

Parma, 7 May 2012

**SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD**  
**Minutes of the 9<sup>th</sup> meeting of the Working Group on Guidance on Food Additives**  
**Amsterdam, 15-16 March 2012**  
**EFSA / FIP Unit /ANS**

**Agreed by the WG on 7 May 2012**

**Participants**

WG Experts	Birgit Dusemund, Pierre Galtier, David Gott (Chair and Rapporteur), Ursula Gundert-Remy, Rainer Gürtler, Jürgen König (15 March, am), Claude Lambré, Alicja Mortensen (15 March), Pasquale Mosesso, Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ine Walkens-Berendsen (16 March), Ruud Woutersen, Matthew Wright.
Hearing Experts	Ivonne Rietjens
Observers (eg.EC)	-
EFSA:	Georges Kass, Anastasia Kesisoglou

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Riccardo Crebelli, Jürgen König (15 March, pm; 16 March), Jean-Charles Leblanc, Iona Pratt, Dominique Parent-Massin, Alicja Mortensen (16 March), Ine Walkens-Berendsen (15 March).

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Adoption of the minutes of the 8<sup>th</sup> WG meeting on Guidance for food additives**

The minutes were adopted without changes.

**5. Information from the Chair**

The Chair thanked the ANS unit for sending out the documents for the meeting.

**6. Information from EFSA secretariat**

The ANS unit provided an update on the SC document on TTC.

**7. Technical guidance document**

The document was discussed together with the comments from the public consultation and changes agreed

**8. Organisation of the work**

The Chair thanked all the WG members and especially the ex-chair I. Rietjens as well as the ANS unit for their work and contributions to the document.

**9. Any other business**

None.

**10. Next meeting date**

No further meetings of the WG were foreseen. The document will be presented for discussion and adoption at the next ANS plenary meeting which will take place in Parma (17-19 April 2012).

Parma, 14 March 2012

**SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD**  
**Minutes of the 8<sup>th</sup> meeting of the Working Group on Guidance on Food Additives**  
**Amsterdam, 3 February 2012**  
**EFSA / FIP Unit /ANS**

**Agreed by the WG on 14 March 2012**

**Participants**

WG Experts	Riccardo Crebelli, Birgit Dusemund, Pierre Galtier, David Gott (rapporteur), Jürgen König, Jean-Charles Leblanc, Pasquale Mosesso, Iona Pratt, Ivonne Rietjens (Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ine Walkens-Berendsen, Matthew Wright.
Hearing Experts	-
Observers (eg.EC)	-
EFSA:	Georges Kass, Hugues Kenigswald, Anastasia Kesisoglou

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were noted for Rainer Gürtler, Ursula Gundert-Remy, Dominique Parent-Massin, Claude Lambre, Alicja Mortensen, Ruud Woutersen.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Information from the Chair**

The Chair thanked the ANS unit for sending out the documents for the meeting. She also informed the members of the WG that she will not be chairing the next WG Guidance meeting (15-16 March 2012) due to her resignation from the ANS Panel and WGs at the end of February 2012. As a result, a new chair needs to be appointed by the ANS Panel.

**5. Information from EFSA secretariat**

The ANS unit provided an update on the SC WG on TTC

**6. Technical guidance document**

The Chair informed the WG members that a total of 114 comments were received on the document from the public consultation. All the comments were addressed and discussed and actions were noted.

**7. Organisation of the work**

A brief discussion took place on the next steps required for the preparation of the guidance document.

**8. Any other business**

None

**9. Next meeting date**

The next meeting will take place in Amsterdam (15-16 March 2012).

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ANS UNIT

Parma, 19 May 2011

**SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD**  
**Minutes of the 7<sup>th</sup> meeting of the Working Group on Guidance on Food Additives**  
**Amsterdam, 12 February 2011**  
**EFSA / Unit /ANS**

**Agreed by the WG on 19 May 2011**

**Participants**

WG Experts	Alicja Mortensen, Birgit Dusemund, David Gott (rapporteur), Claude Lambré, Dominique Parent-Massin, Iona Pratt, Ivonne Rietjens (Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.
Hearing Experts	-
Observers (eg.EC)	Dimitrios Chrysafidis
EFSA:	Anastasia Kesisoglou and Georges Kass

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Pierre Galtier, Rainer Gürtler, Jean-Charles Leblanc and Jürgen König.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and/or Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Adoption of the minutes of the 6<sup>th</sup> meeting of the WG Guidance on Food Additives**

The minutes were adopted with minor changes.

