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MINUTES OF THE 5TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD Held in Brussels on 17-18 February 2004

(the minutes were adopted on 29 March 2004 by written procedure)

AGENDA:

MINUTES OF THE 5TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD (AFC) Held in Brussels on 17-18 February 2004

PARTICIPANTS

Panel Members:
Susan Barlow (chair); Dimitrios Boskou; Laurence Castle; Riccardo Crebelli; Karl-Heinz Engel; Werner Grunow (2nd vice chair); John Christian Larsen (1st vice chair); Catherine Leclercq; Wim C. Mennes; Maria Rosaria Milana; Ivonne Rietjens; Kettil Svensson; Paul Tobback;

Experts
Jørn Gry (2nd day); Bevan Moseley (2nd day) Andreu Palou (1st day)

Apologies
Robert Anton; Wolfgang Dekant; Stephen Forsythe; Fidel Toldrá

EFSA
Torben Hallas-Møller (scientific co-ordinator of AFC Panel), Dimitrios Spyropoulos (assistant scientific co-ordinator of AFC Panel), David Gott (assistant scientific co-ordinator of AFC Panel), Hanne Pedersen (administrative secretary of AFC Panel), Carola Sonderman (Senior Press Officer)

Commission
Taina Säteri; Helen Lee (1st day); Sirkku Heinimaa (1st day); Annette Schäfer (2nd day); Wim Debeuckelaere (2nd day) (DG Health and Consumer Protection)

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 with the addition of item 7.3.

3. DECLARATIONS OF INTEREST

K.H. Engel declared an interest in item 8.1. It was decided that he would not participate in the discussion of that substance. It was agreed that companies involved in submissions should be identified in working documents whenever possible to facilitate recognition of potential conflicts of interest. Working Group (WG) Chairs were asked to bring this to the attention of rapporteurs.

4. MATTERS ARISING FROM THE 4TH PLENARY MEETING ON 9-10 DECEMBER 2003

Action points were noted.

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

The members were introduced to the new staff in the AFC secretariat, Sandra Desmedt, an administrative secretary, and Dr David Gott, a detached national expert from the UK Food Standards Agency, to Carola Sonderman from EFSA Communications and to Wim Debeuckelaere from the Commission who had recently taken over responsibility for flavouring substances.

A new call for expressions of interest in membership of some Panels, including AFC, has been published with a deadline of 15 March.

Progress on the relocation of EFSA to Parma was outlined. As part of this process it was envisaged that Panels would hold some meetings in Parma during 2004. It was suggested that consideration should be given to holding the October or December AFC plenary in Parma. Members noted that additional time was likely to be required for travelling to Parma which needed to be considered in planning meetings for 2005 and that meetings may need to be longer but less frequent. Members suggested that more effective use of electronic procedures might alleviate some of the perceived difficulties.

S Heinimaa informed the meeting of preparations for amending the Food Additives Directive with respect to nitrite/nitrate and other recent opinions of the SCF which are not currently reflected in legislation.

6. FEEDBACK FROM SCIENTIFIC COMMITTEE MEETING HELD ON 18-19 NOVEMBER

The members were informed of the main items discussed at the meeting of the Scientific Committee (SC) held since AFC last met on 15 January 2004.

The Management Board had expressed concerns about the very high work loads of some of the Scientific Panels. There was a need for discussions between EFSA and the Commission on the prioritisation of work. Panels were reminded that they were able to seek external comment on draft opinions where this would be of benefit. It was noted that this would be more applicable to generic issues such as guidelines than opinions on individual substances. Members were informed that the Scientific Committee would be establishing a WG on the benchmark dose approach.

