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MINUTES OF THE 7TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD Held in Brussels on 12-13 July 2004

(the minutes were adopted on 9 September 2004 by written procedure)

AGENDA:

Provisional address :
Rue de Genève 10, B-1140 Bruxelles.
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MINUTES OF THE 7TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD (AFC) Held in Brussels on 12-13 July 2004

PARTICIPANTS

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

Experts
Caroline Tahourdin (2nd day); Gerrit Speijers (1st day); Rainer Gürtler (1st day); Jørn Gry (2nd day).

Apologies
Stephen Forsythe

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); Sandra Desmedt; Dirk Detken (Legal services) (1st day).

Commission
Almut Bitterhof; Olga Solomon; 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. The Chair announced that following agreement by the EFSA Management Board three new members had been appointed to join the Panel. The Chair welcomed Jayne Ireland and Iona Pratt to the Panel. Marina Heinonen will join the Panel from next Plenary.

Apologies were noted.

2. ADOPTION OF THE AGENDA

The chair informed that because of an already heavy agenda two draft opinions had been deferred from the agenda to the October meeting. These were on calcium L-5-methyl folate, and calcium sulphate.

The agenda was adopted.

3. DECLARATIONS OF INTEREST

These are noted under the specific item on pullulan (item 7.4).

4. MATTERS ARISING FROM THE 6TH PLENARY MEETING ON 28-29 APRIL 2004

Action points were noted.

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

The members were updated on the latest news concerning the relocation of EFSA to Parma.

The lease on a temporary building to house EFSA had been signed after agreement by the Management Board. The modifications to this temporary building were commencing. It was anticipated that these would be complete by October and the building would then be fitted out. The move to Parma could commence in November 2004 but would not be complete until September 2005. The AFC Secretariat expected to move around spring 2005.

Members were informed that the EFSA colloquium on dioxins and dioxin-like PCBs had taken place in June. Details of the discussions and conclusions at the colloquium could be found at http://www.efsa.eu.int/science/colloquium_series/no1_dioxins/catindex_en.html.

A report was tabled on the interface of risk assessment and risk management. The report was the outcome of a European Workshop held September 2003 (http://www.ra-rm.com/). Members would be e-mailed and comments requested

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

Due to lack of time, a brief report was tabled to inform members of the main items discussed at the meetings of the Scientific Committee held since AFC last met. Members attention was particularly drawn to the request to identify the top five emerging risks in the Panel's remit, the Secretariat were asked to e-mail Members with suggestions and to elicit further suggestions.

Further details can be found in the minutes from the SC meetings:

http://www.efsa.eu.int/science/sc_commitee/sc_meetings/244/minutes_sc_06_en1.pdf and

http://www.efsa.eu.int/science/sc_commitee/sc_meetings/419/minutes_sc_07_en1.pdf

The Management Board had met in Brussels in June. In addition to the issues mentioned above, the issue of EFSA policy on animal experimentation had been discussed.

http://www.efsa.eu.int/mboard/mb_meetings/479_en.html

7. FOOD ADDITIVES

7.1. Jelly mini-cups.

The rapporteur introduced the draft opinion for discussion. The Chair explained that the information on cases of fatalities came from a variety of internet sites belonging to national or local authorities. It was decided to remove the names of the countries involved from the text but to add citations to these reports in a footnote. A number of further editorial changes were agreed and the opinion was adopted subject to these changes.

From the data presently available, the Panel concluded that any gel-forming additive whether derived from seaweed (E400, E401, E402, E403, E404, E405, E406, E407, E407a) or from non-seaweed origin (E410, E412, E413, E414, E415, E417, E418) or of any other type that gave rise to a confectionery product of a similar size, with similar physical and/or physicochemical properties and that could be ingested in the same way as the jelly mini-cups, would give rise to a risk for choking. This risk would not necessarily be restricted to children.

The full opinion can be seen on
http://www.efsa.eu.int/science/afc/afc_opinions/522_en.html

7.2. Parabens

Directive 2003/114/EC from the Parliament and Council requires that the Commission and the European Food Safety Authority shall review the conditions for the use of additives E 214 to E 219 before 1 July 2004. http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_024/l_02420040129en00580064.pdf

The rapporteur introduced a draft opinion and highlighted the two key elements of the re-evaluation; the discussion on proliferative effects in the rat forestomach and the developmental toxicity. The rapporteur also mentioned that several papers on the interactions of parabens with estrogen receptors and effects on the male reproductive system had also been published recently. The Panel noted that information on uses and use levels in Europe was still very limited, however despite these deficiencies it was possible to base the risk assessment on exposure estimates based on wider permitted use of parabens in food in the USA. The Panel agreed a number of editorial changes and the opinion was adopted subject to these changes.

The Panel established a full group ADI of 0-10 mg/kg bw for the sum of methyl and ethyl p-hydroxybenzoic acid esters and their sodium salts on the basis of the no-observed-adverse-effect levels (NOAELs) of 1000 mg/kg bw/day for each compound in long-term toxicity studies and studies on sex hormones and the male reproductive organs in juvenile rats. The Panel considered that propyl paraben should not be included in this group ADI because propyl paraben, contrary to methyl and ethyl paraben, had effects on sex hormones and the male reproductive organs in juvenile rats.
The Panel is unable to recommend an ADI for propyl paraben because of the lack of a clear NOAEL.