**5. Information from the Chair**

The Chair thanked the EFSA secretariat for sending out the documents for the meeting as well as the members for their contributions towards the meeting.

## **6. Information from EFSA secretariat**

The EFSA secretariat provided an update on the ANS WGs for Exposure and for Chemistry as well as on the SC WGs TTC, Genotoxicity and on Default assumptions.

## **7. Technincal guidance document**

The general organisation of this section was discussed and various editorial changes were made, including changes in the section on reproductive and developmental toxicity. The discussion started from the end of the document to address issues in sections that were not properly discussed in previous meetings. The Annexes were briefly discussed and it was decided to delete Annexes IV and V.

### **7.1. Immunotoxicology, hypersensitivity and food intolerance**

It was agreed that the text should be updated and revised with information from Annex V.

### **7.2. Human studies**

The section was briefly discussed.

## **8. Organisation of the work**

A brief discussion took place on the next steps required for the preparation of the guidance document.

## **9. Any other business**

None

## **10. Next meeting date**

The next discussion of the guidance document will be at the next Plenary meeting (1-3 March 2011, Brussels) and at subsequent Plenaries meetings.

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Amsterdam, 09 February 2011

**SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD**

**Minutes of the 6<sup>th</sup> meeting of the Working Group on Guidance on Food Additives**

**Amsterdam, 12 January 2011**

**EFSA / Unit /ANS**

**Agreed by the WG on 09 February 2011**

**Participants**

WG Experts: Alicja Mortensen, Birgit Dusemund, Pierre Galtier, David Gott (rapporteur), Rainer Guertler, Jürgen König, Claude Lambré, Jean-Charles Leblanc, Dominique Parent-Massin, Iona Pratt, Ivonne Rietjens (Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

Observers: Commission

EFSA: Anastasia Kesisoglou, Georges Kass

**1. Welcome and apologies**

The Chair, I. Rietjens, welcomed the participants. Apologies were received from Pierre Galtier, Rainer Guertler, Jean-Charles Leblanc and the Commission.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and/or Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Adoption of the minutes of the 5th meeting of the WG guidance on food additives**

The minutes were adopted with minor changes. The minutes can be seen on:

<http://www.efsa.europa.eu/en/answgs/documents/answggfa.pdf>

## **5. Information from the Chair**

The Chair thanked the EFSA secretariat for sending out the documents for the meeting as well as the members for their contributions towards the meeting.

## **6. Information from EFSA secretariat**

The EFSA secretariat provided an update on the ANS WGs for Exposure and for Chemistry. No update was provided for the SC WGs on TTC and Genotoxicity.

## **7. Technical guidance document**

The general organisation of this section was discussed.

### **7.1. Terms of reference & Introduction**

The introduction was discussed and slightly revised. The different sections were briefly discussed.

## **8. Organisation of the work**

A brief discussion took place on the next steps required for the preparation of the guidance document.

## **9. Any other business**

None.

## **10. Next meetings**

The next meeting of the WG is on Wednesday 9 February in Amsterdam. Following this, the guidance document will also be discussed at the next Plenary meeting (1-2 March, Brussels). The future WG meeting dates foreseen for 2011 are as follows:

- 6 May (venue to be decided)
  - 16 June (venue to be decided)
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Amsterdam, 12 January 2011

**SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD**  
**Minutes of the 5<sup>th</sup> meeting of the Working Group on Guidance on Food Additives**  
**Amsterdam, 17 November 2010**  
**EFSA / Unit /ANS**

**Agreed by the WG on 12 January 2011**

**Participants**

WG Experts                      Birgit Dusemund, P. Galtier, R. Gürtler, D. Gott (rapporteur), C. Lambré, A. Mortensen, D. Parent-Massin, I. Pratt, I. Rietjens (Chair), I. Stankovic, P. Tobback, T. Verguieva, R. Woutersen

EFSA:                              G. Kass, H. Kenigswald, A. Kesisoglou

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from J. König, J-C. Leblanc and the Commission.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and/or Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Adoption of the minutes of the 4<sup>th</sup> meeting of the WG Guidance of Food Additives**

The minutes were adopted with minor changes. It was recommended that a discussion should take place at the meeting whether the 90-day study, referred to in Tier 1 of the reproductive toxicity section, is a Tier 1 or Tier 2 study. Comments should be provided by the relevant experts.

