SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS 107th meeting of the Working Group on Claims



22 August 2023 09:00-12:00 MINUTES - Agreed on 25 August 2023

Location: Web-conference

Attendees:

Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.

Hearing Experts¹:
 Not Applicable

o EFSA:

Ionut Craciun and Silvia Valtueña Martinez

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. No further interests were declared orally at the start of the meeting.

4. Scientific topic(s) for discussion

a. Draft opinion on 'Appethyl®' and 'Body weight control in the context of overweight (Art. 13(5) claim). Applicant: Greenleaf Medical AB (HC-2022-3072_SE, EFSA-Q-2022-00096)

The WG discussed the applicant's response to the stop-clock letter and the draft opinion. The WG reviewed the issues related to the characterisation of the food/constituent, the studies submitted for the scientific substantiation of the claimed effect, and the proposed mechanism of action. The WG agreed on the conclusions. The draft opinion will be submitted for adoption to the next NDA Plenary meeting to be held on 31 August 2023 by web conference.

5. Any Other Business

None.

As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS 106th meeting of the Working Group on Claims

ersa European FOOD SAFETY AUTHORITY

11 July 2023 09:00-12:00 MINUTES - Agreed on 18 July 2023

Location: Web-conference

Attendees:

o Working Group Members:

Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.

Hearing Experts¹:

Not Applicable

o European Commission and/or Member States representatives:

EC: Panagiota Filippou

o EFSA:

Thibault Fiolet, Leng Heng, Angeliki Sofroniou, Ionut Craciun, Roanna Marie Saad, Pedro Daniel Das Neves Ferreira and Silvia Valtueña Martinez

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process. Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declarations of Interest made at the beginning of the meeting, please refer to the Annex.

4. Scientific topic(s) for discussion

a. Draft opinion on 'Appethyl®' and 'Body weight control in the context of overweight (Art. 13(5) claim). *Applicant: Greenleaf Medical AB* (HC-2022-3072_SE, EFSA-Q-2022-00096)

The WG discussed the draft scientific opinion related to 'Appethyl®' and 'Body weight control' in the context of overweight. The WG reviewed the issues related to the characterization of the food/constituent, the proposed claimed effect, the proposed mechanism of action and the studies submitted for the scientific substantiation of the claimed effect.

As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: https://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

MEETING MINUTES – 11 JULY 2023 106th meeting of the Working Group on Claims



A stop-clock letter incorporating changes will be circulated to the WG Claims for comments, prior to its sending to the Applicant.

5. Any Other Business

None

Annex

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, Dr Frank Thies declared the following interest: Member of the Board of Trustees of the Academy of Nutrition Sciences. In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS 105th meeting of the Working Group on Claims

efsa EUROPEAN FOOD SAFETY AUTHORITY

17 May 2023 09:00-12:00 MINUTES - Agreed on 25 May 2023

Location: EFSA - Parma (Meeting Room 06/B14)/Webconference

Attendees:

o Working Group Members:

Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.

Hearing Experts¹:

Not Applicable

o European Commission and/or Member States representatives:

EC: Stephanie Bodenbach, Panagiota Filippou

o EFSA:

Ionut Craciun, Leng Heng, Thibault Fiolet, Angeliki Sofroniou, and Silvia Valtueña Martinez

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Scientific topic(s) for discussion

 a. Draft opinion on 'Choline and contribution to normal liver function of the foetus and exclusively breastfed infants' (Art. 14 claim). Applicant: Procter & Gamble BV (EFSA-Q-2021-00543)

The WG discussed the draft scientific opinion, and in particular assessed data regarding the characterization of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

b. Draft opinion on 'Appethyl®' and 'Body weight control in the context of overweight' (Art. 13(5) claim). *Applicant: Greenleaf Medical AB* (EFSA-Q-2022-00096)

As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

MEETING MINUTES -17 MAY 2022 105th meeting of the Working Group on Claims



The WG discussed the data regarding the characterization of the food/constituent, the proposed claimed effect, the proposed mechanism of action and the studies submitted for the scientific substantiation of the claimed effect. The WG considered that additional information is needed from the applicant in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

V. Any Other Business

None

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS 104th meeting of the Working Group on Claims

efsa EUROPEAN FOOD SAFETY All HI-HOPITY

2 March 2023 14:00-16:00 MINUTES - Agreed on 15 March 2023

Location: EFSA - Parma (Meeting Room 00/M09)/Webconference

Attendees:

o Working Group Members:

Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.

Hearing Experts¹:

Not Applicable

o European Commission and/or Member States representatives:

EC: Panagiota Filippou, Stephanie Bodenbach

o EFSA:

Thibault Fiolet, Leng Heng, Angeliki Sofroniou and Silvia Valtueña Martinez

I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies for absence were received.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Scientific topic(s) for discussion

 a. Draft opinion on 'choline' and 'contribution to normal foetal and breastfed infant development' (Art. 14 claim). Applicant: Procter & Gamble BV (Serial: 504_BE EFSA-Q-2021-00543)

The WG discussed the draft scientific opinion related to choline and contribution to normal development of the foetus and breastfed infant. The WG reviewed the issues related to the characterization of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: https://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

MEETING MINUTES – 2 MARCH 2022 104th meeting of the Working Group on Claims



V. Any Other Business

None





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SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 103rd MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 3-4 March 2022

(Agreed on 06 March 2022)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- European Commission representatives:
 - SANTE Unit E1: Stephanie Bodenbach.
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Silvia Valtueña Martinez, and Ariane Titz.

Others:

Albert Flynn (hearing expert).

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members





In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 102th Working Group meeting held on 31 January 2022 via web conference.

The minutes of the 102st Working Group meeting were agreed by written procedure on 10 February 2022.

5. Scientific topics for discussion

5.1. Nutrient profiling (EFSA-Q-2021-00026)

The WG discussed the comments received from public consultation on the draft scientific opinion advising on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. All comments were addressed in a technical report that will be published together with the final version of the opinion. The scientific opinion was updated on the basis of these comments. The opinion will be discussed and possibly adopted during the NDA Panel plenary meeting on 23 – 25 March 2022.

6. Any Other Business

Not applicable.

Next meeting

The date of next meeting was not established (it depends on the validation of new health claims applications).

Annex I

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 102nd MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 31 January 2022

(Agreed on 7 February 2022)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- European Commission representatives:
 SANTE Unit E1: Stephanie Bodenbach, Heidi Moens, Panagiota Filippou.
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Silvia Valtueña Martinez, and Ariane Titz.

Others:Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members





In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 100th Working Group meeting held on 6 September 2021 via web conference.

The minutes of the 101st Working Group meeting were agreed by written procedure on 10 October 2021.

5. Scientific topics for discussion

5.1. Nutrient profiling (EFSA-Q-2021-00026)

The WG discussed the comments received from public consultation on the draft scientific opinion advising on the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. All comments are being addressed in a technical report that will be published together with the final version of the opinion. The scientific opinion is being updated on the basis of these comments. The updated opinion will be reviewed by external reviewer and discussed again during the next WG meeting on 3 – 4 March 2022.

6. Any Other Business

The WG discussed Art.14 application on 'choline' and 'contribution to normal foetal and infant brain development and function' (Claim Serial No: 504_BE EFSA-Q-2021-00543) being under validation. The WG discussed whether this application can be evaluated as a claim based on essentiality of a nutrient. It was decided that the letter to the applicant will be sent with respect to this issue.

Next meeting

The next meeting will take place on 3 p.m. – 4 a.m. March via web-conference.

Annex I

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 101st MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 04 October 2021

(Agreed on 09 October 2021)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- European Commission representatives:SANTE Unit E1: Stephanie Bodenbach, Heidi Moens.
- EFSA:

Nutrition Unit: Janusz Ciok, Valeriu Curtui, Leng Heng, Silvia Valtueña Martinez, and Ariane Titz.

Others:Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.





3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 100th Working Group meeting held on 6 September 2021 via web conference.

The minutes of the 100th Working Group meeting were agreed by written procedure on 17 September 2021.

