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MINUTES OF THE 10TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD Held in Brussels on 22-23 February 2005

(The minutes were adopted on 27 April 2005)

AGENDA:

MINUTES OF THE 10TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD (AFC) Held in Brussels on 22-23 February 2005

PARTICIPANTS

Panel Members:
Susan Barlow (chair); Dimitrios Boskou; Laurence Castle; Riccardo Crebelli; Wolfgang Dekant; Karl-Heinz Engel; Werner Grunow (2nd vice chair); Marina Heinonen; John Christian Larsen (1st vice chair); Catherine Leclercq; Wim C. Mennes; Maria Rosaria Milana, Iona Pratt; Kettil Svensson; Paul Tobback; Fidel Toldrá.

Experts
Jean-Claude Lhuguenot (1st day); Jørn Gry; Alicja Mortensen (2nd day); Rainer Gürtler.

Apologies
Robert Anton, Ivonne Rietjens, Stephen Forsythe

EFSA
Torben Hallas-Møller (scientific co-ordinator of AFC Panel), Dimitrios Spyropoulos (assistant scientific co-ordinator of AFC Panel), Anne Théobald (assistant scientific co-ordinator of AFC Panel), Lourdes Suarez Gonzalez (assistant scientific co-ordinator of AFC Panel), Hanne Pedersen and Sandra Desmedt (administrative secretaries of AFC Panel), Ilse Koenig (administrative assistant of AFC Panel).

Commission
Almut Bitterhof; Annette Schäfer (1st day); Olga Solomon (2nd day); Sirkku Heinimaa (2nd day); Mark Willis (2nd day).

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the members and others attending from EFSA and the Commission.

Apologies were noted.

2. ADOPTION OF THE AGENDA

The agenda was adopted.

3. DECLARATIONS OF INTEREST

These are noted under the specific item on di-butyl phthalate (item 10.3).

4. MATTERS ARISING FROM THE 9TH PLENARY MEETING ON 7-9 DECEMBER 2004

Action points were noted. The minutes were adopted and can be seen on http://www.efsa.eu.int/science/afc/afc_meetings/728_en.html

The secretariat informed Members of EFSA's rationale for the release of a press release on the flavouring group evaluations.

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

The relocation of EFSA to Parma had commenced in November and the AFC Secretariat were still scheduled to move in March.

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

The Chair informed of the latest meeting of the Scientific Committee held on 15-16 December 2004. Main issues were Food and feed safety and the use of animals as well as botanicals. Also the interface between risk assessment and risk management and transparency in risk assessment were discussed.

Further details can be found in the minutes from the SC meeting:
http://www.efsa.eu.int/science/sc_commitee/sc_meetings/738_en.html

7. FOOD ADDITIVES

7.1. Propan-2-ol.

The rapporteur introduced a draft opinion and there was extensive discussion of this draft. A number of revisions were agreed to the text and subject to these revisions the opinion was adopted.

The Panel allocated an ADI of 2.4 mg/kg bw/day based on the no observed adverse effect level (NOAEL) of 240 mg/kg bw/day for maternal toxicity in rabbits. It was noted that with the requested use levels as solvent for flavourings in soft drinks the ADI could be reached for a 60 kg adult by the daily consumption of 240 ml of soft drink, which is less than a normal sized can or bottle.

The full opinion can be found at
http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

7.2. Neotame

The rapporteur introduced a draft opinion and there was extensive discussion of this draft. A number of modifications were suggested and several clarifications of the draft opinion were requested. It was agreed that the secretariat should contact the petitioner to clarify these

questions. Meanwhile members were asked to send their comments and suggestions to the rapporteur, who would revise the draft in line with these comments for discussion at a later Plenary, when the additional information from the petitioner had arrived.

7.3. Specific enzyme preparation based on thrombin fibrinogen derived from cattle and/or pigs as a food additive for reconstituting food

The rapporteur introduced a draft opinion and there was extensive discussion of this draft. A large number of revisions were agreed and a few points still required clarification. The Secretariat was asked to contact the applicant for further information and provided it was received in time the opinion could be adopted at next meeting in April.