**5. Information from the Chair**

The Chair thanked the EFSA secretariat for sending out the documents for the meeting as well as the members for their contributions towards the meeting.

## 6. Information from EFSA secretariat

The EFSA secretariat provided an update on the ANS WGs for Chemistry and for Exposure, that took place on 28<sup>th</sup> October (teleconference) and 16<sup>th</sup> November (Amsterdam), respectively. In addition, reference was made to the DG SANCO WG on TTC which is planning to publish its opinion ("Use of the Threshold of Toxicological Concern (TTC) Approach for the Safety Assessment of Chemical Substances") by the end of the year. This WG is in communication with the corresponding WG on TTC of the Scientific Committee (SC). The WG 'Guidance on Food Additives' will take into account the outcomes of the above mentioned WGs.

## 7. Technical guidance document

The general organisation of this section was discussed. The Chair recommended that the rapporteur should create a separate document to save all the deleted text from the guidance document in order to assess at a later stage whether these can be used.

**Action:** D. Gott

### 7.1. Terms of reference & Introduction

#### *Terms of reference*

It was noted and agreed that the name given for the technical data in the Terms of Reference, as provided by EFSA, will be referred to as 'Chemistry & Specifications', with the whole guidance document being updated accordingly.

**Action:** secretariat to edit the guidance document and make the necessary amendments.

#### *Introduction*

It was decided that information on integrated testing strategies (ITS), including the concepts of read across, margin of safety, presumption of safety and uncertainty factors should be added to the introduction. The text needs further simplifying and shortening by removing reference to stages and details on Tiers. A diagram with the tiered approach needs to be added at the end of the document after the discussion.

In the general discussion, the importance of giving the public a clear message was stressed. Tier 1 was confirmed to consist of the 90-day study (OECD TG 408) which will also include endpoints for endocrine disruption and reproductive toxicity. This study should also allow for the identification of chemicals with the potential to cause neurotoxic, immunological and reproductive organ effects, which may warrant further in-depth investigation. It was proposed that for non-absorbed compounds, the number of endpoints related to endocrine disruption (and reproductive toxicity?) may be reduced. Likewise, it will not be necessary to perform a developmental toxicity study for non-absorbed compounds. However, the WG emphasised that in case of doubts about the non-absorption status, Tier 2 must be performed. It was also noted that the substances must be well-defined before the argument of non-absorption can be accepted and the studies are stopped at Tier 1.

### 7.2. Technical data

The Chair noted that there is a need to specify within the document the different extraction methods for various types of chemicals or chemical mixtures, as these may vary depending on the different extraction procedures. The Chair also requested B. Dusemund to update the section on botanicals (1.5), and that the sections on Microorganisms (1.7) and GMM (1.8) be merged and revised. Editorial changes were also proposed.

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- Actions:** (i) secretariat to edit section  
(ii) B. Dusemund to update the section (1.5) on “Additives derived from botanical sources”  
(iii) sections on microorganisms (1.7) and GMM (1.8) to be merged and Modified

### 7.3. Proposed used and use levels

There was no discussion on the section as no exposure experts were present at the meeting. Following the meeting of the WG Exposure (16 November), it was decided that the text will be revised to incorporate the following three sections that will be provided by the corresponding WG.

1. An introduction with more detailed information on the tiered approach to assess exposure.
2. Text on proposed use and use levels. A template based on EU food categorisation will be provided.
3. Additional text to inform the petitioner of the requirement to use the food comprehensive database to report exposure. An example will be provided in the technical annexe to guide the petitioner.

**Action:** J. König to provide the updated text

### 7.4. Toxicokinetics and toxicity

The WG decided to change the title from “Toxicokinetics and toxicology” to “Toxicokinetics and toxicity”. This change will also be implemented in the ToR.

**Action:** secretariat

#### *Toxicokinetics*

All sections on data reporting should be moved to the appropriate part of the document. The section on toxicokinetics should be reorganised. A brief introduction containing the general considerations should be added at the beginning of the section and a paragraph on alternatives at the end of it. Overall, the text needs further shortening.

