrogenic activity of the parabens, methyl-, ethyl- and propyl p-hydroxybenzoate, widely used as antimicrobials in food, and butyl p-hydroxybenzoate, which is used in cosmetic products, and their shared main metabolite p-hydroxybenzoic acid was investigated in a mouse uterotrophic assay. Immature B6D2F1 mice were treated with oral or subcutaneous doses of the test compounds for three consecutive days, p-Hydroxybenzoic acid and butyl p-hydroxybenzoate were also tested by the subcutaneous route in a rat uterotrophic assay. A significant increase in the uterus weight at day 4 was considered an oestrogenic effect. In the mouse assay, none of the compounds tested produced any oestrogenic response at dose levels up to 100 mg/kg body weight per day, for ethyl p-hydroxybenzoate...
even at a dose level of 1000 mg/kg body weight per day. In immature Wistar rats, subcutaneous administration of butyl p-
hydroxybenzoate produced a weak oestrogenic response at 600 mg/kg body weight per day.

**Screening of selected pesticides for inhibition of CYP19 aromatase activity in vitro**

Many pesticides are able to block or activate the steroid hormone receptors and/or to affect the levels of sex hormones,
thereby potentially affecting the development or expression of the male and female reproductive system or both. This
emphasizes the relevance of screening pesticides for a wide range of hormone-mimicking effects. Twenty-two pesticides
were tested for their ability to affect CYP19 aromatase activity in human placental microsomes using the classical [H-3](2)O method. Prochloraz, imazalil, propiconazole, fenarimol, triadimenol, triadimefon (all fungicides), and dicofol (tan
acaricide) gave rise to a statistically significant inhibition of aromatase activity. The IC(50)s of prochloraz, imazalil,
propiconazole fenarimol, triadimenol, and triadimefon were calculated from dose-response curves to be 0.04, 0.34, 6.5,
10, 21 and 32 μM, respectively. The IC50 Of dicofol was greater than 50 μM. The positive control 4-
hydroxyandrostendione (1 μM) caused an inhibition of aromatase activity by 74%. The compounds, which did not affect
the aromatase activity, were bromopropylate, chlorfenvinphos, chlorobenzilate, chlorpyrifos, diuron, heptachlor, iprodion,
linuron, pentachlorophenol, procymidon, propyzamide, quintozen, tetrachlorvinphos and tetradifen. With the purpose of
comparing the results for fenarimol obtained with the microsomal system with data from an intact cell system, an
aromatase assay based on JEG-3 cells was established. 4-Hydroxyandrostendione (1 μM) inhibited the aromatase
activity in JEG-3 cells by 94%. The IC50 for fenarimol in this system was 2 μM, slightly lower than that observed in the
microsomal system. For the first time, fenarimol has been demonstrated to inhibit aromatase activity in human tissues and,
Furthermore, propiconazole, triadimefon, and triadimenol were identified as weak aromatase inhibitors. In conclusion,
seven out of 22 tested pesticides turned out to be weak to moderate aromatase inhibitors in vitro, indicating the relevance
of elucidating the endocrine effects in vivo of these compounds.

We found no difference in semen quality and male fecundity between traditional and organic farmers. Pesticide use by Danish farmers did not influence the different semen parameters Ø a spraying season. The dietary pesticide intake in the study group did not entail a risk of measurable reduced semen quality. However, the exposure assessments used were based on the external exposure.

