

Parma, 12 March 2008

**MINUTES OF THE 27th PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD**

Held in Parma on 29-31 January 2008

Adopted on 6 March 2008 at the 28th Panel meeting

AGENDA:

1.	<i>Welcome; apologies for absence.....</i>	3
2.	<i>Adoption of the agenda.....</i>	3
3.	<i>Declarations of interest.....</i>	3
4.	<i>Matters arising from the 26th plenary meeting held on 27-29 November 2007.....</i>	4
5.	<i>General information from EFSA and the Commission.....</i>	4
6.	<i>Feedback from recent meetings of the Scientific Committee, management board and advisory forum</i>	4
7.	<i>Food Additives.....</i>	5
7.1.	<i>Rosemary extracts (EFSA-Q-2003-140)</i>	5
7.2.	<i>Lycopene (EFSA-Q-2007-001, Q-2007-081).....</i>	5
7.3.	<i>Southampton study on the effect of some colours and benzoic acid on hyperactivity</i>	5
8.	<i>Nutrient Sources</i>	6
8.1.	<i>Vanadium sources (EFSA-Q-2005-162, EFSA-Q-2006-225, EFSA-Q-2006-256, EFSA-Q-2006-257, EFSA-Q-2006-258, EFSA-Q-2006-275, EFSA-Q-2006-281)</i>	6
9.	<i>Flavourings.....</i>	7
9.1.	<i>Flavouring Group Evaluations (FGE).....</i>	7
9.1.1.	<i>FGE.10 Revision 1 (EFSA-Q-2003-153B)</i>	7
9.1.2.	<i>FGE.17 Revision 1 (EFSA-Q-2003-160B)</i>	8
9.1.3.	<i>FGE.18 Revision 1 (EFSA-Q-2003-161B)</i>	8
9.1.4.	<i>FGE.45 (EFSA-Q-2008-049).....</i>	9

9.1.5.	<i>FGE.64 (EFSA-Q-2008-032P)</i>	9
9.1.6.	<i>FGE.69 (EFSA-Q-2008-053)</i>	9
9.1.7.	<i>FGE.74 (EFSA-Q-2008-058)</i>	10
9.1.8.	<i>FGE.76 (EFSA-Q-2008-060)</i>	10
9.1.9.	<i>FGE.77 (EFSA-Q-2008-061)</i>	11
9.1.10.	<i>FGE.84 (EFSA-Q-2008-068)</i>	12
9.1.11.	<i>FGE.34 (EFSA-Q-2008-038) (Not on the original draft Agenda)</i>	12
10.	<i>Food Contact Materials</i>	12
10.1.	<i>Evaluation of substances for the 18th list of monomers and additives</i>	12
11.	<i>Any other business</i>	13

**MINUTES OF THE 27th PLENARY MEETING
OF THE SCIENTIFIC PANEL ON
FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS
AND MATERIALS IN CONTACT WITH FOOD (AFC)
Held in Parma on 29-31 January 2008**

PARTICIPANTS

Panel Members:

Herman Autrup, Susan Barlow (Chair), Laurence Castle, Riccardo Crebelli, Wolfgang Dekant (2nd and 3rd day), Nathalie Gontard, David Gott, Sandro Grilli, Rainer Gürtler, John Christian Larsen (Vice Chair), Jean-Charles Leblanc, Catherine Leclercq, Wim C. Mennes, Maria Rosaria Milana, Iona Pratt (1st and 2nd day), Ivonne Rietjens, Paul Tobback, Fidel Toldrá.

Experts:

Jørn Gry (item 9 only), Werner Grunow (item 8.1 only).

Apologies :

Fernando Aguilar, Karl-Heinz Engel, F. Xavier Malcata.

EFSA:

Torben Hallas-Møller (Scientific co-ordinator of AFC Panel),
Eric Barthélémy, Alexandre Feigenbaum, Hugues Kenigswald, Ana Maria Rincon, Kim Rygaard Nielsen, Dimitrios Spyropoulos, Anne Theobald and Stavroula Tasiopoulou (Assistant scientific co-ordinators of AFC Panel)
Maud Pâques (Administrative secretary of AFC Panel).

Commission:

Wim Debeuckelaere (DG Sanco, E3 (2nd and 3rd day)), Xavier Pavard, (DG Sanco, 03 (teleconference, 2nd day)).