**Action:** D. Gott to revise the section with the help of R. Woutersen

#### *Toxicity testing*

It was decided that the section should be split into two, subchronic and chronic. The text requires general revisions. The acceptance of the different alternative approaches should be clarified.

**Action:** D. Gott and R. Woutersen; secretariat

#### *Genotoxicity*

This section is awaiting revision. The acceptance of the different alternative approaches should be clarified.

Action: R. Gürtler to provide an updated draft of the section to the secretariat.

#### *Chronic toxicity and Carcinogenicity*

The text requires general revisions. The acceptance of the different alternative approaches should be clarified.

Action: D. Gott and R. Woutersen; secretariat

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### *Reproductive toxicity*

For Tier 1 the issue of non-absorbed compounds needs to be mentioned. While the current draft of the guidance indicates that Tier 2 comprises an Extended One-Generation Reproductive Toxicity study (Draft OECD Guideline, not yet adopted by OECD), the prenatal developmental study which is also required for Tier 2 needs describing. The design of the draft one-generation study was discussed and it was agreed that the triggers for inclusion of the F1 cohorts for neurotoxicity and immunotoxicity at Tier 2 need to be described, also the decision as to whether to extend the study to a second generation. More and clearer text describing the triggers for Tier 3 testing (multi-generation study according to OECD 416) needs to be added. The triggers for the second species under Tier 3, and the minipig as a potential second species for Tier 3 need to be mentioned.

The WG unanimously agreed that with data from a second generation there is no need to perform a multigeneration study.

For additives for infant formulae, reference to publication from R. Woutersen (cf in utero exposure) and to the guidelines for novel foods for infant foods (EFSA) should be made.

**Action:** -R. Woutersen and secretariat  
-Secretariat to distribute the OECD guidelines 414 and 421 to the members for the next meeting.

### **7.5. Additional studies**

The Chair requested that a short introduction to the section of 'Additional studies' needs to be added.

#### *Immunotoxicity and food sensitivities*

This section needs revising to fit the Guidance style and to incorporate the tiered approach.

**Action:** C. Lambré and secretariat

#### *Cardiovascular toxicity*

It was proposed that a section addressing the issue of cardiovascular toxicity and appropriate models should be added.

**Action:** A. Mortensen

## **8. Organisation of the work**

A brief discussion took place on the next steps required for the preparation of the guidance document.

The Chair requested the EFSA secretariat to work on the guidance document before the end of December and then forward it to the rapporteur (D. Gott). The rapporteur should send the updated version by Wednesday 5<sup>th</sup> January. The documents should be sent out by Friday 7<sup>th</sup> January, at the latest.

**Actions:** -Secretariat to work on the guidance document and forward it to the rapporteur  
-D. Gott to provide text with arguments to judge non-absorption and write the text on genotoxicity taking into account R. Guertler's comments.  
-P. Galtier to propose a few sentences to R. Woutersen on in vitro models

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-R. Woutersen to update the Alternatives section based on the discussions at the meeting

-All agreed contributions to be sent out to the secretariat by **Monday 20th December**, if possible. After this deadline, contributions should be sent to D. Gott (with secretariat in copy

#### **9. Any other business**

None

#### **10. Next meeting date**

The next meeting of the WG is on Wednesday 12 January in Amsterdam. The future WG meeting dates foreseen for 2011 were presented by the Secretariat and have been confirmed by the WG members as follows:

- 9 February (Amsterdam)

In addition, the Chair recommended to have two days from the WG meeting, scheduled for 1-3 March, devoted to the WG Guidance. However, a final decision will be made depending on the output of the next two scheduled meetings in January and February.

- 1-3 March (Parma?)

- 6 May (meeting/teleconference)

- 16 June (meeting/teleconference)

The venues will be decided at future WG meetings

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**Annex: Action points (noted at the 5<sup>th</sup> WG meeting)**