Further details can been found in the minutes from the SC meeting:

http://www.efsa.eu.int/science/sci_commitee/sci_meetings/144/minutes_sci_05_adopted_en1.pdf

7. FOOD ADDITIVES

7.1. Ethyl cellulose

The draft opinion was discussed and modified. Ethyl cellulose was evaluated on the basis of the safety data of the whole group of closely related cellulose derivatives. Following consideration of the strong hydrophobic character of ethyl cellulose together with its high molecular mass (above 500 kD), the Panel considered that ethyl cellulose would pass essentially unchanged through the gastrointestinal tract following oral ingestion and that adverse effects were unlikely. The AFC Panel decided to include ethyl cellulose in the group ADI "not specified" for modified celluloses established by the SCF in 1992 (published in the 32nd report series in 1994).

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

7.2. Re-evaluation of food additives

Members were reminded that proposed legislation will require re-evaluation of food additives. Discussions on the time-scale for re-evaluations of food additives under the proposed revisions to the Framework Directive on Food Additives were on-going. The Secretariat informed the Panel that they had already received specific requests for the re-evaluation of food additives. It would be essential to confirm before any re-evaluation that the additive was still used. The Chair and Secretariat had arranged to meet the Commission to discuss and prioritise the re-evaluation task. There was a need to develop a strategy and provide guidance on the information required. There was a brief discussion outlining several of the issues and concerns. In view of the amount of work involved, it was likely that outside contractors would be needed, to prepare working documents. It was agreed that development of this strategy should be considered initially in the Additives WG before discussion in the plenary.

7.3. Food additives prepared from GMO's

The GM Panel had been asked to develop guidance to applicants for the preparation and presentation of GM food and feed applications including additives. A WG would be established to develop this guidance and they were seeking members to assist in this process and ensure these were compatible with and complemented the existing guidelines on toxicology. Members noted that the guidance would cover both current additives produced by GMOs and new additives which might have different requirements. It was agreed to seek volunteers from the Additives WG to participate in this task.

8. SOME SUBSTANCES USED AS NUTRIENT SOURCES

8.1. Creatine monohydrate

The draft opinion was discussed at some length. The AFC Panel concluded that the safety and bioavailability of creatine monohydrate as source of creatine is not a matter of concern, provided that there is adequate control of the purity of this source of creatine with respect to dicyandiamide and dihydrotriazine derivatives.

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

The Panel wished to draw the attention to the previous opinion of the Scientific Committee on Food on safety aspects of creatine supplementation, where it concluded that high loading doses of creatine should be avoided, while consumption of lower doses of around 2-3 g/day are similar to the daily turnover rate of 1-2 g/day and are unlikely to pose any risk. The Panel endorsed this view.

This SCF opinion can be found at http://europa.eu.int/comm/food/fs/sc/scf/out70_en.pdf

8.2. Lycopene

The draft opinion was discussed and modified. The rapporteur drew attention to the additional references on lycopene toxicity, which had not been submitted by the petitioner but which had been identified since the draft was last discussed in the Additives WG. Although the available information suggested these references would not change the conclusions, it was desirable to confirm this directly from the references. Provided this could be confirmed by the WG, the opinion could then be agreed by the written procedure.

The Secretariat would write to the petitioner drawing attention to these deficiencies and the requirements in the guidelines to provide relevant references and undertake a literature search.

9. FLAVOURINGS

9.1. Exposure estimates used in flavourings evaluation.

The chair of the Flavourings WG briefly introduced the approach to exposure estimation currently used by the WG in the evaluation of chemically-related groups of flavouring substances and its history of use in other fora. He also described some of the approaches previously suggested by the Scientific Committee for Food for refinement of the procedure. The Panel was given a presentation describing the current and possible alternative approaches to exposure estimation for flavouring compounds, and illustrating the differences in intake estimates for an individual flavouring substance that can be obtained using the modified *per capita* approach compared with estimates made using information on maximum use levels in particular food categories. It was noted that concerns about the current approach had been expressed in the SC Exposure WG.

