An effect-directed strategy for characterizing emerging chemicals in food contact materials made from paper and board

Food contact materials (FCM) are any type of item intended to come into contact with foods and thus represent a potential source for human exposure to chemicals. Regarding FCMs made of paper and board, information pertaining to their chemical constituents and the potential impacts on human health remains scarce, which hampers safety evaluation. We describe an effect-directed strategy to identify and characterize emerging chemicals in paper and board FCMs. Twenty FCMs were tested in eight reporter gene assays, including assays for the AR, ER, AhR, PPARγ, Nrf2 and p53, as well as mutagenicity. All FCMs exhibited activities in at least one assay. As proof-of-principle, FCM samples obtained from a sandwich wrapper and a pizza box were carried through a complete step-by-step multi-tiered approach. The pizza box exhibited ER activity, likely caused by the presence of bisphenol A, dibutyl phthalate, and benzylbutyl phthalate. The sandwich wrapper exhibited AR antagonism, likely caused by abietic acid and dehydroabietic acid. Migration studies confirmed that the active chemicals can transfer from FCMs to food simulants. In conclusion, we report an effect-directed strategy that can identify hazards posed by FCMs made from paper and board, including the identification of the chemical(s) responsible for the observed activity.

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'Mixture effects of chemicals' 'The Cocktail Project' Fødevarekemisk indsats under Fødevareforlig II 2011-2015

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Mixture Genotoxicity of 2,4-Dichlorophenoxyacetic Acid, Acrylamide, and Maleic Hydrazide on Human Caco-2 Cells Assessed with Comet Assay

Assessment of genotoxic properties of chemicals is mainly conducted only for single chemicals, without taking mixture genotoxic effects into consideration. The current study assessed mixture effects of the three known genotoxic chemicals, 2,4-dichlorophenoxyacetic acid (2,4-D), acrylamide (AA), and maleic hydrazide (MH), in an experiment with a fixed ratio design setup. The genotoxic effects were assessed with the single-cell gel electrophoresis assay (comet assay) for both single chemicals and the ternary mixture. The concentration ranges used were 0-1.4, 0-20, and 0-37.7 mM for 2,4-D, AA, and MH, respectively. Mixture toxicity was tested with a fixed ratio design at a 10:23:77% ratio for 2,4-D:AA:MH. Results indicated that the three chemicals yielded a synergistic mixture effect. It is not clear which mechanisms are responsible for this interaction. A few possible interactions are discussed, but further investigations including in vivo studies are needed to clarify how important these more-than-additive effects are for risk assessment.

Polycyclic aromatic hydrocarbons (PAH) in Danish barbecued meat

Barbecuing is known to result in the formation of polycyclic aromatic hydrocarbons (PAHs). A validated method that employed pressurized liquid extraction (PLE), gel permeation chromatography (GPC) followed by solid phase extraction (SPE) on Silica and analytical determination by GC-MS was applied for the detection of 24 PAHs in barbecued meat. In total, 203 commercially barbecued meat samples (beef, pork, chicken, salmon and lamb) and 15 samples barbecued during controlled time and heat conditions were included. The sum of PAH4 (benzo[a]pyrene, benzo[a]anthracene, chrysene and benzo[b]fluoranthene) was highest for a pork tenderloin (195 μg/kg) and lowest for chicken breast (0.1 μg/kg) and controlled barbecued meat.
EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2014. Scientific Opinion on Flavouring Group Evaluation 200 (FGE.200): 74 α, β-unsaturated aldehydes and precursors from subgroup 1.1.1 of FGE.19

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 74 flavouring substances from subgroup 1.1.1 of FGE.19 in the Flavouring Group Evaluation 200 (FGE.200). The Flavour Industry has provided additional genotoxicity studies for one representative substance in FGE.200, namely hex-2(trans)-enal [FL-no 05.073], and for other two substances in the same subgroup, namely 2-dodecenal [05.037] and 2-nonenal [05.171]. The Panel has evaluated these data and concluded that the concern still remains with respect to genotoxicity for the substances of this subgroup and their three representative substances. The Panel confirms, the need for an in vivo Comet assay performed in duodenum and liver for hex-2(trans)-enal [FL-no: 05.073]. For the two other representative substances of subgroup 1.1.1 (nona-2(trans),6(cis)-dienal [FL-no: 05.058] and oct-2-enal [FL-no: 05.060]), a combined in vivo Comet assay and micronucleus assay would be required. For the latter, evidence of bone marrow exposure should be provided.

General information
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Contributors: EFSA publication
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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 the genotoxic potential of 13 flavouring substances from subgroup 2.4 of FGE.19 and one additional substance [FL-no: 07.225] in this revision 1 (FGE.210Rev1). In the first version of FGE.210 the Panel concluded that a genotoxic potential could not be ruled out for any of the 13 substances based on data available at that time. The Flavouring Industry has now submitted additional genotoxicity data. The Panel has evaluated these data and concluded that the concern for genotoxic potential is ruled out for eight of the substances [FL-no: 02.105, 07.007,
07.009, 07.011, 07.036, 07.088, 07.091 and 07.170], while for allyl alpha-ionone [FL-no: 07.061] and for alpha-damascone [FL-no: 07.134] and four structurally related substances [FL-no: 07.130, 07.225, 07.226 and 07.231] the concern still remains with respect to genotoxicity.


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 26 flavouring substances from subgroup 2.7 of FGE.19 in the Flavouring Group Evaluation 213. In the first version of FGE.213 the Panel concluded based on available genotoxicity data that a concern regarding genotoxicity could be ruled out for [FL-no: 07.047, 07.056, 07.057, 07.075, 07.076, 07.080, 07.117, 07.118, 07.119, 07.120 and 07.168], but for the remaining 15 substances in subgroup 2.7 further genotoxicity data were required. Based on new submitted genotoxicity data, the Panel concluded in FGE.213Rev1 that the concern regarding genotoxicity could be ruled out for 13 substances in subgroup 2.7 [FL-no: 02.106, 07.041, 07.083, 07.089, 07.108, 07.109, 07.127, 07.136, 07.200, 07.224 and 09.305] but not for maltol [FL-no: 07.014] and maltyl isobutyrate [FL-no: 09.525].
substances in FGE.215, namely 4-phenylbut-3-en-2-one [FL-no: 07.024] and 1-(4-methoxyphenyl)pent-1-en-3-one [FL-no: 07.030]. Based on these genotoxicity data, the Panel concluded that the genotoxicity concern could not be ruled out and in vivo genotoxicity data are requested.

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Organisations: National Food Institute, Division of Toxicology and Risk Assessment
Contributors: EFSA Publication
Number of pages: 23
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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 four flavouring substances in the Flavouring Group Evaluation 304, Revision 1 (FGE.304Rev1) using the Procedure in Commission Regulation (EC) No 1565/2000. This revision is made due to a re-evaluation of one flavouring substance N-(2-(pyridine-2-yl)ethyl)-3-p-menthanecarboxamide [FL-no: 16.118], as a 90-day dietary rat study has become available. One of the original five flavouring substances [FL-no: 16.124], for which additional data were requested, is no longer supported by the Industry for use as flavouring substance in Europe and will therefore not be considered any further in FGE.304Rev1. Therefore, FGE.304Rev1 will deal with four flavouring substances. None of the four 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 four substances [FL-no: 16.117, 16.118, 16.123 and 16.125] 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. Specifications including complete purity criteria and identity for the materials of commerce have been provided for all four candidate substances.

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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 simple aliphatic sulphides and thioles evaluated by the JECFA at the 53rd meeting in 1999 and the 61st meeting in 2003. 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. For nine substances [FL-no: 12.088, 12.179, 12.198, 12.212, 12.238, 12.239, 12.255, 12.257 and 12.291] considered in this FGE, the Panel concluded that they would pose “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 all nine substances, the information is adequate. Thus, the Panel concluded that nine substances [FL-no: 12.088, 12.179, 12.198, 12.212, 12.238, 12.239, 12.255, 12.257 and 12.291] do not give rise to safety concern at their levels of dietary intake, estimated on the basis of the MSDI approach. For 10 candidate substances in FGE.74Rev3 [FL-no: 12.009, 12.013, 12.020, 12.023, 12.045, 12.074, 12.155, 12.169, 12.241 and 12.280] evaluated through the Procedure, the Panel concluded that additional toxicity data are required.

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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 22 pyridine, pyrrole and quinoline derivatives evaluated by the JECFA (63rd meeting). The revision of this consideration is made since additional toxicity data have become available for isoquinoline [FL-no: 14.001], pyrrole [FL-no: 14.041] and 2-acetylpyrrole [FL-no: 14.047]. The toxicity data on 2-acetylpyrrole should also cover 2-propionylypyrrole [FL-no: 14.068]. Further, additional genotoxicity data on 6-methylquinoline [FL-no: 14.042] have become available. The Panel concluded that for 6-methylquinoline [FL-no: 14.042], the new genotoxicity data did not clear the concern with respect to genotoxicity in vitro and accordingly the substance is not evaluated through the Procedure. For 18 substances [FL-no: 14.001, 14.004, 14.007, 14.030, 14.038, 14.039, 14.041, 14.047, 14.058, 14.059, 14.060, 14.061, 14.065, 14.066, 14.068, 14.071, 14.072 and 14.164] considered in this FGE, the Panel agrees with the JECFA conclusion, “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach. For three substances [FL-no: 13.134, 14.045 and 14.046], additional toxicological data are still required. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been evaluated, and the information is considered adequate for all the substances.
EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2014. Scientific Opinion on Flavouring Group Evaluation 82, Revision 1 (FGE.82Rev1): Consideration of Epoxides evaluated by the JECFA (65th 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 five epoxides evaluated by the JECFA at the 65th meeting in 2005. This revision is made due to inclusion of one additional substance, beta-ionone epoxide [FL-no: 07.170], cleared for genotoxicity concern and due to additional toxicity data have become available for beta-caryophyllene epoxide [FL-no: 16.043]. Since publication of FGE.82 one substance epoxy oxophorone [FL-no: 16.051] is no longer supported for use as flavouring substances in Europe by Industry and will therefore not be considered any further. 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. For four substances [FL-no: 16.015, 16.018, 16.040 and 16.043] the Panel agreed 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: 07.170] 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 four substances, the information is adequate; but for the substance [FL-no: 07.170] further information on stereoisomerism is required.

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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 44 simple aliphatic and aromatic sulphides and thiols evaluated by the JECFA at the 53rd and the 68th meeting. 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. For 36 substances considered in this FGE the Panel concluded that they would pose “No safety concern at estimated levels of intake as flavouring substances” based on the MSDI approach. For seven substances [FL-no: 12.038, 12.085, 12.137, 12.138, 12.145, 12.252 and 12.259] the Panel decided, contrary to the JECFA that these substances could not be evaluated due to absence of a NOAEL from either one of these substances or from a structurally related substance. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for all 44 substances, the information is adequate.