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

7.3. Tertiary butylhydroquinone (TBHQ)

The rapporteur introduced the revised draft opinion requested at the previous Plenary and there was discussion of this draft. A number of further editorial changes were agreed and the opinion was adopted subject to these changes.

Based on the data reviewed, the Panel concluded that TBHQ was not carcinogenic in rats or mice and that further genotoxicity studies are unnecessary. The Panel considered the dog as the most sensitive species and allocated an Acceptable daily Intake (ADI) of 0-0.7 mg/kg bw based on a NOAEL of 72 mg/kg bw per day in dogs to which a 100-fold safety factor was applied.

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

7.4. Pullulan

Paul Tobback informed that he had been contacted by a consultant concerning pullulan. It was decided that this interest would not prevent him from remaining in the meeting and, if called upon, contributing factual information.

The rapporteur introduced the draft opinion and there was extensive discussion of this draft. The Panel noted that the product was not well defined and described in the petition but accepted that this criticism also applied to other products of a similar nature. A number of editorial changes were agreed and the opinion was adopted subject to these changes.

On the basis that pullulan is similar to other poorly digested carbohydrates and that the current proposed usage levels are below the level likely to cause abdominal fullness, the Panel considered that the expected intakes of pullulan would not present a toxicological risk when used as a substitute for gelatine in the production of capsule shells and coated tablets for dietary supplements; and as a matrix for edible flavoured films (breath fresheners).

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

7.5. Propan-2-ol

There was insufficient time to discuss this draft opinion and it was deferred until the October plenary.

7.6. Sucrose esters of fatty acids (E473)

There was insufficient time to discuss this draft opinion and it was deferred until the October plenary.

7.7. Re-evaluation of food additives

The Secretariat tabled a revised paper for information following the further detailed consideration delegated to the Additives Working Group. The strategy will be published on the Panel's website and the Secretariat will initiate the process for outsourcing the information gathering phase.

8. FLAVOURINGS

8.1. Exposure estimates used in flavourings evaluation

Karl-Heinz Engel, Chair of the Flavourings Working Group, outlined the Working Group's draft on the proposed approach to the exposure estimates for flavourings. A copy of a flavouring group evaluation FGE03 revised in line with these proposals was tabled to assist in the discussion but was not discussed in detail. A number of revisions were made to the draft and the document was agreed.

The Panel decided to supplement the previous procedure based on annual production volumes (MSDI) with a calculation of the theoretical added maximum daily intake (TAMDI) based on normal use levels rather than upper use levels and to require further data permitting a more refined intake estimate and possibly additional toxicological data in case the calculated theoretical level exceeds the human exposure threshold for the structural class to which the flavouring substance belongs.

The full text is appended to these minutes and this process will be applied to all future flavouring group evaluations.

8.2. Coumarin

The rapporteur introduced the draft opinion and there was extensive discussion of this draft. A number of substantive changes to the text were agreed, together with a number of editorial changes. The opinion would be adopted by the written procedure after these changes were incorporated.

[Note added after the meeting. Because of new information supplied during the written procedure adoption was deferred until the next Plenary meeting]

8.3. Hydrocyanic acid

There was insufficient time to discuss this draft opinion and it was deferred until the October Plenary.

8.4. Smoke flavour guidelines.

A meeting had been held between the Secretariat, the Commission and industry to ascertain the areas where industry needed further guidance. This information had been conveyed to the sub-group of the Flavourings Working Group which had met on July 8 to discuss draft guidelines on both the procedure for submission and the information required in dossiers submitted on smoke flavours. An initial draft was discussed and would be revised for further discussion in September with the aim of adoption at the October Plenary.

9. FOOD CONTACT MATERIALS

9.1. Fat (consumption) Reduction Factors for children.

The rapporteur introduced the draft opinion and it was extensively discussed. The Panel noted that the concept of fat (consumption) reduction factors was difficult and considered the initial draft did not explain the issues clearly enough. A number of important caveats to the approach were agreed. It was agreed that the rapporteur should revise the document and that subject to these changes, the opinion would be adopted by written procedure.

Post-meeting note: During the written procedure for adoption of the opinion, further substantive issues were raised that require clarification and it was decided to reconsider the opinion at a future Plenary.

9.2. 2,2-bis(4-hydroxyphenyl)propanebis(2,3-epoxypropyl)ether (BADGE)

The rapporteur introduced the draft opinion , describing the history of consideration of BADGE and BADGE derivatives in the Scientific Committee on Food, and highlighted the new information now available on carcinogenicity and genotoxicity. A number of revisions and clarifications were agreed and the opinion was adopted subject to these changes.

The Panel concluded that BADGE was not carcinogenic and established a group Tolerable Daily Intake (TDI) of 0-0.15 mg/kg bw for BADGE and its mono- and bis-diol derivatives. The Panel also concluded that BADGE chlorohydrin derivatives were not genotoxic *in vivo* and the current restriction of 1 mg/kg food remains appropriate.