5. Scientific topics for discussion

5.1. Nutrient profiling (EFSA-Q-2021-00026)

The WG discussed a draft of the following sections: 'Nutrients and non-nutrient components of food for which intakes might exceed recommended levels in most population groups and countries in Europe', 'Nutrients and non-nutrient components of food for which intakes might be inadequate in relation to recommended levels in some population groups and countries in Europe and 'Food groups that have important roles in diets of European populations and subgroups thereof'. An updated draft will be presented at the next NDA plenary meeting on 27-28 October 2021 for further discussion and possible endorsement for release for public consultation. The comments from the Panel members on the draft document will be discussed at the next WG meeting on 25 October 2021.

6. Any Other Business

Not applicable

7. Next meeting

The next meeting will take place on 25 October via web-conference.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 100th MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 6 September 2021

(Agreed on 17 September 2021)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- European Commission representatives:SANTE Unit E1: Stephanie Bodenbach, Heidi Moens.
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Leonard Matijevic, Silvia Valtueña Martinez, and Ariane Titz.

Others:

Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 99th Working Group meeting held on 16 July 2021 via web conference.

The minutes of the 99th Working Group meeting were agreed by written procedure on 25 July 2021.

5. Scientific topics for discussion

5.1. Nutrient profiling (EFSA-Q-2021-00026)

The WG discussed a draft of the following sections: 'Nutrients and non-nutrient components of food for which intakes might exceed recommended levels in most population groups and countries in Europe', 'Nutrients and non-nutrient components of food for which intakes might be inadequate in relation to recommended levels in some population groups and countries in Europe and 'Food groups that have important roles in diets of European populations and subgroups thereof'. An updated draft will be discussed during the next WG meeting.

6. Any Other Business

Not applicable

7. Next meeting

The next meeting will take place on 4 October via web-conference.

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 99th MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 16 July 2021

(Agreed on 25 July 2021)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- Hearing Experts representing industry:

Dr. Konstantinos Makris, Dr. Corina Konstantinou and Dr. Anastasia Perikkou representing Cyprus International Institute for Environmental and Public Health / Cyprus University of Technology (for item 5.2).

European Commission representatives:

SANTE Unit E1: Stephanie Bodenbach, Panagiota Filippou.

EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Leonard Matijevic, Silvia Valtueña Martinez, and Ariane Titz.

Others:

Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.





3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

Applicant's hearing:

Dr. Konstantinos Makris, Dr. Corina Konstantinou and Dr. Anastasia Perikkou were invited to comment/clarify the issues identified by the Working Group (WG) related to the agenda item 5.2 of the present meeting on 16 July 2021 (connected via web on from 14:20-15:00).

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA invited Dr. Konstantinos Makris, Dr. Corina Konstantinou and Dr. Anastasia Perikkou to submit an Annual Declaration of Interest. Their participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group, in accordance with the applicable legal framework⁵.

4. Agreement of the minutes of the 98th Working Group meeting held on 17 June 2021 via web conference.

The minutes of the 98th Working Group meeting were agreed by written procedure on 24 June 2021.

5. Scientific topics for discussion

5.1. Nutrient profiling (EFSA-Q-2021-00026)

The WG discussed a draft of the following sections: 'Nutrients and non-nutrient components of food for which intakes might exceed recommended levels in most population groups and countries in Europe', 'Nutrients and non-nutrient components of food for which intakes might be inadequate in relation to recommended levels in some population groups and countries in Europe and 'Food groups that have important roles in diets of European populations and subgroups thereof'. An updated draft will be discussed during the next WG meeting.

5.2. "Organic food (lower levels of pesticide residues than those in conventional food)" Applicant: Cyprus International Institute for

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁵ Decision of the Executive Director on Competing Interest Management, Article 9
Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels and the selection of external experts to assist EFSA with its scientific work, Article 15





Environmental and Public Health, Cyprus University of Technology (Art 14, Claims, Serial No 1924/2006, EFSA-Q-2021-00055)

Further to the applicant's reply to EFSA stop-the-clock letter, the representatives of the applicant (Dr. Konstantinos Makris, Dr. Corina Konstantinou and Dr. Anastasia Perikkou representing Cyprus International Institute for Environmental and Public Health / Cyprus University of Technology) were invited for the Applicant's hearing via Web.

The WG Chair opened the hearing session by explaining to the applicant the principles and the scientific requirements for substantiation of health claims as outlined in EFSA Guidance document. The Chair outlined the issues identified by the WG in relation to the characterisation of the food proposed as a subject of a health claim (i.e. 'organic food').

Dr. Konstantinos Makris, Dr. Corina Konstantinou and Dr. Anastasia Perikkou were given the opportunity to comment/clarify the issues identified by the WG. The WG took note of the applicant's clarification.

The WG reviewed the draft opinion taking into consideration the data submitted in the present application, the applicant's reply to EFSA stop-the-clock letter and clarifications from the applicant obtained during applicant's hearing. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

5.3. "Consumption of foods/drinks containing Isomaltulose (Palatinose™) replacing other sugars" *Applicant: BENEO GmbH* (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2021-00073)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed. The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

6. Any Other Business

Not applicable

7. Next meeting

The next meeting will take place on 6 September via web-conference.

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 98th MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 17 June 2021

(Agreed on 24 June 2021)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- Hearing Experts: Not Applicable.
- European Commission representatives:
 SANTE Unit E1: Stephanie Bodenbach, Heidi Moens¹, Panagiota Filippou².
- FFCΛ·

Nutrition Unit: Janusz Ciok, Ionut Craciun, Leng Heng, Leonard Matijevic, Silvia Valtueña Martinez, and Ariane Titz.

Others:

Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

² PM

¹ AM





3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management^{4,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 97th Working Group meeting held on 17-18 May 2021 via web conference.

The minutes of the 97th Working Group meeting were agreed by written procedure on 24 May 2021.

5. Scientific topics for discussion

5.1. Nutrient profiling (EFSA-Q-2021-00026)

The WG discussed a draft of the following sections: 'Nutrients and non-nutrient components of food for which intakes might exceed recommended levels in most population groups and countries in Europe', 'Nutrients and non-nutrient components of food for which intakes might be inadequate in relation to recommended levels in some population groups and countries in Europe and 'Food groups that have important roles in diets of European populations and subgroups thereof'. An updated draft will be discussed during the next WG meeting.

5.2. "Frutalose® chicory oligofructose" Applicant: Sensus BV (Royal Cosun) (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-006313)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed. The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

5.3. "MegaNatural®-BP" Applicant: Praline i Čokolada j.d.o.o. (Art. 13.5 Claims, Serial No 1924/2006, EFSA-Q-2020-00718)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed. The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





5.4. "Organic food (lower levels of pesticide residues than those in conventional food)" Applicant: Cyprus International Institute for Environmental and Public Health, Cyprus University of Technology (Art 14, Claims, Serial No 1924/2006, EFSA-Q-2021-00055)

The applicant's reply to EFSA stop-the-clock letter was presented and discussed. The draft opinion incorporating the data submitted for this application and suggestions from the discussion on the applicant's reply will be presented and discussed at the next WG meeting in July.

5.5. "Consumption of foods/drinks containing Isomaltulose (Palatinose™) replacing other sugars" *Applicant: BENEO GmbH* (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2021-00073)

The applicant's reply to EFSA stop-the-clock letter was presented and discussed. The draft opinion incorporating the data submitted for this application and suggestions from the discussion on the applicant's reply will be presented and discussed at the next WG meeting in July.

6. Any Other Business

Not applicable

7. Next meeting

The next meeting will take place on 16 July via web-conference.





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 97th MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 17-18 May 2021

(Agreed on 24 May 2021)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- Hearing Experts: Not Applicable.
- European Commission representatives:SANTE Unit E1: Stephanie Bodenbach, Heidi Moens.
- FFC∧

Nutrition Unit: Janusz Ciok, Leng Heng, Leonard Matijevic, Silvia Valtueña Martinez, and Ariane Titz.

Others:

Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.





3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 96th Working Group meeting held on 15 April 2021 via web conference.

The minutes of the 96th Working Group meeting were agreed by written procedure on 26 April 2021.

5. Scientific topics for discussion

5.1. Nutrient profiling (EFSA-Q-2021-00026)

The WG discussed a draft of the following sections: 'Nutrients and non-nutrient components of food for which intakes might exceed recommended levels in most population groups and countries in Europe', 'Nutrients and non-nutrient components of food for which intakes might be inadequate in relation to recommended levels in some population groups and countries in Europe and 'Food groups that have important roles in diets of European populations and subgroups thereof'. An updated draft will be discussed during the next WG meeting.