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Organisations: National Food Institute, Division of Toxicology and Risk Assessment, Division of Food Chemistry
Contributors: EFSA authors
Number of pages: 34
EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2014. Scientific Opinion on lipase from a genetically modified strain of Aspergillus oryzae (strain NZYM-FL)

The food enzyme considered in this opinion is a lipase (triacylglycerol lipase; EC 3.1.1.3) produced with a genetically modified strain of Aspergillus oryzae. The genetic modifications do not raise safety concern. The food enzyme contains neither the production organism nor recombinant DNA. The lipase is intended to be used in a number of food manufacturing processes, such as oils, fats and eggs processing. The dietary exposure was assessed on the basis of data retrieved from the EFSA Comprehensive European Food Consumption Database. The food enzyme did not induce gene mutations in bacteria nor chromosome aberrations in human lymphocytes. Therefore, there is no concern with respect to genotoxicity. The systemic toxicity was assessed by means of a 90-day subchronic oral toxicity study in rodents. A No Observed Adverse Effect Level was derived, which compared with the dietary exposure results in a sufficiently high Margin of Exposure. The allergenicity was evaluated by searching for similarity of the amino acid sequence to those of known allergens. The Panel considered that the likelihood of food allergic reactions to the enzyme is low and therefore does not raise safety concern. Based on the genetic modifications performed, the manufacturing process, the compositional and biochemical data provided and the toxicological studies, this food enzyme does not raise safety concern under the intended conditions of use.

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2014. Scientific Opinion on xylanase from a genetically modified strain of Aspergillus oryzae (strain NZYM-FB)

The food enzyme considered in this opinion is a xylanase (endo-1,4-β-xylanase; EC 3.2.1.8) produced with a genetically modified strain of Aspergillus oryzae. The genetic modifications do not raise safety concern. The food enzyme contains neither the production organism nor recombinant DNA. The xylanase is intended to be used in a number of food manufacturing processes, such as starch processing, beverage alcohol (distilling), brewing, baking and other cereal based processes. The dietary exposure was assessed according to the Budget method. The food enzyme did not induce gene mutations in bacteria nor chromosome aberrations in human peripheral blood lymphocytes. Therefore, there is no concern with respect to genotoxicity. The systemic toxicity was assessed by means of a 90-day subchronic oral toxicity study in rodents. A No Observed Adverse Effect Level was derived, which compared with the dietary exposure results in a sufficiently high Margin of Exposure. The allergenicity was evaluated by searching for similarity of the amino acid sequence to those of known allergens. The Panel considered that the likelihood of food allergic reactions to the enzyme is low and therefore does not raise safety concern.
low and therefore does not raise safety concern. Based on the genetic modifications performed, the manufacturing process, the compositional and biochemical data provided and the toxicological studies, this food enzyme does not raise safety concern under the intended conditions of use.

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EFSA CEF Penal (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2014. Scientific Opinion on Flavouring Group Evaluation 212, Revision 2 (FGE.212Rev2): α,β-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.6 of FGE.19
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 24 flavouring substances from subgroup 2.6 of FGE.19 in the Flavouring Group Evaluation 212, Revision 2. The Panel concluded in FGE.212, that the genotoxic potential could be ruled out for d-carvone [FL-no: 07.146] together with the structurally related l-carvone [FL-no: 07.147] as well as carveol and the carvyl derivatives [FL-no: 02.062, 09.143, 09.215 and 09.870]. Based on available genotoxicity data and new submitted genotoxicity data from the Industry, the Panel concluded that the genotoxic potential could be ruled out for the 11 isophorone derivatives [FL-no: 02.083, 02.101, 07.035, 07.098, 07.126, 07.129, 07.172, 07.175, 07.196, 07.202 and 07.255] and the two vetiveryl derivatives [FL-no: 02.214 and 09.821] in FGE.212Rev1 and FGE.212Rev2, respectively. For the remaining five substances [FL-no: 07.033, 07.094, 07.112, 07.140 and 07.219] from subgroup 2.6 there is still a genotoxicity concern and additional data are required.

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Contributors: EFSA Publication, Beltoft, V. M., Binderup, M., Nørby, K. K.
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In-vivo study of genotoxic and inflammatory effects of the organo-modified Montmorillonite Cloisite® 30B
Because of the increasing use of clays and organoclays in industrial applications it is of importance to consider the toxicity of these materials. Recently it was reported that the commercially available Montmorillonite clay, Cloisite® 30B, which is surface-modified by organic quaternary ammonium compounds, was genotoxic in vitro. In the present study the in-vivo genotoxic and inflammatory potential of Cloisite® 30B was investigated as a follow-up of the in-vitro studies. Wistar rats
were exposed to Cloisite® 30B twice 24 h apart by oral gavage, at doses ranging from 250 to 1000 mg/kg body weight [indicate duration of treatment; Ed.]. There was no induction of DNA strand-breaks in colon, liver and kidney cells and there was no increase in inflammatory cytokine markers in blood-plasma samples. In order to verify the possible absorption of Cloisite® 30B from the gastrointestinal tract, inductively coupled plasma mass-spectrometry (ICP-MS) analysis was performed on samples of liver, kidney and faeces, with aluminium as a tracer element characteristic to clay. The results showed that aluminium could be detected in faeces, but not in the liver or kidneys. This indicated that there was no systemic exposure to clay particles from Cloisite® 30B. Detection and identification of free quaternary ammonium modifier in the highest dose of Cloisite® 30B was carried out by high-performance liquid chromatography coupled with quadrupole time-of-flight mass spectrometry (HPLC-Q-TOF-MS). This analysis revealed a mixture of three quaternary ammonium analogues. The detected concentration of the organomodifier corresponded to an exposure of rats to about 5 mg quaternary ammonium analogues/kg body weight.

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Scientific Opinion on Flavouring Group Evaluation 401 (FGE.401): γ-Glutamyl-valyl-glycine from chemical group 34
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to carry out a safety assessment of one flavouring substance, γ-glutamyl-valyl-glycine [FL-no: 17.038], in the Flavouring Group Evaluation 401 (FGE.401), in accordance with the Commission Regulation (EC) No 1331/2008. There is no safety concern with respect to genotoxicity for the flavouring substance. It has been demonstrated that the flavouring substance, which is a tripeptide, will be hydrolysed to the three amino acids L-glutamic acid, L-valine and glycine. As the human consumption of these three endogenous amino acids through food is orders of magnitude higher than the anticipated levels of exposure from their use as flavouring substances, the Panel concluded that γ-glutamyl-valyl-glycine [FL-no: 17.038] would be of no safety concern at its estimated level of intake as flavouring substance. The specifications for γ-glutamyl-valyl-glycine [FL-no: 17.038] are considered adequate according to Commission Regulation (EC) no 1334/2008.

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EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2013. Scientific Opinion on Flavouring Group Evaluation 12, Revision 4 (FGE.12Rev4): primary saturated or unsaturated alicyclic alcohols, aldehydes, acids and esters from chemical groups 1 and 7

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 12 flavouring substances in Flavouring Group Evaluation 12, Revision 4 (FGE.12Rev4), including two additional substances, using the Procedure in Commission Regulation (EC) No 1565/2000. The present revision includes two additional flavouring substances: 12-beta-santalen-14-ol [FL-no: 02.216] and 12-alpha-santalen-14-ol [FL-no: 02.217]. None of the substances was 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 and the toxicological threshold of concern and available data on metabolism and toxicity. The Panel concluded that none of the 12 substances [FL-nos: 02.134, 02.186, 02.216, 02.217, 05.157, 05.182, 05.183, 05.198, 08.135, 09.342, 09.670 and 09.829] gives rise to safety concerns at their levels of dietary intake, estimated on the basis of the maximised survey-derived daily intake approach. 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 12 candidate substances.
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 five flavouring substances from subgroup 3.3 of FGE.19. In the Flavouring Group Evaluation 216 (FGE.216) additional genotoxicity data were requested. Additional genotoxicity studies have now been provided for the representative substance 2-phenylcrotonaldehyde [FL-no: 05.062]. Based on these new data the Panel concluded that the concern for genotoxicity could not be ruled out and requests a proof of sufficient systemic exposure of animals treated with 2-phenylcrotonaldehyde. Moreover, since the substance was genotoxic only without metabolic activation, it appears necessary to prove the absence of genotoxic effect locally in the gastro intestinal system using the Comet assay.

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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 the genotoxic potential of 12 flavouring substances from subgroup 4.1 of FGE.19 in the Flavouring Group Evaluation 217 (FGE.217). In FGE.217, 6-methylcoumarin [FL-no: 13.012] was not considered genotoxic and was therefore evaluated through the Procedure in FGE.80Rev1. For the remaining 11 substances, the Panel concluded that based on the data available, a genotoxic potential could not be excluded and accordingly they could not be evaluated through the Procedure. Additional data on genotoxicity for the three representative substances, 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one [FL-no: 10.023], 3,4-dimethyl-5-pentyldenefuran-2(5H)-one [FL-no: 10.042] and furan-2(5H)-one [FL-no: 10.066], have now been provided. Based on the new data, the Panel concluded that 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one [FL-no: 10.023] does not give rise to concern with respect to genotoxicity and can accordingly, together with the structurally related substance, 3-hydroxy-4,5-dimethylfuran-2(5H)-one [FL-no: 10.030] for which it is a representative, be evaluated using the Procedure. For 3,4-dimethyl-5-pentyldenefuran-2(5H)-one [FL-no: 10.042] and furan-2(5H)-one [FL-no: 10.066] the concern for genotoxicity could not be ruled out and a combined micronucleus and Comet assay is requested for these two substances, covering the remaining seven substances [FL-no: 10.034, 10.036, 10.043, 10.046, 10.054, 10.057 and 10.060].