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

9.3. 5th list of substances for food contact materials

There was insufficient time to discuss this draft opinion and it was deferred until the October plenary. The Panel were informed that the organotins would have to be referred back to the WG, which would need to reconsider them in light of the imminent publication of the conclusions of the Contaminants Panel on organotins.

10. SEMICARBAZIDE

Laurence Castle, Chair of the Semicarbazide Working Group briefly outlined the discussions at their second meeting. Little further information on occurrence of semicarbazide in food had been received from national authorities or industry. An opinion

was being drafted evaluating the possible sources of semicarbazide in food previously identified; gaskets, drying and/or bleaching with hypochlorite, imported flour treated with azodicarbonamide, and as a breakdown product from the illegal use of nitrofurans as veterinary drugs. The Working Group was scheduled to meet again in October.

11. WORKING PROGRAMME

Since the last meeting of the Panel the following questions have been received from the Commission. There had been 9 petitions for evaluation and re-evaluations of substances in FCM. Three other new items of work were noted; magnesium L-aspartate, change of specification for titanium dioxide, lycopene from *Blakeslea trispora*,

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

12. ANY OTHER BUSINESS

The Chair announced that due to the workload, it was planned to lengthen the next two Plenary meetings by a day and the additional dates (October 7 and December 9) were agreed.

EFSA
European Food Safety Authority

19 July 2004

EFSA/AFC/FLA/GEN/01-Rev2

ANNEX

Statement of the Scientific Panel on Food Additives, Flavourings, Processing Aids, and Materials in Contact with Food (AFC Panel)

on

Estimation of intakes in the course of the safety assessment of chemically defined flavourings (expressed on 13 July 2004)

As agreed upon in the opinion of the Scientific Committee on Food expressed on 2 December 1999, the evaluation of chemically defined flavouring substances is performed according to a stepwise approach that integrates information on intake from current uses, structure-activity relationships, metabolism and, when needed, toxicity[1]. One of the key elements in the procedure is the subdivision of flavourings into three structural classes (I, II, III) for which human exposure thresholds have been specified below which exposures are not considered to present a safety concern.

The intake estimates are based on annual production volumes of the flavouring substances as surveyed by the industry in 1995. The "Maximized Survey-Derived Daily Intake" (MSDI) is derived by assuming that the production figure only represents 60 % of the use in food due to underreporting and that 10 % of the total EU population are consumers.

The Panel noted that due to year-to-year variability in production volumes, to uncertainties in the underreporting correction factor and to uncertainties in the percentage of consumers, the reliability of intake estimates on the basis of the MSDI-approach is difficult to assess.

The Panel also noted that in contrast to the generally low per capita intake figures estimated on the basis of this MSDI-approach, in some cases the regular consumption of products flavoured at use levels reported by the flavour industry in the submissions would result in much higher intakes. In such cases, the human exposure thresholds below which exposures are not considered to present a safety concern might be exceeded.

Considering that the MSDI model may underestimate the intake of flavouring substances by certain groups of consumers, the SCF recommended to take also into account the results of other intake assessments[1].
One of the alternatives is the "Theoretical Added Maximum Daily Intake" (TAMDI)-approach which is calculated on the basis of standard portions and upper use levels[2] for flavourable beverages and foods in general, with exceptional levels for particular foods. This method is regarded as a conservative estimate of the actual intake in most consumers because it is based on

the assumption that the consumer regularly eats and drinks several food products containing the same flavouring substance at the upper use level.
One option to modify the TAMDI-approach is to base the calculation on normal rather than upper use levels of the flavouring substances. This modified approach is less conservative (e.g., it may underestimate the intake of consumers being loyal to products flavoured at the maximum use levels[3] reported. However, it is considered as a suitable tool to screen and prioritise the flavouring substances according to the need for refined intake data.

Future procedure
In accordance with the procedure suggested by the SCF[1], the Panel will continue to calculate the per capita intakes of flavouring substances on the basis of the maximized annual production volumes (MSDI-approach). In order to identify flavouring substances requiring more accurate intake data, the Panel will additionally estimate the daily intakes using a TAMDI-approach modified by basing the calculations on the normal use levels.

In cases where the intake estimated on the basis of this modified TAMDI approach exceeds the human exposure threshold for the structural class to which the flavouring substance belongs, further information would be required. This would include refined intake data and could include additional toxicological data. For example, detailed information on the use in more specified food categories should be given to allow a more reliable intake estimation. On the basis of such additional data, the indicated substances should be reconsidered along the steps of the procedure.

1 Scientific Committee on Food. Opinion on a programme for the evaluation of flavouring substances (expressed on 2 December 1999). http://europa.eu.int/comm/food/fs/sc/scf/out45_en.pdf

2 Scientific Committee for Food. First annual report on chemically defined flavouring substances. May 1995, 2nd draft prepared by the SCF Working Group on Flavoruing Substances (Submitted by the SCF Secretariat, 17 May 1995). CS/FLAV/FL/140-Rev.2. Annex 6 to Document III/5611/95, European Commission, Directorate-General III, Industry.

3 Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council.