5.2. "Consumption of foods/drinks containing Isomaltulose (Palatinose™) replacing other sugars" *Applicant: BENEO GmbH* (Art. 13.5 Claim, Serial No 0503_DE, EFSA-Q-2021-00073)

An overview of the data submitted for this application was presented and discussed. The WG reviewed the characterisation of the food/constituent and the proposed claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food/constituent and the claimed effect). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6. Any Other Business

Not applicable

7. Next meeting

The next meeting will take place on 17 June via web-conference.

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 96th MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 15 April 2021

(Agreed on 26 April 2021)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- Hearing Experts: Peter Willatts¹

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- European Commission representatives:SANTE Unit E1: Stephanie Bodenbach, Olga Goulaki.
- EFSA:

Nutrition Unit: Janusz Ciok, Craciun Ionut, Leng Heng, Leonard Matijevic, Silvia Valtueña Martinez, and Ariane Titz.

Others:

Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

¹ Participated only 11 a.m. - 1 p.m.





3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 95th Working Group meeting held on 03 March 2021 via web conference.

The minutes of the 95th Working Group meeting were agreed by written procedure on 09 March 2021.

5. Scientific topics for discussion

5.1. Nutrient profiling (EFSA-Q-2021-00026)

The WG discussed the results of a questionnaire sent to Member States to gather information on the diseases/disorders upon which their Food Based Dietary Guidelines are based, on nutrients that are consumed in inadequate amounts in the respective countries and on supplementation programmes in place. The WG also discussed how to structure the section on 'nutrients of public health importance for European populations', the nutrients to be addressed and the type of evidence to be included. An updated draft will be discussed during the next WG meeting.

5.2. "Kiwifruits" Applicant: Zespri International Limited (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00562)

A revised draft opinion incorporating changes was discussed. The draft will be submitted to the NDA Panel for discussion/possible adoption.

5.3. "Affron" Applicant: Pharmactive Biotech Products, SL. (Art. 13.5 Claims, Serial No 1924/2006, EFSA-O-2020-00617)

An overview of the data submitted for this application, as well as the supplementary information provided by the applicant upon request for clarification from EFSA, was presented and discussed. The WG reviewed the proposed claimed effect and the studies submitted for the scientific substantiation of the claim.

A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





5.4. "MegaNatural®-BP" Applicant: Praline i Čokolada j.d.o.o. (Art. 13.5 Claims, Serial No 1924/2006, EFSA-Q-2020-00718)

An overview of the data submitted for this application was presented and discussed. The WG reviewed the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claim.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.5. "Organic food (lower levels of pesticide residues than those in conventional food)" Applicant: Cyprus International Institute for Environmental and Public Health, Cyprus University of Technology (Art 14, Claims, Serial No 1924/2006, EFSA-Q-2021-00055)

An overview of the data submitted for this application was presented and discussed. The WG reviewed the characterisation of the food/constituent and the proposed claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food/constituent). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6. Any Other Business

Not applicable

7. Next meeting

The next meeting will take place on 17-18 May via web-conference.





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 95th MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 03 March 2021

(Agreed on 09 March 2021)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- Hearing Experts:
 Not Applicable
- European Commission representatives:
 SANTE Unit E1: Stephanie Bodenbach, Olga Goulaki.
- FFC∧

Nutrition Unit: Janusz Ciok, Valeriu Curtui, Leng Heng, Leonard Matijevic, Silvia Valtueña Martinez, and Ariane Titz.

Others:

Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.





3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management^{2,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 94th Working Group meeting held on 26-27 January 2021 via web conference.

The minutes of the 94th Working Group meeting were agreed by written procedure on 31 January 2021.

5. Scientific topics for discussion

5.1. "Frutalose® chicory oligofructose" Applicant: Sensus BV (Royal Cosun) (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00631³)

An overview of the data submitted for this application was presented and discussed. The WG reviewed the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claim.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food, the proposed claimed effect, and the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2. "Kiwifruits" Applicant: Zespri International Limited (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-005623)

An overview of the data submitted for this application, as well as the supplementary information provided by the applicant upon request for clarification from EFSA, was presented and discussed. The WG reviewed the proposed claimed effect and the studies submitted for the scientific substantiation of the claim.

A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

5.3. Nutrient profiling (EFSA-Q-2021-00026)³

In line with EFSA's principles for carrying out the scientific assessment process, ⁴ a protocol outlining the approach towards the scientific assessment was discussed. In particular, the WG discussed the assessment questions/sub-questions and the evidence needs based on the (sub-)question formulation. The draft protocol will be circulated to the WG for

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¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

³ Please be aware that EFSA's Register of Questions is unavailable from 21 January until mid-February. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available here

⁴ https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1843





comments before submitting it to the NDA Panel for discussion/possible endorsement during its next plenary meeting.

The deadline for the finalisation of the scientific opinion is March 2022. Within this deadline, EFSA will launch a public consultation on the draft scientific opinion.

6. Any Other Business

Not applicable

7. Next meeting

The next meeting will take place on 15 April via web-conference.





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 94th MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 26-27 January 2021

(Agreed on 31 January 2021)

Participants

- Working Group Members:
 Jean-Louis Bresson¹, Stefaan De Henauw, Alfonso Siani (Chair), and Frank Thies.
- Hearing Experts²: Peter Willatts
- European Commission representatives:
 SANTE Unit E1: Stephanie Bodenbach, Olga Goulaki, Heidi Moens, and Ariane Van der Stappen.
- EFSA:

Nutrition Unit: Janusz Ciok, Valeriu Curtui, Leng Heng, Silvia Valtueña Martinez, and Ariane Titz.

Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ Participated on 26 Jan only.

² As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management^{4,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 93rd Working Group meeting held on 09 December 2020 via web conference.

The minutes of the 93rd Working Group meeting were agreed by written procedure on 10 December 2020.

5. Scientific topics for discussion

5.1. "Affron®" Applicant: (Pharmactive Biotech Products, SL) (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00617⁵)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2. "Beta-glucans" Applicant: Société des Produits Nestlé S.A. (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00447)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁵ Please be aware that EFSA's Register of Questions is unavailable from 21 January until mid-February. The temporary suspension of the tool is necessary to allow us to implement the launch of our new OpenEFSA portal. We apologise for the inconvenience. Further information is available here





5.3. "Kiwifruits" Applicant: Zespri International Limited (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00562)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied. The applicant will be invited for a hearing for the next WG meeting.

5.4. Nutrient profiling (EFSA-Q-2021-00026)

The EC representative introduced the background and terms of references of the Mandate to the WG. In line with EFSA's principles for carrying out the scientific assessment process, a protocol outlining the approach for scientific assessment will be developed. The WG discussed the problem formulation and the assessment questions/sub-questions which will inform the drafting of the protocol. The WG also discussed the evidence needs based on the (sub-)question formulation. The draft protocol will be circulated to the WG for comments and will be further discussed/refined by the WG at its next meeting, prior to its submission to the NDA Panel for possible endorsement.

The deadline for the finalisation of the scientific opinion is March 2022. Within this deadline, EFSA will run a public consultation on the draft scientific opinion.

6. Any Other Business

Not applicable

7. Next meeting

The next meeting will take place on 3 March via web-conference.

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⁶ https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2020.EN-1843





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

Not applicable.





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 93rd MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 09 December 2020

(Agreed on 10 December 2020)

Participants

- Working Group Members:
 Jean-Louis Bresson, Alfonso Siani (Chair), Stefaan De Henauw and Frank Thies.
- Hearing Experts¹: Peter Willatts
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Ariane Titz and Silvia Valtueña Martinez.

Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

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¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 92nd Working Group meeting held on 10 November 2020 via web conference.

The minutes of the 92nd Working Group meeting were agreed by written procedure on 11 November 2020.

5. Scientific topics for discussion

5.1 "Affron®" Applicant: (Pharmactive Biotech Products, SL) (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00617)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided and the claimed effect proposed). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2 "Beta-glucans" Applicant: Société des Produits Nestlé S.A. (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00447)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect. A revised draft opinion incorporating changes will be discussed during the next WG Health Claims meeting.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

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http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





6 Any Other Business

Not applicable

7 Next meeting

The next meeting will take place on 26 January via web-conference.





