EFSA
European Food Safety Authority

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MINUTES OF THE 20TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD

Held in Parma on 28-30 November 2006

Adopted on 26 January 2007 by written procedure

AGENDA:

MINUTES OF THE 20TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD (AFC) Held in Parma on 28-30 November 2006

PARTICIPANTS

Panel Members:
Herman Autrup (1st and 2nd day), Susan Barlow (Chair), Laurence Castle (2nd and 3rd day),Riccardo Crebelli (3rd day); Wolfgang Dekant (1st and 2nd day), Karl-Heinz Engel (Vice Chair) (2nd and 3rd day), David Gott, Rainer Gürtler (1st and 2nd day), John Christian Larsen (Vice Chair) (2nd and 3rd day), Jean-Charles Leblanc, Catherine Leclercq, F. Xavier Malcata, Wim C. Mennes, Maria Rosaria Milana (1st and 2nd day), Iona Pratt (2nd and 3rd day), Ivonne Rietjens, Paul Tobback, Fidel Toldrá.

Experts:
J. Gry (item 10).

Apologies
Fernando Aguilar, Nathalie Gontard, Sandro Grilli.

EFSA
Torben Hallas-Møller (scientific co-ordinator of AFC Panel), Hugues Kenigswald (assistant scientific co-ordinator of AFC Panel), Kim Rygaard Nielsen (assistant scientific co-ordinator of AFC Panel), Dimitrios Spyropoulos (assistant scientific co-ordinator of AFC Panel); Anne Theobald (assistant scientific co-ordinator of AFC Panel); Ilse Koenig (administrative assistant of AFC Panel), Hanne Pedersen (administrative secretary of AFC Panel), Maud Pâques (administrative secretary of AFC Panel).

Commission
Xavier Pavard (DG Health and Consumer Affairs).

1. WELCOME; APOLOGIES FOR ABSENCE

The chair welcomed the participants and the secretariat noted apologies.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. MEETING WITH THE EXECUTIVE DIRECTOR CATHERINE GESLAIN-LANÉELLE

The new Executive Director, Catherine Geslain-Lanéelle (CGL), presented herself and explained the main issues and priorities of EFSA. The need to further develop scientific cooperation and networking with Member States was highlighted. CGL stressed that she was aware that the AFC Panel had one of the highest workloads of the EFSA Panels.

4. DECLARATIONS OF INTEREST

The declarations concerning items on the agenda of this meeting are noted under the specific item on flavouring group evaluation (item 10.2) and food contact materials (bisphenol-A (item 11.1)).

5. MATTERS ARISING FROM THE 19TH PLENARY MEETING HELD ON 26-28 SEPTEMBER

The minutes can be seen on
http://www.efsa.europa.eu/en/science/afc/afc_meetings/afc_19th_plenmeet.html

6. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

None.

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

The chair informed the Panel on the meeting of the Scientific Committee held on 6-7 November 2006.

The secretariat informed the Panel about the recent meetings of the Management Board and the Advisory Forum.

Minutes from the meetings of the Scientific Committee can be found on:
http://www.efsa.europa.eu/science/sc_commitee/sc_meetings/catindex_en.html

Minutes from the Management Board meetings can be found on:
http://www.efsa.europa.eu/mboard/mb_meetings/catindex_en.html

Minutes from the Advisory Forum meeting held on 29 September can be found on
http://www.efsa.europa.eu/advisory_forum/adv_meetings/catindex_en.html

8. FOOD ADDITIVES

8.1. Polyethylene glycol (PEG) as coating agent for food supplements (EFSA-Q-2005-277)

The draft opinion was discussed and a number of revisions were agreed to the text. The opinion was adopted.

The Panel considered that even when assuming similar conservative levels of use and intake of pharmaceutical products and food supplements, the estimated daily intakes of the polyethylene glycols from these combined uses were below the ADI of 0-10 mg/kg body weight allocated by JECFA and the group TDI of 5 mg/kg body weight established by the SCF for the polyethylene glycols.

Therefore, the Panel concluded that overall the data support the conclusion that consumption of polyethylene glycols (PEG 400, PEG 3000, PEG 3350, PEG 4000, PEG 6000, and PEG 8000) used as plasticizers in film-coating formulations for food supplement tablets and/or capsules at the intended use level are not of safety concern.

The full opinion can be seen on
http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej414_polyethyleneglycol.html

8.2. Formaldehyde in food additives (EFSA-Q-2005-032)

The draft opinion on residual levels of formaldehyde in gelling additives was discussed and a number of revisions were agreed to the text. The opinion was adopted.

The Panel examined recent and previous evaluations of formaldehyde and concluded that there is no evidence indicating that formaldehyde is carcinogenic by the oral route.