Action point	Person responsible
<ul style="list-style-type: none"> <li>- More information to be added in the RA paradigm – i.e. text to be expanded to include info on what the applicant needs to do</li> <li>- Issue of how the ADI is going to be addressed; text to be developed further (i.e. how we derive margins of safety and exposure)</li> <li>- Info on what the tiered approach is, including a diagram (which will introduced at the end of the document)</li> <li>- Text on RA paradigm should be short and be kept more general without any specific examples</li> </ul> <p><b><u>Toxicological part</u></b></p> <ul style="list-style-type: none"> <li>- To create a new section at the end of the whole/main document on how studies should be reported</li> <li>- Each endpoint of the Tox core section should be formatted in order to cover the following points: general considerations, tiered approach, alternatives</li> <li>- Section on toxicokinetics to be shortened; paragraphs have been re-ordered and need to be checked for any duplications</li> <li>- Adjust, throughout the document, the use of repeated or repeat dose, in order to maintain consistency</li> <li>- Text on absorption to be re-written and referenced, following the discussion between the members</li> <li>- The toxicity section (as it currently stands) needs to be split into subchronic and chronic, and revised; tiered approach for subchronic and chronic toxicity need to be decided</li> <li>- The text on Tier 2 testing for chronic and carcinogenicity should be updated with explanations an the appropriate requirements (Ruud to assist)</li> <li>- Reproductive toxicology section to be updated including information on the prenatal developmental study</li> </ul>	<p style="color: red;">D. Gott (for some of the actions EFSA secretariat will help)</p>
<p>To update the section on botanicals (1.5)</p>	<p style="color: red;">B. Dusemund</p>
<ul style="list-style-type: none"> <li>- Sections on microorganisms (1.7) and GMM (1.8) to be merged;</li> <li>- Text on GMM (1.8) to be modified</li> <li>- Send OECD guidelines 414 and 421 to WG</li> </ul>	<p style="color: red;">EFSA Secretariat</p>

<p>members</p> <ul style="list-style-type: none"> <li>- OECD guidelines used in the guidance document should be referenced appropriately</li> <li>- Subheadings to be incorporated to each endpoint introducing the alternatives for the particular endpoint</li> </ul>	
<p>Text on proposed uses and exposure assessment to be provided</p>	<p>J. Koenig</p>
<p>Provide some text on the level of acceptance of alternatives in the risk assessment; text to be included at the beginning of each section referring to the order these tests are presented (and also be in line with the Annex)</p>	<p>R. Woutersen</p>
<ul style="list-style-type: none"> <li>- Text on genotoxicity section to be revised and updated; updated text to be circulated to the rapporteur and secretariat before the next meeting</li> </ul>	<p>R. Guertler</p>
<p>Section on alternatives for genotoxicity needs to be referenced appropriately; references also need to be incorporated in the Annex</p>	<p>R. Woutersen</p>
<p>Section on Immunotoxicity and Food sensitivities to be updated</p>	<p>C. Lambre and EFSA Secretariat</p>
<p>Write sth on cardiovascular studies (issue of atherosclerosis), which will go under 'other studies', referring to animal models.</p>	<p>A. Mortensen</p>

Parma, 17 November 2010

**SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD**

**Minutes of the 4<sup>th</sup> meeting of the Working Group on Guidance on Food Additives**

**Brussels, 22 October 2010**

**EFSA / Unit /ANS**

**Agreed by the WG on 17 November 2010**

**Participants**

WG Experts                      Alicja Mortensen, Birgit Dusemund, Pierre Galtier, Rainer Guertler, David Gott (rapporteur), Jürgen König, Claude Lambré, Jean-Charles Leblanc, Dominique Parent-Massin, Iona Pratt, Ivonne Rietjens (Chari), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

EFSA:                              Georges Kass, Anastasia Kesisoglou.

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were noted for Birgit Dusemund, Paul Tobback, Jean-Charles Leblanc and the Commission.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and/or Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Adoption of the minutes of the 3<sup>rd</sup> meeting of the WG Guidance on Food Additives**

The minutes were adopted with minor changes.

**5. Information from the Chair**

The Chair thanked the EFSA secretariat for sending out the documents for the meeting as well as the members for their contributions towards the meeting.



## **6. Information from EFSA Secretariat**

The EFSA secretariat provided an update on the ANS WGs for Chemistry and Exposure, which were scheduled for 28<sup>th</sup> October (teleconference) and 16<sup>th</sup> November (Amsterdam), respectively.

## **7. Technical guidance document**

### *6.4 Toxicological data*

The general organisation of this section was discussed.

## **8. Organisation of the work**

A brief discussion took place on the next steps required for the preparation of the guidance document.

## **9. Any other business**

None.