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

Not applicable.





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 92nd MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 10 November 2020

(Agreed on 11 November 2020)

Participants

- Working Group Members:Jean-Louis Bresson, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng and Ariane Titz.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Stefaan De Henauw.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 91st Working Group meeting held on 6 October 2020 via web conference.

The minutes of the 91st Working Group meeting were agreed by written procedure on 8 October 2020.

5. Scientific topics for discussion

5.1. "Green Kiwifruit" *Applicant: Zespri International Limited* (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00562)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6. Any Other Business

The comments obtained from Tchibo GmbH via the European Commission Services related to the opinion on coffee C21 and protection of DNA from strand breaks (EFSA-Q-2019-00423) adopted on 25 February 2020 were discussed. It was considered that Technical Report covering EFSA reply to the comments will be issued.

The comments obtained from DuPont via the European Commission Services related to the opinion on Bi-07 and lactose digestion (EFSA-Q-2020-00024) adopted on 1 July 2020 were discussed. It was considered that Technical Report covering EFSA reply to the comments will be issued.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





7. Next meeting

The next meeting will take place on 9 December via web-conference.

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

Not applicable.





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 91st MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 6 October 2020

(Agreed on 8 October 2020)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Olga Goulaki
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng and Ariane Titz.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

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¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 90th Working Group meeting held on 8 September 2020 via web conference.

The minutes of the 90th Working Group meeting were agreed by written procedure on 13 September 2020.

5. Scientific topics for discussion

5.1. "Beta-glucans" Applicant: Société des Produits Nestlé S.A. (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00447)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2. "MetabolAid" Applicant: MONTELOEDER (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00128)

This item was not discussed. No response has yet been received from the applicant in reply to stop-the-clock letter.

6. Any Other Business

The comments obtained from Tchibo GmbH via the European Commission Services related to the opinion on coffee C21 and protection of DNA from strand breaks (EFSA-Q-2019-00423) adopted on 25 February 2020 were discussed. It was considered that Technical Report covering EFSA reply to the comments will be issued.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





7. Next meeting

The next working group meeting will be held on 10 November 2020 via tele-conference.





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

Not applicable.





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 90TH MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 8 September 2020

(Agreed on 13 September 2020)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Ariane Titz and Silvia Valtueña Martínez.

Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 89th Working Group meeting held on 15-16 June 2020 via web conference.

The minutes of the 89th Working Group meeting were agreed by written procedure on 18 June 2020.

5. Scientific topics for discussion

5.1. "Anxiofit-1" Applicant: Anxiofit Limited (Art. 14 Claim, Serial No: 1924/2006, EFSA-Q-2020-00032)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

5.2. "MetabolAid" Applicant: MONTELOEDER (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00128)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

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http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





6. Any Other Business

Not applicable

7. Next meeting

The next working group meeting will be held on 6 October 2020 via tele-conference.





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 89TH MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 15-16 June 2020

(Agreed on 18 June 2020)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Ariane Titz and Silvia Valtueña Martínez.

Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants. This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 88th Working Group meeting held on 27 February 2020 via web conference.

The minutes of the 88th Working Group meeting were agreed by written procedure on 3 March 2020.

5. Scientific topics for discussion

5.1. "Anxiofit-1" Applicant: Anxiofit Limited (Art. 14 Claim, Serial No: 1924/2006, EFSA-Q-2020-00032)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2. "Bifidobacterium animalis subsp. lactis Bi" Applicant: DuPont Nutrition Biosciences (Art. 13.5 Claim, Serial No 1924/2006, EFSA-Q-2020-00024)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

2

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





6. Any Other Business

An appraisal system which could be used to assess the risk of bias in the process of evaluation of single study was discussed. It was considered that the system will be used in relation to upcoming applications.

7. Next meeting

The next working group meeting will be held on 8 September 2020 via tele-conference.





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 88TH MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 27 February 2020

(Agreed on 03 March 2020)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Ariane Titz and Silvia Valtueña Martínez.

Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

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¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 87th Working Group meeting held on 7 January 2020 via web conference.

The minutes of the 87th Working Group meeting were agreed by written procedure on 13 January 2020.

5. Scientific topics for discussion

5.1. "Anxiofit-1" Applicant: Anxiofit Limited (Art. 14 Claim Serial No: 0493_HU, EFSA-Q-2020-00032)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2. "Bifidobacterium animalis subsp. lactis Bi" Applicant: DuPont Nutrition Biosciences (Art. 13.5 Claim, Serial No 0492_IE, EFSA-Q-2020-00024)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

2

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





6. Any Other Business

The next working group meeting will be held on 15-16 June 2020 in Parma.





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 87TH MEETING OF THE WORKING GROUP ON CLAIMS

Held on tele-conference on 07 January 2020

(Agreed on 13 January 2020)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Not Applicable
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Ariane Titz and Silvia Valtueña Martínez.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 86th Working Group meeting held on 10 December 2019 via web conference.

The minutes of the 86th Working Group meeting were agreed by written procedure on 13 December 2019.

5. Scientific topics for discussion

 "Coffee C21" and "maintenance of DNA integrity in cells of the body" Applicant: Tchibo GmbH (Art. 13.5. Claim Serial No: 0487_DE, EFSA-Q-2019-00423)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed. The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

5.2. 'Lutemax 2020' and 'contributes to the maintenance of normal vision' - Applicant: OmniActive Health Technologies (Art. 13.5, Claim Serial No: 0484_BE, EFSA-Q-2019-00346)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed. The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

6. Any Other Business

The next working group meeting will be held on 27-28 February 2020 in Parma.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 86TH MEETING OF THE WORKING GROUP ON CLAIMS

Held on 10 December 2019 in Parma

(Agreed on 13 December 2019)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair), Yolanda Sanz and Frank Thies.
- Hearing Experts¹: Carlo Galli (for item 6.1)
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Ariane Titz, Silvia Valtueña Martínez.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

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¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 85th Working Group meeting held on 28-29 October 2019 via web conference.

The minutes of the 85th Working Group meeting were agreed by written procedure on 8 November 2019.

5. Hearing Expert

Prof. Carlo Galli was invited to present his views for item 6.1. of the present meeting.

6. Scientific topics for discussion

6.1. "Lozenges containing *L. reuteri* DSM 17938 and *L. reuteri* ATCC PTA 5289" and "support normal gum function" - *Applicant: BioGaia AB* (Art. 13.5, Claim Serial No: 0485_SE, EFSA-Q-2019-00383)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed. The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





6.2. 'Lutemax 2020' and 'contributes to the maintenance of normal vision' - Applicant: OmniActive Health Technologies (Art. 13.5, Claim Serial No: 0484_BE, EFSA-Q-2019-00346)

A reply from the applicant to EFSA's stop-the-clock letter was discussed. A draft opinion will be discussed during the next WG Claims.

6.3. 'AGEprost' and 'prostate function' - *Applicant: Gencore* (Art. 13.5, Claim Serial No: 0491_IE, EFSA-Q-2019-00657)

An overview of the data submitted in relation to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food/constituent being the subject of the claim and the methodological issues in relation to human study provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

7. Any Other Business

The next working group meeting will be held on 7 January 2020 via web conference.





Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 85TH MEETING OF THE WORKING GROUP ON CLAIMS

Held on 28-29 October 2019 in Parma

(Agreed on 8 November 2019)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹:
 Carlo Galli (for item 6.2)
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Ariane Titz, Silvia Valtueña Martínez.

Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 84th Working Group meeting held on 10 September 2019 via web conference.

The minutes of the 84th Working Group meeting were agreed by written procedure on 18 September 2019.

5. Hearing Expert

Prof. Carlo Galli was invited to present his views for item 6.2. of the meeting.

6. Scientific topics for discussion

6.1. "MenaQ7®, vitamin K2 as menaquinone-7" and "improves arterial stiffness' - Applicant: NattoPharma ASA (Art. 13.5, Claim Serial No: 0483_IE, EFSA-Q-2019-00229)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed.

The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter. A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel for discussion/possible adoption.

