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MINUTES OF THE 6TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD Held in Brussels on 28-29 April 2004

(the minutes were adopted on 28 May 2004 by written procedure)

AGENDA:

Provisional address :
Rue de Genève 10, B-1140 Bruxelles.
http://www.efsa.eu.int

MINUTES OF THE 6TH PLENARY MEETING OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD (AFC) Held in Brussels on 28-29 April 2004

PARTICIPANTS

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

Experts
Bevan Moseley (2nd day); Catherine Simoneau (1st day); Ron Walker (2nd day); Rainer Gürtler (1st day).

Apologies
Robert Anton; Stephen Forsythe; Maria Rosaria Milana; Ivonne Rietjens.

EFSA
Herman Koëter (Deputy Executive Director and Director of Science) (2nd day); 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); Ilse Koenig; Sandra Desmedt.

Commission
Taina Säteri; Sirkku Heinimaa (1st day); Annette Schäfer (2nd day); Wim Debeuckelaere (2nd day); Luigi Rossi (2nd day) (DG Health and Consumer Protection); L. Bouthors (DG ENTR).

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 items on furfural, pulegone and ESBO (items 9.2, 9.3 and 10.2).

4. MATTERS ARISING FROM THE 5TH PLENARY MEETING ON 17-18 FEBRUARY 2004

Action points were noted.

5. GENERAL INFORMATION FROM EFSA AND THE COMMISSION

The members were introduced to the new staff in the AFC secretariat, Ilse Koenig, an administrative assistant.

The deadline for expressions of interest in membership of some Panels, including the AFC, had expired on 15 March. For the AFC Panel around 50 applications have been accepted for evaluation and an evaluation of these individuals is ongoing. It is expected that the new members would be appointed by end of June allowing them to attend the next meeting of the Panel.

Progress on the relocation of EFSA to Parma was outlined. The Seat Agreement had been signed at the Management Board meeting in Parma on 27 May. A temporary building to house EFSA had been identified and negotiations over modifications and lease conditions were on-going. If these were successful, it was anticipated that the move to Parma could commence in the final quarter of 2004 but would not be complete until late 2005.

S Heinimaa informed the meeting of preparations for amending the Food Additives Directive.

L. Rossi informed of the current status of the Framework Directive on Food Contact Materials. This was scheduled to go to the Council meeting on 17 May for adoption. Herman Koëter informed the Panel that concerns over one article, which apparently empowers the Commission to require the Authority to withdraw its decisions or undo its acts, had been discussed by the Management Board and they would be expressing these in writing to the Council and Parliament. Members noted the time restrictions placed on the delivery of opinions in this Directive were more realistic than those in the original draft, however meeting these might not be possible on all occasions. Herman Koëter indicated that EFSA emphasised good science over meeting deadlines when addressing complex issues and that this approach had been endorsed by the Management Board. The Chair suggested that there would be a need for careful records documenting when the clock stopped following requests for further information.

Herman Koëter introduced the latest thinking within EFSA on the guidance on declaration of interests.

Members were informed of the EFSA colloquium on dioxins and dioxin-like PCBs, which will take place in June. John Christian Larsen had been invited to speak and would be asked to inform the Panel on the discussions and conclusions at a future plenary. Details of the colloquium and application forms could be found at
http://www.efsa.eu.int/science/colloquium_series/389_en.html.

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

Due to lack of time, it was not possible to inform members of the main items discussed at the 6th meeting of the Scientific Committee held since AFC last met on 17 March 2004.

However, details can be found in the minutes from the SC meeting:
http://www.efsa.eu.int/science/sc_commitee/sc_meetings/244/minutes_sc_06_en1.pdf

The Management Board had met in Parma on the day before the Panel meeting. In addition to the issues mentioned above, the issue of EFSA policy on animal experimentation had been raised by one of its members and would be discussed at a future Management Board meeting.