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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 59 flavouring substances in the Flavouring Group Evaluation 21, Revision 4, using the Procedure in Commission Regulation (EC) No 1565/2000. This revision is made due to the inclusion of the assessment of new toxicity data on one supporting substance 5,6-dihydro-2,4,6-tris(2-methylpropyl)-4H-1,3,5-dithiazine [FL-no: 15.113], which is considered to be structurally related to the candidate substances 2-butyl-4-methyl(4H)pyrrolidino[1,2]-1,3,5-dithiazine [FL-no: 15.042], dihydro-2,4,6-triethyl-1,3,5(4H)-dithiazine [FL-no: 15.054], 2,4-dimethyl(4H)pyrrolidino[1,2e]-1,3,5-dithiazine [FL-no: 15.055], 5,6-dimethyl-2-(1-methylethyl)dihydro-1,3,5-dithiazine [FL-no: 15.057], 2-isobutylidihydro-4,6-dimethyl-1,3,5-dithiazine [FL-no: 15.079] and ethyl thialdine [FL-no: 15.135]. Furthermore, new in vitro genotoxicity studies have become available on the supporting substance 2-acetyl-2-thiazoline [FL-no: 15.010], which is considered to be structurally related to and a supportive substance for 2-methyl-2-thiazoline [FL-no: 15.086]. Eighteen of the original 59 candidate substances [FL-no: 15.037, 15.042, 15.043, 15.064, 15.070, 15.072, 15.077, 15.088, 15.090, 15.091, 15.092, 15.094, 15.099, 15.106, 15.107, 15.114, 15.129 and 15.133], for which additional data were requested, are no longer supported by Industry for use as flavouring substances in Europe and will therefore not be considered any further. Therefore, FGE.21Rev4 will only deal with 41 candidate substances. Two of the substances, 3-thiazolines, 2,4-dimethyl-3-thiazoline [FL-no: 15.060] and 2-isobutyl-3-thiazoline [FL-no: 15.119], were considered to have genotoxic potential. The remaining 39 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 32 flavouring substances [FL-no: 15.038, 15.039, 15.045, 15.046, 15.047, 15.048, 15.049, 15.053, 15.054, 15.055, 15.056, 15.057, 15.058, 15.059, 15.060, 15.061, 15.062, 15.063, 15.064, 15.065, 15.066, 15.067, 15.068, 15.069, 15.071, 15.072, 15.073, 15.074, 15.075, 15.076, 15.077, 15.078, 15.079, 15.080, 15.081, 15.082, 15.083, 15.084, 15.085, 15.086, 15.087, 15.088, 15.089, 15.090, 15.091, 15.092, 15.093, 15.094, 15.095, 15.096, 15.097, 15.098, 15.099, 15.100, 15.101, 15.102, 15.103, 15.104, 15.105, 15.106, 15.107, 15.108, 15.109, 15.110, 15.111, 15.112, 15.113, 15.114, 15.115, 15.116, 15.117, 15.118, 15.119, 15.120, 15.121, 15.122, 15.123, 15.124, 15.125, 15.126, 15.127, 15.128, 15.129, 15.130, 15.131, 15.132, 15.133] do not give rise to safety concerns at their levels of dietary intake, estimated on the basis of the MSDI approach. For the remaining seven candidate substances [FL-no: 15.040, 15.045, 15.046, 15.047, 15.048, 15.049, 15.050] 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. Adequate specifications including complete purity criteria and identity for the materials of commerce have been provided for all 41 candidate substances.
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 10 flavouring substances from subgroup 4.4 of FGE.19 in the Flavouring Group Evaluation 220 (FGE.220). FGE.220 is subdivided into two subgroups (subgroup 4.4a containing [FL-no: 13.089, 13.117, 13.119, 13.157 and 13.175] and subgroup 4.4b containing [13.010, 13.084 and 13.085, 13.099 and 13.176]). For both subgroups the Panel concluded that the genotoxicity alert could not be ruled out based on the data available and accordingly additional genotoxicity data were requested. In FGE.220, Revision 1, the Panel concluded, based on new submitted data, that for the substances in subgroup 4.4b there is no concern for genotoxicity. The Flavour Industry has now provided additional genotoxicity studies for two representative substances of subgroup 4.4a, 2,5-dimethylfuran-3(2H)-one [FL-no: 13.119] and 4-acetyl-2,5-dimethylfuran-3(2H)-one [FL-no: 13.175]. Based on the new data the Panel concluded that 2,5-dimethylfuran-3(2H)-one [FL-no: 13.119] does not give rise to concern with respect to genotoxicity. For 4-acetyl-2,5-dimethylfuran-3(2H)-one [FL-no: 13.175] the concern for genotoxicity could not be ruled out and therefore the Panel requests a repetition of the submitted micronucleus study in the presence of S9-mix applying the same conditions and possibly in addition modified conditions, or a combined in vivo micronucleus and Comet assay, including analysis of liver. This is also applicable to 2,5-dimethyl-4-methoxyfuran-3(2H)-one [FL-no:13.089] and 2,5-dimethyl-4-ethoxyfuran-3(2H)-one [FL-no:13.117], which are covered by the representative substance 4-acetyl-2,5-dimethylfuran-3(2H)-one [FL-no:13.175]. The Flavour Industry has informed that 5-methylfuran-3(2H)-one [FL-no: 13.157] is not in common use in the flavour industry and is no longer supported.

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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 24 flavouring substances in the Flavouring Group Evaluation 24, Revision 2, using the Procedure in Commission Regulation (EC) No 1565/2000. This revision was made required owing to the inclusion of the assessment of new toxicity data on one supporting substance, 2-acetylpyrrole [FL-no: 14.047], to support the re-evaluation of one candidate substance, 2-acetyl-5-methylpyrrole [FL-no: 14.085]. Nine of the original 33 candidate substances [FL-no: 13.100, 14.002, 14.023, 14.094, 14.107, 14.138, 14.145, 14.163 and 14.169], for which additional data were requested, are no longer supported by Industry for use as flavouring substances in Europe and will therefore not be considered any further. None of the 24 substances were considered to have genotoxic potential. These candidate 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 the 24 substances [FL-no: 14.085, 14.088, 14.089, 14.092, 14.093, 14.103, 14.104, 14.105, 14.106, 14.110, 14.115, 14.116, 14.117, 14.118, 14.120, 14.124, 14.125, 14.131, 14.134, 14.135, 14.136, 14.140, 14.143 and 14.150] 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 for the materials of commerce have been provided for all 24 candidate substances.

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EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2013. Scientific Opinion on Flavouring Group Evaluation 72, Revision 1 (FGE.72Rev1): Consideration of aliphatic, branched-chain saturated and unsaturated alcohols, aldehydes, acids, and related esters evaluated by the JECFA (61st meeting) structurally related to branched- and straight-chain unsaturated carboxylic acids, esters of these and straight-chain aliphatic saturated alcohols evaluated by EFSA in FGE.05Rev2

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 23 aliphatic branched-chain saturated and unsaturated alcohols, aldehydes, acids and related esters, evaluated by the JECFA at their 61st meeting. This revision is made due to inclusion of one additional substance, 2,6-dimethyl-2,5,7-octatriene-1-ol acetate [FL-no: 09.931] cleared for genotoxicity concern in FGE.207. 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 23 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 23 substances, the information is adequate.


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 alicyclic primary alcohols, aldehydes, acids and related esters and one phenethyl ester evaluated by the JECFA at the 59th meeting in 2002. This revision is made due to consideration of two additional substances, santalyl acetate [FL-no: 09.034] and santalyl phenylacetate [FL-no: 09.712], cleared for genotoxicity concern in FGE.207. 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 18 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, 09.034, 09.289, 09.488, 09.534, 09.536, 09.615 and 09.712], 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 18 substances, the information is adequate.

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EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2013. Scientific Opinion on Flavouring Group Evaluation 76, Revision 1 (FGE.76Rev1)
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 (JECFA), and to decide whether further evaluation is necessary, as laid down in Commission Regulation (EC) No 1565/2000. The present opinion concerns a group of 26 sulphur-containing heterocyclic compounds evaluated by the JECFA at the 59th meeting in 2008. This revision is made due to the inclusion of one additional substance, 5-methyl-2-thiophenecarbaldehyde [FL-no: 15.004], cleared for genotoxicity concern in FGE.224. Additionally, new toxicity data have become available for 5,6-dihydro-2,4,6-tris(2-methylpropyl)-4H-1,3,5-dithiazine [FL-no: 15.113]. Since publication of FGE.76, one substance, thiazole [FL-no: 15.028], is no longer supported by Industry for use as a flavouring substance in Europe and will therefore not be considered any further. 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 21, [FL-no: 15.001, 15.002, 15.004, 15.008, 15.011, 15.013, 15.014, 15.015, 15.016, 15.017, 15.019, 15.020, 15.021, 15.022, 15.026, 15.027, 15.033, 15.035, 15.109, 15.113 and 16.027], of the 26 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 five substances [FL-no: 15.005, 15.018, 15.029, 15.030 and 15.032], the Panel could not conclude on their safety when used as flavouring substances, as these substances could not be evaluated because of concern with respect to genotoxicity. Besides the safety assessment of these flavouring substances, the specifications for the materials of commerce have also been considered and for all 26 substances, the information is adequate.

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EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2013. Scientific Opinion on Flavouring Group Evaluation 93, Revision 1 (FGE.93Rev1)

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 five sulphur-containing heterocyclic compounds [FL-no: 15.010, 15.126, 15.128, 15.130 and 15.131] evaluated by the JECFA at its 68th meeting in 2007. This revision is required owing to additional available genotoxicity data on 2-acetyl-2-thiazoline [FL-no: 15.010]. Since the publication of FGE.93, the substance [FL-no: FL-no: 15.127] is no longer supported by Industry for use as a flavouring substance in Europe and will therefore not be considered any further. 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 two substances 5-ethyl-4-methyl-2-(2-methylpropyl)-thiazoline [FL-no: 15.130] and 5-ethyl-4-methyl-2-(2-butyl)-thiazoline [FL-no: 15.131], which are 3-thiazolines, are structural similar to two other 3-thiazolines in FGE.21Rev1 for which the Panel has expressed a genotoxicity concern, and accordingly the Procedure should not be applied to these two substances until adequate genotoxicity data become available. The Panel agrees with the application of the Procedure as performed by the JECFA for the remaining three substances, 2-acetyl-2-thiazoline [FL-no: 15.010], 3-(methylthio)-methylthiophene [FL-no: 15.126] and 2-propionyl-2-thiazoline [FL-no: 15.128], of the five 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 five substances, the information is adequate.

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EFSA CEF Panel (Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2013. Scientific Opinion on Flavouring Group Evaluation 2 07 (FGE.2 07 )

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, 2,6-dimethyl-2,5,7-octatriene-1-ol acetate [FL-no: 09.931], from subgroup 1.1.2 of FGE.19, which is considered to be representative for four substances, 12-beta-santalalen-14-ol [FL-no: 02.216], 12-alpha-santalalen-14-ol [FL-no: 02.217], santalyl acetate [FL-no: 09.034] and santalyl phenylacetate [FL-no: 09.712], from subgroup 2.1 of FGE.19. The Flavour Industry has provided genotoxicity studies for the representative substance 2,6-dimethyl-2,5,7-octatriene-1-ol acetate [FL-no: 09.931] and these data are considered by EFSA to be representative for the four substances [FL-no: 02.216, 02.217, 09.034 and 09.712]. Based on the new data, the Panel concluded that 2,6-dimethyl-2,5,7-octatriene-1-ol acetate [FL-no: 09.931] from FGE.19 subgroup 1.1.2 does not give rise to concern with respect to genotoxicity and can accordingly be evaluated using the Procedure. This conclusion can also be applied to the four substances 12-beta-santalalen-14-ol [FL-no: 02.216], 12-alpha-santalalen-14-ol [FL-no: 02.217], santalyl acetate [FL-no: 09.034] and santalyl phenylacetate [FL-no: 09.712] from FGE.19 subgroup 2.1 for which 2,6-dimethyl-2,5,7-octatriene-1-ol acetate [FL-no: 09.931] is representative.

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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 23, Revision 4, using the Procedure in Commission Regulation (EC) No 1565/2000. This revision is made due to the inclusion of one additional flavouring substance, 2S-cis-tetrahydro-4-methyl-2-(2-methyl-1-propenyl)-2H-pyran [FL-no: 13.170]. 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 21 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, 13.170 and 13.200] 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. Specifications including complete purity criteria and identity for the materials of commerce have been provided for all 21 candidate substances.