6.2. "Lozenges containing *L. reuteri* DSM 17938 and *L. reuteri* ATCC PTA 5289" and "support normal gum function" - *Applicant: BioGaia AB* (Art. 13.5, Claim Serial No: 0485 SE, EFSA-O-2019-00383)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed. The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information (2nd stop-the-clock letter) will be sent to the applicant and a stop-the-clock procedure will be applied.

6.3. "Coffee C21" and "maintenance of DNA integrity in cells of the body" – Applicant: Tchibo GmbH (Art. 13.5, Claim Serial No: 0487_DE, EFSA-Q-2019-00423)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented and discussed. The WG reviewed the draft opinion taking into consideration the data submitted in the present application and the applicant's reply to EFSA stop-the-clock letter.

It was considered that additional information from the applicant is needed (regarding the methodological issues in relation to human studies provided). Therefore, a request for additional information (2nd stop-the-clock letter) will be sent to the applicant and a stop-the-clock procedure will be applied.

6.4. 'Lutemax 2020' and 'contributes to the maintenance of normal vision' - Applicant: OmniActive Health Technologies (Art. 13.5, Claim Serial No: 0484_BE, EFSA-Q-2019-00346)

An overview of the data submitted in relation to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food/constituent being the subject of the claim and the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6.5. 'Kale leaves' and 'maintain normal bone mineral density' - Applicant: Green Gourmet A/S (Art. 13.5, Claim Serial No: 0488_DK, EFSA-Q-2019-00489)

An overview of the data submitted in relation to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food being the subject of the claim and the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.





6.6. 'Kale leaves' and 'reduce blood LDL-cholesterol and increase HDL-cholesterol. Elevated blood LDL-cholesterol is a risk factor in the development of coronary heart disease' - *Applicant: Green Gourmet A/S* (Art. 14, Claim Serial No: 0489_DK, EFSA-Q-2019-00490)

An overview of the data submitted in relation to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food being the subject of the claim and the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6.7. 'Kale leaves' and 'maintain eye health and function' - *Applicant: Green Gourmet A/S* (Art. 13.5, Claim Serial No: 0490_DK, EFSA-Q-2019-00491)

An overview of the data submitted in relation to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food being the subject of the claim, the claimed effects proposed and the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

7. Any Other Business

The next working group meeting will be held on 10 December 2019 via web conference.





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 84th MEETING OF THE WORKING GROUP ON CLAIMS

Held on 10 September 2019, web-conference

(Agreed on 18 September 2019)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Carlo Galli (for item 6.2)
- European Commission and/or Member States representatives:Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Ariane Titz, Silvia Valtueña Martínez.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf





2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management^{3,} EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 83rd Working Group meeting held on 17 May 2019, web conference.

The minutes of the 83rd Working Group meeting were agreed by written procedure on 28 May 2019.

5. Hearing Expert (s)

Prof. Carlo Galli was invited to present his views for item 6.2. of the present meeting.

6. Scientific topics for discussion

6.1. "MenaQ7®, vitamin K2 as menaquinone-7" and "improves arterial stiffness" - *Applicant: NattoPharma ASA* (Art. 13.5, Claim, Serial No: 0483 IE EFSA-0-2019-00229)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food/constituent that is the subject of the claim, characterisation of the claimed effect, the outcome variables that were used to assess the claimed effect in human studies, the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





6.2. "Lozenges containing *L. reuteri* DSM 17938 and *L. reuteri* ATCC PTA 5289" and "support normal gum function" - *Applicant: BioGaia AB* (Art. 13.5. Claim Serial No: 0485_SE, EFSA-Q-2019-00383)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the outcome variables and the methods of measurement that were used to assess the claimed effect in human studies, and the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6.3. "Corinthian raisins" and "lower blood glucose rise after their consumption compared to foods/drinks containing sucrose or glucose" - Applicant: Agricultural Cooperatives Union of Aeghion SA and Currants (Corinthian raisins) Cooperative SA (Art. 13.5. Claim Serial No: 0486_GR EFSA-Q-2019-00381)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food/constituent that is claimed as comparator and the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6.4. "Coffee C21" and "maintenance of DNA integrity in cells of the body" – Applicant: Tchibo GmbH (Art. 13.5. Claim Serial No: 0487_DE EFSA-Q-2019-00423)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the conditions of use proposed and the methodological issues in relation to human studies provided). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

7. Any Other Business

The next working group meeting will be held on 28-29 October 2019 in Parma.





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 83RD MEETING OF THE WORKING GROUP ON CLAIMS

Held on 17 May 2019, web conference

(Agreed on 28 May 2019)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts:

Not Applicable

- European Commission and/or Member States representatives: Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Silvia Valtueña Martínez.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.





3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director on Competing Interest Management², EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 82nd Working Group meeting held on 25 March 2019, web conference.

The minutes of the 82nd Working Group meeting held on 25 March 2019 were agreed by written procedure on 27 March 2019.

5. Scientific topics for discussion

6.1 NSK-SD® fermented soybean extract and contributes to the maintenance of blood pressure" - Applicant: Japan Bio Science Laboratory-USA, Inc. (Art. 13.5, 0481_BE, EFSA-Q-2019-00007)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding methodological issues in relation to human studies provided, the proposed mechanism of action for the claimed effect and its biological plausibility). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6.2 "A combination of beta-sitosterol and beta-sitosterol glucoside and contributes to the normal function of the immune system by restoring balance between TH1- and TH2- mediated immunity" – Applicant: Essential Sterolin Products (Pty) Ltd (Art. 13.5, 0478_NL EFSA-Q-2018-00701)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the characterisation of the food/constituent that is the subject of the claim, characterisation of the claimed effect, the outcome variable(s) and the methods of measurement that were used to assess the claimed effect in human studies). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





6.3 LYC-O-MATO® 6% and helps to improve or maintain the skin health against photo-oxidative damage" – Applicant: Lycored Ltd. (Art 13.5, 0482 FR, EFSA-O-2019-00123)

An overview of the data submitted related to the claim application was presented and discussed. The WG reviewed the issues related to the characterisation of the food/constituent, the proposed claimed effect, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (regarding the claimed effect, the outcome variable(s) and the methods of measurement that were used to assess the claimed effect, the evidence available for the scientific substantiation of the claim, considering the human intervention studies submitted). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

6. Any Other Business

Next working group meeting will be held on 18 June (14:00-17:00) web conference.





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND **FOOD ALLERGENS**

MINUTES OF THE 82nd MEETING OF THE WORKING GROUP ON CLAIMS

Held on 25 March 2019, web conference

(Agreed on 27 March 2019)

Participants

- Working Group Members: Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Anders Sjödin (for item 6.1)
- European Commission and/or Member States representatives: Not Applicable
- EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Silvia Valtueña Martínez.

Others: Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.





2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 81st Working Group meeting held on 20 February 2019, web conference.

The minutes of the 81st Working Group meeting held on 20 February 2019 were agreed by written procedure on 22 February 2019.

5. Hearing Expert

Dr. Anders Sjödin was invited to present his views for item 6.1 of the present meeting.

6. Scientific topic(s) for discussion

6.1 "GlycoLite™ helps to reduce body weight" - Applicant: Omega Pharma Innovation & Development (Art. 13.5, 0476_IE, EFSA-Q-2018-00611)

Further to the applicant's reply to EFSA stop-the-clock letter, a draft opinion was presented. The WG reviewed and discussed the sections related to the characterisation of the food/constituent, the human intervention studies submitted for scientific substantiation of the claimed effect taking into consideration the conditions of use for the proposed claim, the animal efficacy study, and the applicant's proposed mechanisms of action by which the food/constituent could exert the claimed effect.

A revised draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel⁴ for discussion/possible adoption.

7. Any Other Business

Next working group meeting will be held on 17 May (am), web conference.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁴ The next Plenary meeting of the NDA Panel will be held 15-16 March 2019





Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence 5 and the Decision of the Executive Director on Competing Interest Management 6, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 81TH MEETING OF THE WORKING GROUP ON CLAIMS

Held on 20 February 2019, web conference

(Agreed on 22 February 2019)

Participants

- Working Group Members:
 Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.
- Hearing Experts¹: Not applicable
- European Commission:

DG SANTE: Olga Goulaki, Athanasios Raikos.

EFSA:

Nutritition Unit: Janusz Ciok, Leng Heng, Silvia Valtueña Martínez.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.