7. FOOD ADDITIVES

7.1. Tertiary butylhydroquinone (TBHQ)

The rapporteur introduced the draft opinion and there was extensive discussion of this draft. It was concluded that a further discussion of a revised opinion should occur at the next Plenary.

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 Panel has now received some information about the use of parabens in food, but further information has been requested from industry to clarify the uses and use levels in the EU. In the light of this information and other recent published toxicity data, the Panel confirmed that a detailed re-evaluation of the safety of parabens is needed. Preparation of the working papers has already commenced and these will form the basis of the re-evaluation. The re-evaluation will be completed as quickly as possible but the delays in providing the earlier requested information on whether the parabens were actually used in food mean that this cannot occur by the requested deadline of 1 July 2004 as set in Directive 2003/14/EC.

7.3. Re-evaluation of food additives

The Panel were updated on developments since their previous meeting concerning the re-evaluation of food additives. Following a meeting with the Commission to discuss the task, an outline approach for re-evaluation had been discussed by the Additives Working Group. The Secretariat provided a revised paper for this Panel meeting, outlining the strategy and proposals for outsourcing the information gathering phase. The Panel discussed the proposed strategy, in the context of colours, the first group of additives that will be re-evaluated, and was invited to comment on initial draft of the tender for outsourcing the information gathering stage of this work. Several suggestions were made for clarification and improvement of the strategy, however due to the limited time available it was agreed that, if necessary, further detailed consideration should be delegated to the Additives Working Group. The Secretariat and Chair of the Working Group should decide whether further consideration was necessary.

8. SUBSTANCES USED AS NUTRIENT SOURCES

8.1. Calcium sulphate in food in general

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

8.2. Legal situation

The Panel was informed that clarification of the legal situation on whether some nutrient sources (such as lycopene) should be assessed under the novel food regulations was as yet unresolved.

9. FLAVOURINGS

9.1. Hydrocyanic acid

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

9.2. Pulegone and menthofurane

John Christian Larsen and Ron Walker declared an interest as they had been involved in the JECFA evaluations of pulegone. These were not considered to be conflicts of interest and it was decided that this interest would not prevent them participating fully in the discussion.

The rapporteur introduced the draft opinion and this was discussed. Pulegone is present in flavourings as an unavoidable component of certain oils but legally cannot itself be added to food, however menthofuran is a chemically defined flavouring substance which can be added to food. Members concluded that the toxicological database was still incomplete and did not allow a numerical value for the acceptable daily intake to be established. The Panel therefore applied a margin of safety approach, in which the numerical margin between estimated exposures the no-observed-effect level (NOEL) for the critical effect (the effect observed at the lowest dose in the available animal toxicity studies) was calculated. Based on the limited exposure data available, the Panel noted that there appears to be an inadequate margin of safety (less than 100). This reinforces the need for completion of the toxicology studies previously requested by the SCF (to establish a NOEL for (R)-(+)-menthofuran in a 90-day oral toxicity study in rats and further genotoxicity studies at the gene and chromosomal level on (R)-(+)-menthofuran and (R)-(+)-pulegone) together with refined intake estimates and these should be submitted within two years after publication of this opinion.

[Secretariat note: The draft opinion was withdrawn after new data uncovered during the written procedure was considered to require reconsideration of the draft opinion.]

9.3. Furfural and furfural diethylacetal

John Christian Larsen and Ron Walker declared an interest as they had been involved in the JECFA evaluation of furfural. Wim Mennes declared an interest from work undertaken on furfural under Existing Substances legislation. These were not considered to be

conflicts of interest and it was decided that this interest would not prevent them participating fully in the discussion.