1. WELCOME; APOLOGIES FOR ABSENCE

The chair welcomed the participants and the new members of the scientific and administrative secretariat. The secretariat noted apologies.

2. ADOPTION OF THE AGENDA

The agenda was adopted with the addition of a new item 9.1.11. The foreseen item on aluminium was deferred to the next Plenary meeting.

3. DECLARATIONS OF INTEREST

The declarations concerning items on the agenda of this meeting are noted under the specific items on food additives (7.2, 7.3), nutrient sources (8.1) and flavourings (9.1).

4. MATTERS ARISING FROM THE 26TH PLENARY MEETING HELD ON 27-29 NOVEMBER 2007

The minutes had been adopted by written procedure and can be seen on:

http://www.efsa.europa.eu/EFSA/Event_Meeting/afc_minutes_26thplen_en.pdf

The secretariat noted action points. No matters were arising.

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

The secretariat informed about the latest status of the call for the two new Panels replacing the AFC Panel as well as the split of the secretariat to two new units.

Torben Hallas-Møller informed that this would be his last Plenary meeting as his contract will expire by the end of April. The Chair thanked him, on behalf of the Panel, for his tremendous contribution to the functioning of the AFC Panel and its Working Groups and to the smooth running of the meetings through the last 5 years. The chair noted that the very high workload for the secretariat had been successfully covered under his leadership with, up until recently, the assistance of only a relatively small team. The Panel expressed its gratitude for the information and sound guidance he had offered the Panel since its inception and wished him well for his return to his home country.

Wim Debeuckelaere reported back from the last Commission Flavouring Working Group (WG) in Brussels, where Member States, Stakeholders (Industry and Consumer Organisations), the FLAVIS WG, the AFC Flavouring WG and EFSA (Hallas-Møller and Rygaard Nielsen) were represented. The main topic was the status of the evaluation programme and preparation of the Positive List. It was noted that all substances not on the list will be excluded from the market.

6. FEEDBACK FROM RECENT MEETINGS OF THE SCIENTIFIC COMMITTEE, MANAGEMENT BOARD AND ADVISORY FORUM

The Chair informed of the meetings of the SC held on 18-19 November and 19 December 2007.

The minutes from these meetings can be seen on:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178637648399.htm and

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178668258508.htm

The secretariat informed of the recent meeting of the management board held in Parma on 23 January. Particular items mentioned were the budget for 2008 and the Management Plan for 2008 as well as the new structure in EFSA.

The minutes of the MB meetings are published on:

http://www.efsa.europa.eu/EFSA/AboutEfsa/WhoWeAre/ManagementBoard/efsa_locale-1178620753812_MeetingsMB.htm

The secretariat informed of the latest meeting of the Advisory Forum held in The Hague on 6-7 December 2007. Of special interest for the Panel was the discussion on a proposal for a possible new study on aspartame.

The minutes of the AF meetings can be found on:

http://www.efsa.europa.eu/EFSA/EventsMeetings/efsa_locale-1178620753812_EventsMeetingsArchive.htm

7. FOOD ADDITIVES

7.1. Rosemary extracts (EFSA-Q-2003-140)

The rapporteur presented the draft opinion. It was discussed and some changes were suggested. The suggested changes will be introduced to the draft and it will be forwarded to the next Plenary meeting.

7.2. Lycopene (EFSA-Q-2007-001, Q-2007-081)

Sue Barlow declared an indirect interest in this item as her partner has been a consultant on two natural colours. Although he had not consulted at all on lycopene she did not participate in the discussion and the item was chaired by Vice Chair, John C. Larsen.

John C. Larsen declared an interest in this item as he has participated in meetings of JECFA when lycopene was discussed. This was not considered as a conflict of interest and he was invited to participate in the discussion.

The rapporteur presented the draft opinion. It was discussed, some changes were suggested and it was adopted. However because of the number of changes made at the Plenary, the members will receive the revised opinion for final confirmation by written procedure.

The Panel derived an Acceptable Daily Intake (ADI) of 0 - 0.5 mg/kg bw/day using a safety factor of 100, based on a NOAEL from a one-year-study for the non-reversible increase of the level of an hepatic enzyme, alanine transaminase (ALT). This ADI refers to lycopene from all sources.