2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to the Annex. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. Agreement of the minutes of the 80th Working Group meeting held on 16 January 2019, Parma (Italy)

The minutes of the 80th Working Group meeting were agreed by written procedure on 24 January 2019.

5. Scientific topic for discussion: draft Article 13.5 and 14 opinions

5.1. "GlycoLite™ helps to reduce body weight" - Applicant: Omega Pharma Innovation & Development (Art. 13.5, 0476_IE, EFSA-Q-2018-00611)

A draft opinion was presented and discussed. The WG reviewed the sections related to the characterisation of the food/constituent, and the studies submitted for the scientific substantiation of the claimed effect.

It was considered that additional information from the applicant is needed (clarification about the method(s) used for the measurement of enzyme activity, questions on the human intervention studies submitted for substantiation and the conditions in which the claimed effect is achieved, and question about the proposed mechanism of action). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2. "Nutrimune supports the immune system in defence against pathogens in the upper respiratory and gastrointestinal tract of young children" - Applicant: H.J. Heinz Supply Chain Europe B.V. - (Art. 14, 0480_NL, EFSA-Q-2018-00727)

Further to the applicant's reply to EFSA stop-the-clock letter and the applicant's hearing held on 16 January 2019, a draft opinion was presented and discussed.

The WG reviewed the section on the scientific substantiation of the claimed effect taking into consideration the data submitted in the present application, the applicant's reply to EFSA stop-the-clock letter, and the clarification given by the applicant during the hearing particularly on the statistical re-analysis of the two human intervention studies. A revised

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf





draft opinion incorporating changes will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel⁴ for discussion/possible adoption.

6. Any Other Business

The WG was informed about applications received. Information on health claim applications received including their status can be found on EFSA Register of Questions.

7. Next meeting

The next meeting is to be confirmed.

⁴ The next Plenary meeting of the NDA Panel will be held 13-14 March 2019.





Annex

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand.

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁶ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 80th meeting of the Working Group on Claims

16 January 2019, Parma (Italy)
(Agreed on 24 January 2019)

Participants:

Working Group Members:

Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.

Hearing Expert:

Anders Sjödin (for item 5.2).

Hearing Experts representing industry:

Representatives from H.J. Heinz Supply Chain Europe B.V. (for item 5.3):

- Andrea Budelli, VP R&D Europe
- Kathy La Macchia- Head Nutrition Europe
- Veruska Calabretta- Nutritionist
- Wim Calame Research statistician partner
- Prof Roberto Berni Canani Principal Research Investigator

European Commission and/or Member States representatives:

Not Applicable.

• EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Ariane Titz, and Silvia Valtueña Martínez.

APDESK: Remigio Marano

Others:

Not Applicable



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

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

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management², EFSA screened the Annual Declaration of Interest filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

Applicant's hearing:

The applicant's representatives were invited to comment/clarify the issues identified by the Working Group (WG) related to the agenda item 5.3 of the present meeting on 16 January 2019 (connected via web conference from 14:00 to 15:00 (CET)).

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA invited participants representing the applicant to submit an Annual Declaration of Interest. Their participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group, in accordance with the applicable legal framework⁵.

4. General issues on health claims evaluation

Not applicable.

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¹ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management __17.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management 17.pdf

Decision of the Executive Director on Competing Interest Management, Article 9 Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels and the selection of external experts to assist EFSA with its scientific work, Article 15



5. Draft Article 13.5 and 14 opinions

5.1. Zespri International Itd. - "kiwifruit Actinidia deliciosa (var. Hayward)" and "reduces gastrointestinal discomfort" (Art. 13.5, 0475_BE, EFSA-Q-2018-00416)

Further to the Applicant's Hearing (held on 17 December 2018) and EFSA following up with the applicant post-meeting, the WG was given an update on the application and the status.

5.2. Omega Pharma Innovation & Development - "GlycoLite™ helps to reduce body weight" (Art. 13.5, 0476_IE, EFSA-Q-2018-00611)

Further to the applicant's reply to EFSA stop-the-clock letter requesting clarifications on issues identified related to the application, a revised draft opinion was presented. The WG reviewed the sections related to the characterisation of the food/constituent, and the studies submitted for the scientific substantiation of the claimed effect. A draft opinion incorporating changes will be circulated to the next WG Claims⁶ for further consideration, prior to its submission to the NDA Panel⁷ for discussion/possible adoption.

5.3. H.J. Heinz Supply Chain Europe B.V. - "Nutrimune supports the immune system in defence against pathogens in the upper respiratory and gastrointestinal tract of young children" (Art. 14, 0480_NL, EFSA-Q-2018-00727)

Further to the applicant's reply to EFSA stop-the-clock letter, the WG invited the applicant to an Applicant's Hearing on 16 January 2019 via web-conference.

The WG Chair opened the hearing session by presenting to the applicant the issues identified by the WG on the human intervention studies described already in EFSA's previous opinion on Nutrimune® published in 2017. The applicant was also presented with the issues identified by the WG on the additional post-hoc statistical analysis of both afore-mentioned studies submitted in the current new application.

The applicant's representatives were given the opportunity to comment/clarify the issues identified by the WG.

The WG took note of the applicant's clarification. A draft opinion will be discussed at the next WG Claims meeting⁶, prior to its submission to the NDA Panel⁷ for discussion/possible adoption.

⁶ The next meeting of the WG Claims will be held on 20 February 2019.

⁷ The next Plenary meeting of the NDA Panel will be held 13-15 March 2019.



EFSA will follow-up post-meeting with the applicant on the next steps and relative timelines.

5.4. FrieslandCampina Nederland B.V. - "Galacto-oligosaccharides (GOS) support normal defecation by softening the stool in infants" (Art. 14, 0477_NL, EFSA-Q-2018-00613)

Postponed.

6. Any Other Business

- The WG was informed about new applications received. Information on health claim applications received including their status can be found on EFSA Register of Questions.
- The next meeting of the WG Claims will be scheduled on 20 February 2019 via web-conference (pm).



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand. In accordance with EFSA's Policy on Independence⁸ and the Decision of the Executive Director on Competing Interest Management⁹, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management 17.pdf



Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 79th meeting of the Working Group on Claims

WEB-conference, 17 December 2018, Parma (Italy)
(Agreed on 20 December 2018)

Participants:

Working Group Members:

Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.

Hearing Expert:

Anders Sjödin (for item 5.2).

Hearing Experts representing industry:

Zespri International ltd.: Lynley Drummond and Juliet Ansell (for item 5.1)

European Commission and/or Member States representatives:

Not Applicable.

• EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, and Silvia Valtueña

Martínez.

APDESK: Remigio Marano

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.



2. Adoption of agenda

The agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management², EFSA screened the Annual Declaration of Interest filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

Applicant's hearing:

Dr Lynley Drummond and Dr Juliet Ansell were invited to comment/clarify the issues identified by the Working Group (WG) related to the agenda item 5.1 of the present meeting on 17 December 2018 (connected via web conference from 14:30 to 15:30 (CET)).

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA invited Dr Lynley Drummond and Dr Juliet Ansell to submit an Annual Declaration of Interest. Their participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group, in accordance with the applicable legal framework⁵.

4. General issues on health claims evaluation

Not applicable.

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management_17.pdf

 $^{^1\ \} https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf$

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management __17.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_

Decision of the Executive Director on Competing Interest Management, Article 9 Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels and the selection of external experts to assist EFSA with its scientific work, Article 15



5. Draft Article 13.5 and 14 opinions

5.1. Zespri International Itd. - "kiwifruit Actinidia deliciosa (var. Hayward)" and "reduces gastrointestinal discomfort" (Art. 13.5, 0475_BE, EFSA-Q-2018-00416)

Further to the applicant's reply to EFSA stop-the-clock letter, the WG discussed the key human intervention studies submitted for scientific substantiation of the claim related to gastrointestinal discomfort and identified the issues that required clarification by the applicant.

The WG Chair opened the hearing session by explaining to the applicant the principles and the scientific requirements for substantiation of claims related to reduction of gastro-intestinal discomfort for the general population as outlined in EFSA Guidance document. The Chair outlined the issues identified by the WG on the primary efficacy studies submitted by the applicant for the scientific substantiation of the claim related to gastrointestinal discomfort.