The rapporteur introduced the draft opinion and this was discussed. The Panel discussed the new transgenic mouse study described in the opinion and agreed that this appeared to be a well conducted GLP study which complied with the best practice identified for conduct of transgenic mouse studies. The Panel agreed that although no single study was sufficient by itself, the results of the genotoxicity studies were relatively consistent and *in toto* the weight of evidence was that furfural was not genotoxic *in vivo*. An ADI for furfural was established at 0.5 mg/kg body weight, based on the NOEL of 54 mg/kg body weight from the 90-day rat study, to which a 100-fold safety factor was applied. Since furfural diethylacetal is rapidly converted to furfural at physiological pH, the ADI applies also to furfural liberated from the acetal. The Panel noted that estimated combined exposure from natural and flavouring uses appeared to be at or above the proposed ADI and that refined intake estimates would be desirable.

The possible use of furfural in Food Contact Materials was raised. The Secretariat were requested to check the synoptic document to ascertain if any such uses for furfural existed.

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

9.4. Exposure estimates used in flavourings evaluation

Karl-Heinz Engel, Chair of the Flavourings Working Group, outlined the Working Group's discussions on the exposure estimates for flavourings and their proposals to improve these and resolve the concerns discussed at the previous Plenary. He expected a draft on the approach to exposure issues to be discussed at the next Flavourings Working Group meeting and once agreed, it would be brought to the following Plenary together with the flavouring group evaluation, FGE03, which would be revised to reflect the changed approach.

10. FOOD CONTACT MATERIALS

10.1. 4th list of substances for food contact materials

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

Ref. No.:	13317
Name of the substance:	N,N'-Bis[4-(ethoxycarbonyl)phenyl]-1,4,5,8-naphthalenetetracarboxydiimide
CAS number:	132459-54-2
Classified in list:	3
Restriction:	0.05 mg/kg food

Ref. No.:	25540
Name of the substance:	Trimellitic acid
CAS number:	528-44-9
Classified in list:	3
Restriction:	5 mg/kg of food

Ref. No.:	25550
Name of the substance:	Trimellitic anhydride
CAS number:	552-30-7
Classified in list:	3
Restriction:	5 mg/kg of food, expressed as trimellitic acid

Ref. No.:	66930
Name of the substance:	Methylsilsesquioxane
CAS number:	68554-70-1
Classified in list:	3
Restriction:	Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane /kg of methylsilsesquioxane

Ref. No.:	86432
Name of the substance:	Silver-containing glass (Silver-magnesium-calcium-phosphate-borate)
CAS number:	-
Classified in list:	3
Restriction:	Group restriction of 0.05 mg Ag/kg of food

Ref. No.:	86434
Name of the substance:	Silver sodium hydrogen zirconium phosphate
CAS number:	-
Classified in list:	3
Restriction:	Group restriction of 0.05 mg Ag/kg of food

The full opinion together with an explanation of the classification lists can be seen on http://www.efsa.eu.int/science/afc/afc_opinions/catindex_en.html.

The following substance was referred back to the Food Contact Materials Working Group for further consideration and clarification of the proposed restrictions on fluoride release and for identification of any other fluoride-releasing food contact materials.

Ref. No.:	85950
Name of the substance:	Silicic acid, magnesium-sodium-fluoride salt
CAS number:	37296-97-2
Classified in list:	3
Restriction:	0,05mg/kg of food

10.2. Epoxidised soybean oil (ESBO)

Kettil Svensson declared an interest in ESBO as he had participated in discussions on levels in baby food at the Swedish National Food Administration. Laurence Castle and Catherine Simoneau also declared interests in this as authors of papers cited in the opinion. These were not considered to be conflicts of interest and it was decided that this interest would not prevent them participating fully in the discussion.

The draft opinion was discussed and a number of revisions were agreed. Members noted that although in some scenarios exposures from babyfoods exceed the Tolerable Daily Intake (TDI), ESBO was neither genotoxic nor carcinogenic and a threshold approach

could be applied. The Panel confirmed the Tolerable Daily Intake (TDI) of 1 mg/kg body weight set previously by the Scientific Committee on Food. The TDI is based on a no-effect level of 140 mg/kg body weight/day for organ weight changes observed in a 2-year rat study.

