

**MINUTES OF THE 28<sup>TH</sup> PLENARY MEETING OF THE  
SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES  
HELD FROM 29 JUNE TO 2 JULY 2009**

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**PARTICIPANTS**

**Panel members:**

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|-----------------------|------------------------|
| • Jean-Louis Bresson  | • Hildegard Przyrembel |
| • Albert Flynn        | • Sean Strain          |
| • Marina Heinonen     | • Stephan Strobel      |
| • Karin Hulshof       | • Inge Tetens          |
| • Hannu Korhonen      | • Henk van den Berg    |
| • Martinus Løvik      | • Hendrik van Loveren  |
| • Rosangela Marchelli | • Hans Verhagen        |
| • Ambroise Martin     |                        |
| • Bevan Moseley       |                        |

**EFSA staff:**

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|---------------------|----------------------------|
| • Juliane Kleiner   | • Leng Heng                |
| • Reinhard Ackerl   | • Danai Papanastasiou      |
| • Maria Astridou    | • Ariane Titz              |
| • Ulla Bertelsen    | • Emanuela Turla           |
| • Janusz Ciok       | • Silvia Valtueña Martínez |
| • Ellie Daguet      |                            |
| • Wolfgang Gelbmann |                            |

**European Commission:**

- Lars Korsholm<sup>1</sup>
- Sabine Osaer<sup>1</sup>

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<sup>1</sup> DG Health and Consumers

## **1. WELCOME, APOLOGIES FOR ABSENCE**

The Chair welcomed all participants to the plenary meeting. Apologies for absence were received from Pagona Lagiou, Seppo Salminen and Stephan Strobel.

At this last meeting of the Panel in the current composition, the Secretariat took the opportunity to express EFSA acknowledgement to the Panel and its members for their excellent contribution to the work of the Panel.

## **2. ADOPTION OF THE AGENDA AND ADOPTION OF THE MINUTES OF THE LAST MEETING**

The agenda was adopted with changes in the order of items discussed.

The minutes of the 26<sup>th</sup> and 27<sup>th</sup> NDA Plenary meetings were also adopted.

## **3. DECLARATIONS OF INTEREST**

EFSA secretariat screened the ADoI and SDoI filled in by the scientific experts invited to this meeting in accordance with EFSA's Policy on Declarations of Interests. With regard to the specific items on the agenda for this meeting interests were declared and actions were taken as follows:

Agenda item 11.1 in relation to the draft opinion on "Danacol and LDL-Cholesterol" – Jean-Louis Bresson, Ambroise Martin and Sean Strain declared an interest and refrained from discussion for this Agenda item.

Agenda item 11.1 in relation to the draft opinion on "Danacol and LDL-Cholesterol" – - Albert Flynn declared an interest and withdrew from the chair and refrained from discussion for this Agenda item.

No other 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. FEEDBACK FROM EFSA, THE SCIENTIFIC COMMITTEE AND OTHER EFSA PANELS**

Based on the recommendation of an ESCO working group report on botanicals the Scientific Committee will now update its guidance document for the safety assessment of botanicals and botanical preparations intended for use as supplement. The updated guidance document will be presented for possible adoption by the Scientific Committee end of July 2009.

Members were informed that the Guidance document by the Scientific Committee on the use of the benchmark dose approach in risk assessment was adopted and is now published ([http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902629553.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902629553.htm)).

A brief update of the EURRECA project (an EC funded project on aligning micronutrient recommendations across Europe) was given and members were surprised to hear that only a few micronutrients will be completely covered in this project.

## **5. TECHNICAL MEETING WITH APPLICANTS ON RECENT DEVELOPMENTS ON HEALTH CLAIMS APPLICATIONS**

The Chair and the Secretariat provided feedback on the Technical meeting held on 15 June 2009 in Brussels. The meeting was considered as a good opportunity to further explain the EFSA's evaluation process of health claims applications and to receive useful feed-back from the applicants. It was agreed that the NDA Panel will review and seek to improve the transparency of the opinions (e.g. why certain studies are not considered as pertinent, how the evidence is weighted) and the communication with the applicants.

The draft frequently asked questions (FAQ) document related to the EFSA assessment of health claims applications will be updated by taking into account the comments received during the consultation period and at the above-mentioned meeting. As soon as finalised, the updated FAQ will be released on the EFSA website together with a summary of the comments received.