Dr Lynley Drummond and Dr Juliet Ansell representing Zespri were given the opportunity to comment/clarify the issues identified by the WG.

The WG took note of the applicant's clarification. A draft opinion will be submitted to the next NDA plenary meeting⁶ for possible adoption.

EFSA will follow up post-meeting with the applicant on the next steps and relative timelines.

5.2. European Specialist Sports Nutrition (ESSNA) – "Protein increases muscle strength when consumed in conjunction with resistance training" (Art.13.5, 0479_BE, EFSA-Q-2018-00702)

Further to last WG discussions on the Applicant's reply to EFSA stop-the-clock letter requesting clarifications on issues related to the application, the WG was given an update on the application and the status.

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⁶ The next meeting of the NDA Panel will be held on 17-18 January 2019.



6. Any Other Business

• The next meeting of the WG Claims will be scheduled on 16 January 2019 in Parma (09.00-17.00).



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand. In accordance with EFSA's Policy on Independence⁷ and the Decision of the Executive Director on Competing Interest Management⁸, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management 17.pdf



Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 78th meeting of the Working Group on Claims

Held on 28 November 2018, Parma (Italy)

(Agreed on 4 December 2018)

Participants:

• Working Group Members:

Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair) and Frank Thies.

Hearing Experts:

Anders Sjödin (for items 5.1 and 5.2).

• European Commission and/or Member States representatives:

Not Applicable.

• EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Ariane Titz and Silvia Valtueña Martínez.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management², EFSA screened the Annual Declaration of Interest filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claims evaluation

Not applicable.

5. Draft Article 13.5 and 14 opinions

5.1. Omega Pharma Innovation & Development - "GlycoLite™ helps to reduce body weight" (Art. 13.5, 0476_IE, EFSA-Q-2018-00611)

A draft opinion was presented. The WG discussed the sections related to characterisation of the food/constituent, and the new studies submitted for scientific substantiation of the claimed effect in the present application.

It was considered that additional information from the applicant is needed (clarification about the food/constituent that is the subject of the claim and the new human intervention study submitted, and question about other studies not included in the application but the identified by WG in a meta-analysis). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2. European Specialist Sports Nutrition (ESSNA) – "Protein increases muscle strength when consumed in conjunction with resistance training" (Art. 13.5, 0479_BE, <u>EFSA-Q-2018-00702</u>)

The WG discussed the Applicant's reply to EFSA stop-the-clock letter requesting clarifications about the food/constituent that is the subject of the claim, the claimed effect, characterisation of the

¹ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management 17.pdf



target population and the conditions of use for the claim, the human studies submitted and their inclusion/exclusion criteria).

A draft opinion will be presented at the next WG meeting³ for discussion.

5.3. Zespri International Itd. - "kiwifruit Actinidia deliciosa (var. Hayward)" and "reduces gastrointestinal discomfort" (Art. 13.5, 0475_BE, EFSA-Q-2018-00416)

Further to the applicant's reply to EFSA stop-the-clock letter, the WG discussed the key human intervention studies submitted for scientific substantiation of the claim related to gastrointestinal discomfort.

It was considered that further review of the studies should be carried out. An applicant's hearing will be organised to clarify a number of issues identified by the WG at the next WG meeting³.

5.4. FrieslandCampina Nederland B.V. - "Galacto-oligosaccharides (GOS) support normal defecation by softening the stool in infants" (Art. 14, 0477_NL, EFSA-Q-2018-00613)

The WG discussed the characterisation of the food/constituent, the target population, and the studies submitted for the scientific substantiation of the claim.

It was considered that additional clarification from the applicant is needed (about the food/constituent that is the target for the claim, the target population, the studies submitted, the statistical analyses and the methods for assessment of the outcome variable). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.5. H.J. Heinz Supply Chain Europe B.V. - "Nutrimune supports the immune system in defence against pathogens in the upper respiratory and gastrointestinal tract of young children" (Art. 14, 0480_NL, EFSA-Q-2018-00727)

The WG discussed the new data submitted in the present application, which contains a *post-hoc* statistical analysis of the two intervention studies that were already submitted for the scientific substantiation of the claim in a previous application (EFSA-Q-2016-00008) and three studies on the mechanisms by which the food could exert the claimed effect. A stop-the-clock letter will apply to clarify the issues identified by the WG.

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³ WG Claims meeting on 17 December 2018.



6. Any Other Business

- The WG discussed the Technical Report which addresses EFSA response to comments received pursuant to Article 16(6) of Regulation (EC) No 1924/2006 related to the EFSA opinion on "Symbiosal® and lowering of blood pressure" (EFSA-Q-2018-00002). Feedback from the WG was incorporated.
- The next meetings of the WG Claims will be scheduled on:
 - 17 December 2018 via web-conference (13:30-16:30, Parma time)
 - 16 January 2019 in Parma (09.00-17.00).



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof. Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand. In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management 17.pdf



Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 77th meeting of the Working Group on Claims

Held on 25-26 October 2018, Parma (Italy)

(Agreed on 30 October 2018)

Participants:

• Working Group Members:

Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani (Chair), and Frank Thies.

Hearing Experts:

Anders Sjödin (for items 5.1 and 5.3).

• European Commission and/or Member States representatives:

Not Applicable.

EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, and Silvia Valtueña Martínez.

Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.



2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence¹ and the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management², EFSA screened the Annual Declaration of Interest filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claims evaluation

Not applicable.

5. Draft Article 13.5 and 14 opinions

5.1. European Specialist Sports Nutrition (ESSNA) – "Protein increases muscle strength when consumed in conjunction with resistance training" (Art.31.5, 0479_BE, EFSA-Q-2018-00702)

The WG discussed issues identified related to the application. It was considered that additional information from the applicant is needed (clarification about the food/constituent that is the subject of the claim, the claimed effect, characterisation of the target population and the conditions of use for the claim, and questions on the human studies submitted). Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.2. FrieslandCampina Nederland B.V. - "Galactooligosaccharides (GOS) support normal defecation by softening the stool in infants" (Art. 14, 0477_NL, EFSA-Q-2018-00613)

A draft opinion was presented. The WG discussed the sections on characterisation of the food/constituent, the claimed effect, and

¹ https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management 17.pdf



the scientific substantiation of the claim. It was considered that further review of the studies submitted for substantiation should be carried out. A revised draft opinion will be presented at the next WG meeting³ for further discussion.

5.3. Omega Pharma Innovation & Development - "GlycoLite™ helps to reduce body weight" (Art.31.5, 0476_IE, EFSA-Q-2018-00611)

The background related to the application was introduced. An overview of the studies submitted for scientific substantiation was presented and discussed.

A draft opinion will be presented at the next WG meeting³ for further discussion.

5.4. Zespri International Itd. - "kiwifruit Actinidia deliciosa (var. Hayward)" and "reduces gastrointestinal discomfort" (Art.31.5, 0475_BE, EFSA-Q-2018-00416)

The Applicant's reply to EFSA request for clarification on the application (the stop-the-clock letter) was resented and discussed.

A draft opinion will be presented at the next WG meeting³ for further discussion.

6. Any Other Business

The WG was informed of about two applications which are under completeness check:

- The combination of Phytosterols (Beta-sitosterol) and Betasitosterol glucoside contribute to the normal function of the immune system (Art 13.5, 0478 NL, EFSA-Q-2018-00701)
- "Nutrimune supports the immune system in defence against pathogens in the upper respiratory and gastrointestinal tract of young children" (Art. 14, 0480_NL, EFSA-Q-2018-00727)

Information on health claim applications received including their status can be found on EFSA Register of Questions.

The next meeting of the Working Group on Claims will be held on 28 November 2018 in Parma.

A web-conference meeting will be held on 17 December 2018 (13:30-16:30, Parma time).

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³ WG Claims meeting on 28 November 2018.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof. Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand. In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management 17.pdf



Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 76th meeting of the Working Group on Claims

Held on 11-12 September 2018, Parma (Italy)

(Agreed on 19 September 2018)

Participants:

• Working Group Members:

Jean-Louis Bresson¹, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Alfonso Siani (Chair), Anders Mikael Sjödin, John Joseph Strain, Peter Willatts

Hearing Experts representing industry²:

AVVA Pharmaceuticals Ltd.: Thanasis Athanasiou and Dragana Savkov (for item 5.1).