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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 56 flavouring substances in the Flavouring Group Evaluation 6, Revision 4, using the Procedure in Commission Regulation (EC) No 1565/2000. This revision is made due to the inclusion of six additional flavouring substances, (-)-3,7-dimethyl-6-octen-1-ol [FL-no: 02.229], dec-4(cis)-enal [FL-no: 05.137], neral [FL-no: 05.170], trans-3,7-dimethylcyclocta-2,6-dienal (geranial) [FL-no: 05.188], trans-3-hexenyl formate [FL-no: 09.562] and cis-3-hexenyl 2-methylbutanoate [FL-no: 09.854]. 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 56 substances [FL-no: 02.125, 02.138, 02.152, 02.170, 02.175, 02.176, 02.195, 02.201, 02.222, 02.229, 02.234, 05.061, 05.082, 05.137, 05.143, 05.170, 05.174, 05.188, 05.203, 05.217, 05.218, 05.220, 05.226, 08.074, 08.100, 08.102, 09.341, 09.368, 09.377, 09.562, 09.569, 09.572, 09.575, 09.612, 09.638, 09.640, 09.643, 09.672, 09.673, 09.674, 09.831, 09.838, 09.854, 09.855, 09.857, 09.871, 09.872, 09.884, 09.885, 09.897, 09.898, 09.928, 09.937, 09.938, 09.939 and 09.950] 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 for the materials of commerce have been provided for all 56 candidate substances.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 224 (FGE.224): Consideration of genotoxic potential for two α,β-unsaturated thiophenes from subgroup 5.2 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 evaluate the genotoxic potential of two flavouring substances from subgroup 5.2 of FGE.19 in the Flavouring Group Evaluation 224 (FGE.224). The Flavour Industry has provided additional genotoxicity studies for one of the two substances in FGE.224, namely 5-methyl-2-thiophenecarbaldehyde [FL-no: 15.004]. The data requested by EFSA for the other substance, 3-acetyl-2,5-dimethylthiophene [FL-no: 15.024] of FGE.224 will be provided subsequently according to the Flavour Industry. Based on the new data the Panel concluded that 5-methyl-2-thiophenecarbaldehyde does not give rise to concern with respect to genotoxicity and can accordingly be evaluated using the Procedure. For the other substance in subgroup 5.2, 3-acetyl-2,5-dimethylthiophene, the requested genotoxicity data are still pending and no conclusion could be drawn in the present FGE.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 305 (FGE.305): L-Methionylglycine of chemical group 34

The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate one flavouring substance, the dipeptide L-methionylglycine [FL-no: 17.037], in the Flavouring Group Evaluation 305, using the Procedure in Commission Regulation (EC) No 1565/2000. The substance was considered not to have genotoxic potential. The substance was evaluated through a stepwise approach (the Procedure) 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 for the flavouring substance, evaluated through the Procedure, no appropriate NOAEL was available and additional data are required. The present evaluation of the candidate substance L-methionylglycine [FL-no: 17.037] is only applicable for its use in foods that are not heated or intended to be heated. Besides the safety assessment of the flavouring substance, the specifications for the material of commerce have also been considered. Adequate specifications including complete purity criteria and identity for the material of commerce have been provided for the candidate substance.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 63, Revision 2 (FGE.63Rev2): 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.07 Rev4

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 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 one additional substance, 4-methylpent-3-en-2-one [FL-no: 07.101], 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 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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Systemic Absorption of Nanomaterials by Oral Exposure: Part of the "Better control of nano" initiative 2012-2015

This report and accompanying database systematically evaluates the reliability and relevance of the existing scientific literature regarding systemic absorption of nanomaterials by oral exposure and makes specific recommendations for future
testing approaches.

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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.

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EFSA EFSA ; Scientific Opinion on Flavouring Group Evaluation 99 (FGE.99): Consideration of furanone derivatives evaluated by the JECFA (53rd, 65th and 69th meetings)
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 five furanone derivatives
evaluated by the JECFA at their 63rd, 65th and 69th meetings. 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 one of the five substances [FL-no: 13.010]. Contrary to the JECFA the Panel allocate three substances [FL-no: 13.084, 13.085 and 13.099] to structural class III due to lack of information on natural occurrence. With regards to the substance [FL-no: 13.176] for which the JECFA concluded that the Procedure for the Safety Evaluation of Flavouring Agents could not be applied because of the unresolved toxicological concerns relating to the epoxidation and opening of the furan ring, the Panel concluded that adequate NOAELs exist and accordingly concluded, “No safety concern at the estimated level of intake”. Therefore, the Panel concluded that all five 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 and for all five 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 201Rev1: 2-Alkylated, aliphatic, 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.

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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, 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.

General information
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Organisations: National Food Institute, Division of Toxicology and Risk Assessment, Division of Food Chemistry
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-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-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 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-methyl/propane-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-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 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.

General information
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 12, Revision 3 (FGE.12Rev3): Primary saturated or unsaturated alicyclic alcohol, aldehyde, acid, and esters from chemical group 7

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 204 (FGE.204): Consideration of genotoxicity data on representatives for 18 mono-unsaturated, aliphatic, α,β-unsaturated ketones and precursors from chemical subgroup 1.2.1 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 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.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 20, Revision 4 (FGE.20Rev4): Benzyl alcohols, benzaldehydes, a related acetal, benzoic acids, and related esters from chemical groups 23 and 30

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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, 15.099, 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 [FL-no: 15.053, 15.054, 15.055, 15.056, 15.057, 15.058, 15.059, 15.060, 15.061, 15.062, 15.063, 15.064, 15.065, 15.066, 15.067, 15.068, 15.069, 15.070, 15.071, 15.072, 15.073, 15.074, 15.075, 15.076, 15.077, 15.078, 15.079, 15.080, 15.081, 15.082, 15.083, 15.084, 15.085, 15.086, 15.087, 15.088, 15.089, 15.090, 15.091, 15.092, 15.093, 15.094, 15.095, 15.096, 15.097, 15.098, 15.099, 15.100, 15.101, 15.102, 15.103, 15.104, 15.105, 15.106, 15.107, 15.108, 15.109, 15.110, 15.111, 15.112, 15.113, 15.114, 15.115, 15.116, 15.117, 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: 15.038, 15.039, 15.040, 15.041, 15.042, 15.043, 15.044, 15.045, 15.046, 15.047, 15.048, 15.049, 15.050, 15.051, 15.052, 15.053, 15.054, 15.055, 15.056, 15.057, 15.058, 15.059, 15.060, 15.061, 15.062, 15.063, 15.064, 15.065, 15.066, 15.067, 15.068, 15.069, 15.070, 15.071, 15.072, 15.073, 15.074, 15.075, 15.076, 15.077, 15.078, 15.079, 15.080, 15.081, 15.082, 15.083, 15.084, 15.085, 15.086, 15.087, 15.088, 15.089, 15.090, 15.091, 15.092, 15.093, 15.094, 15.095, 15.096, 15.097, 15.098, 15.099, 15.100, 15.101, 15.102, 15.103, 15.104, 15.105, 15.106, 15.107, 15.108, 15.109, 15.110, 15.111, 15.112, 15.113, 15.114, 15.115, 15.116, 15.117, 15.118] 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.

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-methan-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
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.

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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.

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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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The mTAMDI value is 220 microgram/person/day. This value is above the threshold for structural class III of 90 microgram/person/day. For one of the substances from structural class III, ammonium hydrogen sulphide [FL-no: 16.059], microgram/person/day, respectively. These values are above the threshold of concern for structural class I of 1800 ammonia and ammonium chloride [FL-no: 16.009 and 16.048], are 110000 microgram/person/day and 220000 estimated intakes were based on the mTAMDI approach the values for the two substances from structural class I, rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances. When the Procedure. On the basis of the default MSDI approach the Panel concluded that the flavouring substances would not give toxicity data were available they were consistent with the conclusions in the present flavouring group evaluation using the mTAMDI approach indicated that the intake of a flavouring substance might exceed its corresponding threshold of concern, the Panel decided not to carry out a formal safety assessment using the Procedure. In these cases the Panel requires more precise data on use and use levels. According to the default MSDI approach, the two flavouring substances [FL-no: 16.009 and 16.048] belonging to structural class I have estimated intakes in Europe of 34 and 140 microgram/capita/day, respectively, which are below the threshold of concern for structural class I substances (1800 microgram/person/day). The two substances belonging to structural class III have estimated intake in Europe of 62 and 5.6 microgram/capita/day, respectively, which is below the threshold of concern for structural class III substances (90 microgram/person/day). 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 thiocarbonate 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 are 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. The remaining two substances [FL-no: 05.143 and 09.884] are classified into structural class II. Thirty-eight of the flavouring substances in the present group have been reported to occur naturally in a wide range of food items. According to the default MSDI approach, the 48 flavouring substances in this group have intakes in Europe from 0.001 to 120 microgram/capita/day, which are below the thresholds of concern for both structural class I (1800 microgram/person/day) and structural class II (540 microgram/person/day) substances. On the basis of the reported annual production volumes in Europe (MSDI approach), the combined intake of the 46 candidate substances belonging 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-enyl 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 concerns 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, 09.831 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, 02.195, 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, 09.643, 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, 09.897, 09.898, 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 aliphatic diketones or their corresponding alcohols or ketals [FL-no: 02.133], 06.134, 07.071, 07.152, 07.167, 07.168, 07.238, 07.248 and 07.260], and three beta-diketones or their corresponding hydroxyketones (of which one is a tertiary alcohol) [FL-no: 07.097, 07.165 and 07.184] all belonging to chemical groups 8 and 10. One of the 12 candidate substances possesses four chiral centres [FL-no: 06.134] two possess 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 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 decided also to perform an estimate of the daily intakes per person using a “modified Theoretical Added Maximum Daily Intake” (mTAMDI) approach based on the normal use levels reported by Industry. In those cases where the mTAMDI approach indicated that the intake of a flavouring substance might exceed its corresponding threshold of concern, the Panel decided not to carry out a formal safety assessment using the Procedure. In these cases the Panel requires more precise data on use and use levels. According to the default MSDI approach, the 12 candidate substances have European daily per capita intakes ranging from 0.0012 to 15 microgram, which are below the thresholds of concern for structural class I, II and III (1800, 540 and 90 microgram/person/day, respectively). The candidate substance 3-methyl-2,4-nonadione [FL-no: 07.184] contains a structural 2,4-diene element similar to pentan-2,4-diene. 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-diene 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-diene structure) the Procedure was not applied for 3-methyl-2,4-nonadione [FL-no: 07.184] and accordingly additional data on genotoxicity are required. For the remaining candidate substances, genotoxicity data are only available for a limited number of substances, and the genotoxicity could not be assessed adequately. However, the genotoxicity data available on these remaining 11 candidate substances do not preclude evaluation using the Procedure. Ten of the 11 flavouring substances evaluated through the Procedure are expected to be metabolised to innocuous products. For the remaining candidate substance evaluated through the Procedure, diacetyl-trimer [FL-no: 06.134] the data available do not allow to anticipate hydrolysis to innocuous products. No No Observed Adverse Effect Level (NOAEL) exists for the substance or a structurally related substance to provide an adequate margin of safety under the conditions of intended use and accordingly additional data are required. It was noted that where toxicity data were available they were consistent with the conclusions in the present flavouring group evaluation using the Procedure. It is considered that on the basis of the default MSDI approach the ten of the 11 candidate substances evaluated through the Procedure [FL-no: 02.133, 07.071, 07.097, 07.152, 07.165, 07.167, 07.168, 07.238, 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], which have mTAMDI intake estimates below the threshold of concern for structural class I are also expected to be metabolised to innocuous products. Thus, for seven of the 11 candidate substances evaluated through the Procedure [FL-no: 02.133, 06.134, 07.071, 07.152, 07.168, 07.248 and 07.260] the intakes, estimated on the basis of the mTAMDI exceed the threshold for the structural class, to which the flavouring substances have been assigned. Therefore, more reliable exposure data are required. On the basis of such additional data, the substances should be reconsidered along the steps of the Procedure. Following this procedure additional toxicological data might become necessary. In order to determine whether the conclusion for the candidate substances can be applied to the materials of commerce, it is necessary to consider the available specifications. The stereoisomeric compositions have not been specified for three of the substances [FL-no: 06.134, 07.184 and 07.260]. One of the substances [FL-no: 07.260] is a mixture of four isomers (three positional isomers, where one of these can exists as two stereoisomers) and the composition of mixture is not specified. Furthermore, for [FL-no: 07.097] the minimum assay is
too low, so information on secondary components of [FL-no: 07.097] is missing. Thus, the final evaluation of the materials of commerce cannot be performed for four substances [FL-no: 06.134, 07.097, 07.184 and 07.260], pending further information. For the candidate substance diacetel-trimer [FL-no: 06.134] additional metabolism/toxicity data are required, and for 3-methyl-2,4-nonadione [FL-no: 07.184] data on genotoxicity are required before it can be evaluated through the Procedure. The remaining eight substances [FL-no: 02.133, 07.071, 07.152, 07.165, 07.167, 07.168, 07.238 and 07.248] would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