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Source: orbit
Source-ID: 245909
Research output: Book/Report › Report – Annual report year: 1999 › Research › peer-review

Rapid and sensitive reporter gene assays for detection of antiandrogenic and estrogenic effects of environmental chemicals

Reports on increasing incidences in developmental abnormalities of the human male reproductive tract and the recent identifications of environmental chemicals with antiandrogenic activity necessitate the screening of a larger number of compounds in order to get an overview of potential antiandrogenic chemicals present in our environment. Thus, there is a great need for an effective in vitro screening method for (anti)androgenic chemicals. We have developed a rapid, sensitive, and reproducible reporter gene assay for detection of antiandrogenic chemicals. Chinese Hamster Ovary cells were cotransfected with the human androgen receptor expression vector and the mouse mammary tumour virus (MMTV)(2)-luciferase vector using the new nonliposomal transfection reagent FuGene, Stimulation of the cells for 24 h with the synthetic androgen receptor agonist, R1881 (10 nM), resulted in a 30- to 60-fold induction of luciferase activity. The classical antiandrogenic compounds hydroxy-flutamide, bicalutamide, spironolactone, and cyproterone acetate together with the pesticide(metabolite)s, vinclozolin, p,p'-DDE, and procymidone all potently inhibited the response to 0.1 nM R1881. Compared to the traditional calcium phosphate transfection method, this method has the advantage of being more feasible, as the assay can be scaled down to the microtiter plate format. Furthermore, the transfection reagent is noncytotoxic, allowing its addition together with the test compounds thereby reducing the hands-on laboratory time. This assay is a powerful tool for the efficient and accurate determination and quantification of the effects of antiandrogens on reporter gene transcription. To extend the application of FuGene, the reagent was shown to be superior compared to Lipofectin for transfecting MCF7 human breast cancer cells with an estrogen response element-luciferase vector. Thus, FuGene may prove to be valuable in diverse reporter gene assays involving transient transfections for screening of potential endocrine disrupters for (anti)androgenic and (anti)estrogenic properties.

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Organisations: National Food Institute, Division of Toxicology and Risk Assessment
Contributors: Vinggaard, A., Jørgensen, E., Larsen, J. C.
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Publication information
Journal: Toxicology and Applied Pharmacology
Volume: 155
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ISSN (Print): 0041-008X
Ratings:
Scopus rating (1999): SJR 1.004 SNIP 1.254
Screening of selected pesticides for oestrogen receptor activation in vitro

Twenty pesticides were tested for their ability to activate the oestrogen receptor in vitro using an MCF7 cell proliferation assay and a Yeast Oestrogen Screen. The fungicides fenarimol, triadimefon, and triadimenol were identified as weak oestrogen receptor agonists, which at 10 μM induces a 2.0, 2.4, and 1.9-fold increase in proliferation of human MCF7 breast cancer cells (E3 clone). The relative proliferation efficiency (RPE) was 43-69%, indicating partial agonism at the oestrogen receptor. Several pesticides did not have any effect on the proliferation response after 6 days of exposure, including, chlorpyrifos, diuron, iprodion, linuron, pentachlorophenol, prochloraz, propiconazol, propyzamine, quintozene, tetrachlorvinphos and tetrodifen. Some pesticides resulted in a negligible proliferation response, which was not statistically significant under the present experimental conditions. These were. bromopropylate, chlorfenvinphos, chlorobenzilate, dicofol, heptachlor, and imazalil. Fenarimol and dicofol also gave rise to a positive oestrogenic response in yeast cells transfected with rite oestrogen receptor alpha, whereas the remaining compounds resulted in a negative response due either to biological inactivity or cytotoxicity to the yeast cells. The EC50 for fenarimol has estimated to be 13 μM in the yeast cells, compared with an EC50 of 3 μM in the MCF7 cells, indicating higher sensitivity of the latter assay. No in vivo data for fenarimol, triadimefon or triadimenol have previously been published that support oestrogenic activity in the intact animal. Thus, from the present results Mie suggest that oestrogen receptor activation may not be an important mode of action for these compounds. The need to include at least two bioassays in a screening procedure and for combining in vitro and in vivo data is emphasized.