8. SUBSTANCES USED AS NUTRIENT SOURCES

8.1. Tocopheryl acid succinate (TAS)

The rapporteur introduced a draft opinion and there was extensive discussion of this draft. A large number of revisions were agreed to the text and it was decided that subject to these revisions the opinion should be adopted by written procedure or at the next meeting in April.

9. FLAVOURINGS

9.1. Flavouring group evaluations

The opinions on the following flavouring group evaluations (FGEs) were introduced by the rapporteur. There was extensive discussion of these drafts. A number of substantive changes to the text were agreed, together with a number of editorial changes. The Chair of the Flavourings Working Group, the Flavis Secretariat and the Panel Secretariat would revise the documents.

Note on terminal double bonds:
Terminal double bonds may be oxidized to the corresponding epoxides. Although there are ways of detoxification by conjugation with glutathione or by epoxide hydrolase- mediated hydrolysis, certain epoxides have been shown to be genotoxic/carcinogenic as demonstrated for some aliphatic alkenes like ethylene and isoprene.

Therefore the Panel has discussed whether a terminal double bond distal to a functional group, e.g. carboxylic acid, could also be considered as a structural alert for (potential) genotoxicity.

- Genotoxicity data available for seven out of 48 flavouring substances with terminal double bonds from the Register (Commission Decision 1999/217/EC of 23 February 1999. O.J. 27.3.1999, L 84, 1-137) do not indicate that a terminal double bond distal to a functional group is a structural alert for genotoxicity.

- If terminal double bonds are present in the carboxylic acid moieties, biochemical attack of these moieties via beta-oxidation is considered to be more efficient and rapid than microsomal oxidation.

Therefore the Panel concluded that the data available do not indicate that terminal double bonds distal to a carboxylic acid moiety are structural alerts for genotoxicity

9.1.1. *FGE05 Esters of 23 branched- and straight-chain aliphatic saturated primary alcohols and of one secondary alcohol, and 24 branched- and straight-chain unsaturated carboxylic acids from chemical groups 1, 2 and 5*

The Panel was asked to evaluate 24 flavouring substances in the Flavouring Group Evaluation FGE.05, using the procedure as referred to in the Commission Regulation EC No 1565/2000.
All 24 flavouring substances are expected to participate in common routes of absorption, distribution and metabolism, and exhibit similar toxicological properties. Data for short and medium length linear and branched-chain alcohols and the carboxylic acids included in the present Flavouring Group Evaluation and general information for this class of chemicals indicate that they are rapidly absorbed from the intestinal tract, metabolised and excreted, and it can be expected that the 24 esters of the group will be hydrolysed to their corresponding acids and alcohols in humans within a relatively short time.
There are three methacrylates in this group of 24 flavouring substances, i.e. ethyl methacrylate methyl methacrylate and isobutyl 2-methylprop-2-enoate which induce or are suspected to induce neurotoxicity. As no NOAEL has been established additional toxicity data are required for these three methacrylates and their evaluation has been deferred. Genotoxicity data are limited and the genotoxicity could not be assessed adequately. However, the available data as well as the chemical structures of the candidate substances do not raise concerns about genotoxicity for the flavouring substances in this group.
It is considered that on the basis of the default Maximised Survey-derived Daily Intakes (MSDIs) approach to estimate the per capita intakes of the flavouring substances in Europe, 21 of the 24 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 modified Theoretical Added Maximum Daily Intake (mTAMDI) approach based on the normal use levels reported by industry, the 24 flavouring substances the intakes exceed the threshold for the structural class, for which the flavouring has been assigned. Therefore, more reliable exposure data are required. On the basis of such additional data, these flavouring substances should be reconsidered.