## **10. Next meetings**

The next meeting of the WG is on Wednesday 17 November in Amsterdam. The future WG meeting dates foreseen for 2011 were presented by the Secretariat and have been confirmed by the WG members as follows:

- 12 January (meeting/teleconference)
- 9 February (meeting/teleconference)
- 6 May (meeting/teleconference)
- 16 June (meeting/teleconference)

The venues will be decided at the next WG meeting in Amsterdam on 17<sup>th</sup> November.

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Parma, 22 October 2010

**SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD**

**Minutes of the 3<sup>rd</sup> meeting of the Working Group on Guidance on Food Additives**

**Web conference, 29 September 2010**

**EFSA / Unit /ANS**

**Agreed by the WG on 22 October 2010**

**Participants**

WG Experts

Alicja Mortensen, Birgit Dusemund, Pierre Galtier, David Gott (rapporteur), Jürgen König, Claude Lambré, Dominique Parent-Massin, Iona Pratt, Ivonne Rietjens (Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

Hearing Experts

Observers (eg.EC)

EFSA:

Georges Kass, Anastasia Kesisoglou, Hugues Kenigswald (morning only).

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies for absence were noted for Paul Tobback, Jean-Charles Leblanc and the Commission.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Adoption of the minutes of the 2<sup>nd</sup> meeting of the WG Guidance on Food**

**Additives**

The minutes were adopted with minor editorial changes.

**5. Information from the Chair**

The Chair requested that a complete first draft on the Exposure assessment section should be ready for discussion at the next WG Guidance meeting in October. The EFSA secretariat should liaise with the secretariat of the WG Exposure and communicate the request in order

to ensure that the action is implemented on time. Similarly, the introductory text for the Chemistry/Technical section should be finalised by the WG Chemistry. Finally, the Chair expressed concern about the procedural problem of members of this WG not being able to participate at meetings of the WG Chemistry and Exposure when issues pertinent to the Guidance Document are discussed if they are not members of the latter WGs.

## **6. Information from EFSA Secretariat**

The EFSA secretariat provided an update on the ANS WGs for Exposure and Chemistry and the Scientific Committee (SC) WGs on Genotoxicity and TTC.

## **7. Technical guidance document**

### *7.1 Terms of Reference*

Feedback was provided by the EFSA secretariat in relation to the clarification requests made by the WG members to the Commission.

### *7.2 Introduction*

This section requires further editorial changes.

### *7.3 Technical data*

No discussion took place on this section.

### *7.4 Exposure*

There was no discussion on this section.

### *7.5 Toxicological data*

The general organisation of this section was discussed.

## **8. Organisation of the work**

A brief discussion took place on the preliminary technical guidance draft document and the next steps required for its preparation.

## **9. Any other business**

None.

## **10. Next meetings**

Meetings of the working group are foreseen in the following dates:

- Friday 22 October (Brussels)
- Wednesday 17 November (Amsterdam)

Parma, 29 September 2010

**SCIENTIFIC PANEL ON FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD**

**Minutes of the 2<sup>nd</sup> meeting of the Working Group on Guidance on Food Additives**

**Amsterdam, 30 June 2010**

**EFSA / Unit /ANS**

**Agreed by the WG on 29 September 2010)**

**Participants**

WG Experts                      Alicja Mortensen, Birgit Dusemund, Pierre Galtier, David Gott (rapporteur), Jürgen König, Claude Lambré, Dominique Parent-Massin, Iona Pratt, Ivonne Rietjens (Chari), Ivan Stanlovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

Hearing Experts

Observers (eg.EC)

EFSA:                              Georges Kass, Anastasia Kesisoglou.

**1. Welcome and apologies**

The Chair welcomed the participants. Apologies were received from Rainer Gürtler, Jean-Charles Leblanc and the Commission.

**2. Adoption of agenda**

The agenda was adopted without changes.

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Adoption of the minutes of the 1<sup>st</sup> meeting of the WG Guidance on Food Additives**

The minutes were adopted with some minor editorial changes.

## **5. Information from the Chair**

The Chair referred to the new EFSA policy on having teleconferences for at least 10% of the meetings due to budget issues.

The Chair also enquired about the deadline of the genotoxicity guidelines prepared by the Scientific Committee (SC) and the impact these will have on the genotoxicity section of the ANS Food Additives guidance document.

## **6. Information from EFSA Secretariat**

The EFSA secretariat provided an update on the ANS working groups (WGs) for Exposure, Chemistry and Toxicology, which have now been established.