Members noted that these issues had also been discussed extensively in other fora involved in the evaluation of flavouring substances. There was an extensive discussion of the method of exposure estimation used in the flavouring group evaluations. The Panel recognised that there remained concerns over exposure estimation which needed to be addressed and noted the offer of assistance from the SC Exposure WG but considered that any request to them should await discussion of exposure estimation methods at the forthcoming flavours WG.

9.2. Flavouring Group Evaluation 3

The Panel was introduced to the general scheme for the evaluation of chemically-related groups of flavouring substances and to the draft opinion on the flavouring group 3: acetals of branched- and straight-chain aliphatic saturated primary alcohols and branched- and straight-chain saturated aldehydes, and an orthoester of formic acid from chemical groups 1 and 2 (FGE.03). A number of modifications were made to the draft opinion. It was agreed to

defer adoption of this opinion until after discussion of exposure estimates by the flavours WG.

10. FOOD CONTACT MATERIALS

10.1. Use of biocides in food contact materials

The meeting was reminded of the background to the development of the guidelines for the assessment of the microbiological properties of a biocidal substance incorporated into a food contact material. The requirements of these guidelines and the rationale for their inclusion were outlined, together with possible limitations of some of the test methods used. The key elements of the guidance are: intended use, spectrum of activity, use level, possible consequences of biocide use, efficacy and lack of effect on food. Members noted that there could be additional concerns with these materials outwith the remit of the AFC Panel.

The guidelines can be seen in their entirety in section 7 of Chapter 3 of the note for guidance on Food Contact Materials at
http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/note_guidance_en.pdf

10.2. 3rd list of substances for food contact materials

The draft opinion on the following substance was modified and adopted.

Ref. No.:	93930
Name of the substance:	2,4,4'-Trichloro-2'-hydroxydiphenyl ether (triclosan)
CAS number:	3380-34-5
Classified in list:	3
Restriction:	5 mg/kg of food

It was agreed that the draft opinions on the following substances should be adopted by the written procedure.

Ref. No.:	80000
Name of the substance:	Polyethylene wax
CAS number:	9002-88-4
Classified in list:	3
Restriction:	None

Ref. No.:	81060
Name of the substance:	Polypropylene wax
CAS number:	009003-07-0
Classified in list:	3
Restriction:	None

The full opinion can be seen on http://www.efsa.eu.int/science/afc/afc_opinions/11_en.html

10.3. Use of previous data in re-evaluations

There was insufficient time remaining for detailed discussion of this item. The Panels initial view was that it was for petitioners, not the Panel, to agree on any data sharing, however the Secretariat will redistribute the paper for further comments by the written procedure.

11. OTHER ITEMS WITHIN THE REMIT OF THE PANEL

11.1. Semicarbazide

The Commission informed the Panel that the Standing Committee on the food chain and animal health has adopted a directive to phase out the use of azodicarbonamide (the precursor of semicarbazide in gaskets) for use in materials in contact with food http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_007/l_00720040113en00450046.pdf.

The Panel reviewed a report of a recent mouse unscheduled DNA synthesis (UDS) assay on semicarbazide and considered the results of this study, albeit negative, would not alter the overall evaluation. Industry intends to publish these and other genotoxicity data. The panel noted recent Spanish data reporting semicarbazide levels in food and that further details of this study and any other relevant information should be requested for the WG meeting on March 26.

11.2. Acceptance of studies from non-GLP certified laboratories

As required in the current guidelines, newly commissioned routine toxicological studies to standard protocols in compliance with OECD guidelines would be unacceptable unless complying with GLP principles and conducted in GLP-certified laboratories. The Panel noted that they would not require chemical analyses to be conducted in GLP-certified laboratories provided analytical validation could be demonstrated. The Panel also noted that while research studies were not performed under GLP, relevant research could be included in an opinion, as could relevant toxicological studies conducted before GLP was widely adopted.

12. WORKING PROGRAMME

The updated register of questions can be seen on the EFSA website.

13. ANY OTHER BUSINESS

None.