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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 and use levels provided and the intake estimates obtained by the MSDI approach. In the absence of more precise information that would enable the Panel to make a more realistic estimate of the intakes of the flavouring substances, the Panel has decided also to perform an estimate of the daily intakes per person using a "modified Theoretical Added Maximum Daily Intake" (mTAMDI) approach based on the normal use levels reported by Industry. In those cases where the mTAMDI approach indicated that the intake of a flavouring substance might exceed its corresponding threshold of concern, the Panel decided not to carry out a formal safety assessment using the Procedure. In these cases the Panel requires more precise data on use and use levels. According to the default MSDI approach, the nine flavouring substances in this group have intakes in Europe from 0.011 to 43 micrograms/capita/day, which are below the threshold of concern 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
treshold 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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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on
Flavouring Group Evaluation 13, Revision 2 (FGE.13 Rev2) Furfuryl and furan derivatives with and without additional side-
chain substituents and heteroatoms from chemical group 14
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority
was requested to evaluate 27 flavouring substances in the Flavouring Group Evaluation 13, Revision 2, using the
were considered to have genotoxic potential. The remaining 24 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 24 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. Adequate specifications including complete purity criteria and identity for the materials of commerce have
been provided for all 24 flavouring substances evaluated through the Procedure.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 17, Revision 2 (FEG.17Rev2): Pyrazine derivatives from chemical group 24

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, 14.127, 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.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 17, Revision 3 (FEG.17Rev3): Pyrazine derivatives from chemical group 24

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 17, including seven additional substances considered in this Revision 3, 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, until adequate data showing absence of genotoxicity are provided. For one substance [FL-no: 14.051] no intake data are available preventing it from being evaluated through the Procedure. The remaining 25 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 24 substances [FL-no: 14.057, 14.081, 14.083, 14.084, 14.086, 14.087, 14.091, 14.097, 14.099, 14.101, 14.102, 14.108, 14.109, 14.111, 14.112, 14.113, 14.122, 14.126, 14.127, 14.128, 14.129, 14.148, 14.161 and 14.170] 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 one substance [FL-no:
14.102], the composition of mixture 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 18, Revision 2 (FGE.18Rev2): Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters from chemical groups 6 and 8
The Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids of the European Food Safety Authority was requested to evaluate 32 flavouring substances in the Flavouring Group Evaluation 18, 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 28 substances [FL-no: 02.041, 02.052, 02.054, 02.120, 02.123, 02.129, 02.140, 02.144, 02.147, 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
EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 209 (FGE.209): Consideration of gentoxicity data on one alpha,beta-unsaturated aldehyde from chemical subgroup 2.3 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 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.
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.

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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 21, Revision 2 (FGE.21Rev2): Thiazoles, thiophene, thiazoline and thienyl derivatives from chemical group 29. Miscellaneous substances 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 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.
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. 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 concerns.

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 concerns.

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 concerns.

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 concerns.
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. 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 II 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 [FL-no: 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 13.200] 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. Specifications including complete purity criteria and identity for the materials of commerce have been provided for all 20 candidate substances.
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 flavouring 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 flavouring 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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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 303 (FGE.303): Spilanthol from chemical group 30
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 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-1-enyl)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 been specified.

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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.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 3, Revision 2 (FGE.03Rev2): 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 and 4

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.

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, 14.058, 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.
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 1965/2000. 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 sulphides 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: 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, 12.169, 12.238, 12.239 and 12.291] the Panel has reservations (no 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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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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EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on Flavouring Group Evaluation 96 (FGE.96): Consideration of 88 flavouring substances considered by EFSA for which EU production volumes / anticipated production volumes have been submitted on request by DG SANCO. Addendum to FGE. 51, 52, 53, 54, 56, 58, 61, 62, 63, 64, 68, 69, 70, 71, 73, 76, 77, 79, 80, 83, 84, 85 and 87

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 FGE.96 concerns 88 JECFA-evaluated substances from different FGEs. Common for all the 88 substances was that for none of them European production volumes were available at the time for the first consideration of the FGEs in question. As a consequence, no MSDI could be calculated for EU and 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.

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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 considered. Specifications including complete purity criteria and identity for the materials of commerce have been provided for all 17 candidate substances.

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URLs:
Source: orbit
Source-ID: 286602
Research output: Book/Report › Report – Annual report year: 2011 › Research › peer-review

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.

General information
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Research output: Book/Report › Report – Annual report year: 2011 › Research › peer-review

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.

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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EFSA Scientific Opinion on Flavouring Group Evaluation 67, Revision 1 (FGE.67Rev.1): 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, 13.092, 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, 13.074, 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.

General information
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Source-ID: 286632
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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 substance [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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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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In vitro cytotoxicity of fungi spoiling maize silage

Penicillium roqueforti, Penicillium paneum, Monascus ruber, Alternaria tenuissima, Fusarium graminearum, Fusarium avenaceum, Byssoschlamys nivea and Aspergillus fumigatus have previously been identified as major fungal contaminants of Danish maize silage. In the present study their metabolite production and in vitro cytotoxicity have been determined for fungal agar and silage extracts. All 8 fungal species significantly affected Caco-2 cell viability in the resazurin assay, with large variations for each species and growth medium. The 50% inhibition concentrations (IC50) of the major P. roqueforti metabolites roquefortine C (48μg/mL), andrastin A (>50μg/mL), mycophenolic acid (>100μg/mL) and 1-hydroxyeremophil-7(11,9(10))-dien-8-one (>280μg/mL) were high. Fractionating of agar extracts identified PR-toxin as an important cytotoxic P. roqueforti metabolite, also detectable in maize silage. The strongly cytotoxic B. nivea and P. paneum agar extracts contained patulin above the IC50 of 0.6μg/mL, however inoculated onto maize silage B. nivea and P. paneum did not produce patulin (>371μg/kg). Still B. nivea infected maize silage containing mycophenolic acid (~50mg/kg), byssochlamic acid and other metabolites, was cytotoxic. In contrast hot-spots of P. roqueforti, P. paneum, M. ruber and A. fumigatus were not more cytotoxic than uninoculated silage.

Lack of genotoxic potential of acetylated monoglyceride: An alternative plasticiser to phthalates

Purpose: With a yearly polymer production of more than 400 million tons, phthalates based on non sustainable petrochemical materials are the most used group of plasticisers. Their low biodegradability and endocrine activity suspected to affect reproductive ability of animals and humans caused an interest in alternatives. Biodegradable plasticisers produced from sustainable materials, of low toxicity and no endocrine activity offer desirable alternatives to phthalates. The aim of the project was to screen an alternative plasticiser acetoxylated monoglyceride for genotoxic potential. Methods: The ability of acetylated monoglyceride to induce genotoxicity in vitro was investigated in silico by (Q)SAR modelling. The first step was to assure that an obtained prediction falls within the applicability domain of the models – that there was sufficient similarity (in relevant descriptors) between the query substance and the substances in the training set of the model. The (Q)SAR's prediction was followed by in vitro testing using Salmonella/microsome assay (Ames test) with strains TA 98 and TA 100, with and without metabolic activation. Results: There were no warnings for genotoxic fragments (Ashby-Tenant rules) and predictions were negative for several assays: Ames test, chromosomal aberration in Chinese hamster lung cells, mouse lymphoma TK cell mutation and unscheduled DNA synthesis in rat hepatocytes. The in vitro Ames test showed that the plasticiser did not induce gene mutations in bacteria. Presently, an in vivo comet assay to investigate the ability of the plasticiser to induce DNA strand breaks after oral exposure in the liver and kidney of rats is under conduction.
Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials

Based on a literature review this report provides a general description as well as an environmental and health profile of 7 nanomaterials. The examined nanomaterials are selected because of expected high use or specific environmental and health properties. Fullerenes, iron, silver, nanoclay and titanium-, cerium-, and silicondioxides were studied in the project. Based on current uses, it is concluded that current applications of nano-iron and nanoclay can not cause unexpected "nano-associated" health or environmental problems. Although no specific risk associated with current uses of any of the 7 other nanomaterials were identified, there are areas where there may be reason for attention and thus need for more knowledge.

The Effect of Apple Feeding on Markers of Colon Carcinogenesis

Regular consumption of fruits and vegetables is associated with reduced risks of certain cancers and other diseases in observational studies and animal models of human diseases. The aim of the present study was to investigate whether feeding of rats with whole raw apple has potentially chemopreventive properties by affecting markers of colon cancer. The end-point was preneoplastic changes in the colon known as aberrant crypt foci (ACF). Rats initiated with the colon carcinogen 1,2-dimethylhydrazine dihydrochloride (DMH) were given 0, 5, or 10 g apple/day for 13 wk. The group fed 5 g apple but not 10 g had a significantly lower number of ACF (P = 0.009) compared to the initiated control. DNA damage evaluated by the comet assay was significantly increased in leucocytes of DMH-treated animals (P = 0.021). No
antigenotoxic effect of apple feeding was apparent in the colon. Apple feeding tended to lower DNA damage in the liver (P = 0.136 in DMH-initiated and P = 0.284 in noninitiated rats). Liver alanine aminotransferase was significantly increased in rats fed apples (P = 0.008 in DMH-initiated and P = 0.019 in noninitiated rats). In conclusion, feeding whole fresh apple may affect the occurrence of preneoplastic changes in the rat colon, but the effect was not gradual.

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DNA damage detected by the alkaline comet assay in the liver of mice after oral administration of tetrachloroethylene
Induction of DNA damage in the liver and kidney of male CD1 mice was studied by means of the alkaline Comet assay after oral administration of tetrachloroethylene at the doses of 1000 and 2000 mg/kg/day. A statistically significant dose-related increase in tail intensity was established in hepatocytes, indicating that tetrachloroethylene induced DNA damage in the liver. No effect on DNA damage was observed in the kidney. The results are in agreement with carcinogenicity data in mice, in which tetrachloroethylene induced tumours in the liver but not in the kidney, and support that a genotoxic mode of action might be involved in liver carcinogenicity in mice. An alternative interpretation of the results conveyed by the Study director at the test facility, involving that tetrachloroethylene did not induce DNA damage in the liver and kidney of mice, is also presented and discussed.