The Panel noted that specifications for lycopene from tomatoes may need to be updated taking the actual lycopene content in current colouring preparations into account.

The Panel also concluded that with the uses and use levels presented in the opinion, which are lower than the maximum use-levels permitted for food colours under Directive 94/36/EC, the intake of lycopene from natural sources and as a food colour would generally be expected to remain within the ADI of 0.5 mg/kg bw/day. However this does not necessarily hold for potential high level intakes by children and young people.

The Panel noted that non-alcoholic flavoured drinks constitutes more than 90% of the total calculated intake of lycopene in the exposure estimates for children and young people.

The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

7.3. Southampton study on the effect of some colours and benzoic acid on hyperactivity

Sue Barlow declared an indirect interest in this item as her partner has been a consultant on natural colours and therefore the Vice Chair, John C. Larsen, chaired this part of the meeting. She did not participate in the discussion.

Fernando Aguilar (at the previous meeting), Rainer Guertler, John C. Larsen and Iona Pratt declared an interest because they have been involved in preliminary discussions in their national institutes on the study. It was found that this was not a conflict of interest and they were invited to participate in the discussion.

David Gott declared a direct interest because he works for the Food Standards Agency (FSA) who commissioned the study and has participated in the Secretariat to the meetings of the Committee on Toxicity of the FSA where the results of the study were discussed. He did not participate in the discussion but was present to answer questions.

The working group chair gave a status report on the outcome of the working group meetings and the foreseen timeline to achieve the full assessment of the study. The Panel had a discussion on a draft document outlining the methods, the findings and the analysis of the study so far by the working group, which will form the basis for the draft opinion. The Panel hopes to be able to adopt an opinion on the Southampton study at its next Plenary meeting on 6-7 March.

8. NUTRIENT SOURCES

8.1. Vanadium sources (EFSA-Q-2005-162, EFSA-Q-2006-225, EFSA-Q-2006-256, EFSA-Q-2006-257, EFSA-Q-2006-258, EFSA-Q-2006-275, EFSA-Q-2006-281)

Sue Barlow declared an interest in this item as she had advised a vanadium producing company on classification and labelling in the non-food area and therefore the Vice Chair, John C. Larsen, chaired this part of the meeting. She did not participate in the discussion.

Riccardo Crebelli declared an interest in this item as he has advised the Italian Authorities on vanadium in drinking water. This was not considered as a conflict of interest and he was invited to participate in the discussion.

The rapporteur presented the draft opinion. It was discussed, some changes were suggested and it was adopted.

The Panel concluded that the available data indicate that, with the exception of vanadium pentoxide, the bioavailability of vanadium from most of the vanadium sources requested is higher than has been estimated for the absorption of vanadium from the normal diet in humans (EVM, 2003; EFSA, 2004).

The Panel also noted the conclusions and risk characterisation in the opinion of the NDA Panel on vanadium (EFSA, 2004) that a NOAEL could not be derived from the available studies and that therefore a tolerable upper intake level for vanadium could not be derived. The AFC Panel considers that these conclusions are relevant, not only for vanadium itself, but also for the vanadium sources under consideration in the present opinion.

Although data on use levels and the categories of foods intended for particular nutritional uses had not been provided by the applicant, based on the available information on bioavailability of vanadium and the conclusions of the NDA Panel, the AFC Panel concluded that safe use of these sources in this application cannot be established.

The full opinion can be seen on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

9. FLAVOURINGS

9.1. Flavouring Group Evaluations (FGE)

Ivonne Rietjens declared that she is a member of the FEMA (Flavour and Extract Manufacturers Association) Expert Panel. Although this was not considered a direct conflict of interest for the particular flavouring groups under evaluation at this meeting, it was decided that she should not participate in the discussion on these flavouring group evaluations.

Wim Mennes declared an interest in FGE.10 concerning 2-butoxyethan-1-ol [Fl no: 02.242]), as he had participated in the discussions leading to the EU Risk Assessment report for this substance. He also declared an interest in the anthranilates in one of the JECFA flavourings re-evaluations (FGE.84) as he had contributed to the drafting of the early versions of the JECFA opinion. These were not considered as conflicts of interest and he was invited to participate in the discussions.