## **6. FEEDBACK FROM THE COMMISSION ON MATTERS RELATING TO THE PANEL**

The Commission Services presented a report on how the NDA scientific outputs over the last three years were used by the European Commission. The NDA panel appreciated the feedback.

## **7. ARTICLE 13 HEALTH CLAIMS' LIST – GENERAL UPDATE**

A letter was sent by the Commission to EFSA on 26 June 2009, asking to consider delaying for some weeks the final decision on Article 13 opinions.

The EFSA's NDA Panel, agreed to proceed with the adoption of the first set of Article 13 opinions according to the agreed time frame. It was also emphasised that delivering Article 13 opinions in batches is the only feasible approach, taking into account the very large number of claims on the list.

Given the large number of opinions to be edited after adoption, publication is not foreseen before September 2009.

Members felt that there is a need to organise a meeting to have an exchange of views between relevant experts from Member States, Commission Services and EFSA Panel experts to discuss issues concerning the Article 13 list that have arisen during the evaluation process.

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## **8. STATUS OF APPLICATIONS UNDER ARTICLE 14/13(5) HEALTH CLAIMS**

**Article 14 claims:** By 25 June 2009, EFSA has received 254 Article 14 applications (215 referring to children's health and development and 39 referring to reduction of disease risk claims); 7 applications are under evaluation and 14 were withdrawn. By now EFSA adopted 51 opinions (covering 58 applications). For many of the applications, additional information is still awaited from the applicants. For some of the applications, EFSA went back to the respective National Competent Authority and the Commission seeking clarification on whether the application would fall in the scope of EC 1924/2006 Health Claims Regulation.

**Article 18/13(5) claims:** By 11 May 2009, EFSA has received 20 applications under Article 13(5) (claims based on newly developed science and/or which include a request for the protection of proprietary data): 7 are under evaluation, 7 were adopted and 6 were withdrawn.

## **9. DRAFT OPINION ON HEALTH CLAIMS ON PLANT STEROLS/STANOLS**

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902768432.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902768432.htm)

## **10. DRAFT OPINION ON LABELLING REFERENCE INTAKE VALUES FOR n-3 AND n-6 FATTY ACIDS**

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902671518.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902671518.htm)

## **11. APPLICATIONS PURSUANT TO ARTICLES 14/13(5) OF REGULATION (EC) No 1924/2006**

### **11.1. “Danacol<sup>®</sup> and LDL Cholesterol”**

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902768493.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902768493.htm)

### **11.2. “Gum periobalance<sup>®</sup> tablets and chewing gum and oral health”**

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902688755.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902688755.htm)

### **11.3. “Lycopene-whey complex (bioavailable lycopene)” and “the risk of arterial plaques”**

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902775091.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902775091.htm)

### **11.4. “Calcium + Vitamin D chewing tablets” and “the risk of osteoporotic fractures”**

The draft opinion was discussed and adopted subject to the incorporation of modifications agreed upon by the Panel. The text of the full opinion appears on the EFSA web site, available at: [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902785434.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902785434.htm)

## **12. DRAFT ARTICLE 13 OPINIONS**

The Panel discussed and adopted 93 opinions covering 525 Article 13 claims related to vitamins, minerals, macronutrients, probiotics, fibres, foods, other substances and botanicals. More details on which claims were adopted at the meeting can be found in the EFSA register of Questions:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=NDA&foodsectorarea=26>

The adopted opinions are subject to the incorporation of modifications agreed upon by the Panel and will be released on the website as soon as finalised.

### **13. DIETARY REFERENCE VALUES**

The draft opinion on fat was discussed and endorsed for release for public consultation subject to the incorporation of modifications agreed upon by the Panel. The text of the draft opinion appears on the EFSA website, available at:

[http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/nda\\_op\\_drv\\_fat\\_draft\\_en\\_released%20for%20consultation,0.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/nda_op_drv_fat_draft_en_released%20for%20consultation,0.pdf?ssbinary=true)

### **14. ANY OTHER BUSINESS**

The chair closed the last meeting of the NDA Panel in this mandate (2006-2009) by expressing his great appreciation to all members for the work that has been carried out over the last 3 years. He also thanked the NDA secretariat warmly for their support to the Panel. The NDA secretariat thanked the members very much for the high commitment they have shown that enabled the Panel to fulfil its broad mandate. Panel members and the NDA secretariat thanked the chair for the excellent chairmanship.

These minutes were adopted on 18 August 2009.