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Scopus rating (2010): SJR 1.246 SNIP 1.448
Web of Science (2010): Impact factor 3.983
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Genotoxicity of clays with potential use in biopolymers for food packaging

Genotoxicity of clays with potential use in biopolymers for food packaging. Plastics produced from biopolymers are of commercial interest as they are manufactured from renewable resources such as agricultural crop wastes and have the potential to meet environmental and health requirements. Biopolymers that are strengthened using reinforcing nano-scale fillers may improve the packaging quality by increasing barrier function and heat-resistance. Toxicological data on clays containing a nano-fraction and organo-modified clays remain very limited. The aim of this study is to investigate the genotoxic potential of clays that can be used in biopolymers for food contact materials. Two clays were tested in the comet assay using Caco-2 cells (a human colon cancer cell line): a natural montmorillonite (Cloisite®Na+) and an organo-modified montmorillonite (Cloisite®30B). Both clays were tested in crude suspensions (suspended in cell culture medium) and crude suspensions filtrated through a 0.2 µm pore size filter in order to investigate the potential effect of "nanoparticles" only. The two clays showed noticeable differences in genotoxicity; both crude and filtered suspensions of Cloisite®Na+ showed negative results, while crude and filtered suspensions of Cloisite®30B were genotoxic in a clear concentration related manner. Analysis of inorganic elements and particle size distributions of filtered suspensions of Cloisite®30B indicated that no clay particle were present. However, the organo-modifier was detected in filtered suspensions of Cloisite®30B by HPLC-MS, thus indicating that the organo-modifier was at least partly responsible for the genotoxic effect. As a follow up on the in vitro results the compounds will be tested in an in vivo comet assay experiment. Wistar rats will be exposed to Cloisite®30B and Cloisite®Na+ by oral gavage and the comet assay will be performed on cells from different organs including the liver, colon and kidney. A fully automated comet assay scoring system (Imstar) will be used to evaluate the genotoxic potential.

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Genotoxicity of unmodified and organo-modified montmorillonite

The natural clay mineral montmorillonite (Cloisite (R) Na+) and an organo-modified montmorillonite (Cloisite (R) 30B) were investigated for genotoxic potential as crude suspensions and as suspensions filtrated through a 0.2-µm pore-size filter to remove particles above the nanometre range. Filtered and unfiltered water suspensions of both clays did not induce mutations in the Salmonella/microsome assay at concentrations up to 141 µg/ml of the crude clay, using the tester strains TA98 and TA100. Filtered and unfiltered Cloisite (R) Na+ suspensions in culture medium did not induce DNA strand-breaks in Caco-2 cells after 24 h of exposure, as tested in the alkaline comet assay. However, both the filtered and the unfiltered samples of Cloisite (R) 30B induced DNA strand-breaks in a concentration-dependent manner and the two highest test concentrations produced statistically significantly different results from those seen with control samples (p <0.01 and p <0.001) and (p <0.05 and p <0.01), respectively. The unfiltered samples were tested up to concentrations of 170 µg/ml and the filtered samples up to 216 µg/ml before filtration. When tested in the same concentration range as used in the comet assay, none of the clays produced ROS in a cell-free test system (the DCFH-DA assay). Inductively coupled plasma mass-spectrometry (ICP-MS) was used to detect clay particles in the filtered samples using aluminium as a tracer element characteristic to clay. The results indicated that clay particles were absent in the filtered samples, which was independently confirmed by dynamic light-scattering measurements. Detection and identification of free quaternary ammonium modifier in the filtered sample was carried out by HPLC-Q-TOF/MS and revealed a total concentration of a mixture of quaternary ammonium analogues of 1.57 µg/ml. These findings suggest that the genotoxicity of organo-modified montmorillonite was caused by the organo-modifier. The detected organo-modifier mixture was synthesized and comet-assay results showed that the genotoxic potency of this synthesized organo-modifier was in the same order of magnitude at equimolar concentrations of organo-modifier in filtrated Cloisite (R) 30B suspensions, and could therefore at least partly explain the genotoxic effect of Cloisite (R) 30B.

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Publication date: 2010
Peer-reviewed: Yes
Primary aromatic amines (PAAs) in black nylon and other food-contact materials, 2004-2009

Primary aromatic amines (PAAs) were analysed by liquid chromatography-tandem mass spectrometry (LC-MS/MS) in migrants from 234 samples of food-contact materials, including black nylon (polyamide) kitchen utensils (n = 136), coloured plastics (28), and clear/printed multilayer film/laminates (41), from retailers, importers, and food producers. A further 29 utensils in use were obtained from colleagues. Very high PAA migration was found from black nylon kitchen utensils to the food simulant 3% acetic acid: the ‘non-detectable’ limit (20 μg aniline equivalents kg⁻¹ food) was exceeded by up to 2100 times. All the other materials were compliant. The majority of the non-compliant utensils came from China. The predominant PAAs were aniline and 4,4'-methyleneedianiline (4,4'-MDA). The frequency of violations decreased from the year 2004 (55%) to the autumn of 2005 (13%), possibly due to increased demands for in-house documentation, but they remained almost constant from 2005 to 2009. The validity of the results was shown by recovery studies, participation in proficiency testing, and comparative testing of utensils by two laboratories. Migration modelling was used to compare how various compliance migration test conditions influenced the final test results. Long-term release of PAAs was fitted by diffusion modelling experiments and long-term release was also seen as expected from used utensils. Toxicologists consider these migration levels of the suspected carcinogenic PAAs as a problem of major concern.
Scientific Opinion on Flavouring Group Evaluation 32 (FGE.32): Flavonoids (Flavanones and dihydrochalcones) from chemical groups 25: EFSA-Q-2008-036

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
Contributors: EFSA Publication
Publication date: 2010


General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2010

Scientific Opinion on Flavouring Group Evaluation 5, Revision 2 (FGE.05Rev2): Branched- and straight-chain unsaturated carboxylic acids and esters of these with aliphatic saturated alcohols from chemical groups 1, 2, 3 and 5: EFSA-Q-2009-00904

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Larsen, J. C., Nerby, K. K., Beltoft, V. M., Lund, P., Binderup, M.
Publication date: 2010

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Larsen, J. C., Nørby, K. K., Beltoft, V. M., Lund, P., Binderup, M.
Publication date: 2010

Scientific Opinion on Flavouring Group Evaluation 65 (FGE.65): Consideration of sulfur-substituted furan derivatives used as flavouring agents evaluated by JECFA (59th meeting) structurally related to a subgroup of substances within the group of "Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms from chemical group 14" evaluated by EFSA in FGE.13Rev1 (2009): EFSA-Q-2008-032Q

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2010


General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Larsen, J. C., Nørby, K. K., Beltoft, V. M., Lund, P., Binderup, M.
Publication date: 2010

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2010

Publication information
Publisher: European Food Safety Authority
Original language: English
DOI: 10.2903/j.efsa.2010.1401
Research output: Book/Report › Report – Annual report year: 2010 › Research › peer-review

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

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Larsen, J. C., Nørby, K. K., Beltoft, V. M., Lund, P., Binderup, M.
Publication date: 2010

Publication information
Publisher: European Food Safety Authority
Original language: English
DOI: 10.2903/j.efsa.2010.1402
Research output: Book/Report › Report – Annual report year: 2010 › Research › peer-review


General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Larsen, J. C., Nørby, K. K., Beltoft, V. M., Lund, P., Binderup, M.
Publication date: 2010

Publication information
Publisher: European Food Safety Authority
Original language: English
DOI: 10.2903/j.efsa.2010.1845
Research output: Book/Report › Report – Annual report year: 2010 › Research › peer-review


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
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2010

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

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Larsen, J. C., Nerby, K. K., Beltoft, V. M., Lund, P., Binderup, M.
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

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Larsen, J. C., Nerby, K. K., Beltoft, V. M., Lund, P., Binderup, M.
Publication date: 2010

Effects of an onion by-product on bioactivity and safety markers in healthy rats
Onions are excellent sources of bioactive compounds including fructo-oligosaccharides (FOS) and polyphenols. An onion by-product was characterised in order to be developed as a potentially bioactive food ingredient. Our main aim was to investigate whether the potential health and safety effects of this onion by-product were shared by either of two derived fractions, an extract containing the onion FOS and polyphenols and a residue fraction containing mainly cell wall materials. We report here on the effects of feeding these products on markers of potential toxicity, protective enzymes and gut environment in healthy rats. Rats were fed during 4 weeks with a diet containing the products or a control feed balanced in carbohydrate. The onion by-product and the extract caused anaemia as expected in rodents for Allium products. No other
toxicity was observed, including genotoxicity. Glutathione reductase (GR) and glutathione peroxidase (GPx1) activities in erythrocytes increased when rats were fed with the onion extract. Hepatic gene expression of Gr, Gpx1, catalase, 5-aminolevulinate synthase and NAD(P)H:quinone oxidoreductase was not altered in any group of the onion fed rats. By contrast, γ-glutamate cysteine ligase catalytic subunit gene expression was upregulated but only in rats given the onion residue. The onion by-products as well as the soluble and insoluble fractions had prebiotic effects as evidenced by decreased pH, increased butyrate production and altered gut microbiota enzyme activities. In conclusion, the onion by-products have no in vivo genotoxicity, may support in vivo antioxidative defence and alter the functionality of the rat gut microbiota.

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, CSIC, Technical University of Denmark, University of Copenhagen
Contributors: Roldan-Marin, E., Krath, B., Poulsen, M., Binderup, M., Nielsen, T. H., Hansen, M., Barri, T., Langkilde, S., Pilar Cano, M., Sanchez-Moreno, C., Dragsted, L. O.
Pages: 1574-1582
Publication date: 2009
Peer-reviewed: Yes

Publication information
Journal: British Journal of Nutrition
Volume: 102
Issue number: 11
ISSN (Print): 0007-1145
Ratings:
BFI (2009): BFI-level 1
Scopus rating (2009): SJR 1.216 SNIP 1.208
Web of Science (2009): Indexed yes
Original language: English
DOIs:
10.1017/S0007114509990870
Source: orbit
Source-ID: 246920
Research output: Contribution to journal › Journal article – Annual report year: 2009 › Research › peer-review

EFSA; Opinion on Flavouring Group Evaluation 16 Rev2: Question No EFSA-Q-2009-00480

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

Publication information
Publisher: European Food Safety Authority
Original language: English
(The EFSA Journal; No. 1022).
DOIs:
10.2903/j.efsa.2009.1022
URLs:
Source: orbit
Source-ID: 255796
Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids; Scientific Opinion on Flavouring Group Evaluation 42: Iron containing organic substances from chemical group 30 on request from the European Commission: Question No EFSA-Q-2008-046

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
Mængden af PAH kan mindskes

General information
Publication status: Published
Organisations: Division of Food Chemistry, National Food Institute, Division of Toxicology and Risk Assessment, Section for Aquatic Lipids and Oxidation, National Institute of Aquatic Resources, Section for Aquatic Process and Product Technology
Contributors: Duedahl-Olesen, L., Binderup, M., Granby, K., Timm Heinrich, M., Fischer, K., Østerberg, C.
Pages: 24-25
Publication date: 2009

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 a request from the Commission on Flavouring Group Evaluation 7 revision 2: Question No EFSA-Q-2009-00478

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

Research output: Contribution to journal › Journal article – Annual report year: 2009 › Communication

Scientific Opinion of the Panel on Food Contact Material, Enzymes, Flavourings & Processing Aids on a request from the Commission on 3-Alkylated aliphatic acyclic alpha,beta-unsaturated aldehydes and precursors with or without additional double bonds from chemical subgroup 1.1.3 of FGE.19: Question No EFSA-Q-2008-759