9.1.1. *FGE.10 Revision 1 (EFSA-Q-2003-153B)*

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 draft opinion was presented and discussed. Due to further information on 1-hydroxypropan-2-one [FL-no: 07.169], 2-butoxyethan-1-ol [FL-no: 02.242] and the structurally related 1,1,3-triethoxypropane [FL-no: 06.097], these three substances were reconsidered and evaluated through the Procedure. They were concluded to be of no safety concern.

The Panel has reservations for the following substances [FL-no: 06.088, 06.095, 06.102, 06.135, 09.565, 09.916, 10.038, 10.040, 10.168] as the stereoisomeric composition has not been specified, and for the two substances [FL-no: 06.088, 06.095] additionally identity tests are missing.

The Panel further concluded that the remaining candidate substances would present no safety concern at the level of intake estimated on the basis of the Maximised Survey-derived Daily Intake (MSDI) approach.

The opinion was adopted subject to the proposed changes. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm, as an update of the previously adopted opinion on FGE.10.

9.1.2. ***FGE.17 Revision 1 (EFSA-Q-2003-160B)***

Pyrazine derivatives from chemical group 24.

The Panel has formerly concluded that for the three substances 2,3 dimethylquinoxaline [FL-no: 14.108], 2-methylquinoxaline [FL-no: 14.139] and quinoxaline [FL-no: 14.147] there is a possible genotoxic potential *in vitro*, and therefore the Procedure could not be applied to these substances until adequate *in vivo* genotoxicity data become available.

The Panel additionally concluded that for isopropenylpyrazine [FL-no: 14.052] further toxicity data are needed, as no valid toxicity study from which a NOAEL could be established was available for isopropenylpyrazine or for any relevant supporting substance.

The final evaluation of the materials of commerce cannot be performed for 6,7-dihydro-5,7-dimethyl-5H-cyclopentapyrazine [FL-no: 14.099] and 5,6-dimethyldihydrocyclopentapyrazine [FL-no: 14.102] pending further information on composition of mixture and/or chirality.

The Panel further concluded that the remaining candidate substances would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

The opinion was adopted. The full opinion will be published on:
http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm, as an update of the previously adopted opinion on FGE.17.

9.1.3. ***FGE.18 Revision 1 (EFSA-Q-2003-161B)***

Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols, aromatic tertiary alcohols and their esters. From chemical group 6 and 8.

The draft opinion was presented and discussed. Minor revisions were proposed.

The Panel has concluded that for eight flavouring substances [FL-no: 02.120, 02.144, 02.185, 02.191, 02.197, 09.171, 09.669 and 09.808] additional toxicity data are needed.

Information on the stereoisomeric composition / composition of mixture needs to be specified for the substances [FL-no: 02.147, 02.168, 02.191, 02.197, 02.230 and 02.253], for which the final evaluation of the materials of commerce cannot be performed pending further information.

For the remaining substances evaluated using the Procedure the Panel concluded that they would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

The opinion was adopted subject to the proposed changes. The full opinion will be published on:
http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm, as an update of the previously adopted opinion on FGE.18.

9.1.4. ***FGE.45 (EFSA-Q-2008-049)***

One tertiary amine from chemical group 28.

The draft opinion was discussed and minor editorial changes were proposed. The Panel concluded that 1-methylpyrrolidine [FL-no: 14.137] would present no safety concern at the level of intake estimated on the basis of the MSDI approach.

The opinion was adopted. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm.

9.1.5. ***FGE.64 (EFSA-Q-2008-032P)***

Consideration of aliphatic acyclic diols, triols, and related substances evaluated by JECFA (57th meeting).

The draft opinion was presented and discussed and revisions to the text were proposed.

For 18 substances [FL-no: 06.029, 06.039, 06.094, 06.098, 08.004, 09.433, 09.434, 09.491, 09.543, 09.544, 09.545, 09.552, 09.553, 09.554, 09.555, 09.556, 09.557 and 16.039] no information on the isomeric composition has been given and for three substances further information on the composition is requested [FL-no: 06.029, 09.543 and 09.544], for which the Panel has reservations. For the remaining seven the Panel concluded they would present no safety concern at estimated levels of intake estimated on the basis of the MSDI approach.

The opinion was adopted subject to the proposed changes. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm.