The estimated exposure of infants aged 6-12 months to ESBO migrating into baby foods packaged in glass jars and bottles with metal lids sealed with PVC gaskets can sometimes exceed the TDI by up to 4- to 5-fold. Since there is an inbuilt safety factor of more than 100 in the derivation of the TDI, exceeding the TDI 4- to 5-fold does not imply that there will be adverse health effects in infants. However, such a situation does reduce the safety margin between exposure and adverse effects on a regular basis. The Panel therefore recommended that a specific migration limit for ESBO in baby foods be developed, derived from the TDI of 1 mg/kg body weight and taking into consideration the amounts of food which might be eaten on a daily basis by an infant of 6 months of age, weighing 7.5 kg, fed mainly or exclusively on processed baby foods.

On ESBO derivatives, the Panel noted that there were only limited toxicological data and that industry were initiating further toxicological studies on these derivatives. The Panel requested that the Food Contact Materials Working Group should consider the results of the existing and planned studies assess whether the overall research programme was adequate to address the potential safety issues and whether any further analytical data on derivatives was needed, and report back to the Plenary in due course.

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

10.3. Reclassification of some phthalates

The Secretariat outlined the background to this proposal to reclassify certain phthalates in food contact materials. The SCF had originally classified these phthalates in lists 3, 6B or 9 according to its old guidelines. Since then the SCF had elaborated more recent guidelines *http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/note_guidance_en.pdf* and since no additional data have ever been submitted for these phthalates, it was appropriate to re-classify them according to the new guidelines into lists 7 and 8. These phthalates were listed in positive national lists for Food Contact Materials and were also included in the list of additives in the Synoptic Document that the Commission used to draft a list of substances for use in FCM
(http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/synoptic_doc_en.pdf.)
No company has ever requested inclusion of any of these 23 phthalates in the relevant Directive (2002/72/EC). However due to their inclusion in the Synoptic Document, they may be used according to the national restrictions until there is a decision on inclusion into the Directive. The Panel agreed to re-classify these phthalates according to the new SCF guidelines into lists 7 or 8, indicating that more data are required by the deadline of 31 December 2006. Failure to provide these data by this deadline will result in these substances being excluded from the positive list of additives in the Directive that will be established in 2007. If a company subsequently wished to use any excluded phthalates, they would have to submit a "new" petition in line with the latest guidelines. It was noted that the reproductive toxicity only one of these phthalates, di-*n*-octyl phthalate, had been assessed by the NTP programme, and that while it produced reproductive toxicity, this was only seen at high doses.

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

10.4. Use of previous data in re-evaluations

It was noted that the new Framework Directive on materials and articles intended to come into contact with food specifically addressed data sharing in one of its articles. However, the Secretariat sought the Panel's views on whether additional submissions on old dossiers should only be required to provide the information requested by the SCF at the time of the original assessment or should comply with the current guidelines. The Panel noted that in many instances, no new submission had been made despite considerable time elapsing since the SCF first made the data request. It was agreed that, in principle, these submissions should comply with the current guidelines irrespective of what the SCF had requested in the past. However there should be a case by case decision to minimise potentially unnecessary animal studies. Members considered that where possible data sharing should be encouraged on animal welfare grounds.

11. SEMICARBAZIDE

Laurence Castle had been appointed Chair of the Semicarbazide Working Group of the Panel and outlined the discussions at their first meeting. Four possible sources of semicarbazide in food had been 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 Advisory Forum had been requested to provide any further information on occurrence of semicarbazide in food. The Working Group was scheduled to meet again on July 6.

12. WORKING PROGRAMME

Since the last meeting of the Panel the following questions have been received from the Commission. There had been 12 petitions for evaluation of substances in FCM. Three other new items of work were noted; jelly mini cups, guidance on data requirements for smoke flavours and exposure to certain flavourings in yoghurt in Denmark.

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

Since this Plenary was only quorate on the first day, opinions would need to be formally adopted by the written procedure after the meeting.