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 201: 2-Alkylated aliphatic acyclic alpha,beta-unsaturated aldehydes and precursors with or without additional double bonds from chemical subgroup 1.1.2 of FGE.19: Question No EFSA-Q-2008-758

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 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

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

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

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 1169).
URLs:
Source: orbit
Source-ID: 255779
Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review


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

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 1206).
URLs:
Source: orbit
Source-ID: 255784
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 a request from the Commission on Flavouring Group Evaluation 220 alpha,beta-Unsaturated ketones and precursors from chemical subgroup 4.4 of FGE.19: 3(2H)-Furanones: Question No EFSA-Q-2009-763

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

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. ON-1061).
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

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

Publication information
Publisher: European Food Safety Authority
Original language: English
URLs:
Source: orbit
Source-ID: 255760
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 Comission on Flavouring Group Evaluation 203: alpha,beta-Unsaturated aliphatic aldehydes and precursors from chemical subgroup 1.1.4 of FGE.19 with two or more conjugated double bonds and with or without additional non-conjugated double bonds: Question No EFSA-Q-2008-765

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

Publication information
Publisher: European Food Safety Authority
Original language: English
URLs:
Source: orbit
Source-ID: 255629
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 Comission on Flavouring Group Evaluation 210: alpha,beta-Unsaturated aliphatic aldehydes and precursors from chemical subgroup 1.1.4 of FGE.19 with two or more conjugated double bonds and with or without additional non-conjugated double bonds: Question No EFSA-Q-2008-766

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

Publication information
Publisher: European Food Safety Authority
Original language: English
URLs:
Source: orbit
Source-ID: 255751
Research output: Book/Report › Report – Annual report year: 2009 › Research › peer-review

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

Publication information
Publisher: European Food Safety Authority
Original language: English
URLs:
Source: orbit
Source-ID: 255628


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

Publication information
Publisher: European Food Safety Authority
Original language: English
URLs:
10.2903/j.efsa.2009.1032
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Source-ID: 255794

Sensitisation caused by exposure to cosmetic products: Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

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

Publication information
Publisher: Norwegian Scientific Committee for Food Safety
ISBN (Print): 82-80-82298-4
Original language: English
(Uden navn; No. Dok nr 07/404).
Source: orbit
Source-ID: 236851
Combined toxic effects of multiple chemical exposures

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2008

Publication information
Publisher: Norwegian Scientific Committee for Food Safety
ISBN (Print): 82-80-82232-1
ISBN (Electronic): 82-80-82233-X
Original language: English
(Uden navn; No. Dok nr 06/406).
Source: orbit
Source-ID: 236616
Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review

Effect of apple consumption on aberrant crypt foci, an intermediate colon cancer biomarker - an example of research activities within ISAFRUIT project

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Center for Systems Microbiology, Department of Systems Biology
Contributors: Mortensen, A., Poulsen, M., Binderup, M., Hansen, M., Krath, B., Plocharski, W., Dragsted, L. O.
Publication date: 2008

Publication information
Publisher: Wydawnictwo SGGW
ISBN (Print): 978-83-7244-959-7
Original language: English
Source: orbit
Source-ID: 233495
Research output: Book/Report › Book – Annual report year: 2008 › Research › peer-review

Evaluation of the relevance of the Southampton study on hyperactive behaviour and artificial food colours in combination with sodium benzoate in Norway: Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Binderup, M.
Publication date: 2008

Publication information
Publisher: Norwegian Scientific Committee for Food Safety
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Original language: English
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Source: orbit
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Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review

Genotoxicity testing on nanoclays used in biopolymers for food packaging

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Sharma, A. K., Binderup, M.
Pages: 66-66
Genotoxicity testing on nanoclays used in biopolymers for food packaging

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Sharma, A. K., Binderup, M.
Publication date: 2008
Peer-reviewed: No
Source: orbit
Source-ID: 235869
Research output: Contribution to conference > Poster – Annual report year: 2008 > Research

Nanomaterialer - muligheder og risici

General information
Publication status: Published
Organisations: Urban Water Engineering, Department of Environmental Engineering, Environmental Chemistry, Innovation and Sustainability, Department of Management Engineering, National Food Institute
Contributors: Baun, A., Hansen, S. F., Hartmann, N. I. B., Olsen, S. I., Binderup, M., Lam, H. R.
Pages: 195-221
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
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 19
Publication date: 2008
Risk assessment of N-ethyl-toluenesulfonamide (NETSA) used as plasticizer in printing inks on food packaging materials: Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2008

Publication information
Publisher: Norwegian Scientific Committee for Food Safety
ISBN (Print): 82-80-82230-7
Original language: English
(Uden navn; No. Dok nr 07/406).
Source: orbit
Source-ID: 236621
Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review

Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC): Safety in use of the treatments for the removal of manganese, iron and arsenic from natural mineral waters by oxyhydroxide media: Question No EFSA-Q-2005-177

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 19
Publication date: 2008

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 784).
Source: orbit
Source-ID: 235915
Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review

Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) on 21st list of substances for food contact materials: Question Number EFSA-Q-2005-151, EFSA-Q-2006-324, EFSA-Q-2006-323

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 14
Publication date: 2008

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 888-890).
Source: orbit
Source-ID: 235897
Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review

Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) on a 20th list of substances for food contact materials

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

Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review
Smoking of trout – the influence of process parameters on product quality

General information
Publication status: Published
Organisations: Division of Food Chemistry, National Food Institute, National Veterinary Institute, Division of Toxicology and Risk Assessment
Publication date: 2008

Publication information
Publisher: European Food Safety Authority
Original language: English
Source: orbit
Source-ID: 235912
Research output: Book/Report › Report – Annual report year: 2008 › Research › peer-review

Toksikologisk forskning i nanomaterialer

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Sharma, A. K., Binderup, M.
Pages: 14-22
Publication date: 2008
Peer-reviewed: Unknown

Publication information
Publisher: Danmarks Fiskeriundersøgelser
Original language: English
Source: orbit
Source-ID: 236788
Research output: Book/Report › Report – Annual report year: 2008 › Research

Begrænsning af forurening med tjærestoffer

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Karlson, U., Binderup, M., Glasius, M.
Publication date: 2007
Peer-reviewed: Unknown

Publication information
Publisher: Danmarks Fiskeriundersøgelser
Original language: Danish
Source: orbit
Source-ID: 233554
Research output: Contribution to journal › Journal article – Annual report year: 2008 › Communication
Evaluation of health risk connected to consumption of barbequed Food

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Binderup, M., Vikse, R., Øvrebe, S., Knutsen, H.
Publication date: 2007
Peer-reviewed: No
Source: orbit
Source-ID: 236864
Research output: Contribution to conference › Conference abstract for conference – Annual report year: 2007 › Research

Evaluation of health risk connected to consumption of barbequed Food

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Binderup, M., Vikse, R., Øvrebe, S., Knutsen, H.
Publication date: 2007
Peer-reviewed: No
Source: orbit
Source-ID: 236865
Research output: Contribution to conference › Poster – Annual report year: 2007 › Research

Impact on health when sugar is replaced with intense

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2007

Publication information
Publisher: Norwegian Scientific Committee for Food Safety
ISBN (Print): 978-82-8082-200-0
Original language: English
(Uden navn; No. Dok nr 05/704).
Source: orbit
Source-ID: 236863
Research output: Book/Report › Report – Annual report year: 2007 › Research › peer-review

ISAFRUIT health research: Integrating experimental and observational studies on fruit and health with nutrigenomics

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Microbiology and Risk Assessment, Technical University of Denmark
Publication date: 2007
Peer-reviewed: No
Event: Abstract from The International meeting in FAV, Houston, Texas,
Source: orbit
Source-ID: 245276
Research output: Contribution to conference › Conference abstract for conference – Annual report year: 2007 › Research

Når der er røg i maden
Risikovurdering av koffein i kosttilskudd: Uttalelse fra Faggruppen for tilsetningsstoffer, aroma, matemballasje og kosmetikk i Vitenskapskomiteen for mattrygghet

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2007

Risk assessment of health hazards from nickel, cobalt, zinc, iron, copper and manganese migrated from ceramic articles: Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2007

Risk assessment related to solar radiation and the use of sun protection products: Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Publication date: 2007
Scientific Opinion of the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 16th list of substances for food contact materials

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: EFSA Publication
Number of pages: 31
Publication date: 2007

Publication information
Publisher: European Food Safety Authority
Original language: English
(the EFSA Journal; No. 555-563).
Source: orbit
Source-ID: 239279
Research output: Book/Report › Report – Annual report year: 2007 › Research › peer-review

The cda GenoTox assay: A new and sensitive method for detection of environmental genotoxins, including nitroarenes and aromatic amines
A new bacterial test system for detection of genotoxic compounds was developed, based on two new Sahnonella typhimurium tester strains, TGO1 and TGO2. Both strains contain a gene fusion between a strong SOS-promotor, P-nda, and the gfp gene, which allows detection of genotoxic compounds that induce the SOS response. SOS induction was detected by means of flow cytometry. TGO1 showed an increased sensitivity to N-methyl-N'-nitro-N-nitrosoguanidine compared with a previously developed strain, which had an Escherichia coli strain as host instead of S. typhimurium. S9 mix was introduced into the assay, making the test system suitable for detection of indirect mutagens. Furthermore, the genes for bacterial nitro-reductase (NR) and o-acetyl transferase (o-AT) were inserted into TGO2, making it an NR- and o-AT-over-expressing strain. This resulted in an assay that was able to detect the nitroarene 1-nitropyrene and the aromatic amine 2-aminoanthracene with high sensitivity.

General information
Publication status: Published
Organisations: Risø National Laboratory for Sustainable Energy, Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Østergaard, T. G., Hansen, L. H., Binderup, M., Norman, A., Sørensen, S. J.
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Source: orbit
Source-ID: 214306
Research output: Contribution to journal › Journal article – Annual report year: 2007 › Research › peer-review

The cda GenoTox assay: A new sensitive Salmonella typhimurium tester strain, TGO2, carrying a cda::gfp reporter plasmid for the detection of nitroarenes and aromatic amines

General information
Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Østergaard, T. G., Binderup, M., Hansen, L., Søren, S. J.
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Assessment of four studies on developmental neurotoxicity of bisphenol A: Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

Biodegradation, bioaccessibility, and genotoxicity of diffuse polycyclic aromatic hydrocarbon (PAH) pollution at a motorway site

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Polycyclic Aromatic Hydrocarbons in Danish smoked Fish and Meat Products

General information
Publication status: Published
Organisations: Division of Food Chemistry, National Food Institute, Division of Toxicology and Risk Assessment
Contributors: Duedahl-Olesen, L., Binderup, M.
Publication date: 2006
Peer-reviewed: No

Publication information
Journal: Organohalogen Compounds
ISSN (Print): 1026-4892
Ratings:
Web of Science (2006): Indexed yes
Original language: English
Source: orbit
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Research output: Contribution to journal › Conference article – Annual report year: 2006 › Research

Polycyclic Aromatic Hydrocarbons (PAH) in Danish Smoked Fish and Meat Products
Twenty seven PAH were detected in 45 selected smoked food samples produced in Denmark, including mackerel, herring, trout, small sausages, salami, and bacon. The sum of PAH in smoked meat products ranged from 24 μg/kg for salami to 64 μg/kg in bacon, while those in fish products ranged from 22 μg/kg in smoked mackerel prepared in an electric oven to 1387 μg/kg in herring smoked by direct smoking. The concentration of benzo[a]pyrene for all sample types were below the maximum level of 5 μg/kg for smoked fish and meat set by the European Commission. Results from this survey confirm that the actual level of individual PAH in fish products is dependent on variables such as the type of wood used in the smoking process. Furthermore, the use of the benzo[a]pyrene approach for estimation of the carcinogenicity of PAH in food is confirmed. The Danish intake of benzo[a]pyrene from these smoked products is 2 to 4 ng/person/day.