9.1.6. ***FGE.69 (EFSA-Q-2008-053)***

Consideration of aromatic substituted secondary alcohols, ketones and related esters evaluated by JECFA (57th meeting).

For 4-acetyl-6-*t*-butyl-1,1-dimethylindane, [FL-no: 07.133] the Panel has concluded that additional toxicity data are requested as no NOAEL could be established.

For four substances, 1-phenylpropyl butyrate [FL-no: 09.189], 1-methyl-3-phenylpropyl acetate [FL-no: 09.200], ethyl 2-acetyl-3-phenylpropionate [FL-no: 09.501] and 3-benzylheptan-4-one [FL-no: 07.070] EU production figures are needed in order to finalise the evaluation.

For 17 substances [FL-no: 02.033, 02.034, 02.036, 02.064, 02.065, 02.080, 07.028, 07.070, 09.144, 09.178, 09.179, 09.189, 09.200, 09.231, 09.249, 09.486 and 09.501] the Panel has reservations, as no information on the isomeric composition has been given and for four

substances further information on the composition is requested [FL-no: 07.038, 07.042, 09.179 and 09.476].

The Panel concluded that the remaining candidate substances would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

The opinion was adopted subject to the proposed changes. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm.

9.1.7. **FGE.74 (EFSA-Q-2008-058)**

Consideration of Simple Aliphatic Sulfides and Thiols evaluated by JECFA (61st meeting).

The Panel has reservations for 3-mercapto-2-methylpentanal [FL-no: 12.239] as the stereoisomeric composition has not been specified.

The Panel concluded that 2-methyl-4-oxopentane-2-thiol [FL-no: 12.169] and 2-mercapto-2-methylpentan-1-ol [FL-no: 12.241] should not be evaluated through the Procedure, as they are structurally related to 2-methylpropane-2-thiol [FL-no: 12.174], methyl methanethiosulphonate [FL-no: 12.159] and 2,4,4-trimethyl-1,3-oxathiane [FL-no: 16.057] for which the Panel has previously concluded that they could not be evaluated through the Procedure due to concern with respect to genotoxicity *in vitro*. For these substances *in vivo* genotoxicity data are needed.

The Panel further concluded that the remaining candidate substances would present no safety concern at the level of intake estimated on the basis of the MSDI approach.

The draft opinion was adopted. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

9.1.8. **FGE.76 (EFSA-Q-2008-060)**

Consideration of sulphur-containing heterocyclic compounds evaluated by JECFA (59th meeting).

The Panel considered the following substances, thiazole [FL-no: 15.028], 2-(sec-butyl)-4,5-dimethyl-3-thiazoline [FL-no: 15.029], 4,5-dimethyl-2-ethyl-3-thiazoline [FL-no: 15.030] and 4,5-dimethyl-2-isobutyl-3-thiazoline [FL-no: 15.032] to have genotoxic potential, and therefore the Panel decided that the Procedure should not be applied to these four flavouring substances until adequate *in vivo* genotoxicity data become available. Additionally, the Panel noted the presence of a terminal conjugated double bond in the substances 2,4-dimethyl-5-vinylthiazole [FL-no:15.005] and 4-methyl-5-vinylthiazole [FL-no:15.018], which raised concern for genotoxicity. The Panel decided that the Procedure should also not be applied to these two substances until genotoxicity data become available.

Following application of the Procedure, the Panel considers that for the substances 2,4,6-trimethyldihydro-1,3,5(4H)-dithiazine [FL-no: 15.109] and 5,6-dihydro-2,4,6, tris(2-methylpropyl)4H-,3,5-dithiazine [FL-no: 15.113] there are insufficient data available to provide margins of safety from their use as flavouring substances and that additional toxicity data are needed.

For eight substances [FL-no: 15.002, 15.005, 15.008, 15.027, 15.029, 15.030, 15.109 and 15.113] EU production figures are needed in order to finalise the evaluation of these substances.

For five substances [FL-no: 15.022, 15.029, 15.030, 15.109 and 15.113] no information on the isomeric composition has been given, and for [FL-no: 15.113] further information on the stereoisomeric composition is requested.

The Panel further concluded that the remaining candidate substances would present no safety concern at the levels of intake estimated on the basis of the MSDI approach.