The Panel considered a conservative exposure scenario which assumes that an adult could eat 1 kg of food per day containing 2 % of any gelling agent containing 50 mg formaldehyde/kg. Under these conditions formaldehyde exposure levels would be 1 mg per person per day or for a 60 kg individual approximately 17 µg/kg bw/day.

Considering that the potential dietary exposures estimates remain low compared to the toxicological reference values (Tolerable Daily Intake value of 150 µg/kg body weight set by WHO) and that no systemic exposure to formaldehyde would be expected at the estimated residual levels, the Panel estimates that exposure to gelling additives containing residual formaldehyde at levels up to 50 mg/kg of additive would be of no safety concern.

The full opinion can be seen on
http://www.efsa.europa.eu/en/science/afc/afc_opinions/ej415_formaldehyde.html

8.3. 1,2-Benzisothiazolin-3-one (BIT) in saccharin (EFSA-Q-2004-133)

The draft opinion was discussed and a number of revisions were agreed to the text. The opinion was adopted.

Results from analyses have demonstrated the presence of BIT in some samples of commercial saccharin at concentrations in the range of 40-800 mg/kg, with an average value of 200 mg/kg.

The Panel has estimated the intake of BIT from consumption of saccharin at the Acceptable Daily Intake (ADI) for sodium saccharin of 0-5 mg/kg bw and assuming this saccharin contained BIT at the highest reported concentration (800 mg/kg). Using these assumptions an intake of 0.004 mg BIT/kg body weight/day would result.

The Panel concluded that even the highest levels of BIT detected in these samples do not represent a safety concern.

Following a question from the Panel on the existence of a legal requirement for the assessment of the safety of impurities that may be linked to differences in the manufacturing process of additives, the European Commission clarified that it is laid down in the legislation

that if the production method or starting materials are different from those included in the evaluation of the EFSA (SCF) or different from those mentioned in the Directive authorizing the food additives, the food additives shall be submitted for the purposes of a full evaluation with emphasis on the purity criteria.

The full opinion can be seen on http://www.efsa.europa.eu/en/science/afc/afc_opinions.html

8.4. Re-evaluation of food colours – clarification of procedure

The item was not discussed because of lack of time.

9. NUTRIENT SOURCES

No items on the agenda

10. FLAVOURINGS

10.1. Camphor (EFSA-Q-2003-144)

The draft opinion was deferred to next meeting.

10.2. Flavouring group evaluations

I. 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 for the particular flavouring groups under evaluation at this meeting, it was decided that she should not participate in the discussion on flavouring group evaluations.

10.2.1. FGE.21. (EFSA-Q-2003-164)

Thiazoles, thiophene, thiazoline and thienyl derivatives from chemical group 29.
Miscellaneous substances from chemical group 30.

The draft opinion was presented by J. Gry. Concern was raised for some of the thiazoles and thiazolines especially with respect to genotoxicity. These issues will be further discussed at the next Flavouring Working Group Meeting in January 2007 and presented at the next Plenary Meeting in February 2007.

10.2.2. FGE.23 (EFSA-Q-2003-166)

Aliphatic, alicyclic and aromatic ethers including anisole derivatives from chemical groups 15, 16 and 26.

The draft opinion was presented by J. Gry. There were only minor comments to the draft opinion, which was adopted.

The full opinion will be published on
http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

10.2.3. FGE.19 (EFSA-Q-2003-162)

Discussion paper on the use of the (Quantitative) Structure Activity Relationship ((Q)SAR) method in the evaluation of alpha-, beta-unsaturated carbonyls.

The topic was extensively discussed and doubt was raised concerning the possibility of progressing a substance through the procedure only on basis of a negative (Q)SAR result.
It was concluded that the (Q)SAR approach could be a useful additional tool for estimation of the genotoxicity potential, at least in prioritizing any compounds which may give structural alert for genotoxicity. The Flavourings Working Group was asked to continue the work with the ad hoc experts on the QSAR approach.

10.3. Time frame for remaining flavouring evaluations

J. Gry gave an overview of the number of remaining flavouring substances to be evaluated or considered in 2007 and a proposal for a time frame.

Overview:

Groups	***No. of group evaluations***	***No. of substances***
FGE 04	1	4
FGE 08	1	52
FGE 19	1	265 (of which 190 are "JECFA compounds"
FGE 21	1	54
JECFA evaluated compounds to be considered	37	911
FGE revision	21	663 (530 formerly evaluated "EFSA compounds" + 133 "new" compounds)
FGE x ("confidential compounds")	8	19
FGE y ("new compounds")	8	23
FGE z ("priority compounds")		1 (vinyl benzene)

In order to ensure that the evaluations on flavourings were completed by the deadline it was decided to extend the next Plenary Meeting in February 2007 with half a day.