General information
Publication status: Published
Organisations: Division of Food Chemistry, National Food Institute, Division of Toxicology and Risk Assessment
Contributors: Duedahl-Olesen, L., White, S., Binderup, M.
Pages: 163-184
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Peer-reviewed: Yes

Publication information
Journal: Polycyclic Aromatic Compounds
Volume: 26
Issue number: 3
ISSN (Print): 1040-6638
Ratings:
Scopus rating (2006): SJR 0.329 SNIP 0.415
Web of Science (2006): Indexed yes
Original language: English
DOIs:
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Source: orbit
Source-ID: 239616
Research output: Contribution to journal › Journal article – Annual report year: 2006 › Research › peer-review

Tjærestoffer. Danmarks Miljøundersøgelser

General information
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DNA damage in lung after oral exposure to diesel exhaust particles in Big Blue (R) rats

Several chemical mutagens and carcinogens, including polycyclic aromatic hydrocarbons (PAHs) and nitrated PAHs, are adsorbed to the surface of diesel exhaust particles (DEP). DEP can induce formation of reactive oxygen species and cause oxidative DNA damage as well as bulky carcinogen DNA adducts. Lung tissue is a target organ for DEP induced cancer following inhalation. Recent studies have provided evidence that the lung is also a target organ for DNA damage and cancer after oral exposure to other complex mixtures of PAHs. The genotoxic effect of oral administration of DEP was investigated, in terms of markers of DNA damage, mutations and repair, in the lung of Big Blue(R) rats fed a diet with 0, 0.2, 0.8, 2, 8, 20 or 80 mg DEP/kg feed for 21 days. There was no significant increase in the mutation frequency in the cII gene. However, an increase of DNA damage measured as DNA strand breaks (comet assay) and bulky DNA adducts (P-32 post labeling) was observed. The level of DNA strand breaks increased significantly at all dose levels while the level of DNA adducts increased significantly only at the intermediate dose levels. Similarly, the number of oxidized DNA bases measured as endonuclease III and fapyguanine glycosylase (FPG) sensitive sites increased at the intermediate dose levels. The induction of DNA damage by DEP exposure did not increase the expression of the repair genes OGG1 and ERCC1 at the mRNA level. The present study indicates that the lung is a target organ for primary DNA damage following oral exposure to DEP. DNA damage was induced following exposure to relatively low levels of DEP, but under the conditions used in the present experiment DNA damage did not result in an increased mutation rate.

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Organisations: National Food Institute, Division of Toxicology and Risk Assessment, Technical University of Denmark
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Ratings:
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Migration testing of kitchen- and tableware

General information
Publication status: Published
Organisations: Division of Food Chemistry, National Food Institute, Division of Toxicology and Risk Assessment
Contributors: Pedersen, G. A., Svendsen, G. W., Binderup, M., Petersen, J. H.
Publication date: 2004
Peer-reviewed: Yes
Event: Abstract from The 3rd International Food Packaging Symposium, Barcelona, Spain.
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Research output: Contribution to conference › Conference abstract for conference – Annual report year: 2004 › Research › peer-review

Migration testing of kitchen- and tableware

General information
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Organisations: Division of Food Chemistry, National Food Institute, Division of Toxicology and Risk Assessment
Contributors: Pedersen, G. A., Svendsen, G. W., Binderup, M., Petersen, J. H.
Publication date: 2004
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The effect of oil spills on seafood safety: An example of the application of the

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Publication status: Published
Organisations: Division of Toxicology and Risk Assessment, National Food Institute, Division of Food Chemistry
Publication date: 2004

Publication information
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ISBN (Print): 92-893-1056-1
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Source: orbit
Source-ID: 239623
Research output: Book/Report › Report – Annual report year: 2004 › Research

Urinary 1-hydroxypyrene and mutagenicity in bus drivers and mail carriers exposed to urban air pollution in Denmark
Background: Previous studies in Denmark have shown that bus drivers and tramway employees were at an increased risk for developing several types of cancer and that bus drives from central Copenhagen have high levels of biomarkers of DNA damage. Aims: The present study evaluates 1-hydroxypyrene concentrations and mutagenic activity in urine as biomarkers of exposure in non-smoking bus drivers in city and rural areas on a work day and a day off and in non-smoking mail carriers working outdoors (in the streets) and indoors (in the office). Methods: Twenty-four hour urine samples were collected on a working day and a day off from 60 non-smoking bus drivers in city and rural areas and from 88 non-smoking mail carriers working outdoors (in the streets) and indoors (in the office). The concentration of 1-hydroxypyrene was measured by means of HPLC and the mutagenic activity was assessed by the Ames assay with Salmonella tester strain YG1021 and S9 mix. The N-acetyltransferase (NAT2) phenotype was used as a biomarker for susceptibility to mutagenic/carcinogenic compounds. Results: Bus drivers excreted more 1-hydroxypyrene in urine than did mail carriers.
The differences were slightly smaller when NAT2 phenotype, cooking at home, exposure to vehicle exhaust, and performing physical exercise after work were included. The NAT2 slow acetylators had 29% (1.29 [CI: 1.15-1.98]) higher 1-hydroxypyrene concentrations in urine than the fast acetylators. Male bus drivers had 0.92 revertants/mol creatinine [CI 0.37-1.47] and female bus drivers 1.90 revertants/mol creatinine [CI: 1.01-2.79] higher mutagenic activity in urine than mail carriers. Conclusion: The present study indicates that bus drivers are more exposed to polycyclic aromatic hydrocarbons (PAH) and mutagens than mail carriers. Mail carriers who worked outdoors had higher urinary concentration of 1-hydroxypyrene, a marker of exposure to PAH, than those working indoors. The individual levels of urinary mutagenic activity were not correlated to excretion of 1-hydroxypyrene. This might be due to the fact that the most potent mutagenic compounds in diesel exhaust are not PAH but dinitro-pyrenes. Among bus drivers, fast NAT2 acetylators had higher mutagenic activity in urine than slow NAT2 acetylators and female bus drivers had higher mutagenic activity than male bus drivers.

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Source-ID: 229676
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Combined Actions and Interactions of Chemicals in Mixtures: The Toxicological Effects of Exposure to Mixtures of Industrial and Environmental Chemicals

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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
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Original language: English
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Research output: Book/Report > Report – Annual report year: 2003 > Research

Risk assessment of PAC-polluted and bioremediated soils

General information
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Organisations: Division of Toxicology and Risk Assessment, National Food Institute
Contributors: Binderup, M., Christensen, M., Scott-Fordsmand, J.
Publication date: 2003
Peer-reviewed: No
Observations of the effect of atmospheric processes on the genotoxic potency of airborne particulate matter

In this study, the relationship between genotoxic potency and the occurrence of polycyclic aromatic hydrocarbons (PAH), including benzo(a)pyrene (BaP), and nitro-PAH in urban and semi-rural air masses has been investigated. The Salmonella/microsome assay has been used as a measure of genotoxic potency. We find that the ratios of BaP/mutagenicity and PAH/mutagenicity are highly variable. The processes responsible for the variation are formation and degradation of mutagens and transport of polluted air masses from heavily industrialized regions. Air masses from Central Europe are shown to be highly enriched in mutagens as well as in PAH and nitro-PAH. However, the mutagenic activity is much more elevated than the PAH levels when these air masses are mixed with local urban air. Part of the variation in the PAH/mutagenicity ratio can be explained by photochemical transformation. Since BaP has been used in the past as an indicator of the carcinogenic risk of airborne particles, it is suggested that the cancer risk of air pollution has to be re-evaluated.

General information
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Organisations: Risø National Laboratory for Sustainable Energy, Division of Toxicology and Risk Assessment, National Food Institute, Department of Environmental Engineering
Contributors: Feilberg, A., Nielsen, T., Binderup, M., Skov, H., Poulsen, M.
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Research output: Contribution to journal › Journal article – Annual report year: 2002 › Research › peer-review

Toxicity testing and chemical analyses of recycled fibre-based paper for food contact

Food-contact materials, including paper, have to comply with a basic set of criteria concerning safety. This means that paper for food contact should not give rise to migration of components, which can endanger human health. The objectives of this pilot study were, first, to compare paper of different qualities as food-contact materials and to perform a preliminary evaluation of their suitability from a safety point of view, and, second, to evaluate the use of different in vitro toxicity tests for screening of paper and board. Paper produced from three different categories of recycled fibres (B-D) and a raw material produced from virgin fibres (A) were obtained from industry, and extracts were examined by chemical analyses and diverse in vitro toxicity test systems. The products tested were either based on different raw materials or different treatments were applied. Paper category B was made from 40% virgin fibres, 40% unprinted cuttings from newspapers, and 20% de-inked newspapers and magazines. Paper categories C and D were based on newspapers and magazines. However, paper D was de-inked, whereas C was not. To identify constituents of the papers with a potential to migrate into foodstuffs, samples of the paper products were extracted with either 99% ethanol or water. Potential migrants in the extracts were identified and semiquantified by GC-1R-MS or GC-HRMS. In parallel to the chemical analyses, a battery of four different in vitro toxicity tests with different endpoints were applied to the same extracts: (1) a cytotoxicity test using normal human skin fibroblasts. The test was based on measurements of the reduction of resazurin to resorufin by cellular redox processes and used as a screening test for acute or general toxicity; (2) a Salmonella/microsome assay (Ames test) as a screening test for mutagenic and potentially carcinogenic compounds; (3) a recombinant yeast cell bioassay as a screening test for compounds with oestrogenic activity; (4) an aryl hydrocarbon (Ah)-receptor assay (CALUX assay) as a screening test for compounds with dioxin-like activity. In addition, the papers were tested for microbial content and, in general, the microbiological load was quite low. The following microorganisms were counted and identified on both surface and homogenized pulp samples: the total number of aerobic bacteria, the number of aerobic and anaerobic spore formers, the number of Bacillus cereus/thuringiensis, and the number of yeast and moulds. The chemical analyses showed a significantly higher amount and different composition pattern of chemicals extracted with ethanol compared with water.
Analyses of the ethanol extracts showed a distinctly smaller number and lower concentrations of chemicals in extracts prepared from sample A compared with extracts of samples B-D. The compounds identified in B-D were similar, but the amounts were lower in B compared with C and D. In accordance with the chemical analyses, the water extracts were less cytotoxic than the ethanol extracts. The extract prepared from virgin fibres was less cytotoxic than the extracts prepared from paper made from recycled fibres, and extracts prepared from C was the most cytotoxic. None of the extracts showed mutagenic activity. No conclusion about the oestrogenic activity could be made, because all extracts were cytotoxic to the test organism (yeast cells). Ethanol extracts of A and B showed a negligible positive response in the Ah-receptor assay at the highest nontoxic concentration, whereas C and D showed a more pronounced positive effect with C being the most potent. A comparable weak effect of water extracts of samples B-D was.