The opinion was adopted subject to the proposed changes. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm.

9.1.9. ***FGE.77 (EFSA-Q-2008-061)***

Consideration of Pyridine, Pyrrole and Quinoline Derivatives evaluated by JECFA (63rd meeting).

The Panel concluded that 6-methylquinoline [FL-no: 14.042] should not be evaluated through the Procedure due to concern with respect to genotoxicity *in vitro*. For this substance *in vivo* genotoxicity data are needed.

For pyrrole and the five pyrrole derivatives and for isoquinoline [FL-no: 13.134, 14.001, 14.041, 14.045, 14.046, 14.047 and 14.068] NOAELs could not be derived for the substances as such or for structurally related substances. Accordingly, additional toxicological data are required for these seven substances. For the remaining nine substances NOAELs could be derived to provide adequate margins of safety to the estimated level of intakes as flavouring substance.

For four substances [FL-no: 14.045, 14.058, 14.059 and 14.164] EU production figures are needed in order to finalise the evaluation of these substances. Six substances lack data on solubility in water [FL-no: 13.134, 14.007, 14.030, 14.038, 14.045, and 14.046], for which the Panel has reservations.

For the remaining substances the Panel concluded there was no safety concern at the levels of intake estimated on the basis of the MSDI approach.

The opinion was adopted subject to the proposed changes. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm.

9.1.10. **FGE.84 (EFSA-Q-2008-068)**

Consideration of Anthranilate derivatives evaluated by JECFA (65th meeting).

The draft opinion was deferred back to the FLAVIS Working Group for a closer look at the hydrolysis of the three amides.

9.1.11. **FGE.34 (EFSA-Q-2008-038)** (Not on the original draft Agenda)

One tetrahydroquinoline derivative from chemical group 28.

The draft opinion was presented and discussed.

For the candidate substance 1,2,3,4-tetrahydro-6-methylquinoline [FL-no: 14.149] no toxicity data were available or for any sufficiently structurally related substances. Therefore the Panel concluded that additional data are required for the candidate substance or for sufficiently structurally related substances.

The opinion was adopted. The full opinion will be published on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm.

10. FOOD CONTACT MATERIALS

10.1. Evaluation of substances for the 18th list of monomers and additives

The draft opinions on the following substances were discussed, modified and adopted:

Ref. No.:	18117
Name of the substance:	Glycolic acid
CAS number:	79-14-1
SCF_List:	3
Restriction:	Only to be used behind a PET layer
Remark for Commission:	None
Ref. No.:	40155
Name of the substance:	N,N'-Bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N'-diformylhexamethylenediamine
CAS number:	124172-53-8
SCF_List:	3
Restriction:	0.05 mg/kg food
Remark for Commission:	Migration from polyolefines may exceed this restriction Migration into fatty foods may exceed this restriction

Ref. No.: 62215
Name of the substance: Iron
CAS number: 7439-89-6
SCF_List: 3
Restriction: None
Remark for Commission: The substance is intended for use in PET based food contact materials

Ref. No.: 72141
Name of the substance: 2,2'-(1,4-Phenylene)bis[4H-3,1-benzoxazin-4-one]
CAS number: 18600-59-4
SCF_List: 3
Restriction: 0.05 mg/kg food, including hydrolysis products
Remark for Commission: Fat consumption Reduction Factor (FRF) is applicable

Ref. No.: 76807
Name of the substance: Polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol
CAS number: 073018-26-5
SCF_List: 2
Restriction: Group-TDI: 0.5 mg/kg .b.w. (with Ref. Nos. 76780, 76790, 76866)
Remark for Commission: FRF is applicable

Ref. No.: 92200
Name of the substance: Terephthalic acid, bis(2-ethylhexyl)ester
CAS number: 6422-86-2
SCF_List: 2
Restriction: TDI = 1 mg/kg bw
Remark for Commission: None

The full opinions as adopted can be seen on:

http://www.efsa.europa.eu/EFSA/ScientificPanels/AFC/efsa_locale-1178620753812_Opinions425.htm

The opinion on the substance Polyethyleneglycol (EO = 1-50) ethers of linear and branched C₈ - C₂₂ alcohols, REF. No, 77708, was deferred to the next meeting.

11. ANY OTHER BUSINESS

None.