The members of the Chemistry WG include J. Gilbert (chair), I. Stankovic, P. Tobback and D. Boskou. The first meeting has been scheduled, via teleconference, for Thursday 15 July.

The members of the Exposure WG consist of J-C. Leblanc (chair), J. Koenig, N. Bemrah, A. Hearty, M. Bakker and C. Tlustos. The first meeting has been scheduled for Monday 12 July.

The secretariat provided clarification in relation to the Scientific Committee, the GMO and NDA Units. These Units were informed about the ongoing work on the ANS guidance document on Food Additives and the ongoing work by the dedicated WG, and were asked for recommendations in the areas pertinent to their activities.

## **7. Technical guidance document**

### *7.1 Terms of Reference and Introduction*

The rapporteur informed the WG members about the discussion that took place at the 15th plenary meeting of the ANS Panel held in Parma, 22 June 2010, and where the Terms of Reference were presented and discussed by the Panel members.

Next, the Chairman opened the discussion on the structure of the Guidance Document by seeking the WG's opinion on a tiered approach for the Risk Assessment (RA) strategy. The WG supported the idea, and the ensuing discussion focused on how a tiered approach could be adapted to cover the core studies necessary to perform a risk assessment on food additives.

### *7.2 Technical data*

The section was renamed to 'Chemistry and Specifications' based on the new naming approved in the Terms of Reference. No discussion took place on the section as the chemists will participate in the WG Chemistry teleconference scheduled for 15th July, where all the issues previously addressed will be discussed in detail with the other chemist members of the WG Chemistry.

### *7.3 Exposure*

The section was renamed to 'Proposed uses and use levels and Exposure' based on the new naming approved in the Terms of Reference. There was no discussion on this section as the issues raised during the first meeting, will be addressed at the WG Exposure, scheduled for 12th July.

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#### 7.4 *Toxicological data*

The section was renamed to 'Toxicokinetics and Toxicology' based on the new naming approved in the Terms of Reference. The core studies were discussed in the context of a tiered approach.

#### 7.5 *Alternative testing*

The different alternative and complementary studies that should be included in the guidance document were discussed by the WG.

### **8. Organisation of the work**

A brief discussion took place on the preliminary technical guidance draft document and the next steps to prepare the guidance document.

### **9. Any other business**

None.

### **10. Next meetings**

Meetings of the working group are foreseen in the following dates:

- Wednesday 29 September (Teleconference)
  - Friday 22 October (Brussels)
  - Wednesday 17 November (Amsterdam)
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ANS UNIT

Parma, 30 June 2010

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**SCIENTIFIC PANEL ON**

**FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)**

**Minutes of the 1<sup>st</sup> meeting of the Working Group on Guidance on Food Additives**

**Amsterdam, 28 April 2010**

**EFSA / ANS / WG Guidance on Food Additives**

**(Agreed by the WG on 30 June 2010)**

**Participants**

WG Experts                      Alicja Mortensen, Birgit Dusemund, David Gott, Jürgen König, Claude Lambré, Iona Pratt, Ivonne Rietjens (Chair), Ivan Stankovic, Paul Tobback, Tatjana Verguieva, Ruud Woutersen.

EFSA:                              Hugues Kenigswald, George Kass, Kim Petersen, Anastasia Kesisoglou.

**1. Welcome and apologies**

Ivonne Rietjens, the chair, welcomed the participants. Apologies for absence were noted from Pierre Galtier, Rainer Guertler, Jean-Charles Leblanc, Dominique Parent-Massin and the Commission.

**2. Adoption of the agenda**

The agenda was adopted without changes.

**ANS UNIT**

**3. Declarations of interest**

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of Interest (ADoI). No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

**4. Information from the Chair**

The Chair referred to the notes for discussion that were circulated before the meeting.

**5. Terms of reference**

The Chair outlined the questions that need to be considered and addressed by the WG members emphasising the need to clarify the objectives.

**6. Discussion on existing guidance document**

Taking the SCF 2001 guidance document as a starting point, the working group discussed the items to be considered.

**7. Discussion on the preliminary draft document and Organisation of the work**

A brief discussion took place on the preliminary draft document and the next steps to prepare the guidance document.

**8. Any other business**

None.

**9. Next meetings**

- Week of 28 June to 2 July
- Week of 29 September to 1 October
- Week of 18 – 22 October
- Week of 15 – 19 November