The possibility to extend the Plenary Meetings in April and July 2007 with a half day will be discussed at the February Plenary Meeting. If necessary the possibility to extend the meeting with a Friday will be considered as well.

In addition, an extra Plenary Meeting was agreed on 15-16 May 2007.

11. FOOD CONTACT MATERIALS

11.1. Bisphenol-A (EFSA-Q-2005-100)

The following members of the Panel declared an interest:

Ivonne Rietjens because her associate professor carries out research on bisphenol-A (BPA) funded by the Netherlands Organization for Health Research and Development. David Gott was a member of the secretariat in the English scientific committee which evaluated BPA. Maria Rosaria Milana has provided scientific advice to her national management authority on BPA. Wim Mennes had participated in European Chemicals Bureau's meetings for the EU RAR on BPA. Laurence Castle expressed an interest because his laboratory had performed analyses for bisphenol-A migration in the past.

None of these was considered as a conflict of interest and they were all invited to participate in the discussions.

The draft opinion which included the recently finalised 2-generation reproductive study on mice was discussed and changes to the text were noted. Subject to these changes, the opinion was adopted in principle. It was agreed that the draft opinion would be circulated to the members of the Panel for any final editorial remarks regarding mainly the Summary and the Conclusions of the opinion.

The Panel's conclusions are based on the now available, extensive database on repeated-dose toxicity, reproductive and developmental toxicity of BPA in rodents and on the comparison of toxicokinetics in primates, including humans, and rodents. The Panel concluded that the new studies provide a basis for revising the uncertainty factors that were used by the SCF to derive the temporary TDI of 0.01 mg/kg body weight in 2002. In particular, the Panel now considers that the database concerning reproduction and development has been considerably strengthened and that the additional uncertainty factor of 5, introduced by the SCF in 2002 for the uncertainties in the database on reproduction and development, is no longer required. The Panel also concluded, in view of the well described species differences in toxicokinetics, showing a low level of free BPA in humans compared with rats, that a default uncertainty factor of 100 applied to the overall NOAEL from the rodent studies can be considered as conservative. The Panel therefore established a full TDI of 0.05 mg BPA/kg body weight, derived by applying a 100-fold uncertainty factor to the overall NOAEL of 5 mg/kg body weight/day.

The Panel noted that the conservative estimates of exposure were less than 30% of the TDI in all population groups considered, including infants, which have the highest potential exposure on a body weight basis. These exposure estimates include BPA migration into infant formula, canned foods and into food in contact with polycarbonate table ware or storage receptacles.

The full opinion as adopted can be seen on the EFSA website at:
http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

11.2. 13th list of substances for food contact materials

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

Ref. No.:	19180
Name of the substance:	Isophthalic acid dichloride
CAS number:	99-63-8
Classified in list:	3
Restriction:	5 mg/kg food (expressed as isophthalic acid)

Ref. No.:	26305
Name of the substance:	Vinyltriethoxysilane
CAS number:	78-08-0
Classified in list:	3
Restriction:	0.05 mg/kg of food To be used as a surface treatment agent

Ref. No.:	48960
Name of the substance:	9,10-dihydroxy stearic acid and its oligomers
CAS number:	
Classified in list:	3
Restriction:	5 mg/kg food

Ref. No.:	53670
Name of the substance:	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]
CAS number:	32509-66-33
Classified in list:	2
Restriction:	TDI = 0.1 mg/kg bw

Ref. No.:	60025
Name of the substance:	Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene
CAS number:	-
Classified in list:	3
Restriction:	None

Ref. No.:	72081/10
Name of the substance:	Petroleum Hydrocarbon Resins (hydrogenated)
CAS number:	-
Classified in list:	3
Restriction:	None

Ref. No.:	77732
Name of the substance:	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/kg of food Only for the requested use in PET

Ref. No.:	77733
Name of the substance:	Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/kg food. Only for the requested use in PET

Ref. No.:	79985
Name of the substance:	Poly(ethylene propylene)glycol tridecyl ether
CAS number:	61725-89-1 and 65150-81-4
Classified in list:	3
Restriction:	0.05 mg/kg food To be used in PTFE items sintered at high temperatures

Ref. No.:	95858
Name of the substance:	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/food Not to be used for articles in contact with fatty foods.

The full opinion as adopted can be seen on the EFSA website at:
http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

12. PROCEDURE FOR HANDLING URGENT QUESTIONS

A proposal for a quick procedure for handling urgent questions was considered. The proposal was agreed, with some suggested changes and will be forwarded to the Scientific Committee who will decide the procedure for all EFSA Panels.

13. ANY OTHER BUSINESS

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