The opinion was adopted and the full opinion can be found at
http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

9.1.2. *FGE.12 Primary saturated or unsaturated alicyclic alcohol, aldehyde, and esters from chemical group 7*

The Panel was asked to evaluate four flavouring substances in the Flavouring Group Evaluation FGE.12 using the procedure as referred to the Commission Regulation EC No 1565/2000.
The flavouring substances are expected to be metabolised to innocuous products at the estimated levels of use as flavouring substances.
The genotoxic potential of this group of flavouring substances cannot be assessed since there is no genotoxicity information on the candidate and supporting substances however, neither the chemical structures of the candidate substances in this group nor the metabolic data

available suggest that reactive metabolites could be generated. However the lack of genotoxicity data does not preclude applying the procedure for flavouring substances.
It is considered that on the basis of the default Maximised Survey-derived Daily Intakes (MSDIs) approach to estimate the *per capita* intakes of the flavouring substances in Europe these four 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 modified Theoretical Added Maximum Daily Intake (mTAMDI) approach based on the normal use levels reported by industry for three of the four flavouring substances considered in this opinion the intakes, estimated on the basis of the mTAMDI, exceed the relevant threshold for their structural class, to which the flavouring substance has been assigned. Therefore, for these three substances more reliable exposure data are required. On the basis of such additional data, these flavouring substances should be reconsidered.

The opinion was adopted and the full opinion can be found at
http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html

9.1.3. *FGE14 Phenethyl alcohol, aldehyde, esters, and related phenylacetic acid esters from chemical group 15*

There was insufficient time to discuss the draft opinion and this item was deferred until the next meeting.

10. FOOD CONTACT MATERIALS

10.1. Statement on Organotins

The rapporteur introduced a draft statement and there was extensive discussion of this draft. A large number of revisions were agreed to the text and subject to these revisions the opinion was adopted. The Secretariat produced a revised version during the meeting

On 22 September 2004 the Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) issued an opinion on the health risks to consumers associated with exposure to organotins in foodstuffs. In its opinion the CONTAM Panel established a group TDI of 0.0001 mg/kg bw (expressed as Sn) covering triphenyltin (TPT), tributyltin (TBT), dibutyltin (DBT) and di-n-octyltin substances (DOT). Previously, the Scientific Committee on Food had set a group-TDI of 0.0006 mg/kg bw (expressed as Sn) for di-n-octyltin compounds used in food contact materials.

The AFC Panel agrees with the group-TDI of 0.0001 mg/kg bw (as Sn) set by the CONTAM Panel and concludes that the DOT compounds used in food contact materials should be included in this group TDI.

Considering that the exposure to organotins from food contact materials may be lower than the exposure to organotins from other sources, this should be taken into account when setting specific migration limits (SMLs) for these DOT compounds.
The Panel understands that the results of ongoing studies on the exposure to organotins from FCM will be available within this year. It may then be possible to give more detailed advice.

The full statement can be found at
http://www.efsa.eu.int/science/afc/afc_documents/835_en.html

10.2. Possibility to apply for DEHA the TRF (Total Reduction Factor = DRF x FRF) of 5

There was insufficient time to discuss the draft opinion and this item was deferred until the next meeting.

10.3. Di-butyl phthalate (DBP) REF No 74880

The Chair indicated that she had an indirect interest in phthalates and would therefore vacate the Chair in favour of the 1st Vice Chair. Following consultation with the Deputy Executive Director, it was decided that although this was not a conflict of interest the Chair should not participate in the discussion. Interests (advising national authorities or conducting studies on phthalates) were also declared by the following Members; Laurence Castle, Wim Mennes; Maria Rosaria Milana, Iona Pratt and Kettil Svensson. None of these were considered conflicts of interest by the 1st Vice Chair and all were invited to participate in the discussion.

The rapporteur introduced the changes to the draft opinion and there was extensive discussion of the draft. A number of changes to the text were requested, together with a number of editorial changes. It was decided to defer the final adoption of the opinion till next meeting as it should be discussed in connection with two other phthalates with potentially the same endpoint for toxicity. It was agreed that further comments should be sent to the secretariat, which would circulate them to the rapporteur and the small support group of Panel Members.