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Organisations: National Food Institute, Division of Toxicology and Risk Assessment, Technical University of Denmark
Contributors: Vinggaard, A., Breinholt, V., Larsen, J. C.
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10.1080/026520399283678
Source: orbit
Source-ID: 230902
Research output: Contribution to journal › Journal article – Annual report year: 1999 › Research › peer-review

Detection of weak estrogenic flavonoids using a recombinant yeast strain and a modified MCF7 cell proliferation assay

A newly developed recombinant yeast strain, in which the human estrogen receptor has been stably integrated into the genome of the yeast, was used to gain information on the estrogenic activity of a large series of dietary flavonoids. Among 23 flavonoids investigated, 8 were found to markedly stimulate the transcriptional activity of the human estrogen receptor in the yeast assay increasing transcriptional activity 5-13-fold above background level, corresponding to EC50 values between 0.1 and 25 μM. Five compounds increased the transcriptional activity 2-5-fold over the control, with EC50 values ranging from 84 to 102 μM, whereas the remaining flavonoids were devoid of activity. The most potent flavonoid estrogens tested were naringenin, apigenin, kaempferol, phloretin, and the four isoflavonoids equol, genistein, daidzein, and biochanin A. With the exception of biochanin A, the main feature required to confer estrogenicity was the presence of a single hydroxyl group in the 4'-position of the B-ring of the flavan nucleus, corresponding to the 4-position on phloretin. The estrogenic potency of the flavonoids was found to be 4 000-4 000 000 times lower than that observed for 17 beta-estradiol, when compared on the basis of EC50 values. The estrogenic activity of the dietary flavonoids was further investigated in estrogen-dependent human MCF7 breast cancer cells. In this system several of the flavonoids were likewise capable of mimicking natural estrogens and thereby induce cell proliferation. Similar structural requirements for estrogenic activity were found for the two assays. The present results provide evidence that several of the flavo-estrogens possess estrogenic properties comparable in activity to the well-established isoflavonoid estrogens. The use of Alamar Blue, a vital dye which is metabolically reduced by cellular enzymes to a fluorescent product, was found to greatly simplify the MCF7 cell-based estrogen screen, making this mammalian assay applicable as a large-scale screening tool for estrogenic compounds.
Male reproductive health and environmental xenoestrogens

Male reproductive health has deteriorated in many countries during the last few decades. In the 1990s, declining semen quality has been reported from Belgium, Denmark, France, and Great Britain. The incidence of testicular cancer has increased during the same time. Incidences of hypospadias and cryptorchidism also appear to be increasing. Similar reproductive problems occur in many wildlife species. There are marked geographic differences in the prevalence of male reproductive disorders. While the reasons for these differences are currently unknown, both clinical and laboratory research suggest that the adverse changes may be inter-related and have a common origin in fetal life or childhood.

Exposure of the male fetus to supranormal levels of estrogens, such as diethylnstilbestrol, can result in the above-mentioned reproductive defects. The growing number of reports demonstrating that common environmental contaminants and natural factors possess estrogenic activity presents the working hypothesis that the adverse trends in male reproductive health may be, at least in part, associated with exposure to estrogenic or other hormonally active (e.g., antiandrogenic) environmental chemicals during fetal and childhood development. An extensive research program is needed to understand the extent of the problem, its underlying etiology, and the development of a strategy for prevention and intervention.
Mandlig reproduktion og kemiske stoffer med østrogenlignende effekter: Miljøprojekt

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Teratogenicity and in vitro mutagenicity studies on nonoxynol-9- and -30

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SUBCHRONIC ORAL TOXICITY OF TURMERIC OLEORESIN IN PIGS

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**ACTIVATION OF 2-NAPHTHYLAMINE IN BLADDER CELL-LINES STUDIED BY THE SALMONELLA MAMMALIAN MICROSOME TEST**

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**MUTAGENIC ACTIVITY OF COMMERCIAL BEER IN THE SALMONELLA MAMMALIAN MICROSOME TEST**

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Contributors: Knudsen, I., Larsen, J. C., Jensen, N.  
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**METABOLISM OF BIPHENYL .3. PHENOLIC METABOLITES IN PIG**

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