10.4. 7th list of substances for food contact materials

The draft opinion on the following substances was modified and adopted by written procedure:

Ref. No.:	12786
Name of the substance:	3-aminopropyltriethoxysilane
CAS number:	000919-30-2
Classified in list:	3
Restriction:	Residual extractable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler.

Ref. No.:	66350
Name of the substance:	2,2'-Methylenebis(4,6-di-tert-butylphenyl) lithium phosphate
CAS number:	85209-93-4
Classified in list:	3
Restriction:	5 mg/kg food

Ref. No.:	66905
Name of the substance:	N-methyl-2-pyrrolidone
CAS number:	872-50-4
Classified in list:	2
Restriction:	None

Ref. No.:	76845

Name of the substance:	Polyester of 1,4-butanediol with caprolactone
CAS number:	31831-53-5
Classified in list:	3
Restriction:	None

Ref. No.:	86437
Name of the substance:	Silver Zeolite A (Silver zinc sodium ammonium alumino silicate), silver content 2 – 5 %
CAS number:	-
Classified in list:	3
Restriction:	Group restriction: 0.05 mg Ag/kg food, based on the human NOAEL of about 10 g of silver for a total lifetime oral intake allocated by WHO (WHO, 2004) for drinking water. Maximum content in polymer: 10% (w/w) of silver zeolite A containing ≤ 5% silver. Only for repeated use articles made from polyolefins (up to 40°C for contact times below 1 day) and for poly(alkylene terephthalate) based polymers (up to 99°C for contact times below 2 hours)

Ref. No.:	86437/50
Name of the substance:	Silver-zinc- aluminium – boron – phosphate glass, mixed with 5-20% barium sulphate, silver content 0.35 – 0.6 %
CAS number:	-
Classified in list:	3
Restriction:	Group restriction: 0.05 mg Ag/kg food, based on the human NOAEL of about 10 g of silver for a total lifetime oral intake allocated by WHO (WHO, 2004) for drinking water. Group restriction: 1 mg Ba/kg food Group restriction: 6 mg B/kg food Maximum content in plastic: 1% (w/w)

Ref. No.:	86438 and 86438/50
Name of the substance:	REF No. 86438: Silver zinc zeolite A (silver-zinc sodium alumino silicate calcium metaphosphate), silver content 1 -1.6 % REF No. 86438/50:Silver zinc zeolite A (silver-zinc sodium magnesium alumino silicate calcium phosphate), silver content 0.34 - 0.54 %
CAS number:	-
Classified in list:	3
Restriction:	Group restriction: 0.05 mg Ag/kg of food, based on the human NOAEL of about 10 g of silver for a total lifetime oral intake allocated by WHO (WHO, 2004) for drinking water.

The full opinion can be found at
http://www.efsa.eu.int/science/afc/afc_opinions/890_en.html

The following substances were deferred until the next plenary:

Ref. No.:	47500

Name of the substance:	N,N'-dicyclohexyl-2,6-naphthalene dicarboxamide
CAS number:	153250-52-3
Ref. No.:	67360 and 47600
Name of the substance:	Mono-n-dodecyltin tris(isooctyl mercaptoacetate) and Di-n-dodecyltin bis(isooctyl mercaptoacetate)
CAS number:	067649-65-4 and 084030-61-5
Ref. No.:	72081/10
Name of the substance:	Petroleum hydrocarbon resins (hydrogenated)
CAS number:	088526-47-0

11. SEMICARBAZIDE

The rapporteur presented the draft opinion and it was discussed and changes were suggested. The members were asked to send their comments and suggestions to the rapporteur in writing and a revised draft would be discussed at the next meeting.

12. WORKING PROGRAMME

Since the last meeting of the Panel the following questions have been received from the Commission. There had been 3 petitions for evaluation and re-evaluations of substances in FCM.

The updated register of questions can be seen on the EFSA website at http://www.efsa.eu.int/register/qr_panels_en.html.

13. ANY OTHER BUSINESS

There was no further business.