• European Commission and/or Member States representatives: Not Applicable.

• EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, and Silvia Valtueña Martínez.

Others:

Not Applicable

¹ Participated only on 11th September 2018.

² As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



The Chair welcomed the participants.

Apologies were received from Yolanda Sanz and Henk van Loveren.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management⁴, EFSA screened the Annual Declaration of Interest filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the Annual Declarations of Interest, please refer to Annex I. Oral Declaration(s) of Interest were asked at the beginning of the meeting and no additional interest was declared.

Applicant's hearing:

Mr. Thanasis Athanasiou and Dragana Savkov were invited to answer to specific questions related to agenda item 5.1 of the present meeting on 11 September 2018.

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA invited Mr. Thanasis Athanasiou and Dragana Savkov to submit an Annual Declaration of Interest. Their participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group, in accordance with the applicable legal framework⁷.

4. General issues on health claims evaluation

6 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
 http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_

management_17.pdf http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

Decision of the Executive Director on Competing Interest Management, Article 9 Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels and the selection of external experts to assist EFSA with its scientific work, Article 15



4.1. Update on Article 13(5) and 14 applications

The EFSA Unit updated the WG Members on the status of health claim applications since the last meeting. Information on health claim applications received including their status can be found on EFSA Register of Questions.

4.2. Outcome of the Public consultation on the draft guidance for the scientific requirements for health claims related to physical performance (revision 1) (EFSA-Q-2018-00540) / Draft guidance on the scientific requirements for health claims related to muscle function and physical performance (revision 1) (EFSA-Q-2018-00243)

A technical report on the outcome of a public consultation on the draft guidance was presented and discussed.

EFSA received comments from three interested parties. The report summarises the comments received during the public consultation on this opinion (which was open from 16^{th} July to 2^{nd} September 2018) and how the comments were addressed.

The WG reviewed and discussed the comments received, which were related to the scope of the guidance, the definition of the terms used, the characterisation of the target population, claims on the muscle function and claims on physical performance.

The scope of the guidance was further clarified and relevant comments received were introduced in the updated guidance document.

The technical report and the updated guidance will be circulated to the WG Claims for comments, prior to its submission to the NDA panel⁸ for possible endorsement and possible adoption, respectively.

5. Draft Article 13.5 opinions

5.1. AVVA Pharmaceuticals Ltd. - "Lignin hydrolysed (Filtrum) and defence against pathogenic bacteria and viruses in the intestine" (Art. 13.5, 0468-0469_CY, EFSA-Q-2018-00004-5)

The WG Chair opened the hearing session by explaining to the applicant the regulatory requirements for health claims made on foods, which frame the principles applied by the EFSA NDA Panel for scientific substantiation of health claims. The scientific requirements for health claims related defence against pathogens in the GI tract were highlighted, particularly the study groups that could be

⁸ The next meeting of NDA Panel will be held on 26-27 September 2018.



suitable for substantiation of such claims targeting the general population or subgroups thereof.

Further to the applicant's reply to EFSA stop-the-clock letter and upon request from the WG, the applicant was requested to clarify outstanding issues on the application, particularly the rationale for extrapolation of the results of studies performed in study groups with acute intestinal infections causing diarrhoea to the general population and the proposed mechanism by which the food could exert the claimed effect.

The WG took note of the applicant's clarification given at the present hearing. A draft opinion will be circulated to the WG Claims for comments, prior to its submission to the NDA panel⁹ for possible adoption.

EFSA will follow up post-meeting with the applicant on the next steps and relative timelines.

5.2. Zespri International ltd. - "kiwifruit Actinidia deliciosa (var. Hayward)" and "reduces gastrointestinal discomfort" (Art.31.5. 0475_BE, EFSA-Q-2018-00416)

An overview of the data submitted in the application was presented. The WG discussed the characterisation of the food/constituent, the claimed effect, and the scientific substantiation of the claim. The human intervention studies submitted for scientific substantiation were discussed. Further review of the key studies submitted will be carried out (regarding the study designs and the statistical analyses applied, the outcome measures, and validation of the questionnaires used to assess GI discomfort) prior to issuing a stop-the-clock letter for requesting additional information from the applicant.

6. Any Other Business

The Nutrition Unit joined the chair to express their great appreciation to all members of the WG Claims for their hard work and high commitment.

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⁹ The next meeting of NDA Panel will be held on 26-27 September 2018.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

In the Annual Declaration of Interest filled by Prof. Jean-Louis Bresson the following interest has been declared: past involvement with Syndifrais (Fermented milk producers intersyndicate) for the appraisal, audit and follow-up of call for tenders for scientific research projects about probiotic mechanisms of action and human microbiota effects on host (period 01/2010-06/2018), which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand. In accordance with EFSA's Policy on Independence¹⁰ and the Decision of the Executive Director on Competing Interest Management¹¹, and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management.

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert was allowed to take part in the discussion and in the drafting phase of the scientific outputs on the agenda, and has not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

 $^{^{10}\} http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf$

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management 17.pdf



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 75th meeting of the Working Group on Claims

Held on 5-6 June 2018, Parma (Italy)

(Agreed on 25 June 2018)

Participants

Working Group Members:

Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Yolanda Sanz, Alfonso Siani (Chair), Sean Strain, Henk van Loveren and Peter Willatts.

Hearing Experts¹:

Not Applicable.

• European Commission and/or Member States representatives:

Olga Goulaki (DG SANTE) (participated via teleconference for item 4).

• EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Ariane Titz, Silvia Valtueña Martínez.

Others:

Not Applicable.

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As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



The Chair welcomed the participants. Apologies were received from Anders Sjödin.

2. Adoption of agenda

The agenda was adopted with changes in the order of the discussion.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claim evaluations

The Commission representative provided an update on the Commission's REFIT evaluation of the Health Claims Regulation, regulatory issues related to health claims and the status of its decision-making process related to the EFSA-adopted scientific opinions on health claim applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.1. Update on Article 13(5) and 14 applications

The EFSA Unit updated the WG Members on the status of health claim applications since the last meeting.

4.2. Updating of the guidance on the scientific requirements for health claims related to physical performance⁴ (EFSA-Q-2018-00243)

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² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁴ https://www.efsa.europa.eu/en/efsajournal/pub/2817



A draft guidance document on the scientific requirements for health claims related to muscle function and physical performance, which updates the existing published in 2011, was presented and discussed.

Examples of claims evaluated by the NDA Panel (in the context of Article 13(1) claims and health claim applications) have been used to provide guidance to applicants and to illustrate the scientific requirements for the substantiation of claims in specific areas. The lack of consensus with respect to the terminology used in sport science was highlighted. In this context, emphasis was given to define the terms used for the purpose of the scientific evaluation of health claims in the area of muscle function and physical performance, and particularly to characterise the claimed effect, to define the target population and the conditions of use for the claim.

The document will be further elaborated and circulated to the WG Claims for comments, prior to its submission to the NDA panel⁵ for possible endorsement for release for public consultation.

5. Draft Article 14 and 13.5 opinions

5.1. Han-Asiabiotech GmbH – "Symbiosal and lowering the rise of blood pressure when used as a replacement to table salt. The rising of blood pressure is a risk factor for hypertension" (Art. 14, 0467_DE, EFSA-Q-2018-00002)

The WG considered the data submitted in the application and the applicant's response to EFSA's request for clarification. The draft scientific opinion related to the section on scientific substantiation of the claimed effect was reviewed and discussed. The WG considered the human studies submitted in the present application (one of which was already assessed by the Panel in the previous opinion).

A revised draft will be circulated to the WG Claims for comments, prior to its submission to the NDA Panel⁵ for possible adoption.

5.2. Probi AB - "Lactobacillus plantarum 299v increases nonheme iron absorption" (Art. 13.5, 0466_SE, EFSA-Q-2017-00820)

The WG considered the data submitted in the present application and the applicant's response to EFSA's first request for

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⁵ The next meeting of NDA Panel will be held on 27-29 July 2018



clarification. The WG Claims re-discussed the new evidence (an unpublished study) submitted in the present application, which was intended to address the previous reservations of the Panel that a time effect on iron absorption in non-randomised studies with a sequential administration of the control and the intervention food may not be excluded⁶. The WG decided to reanalyse the data provided in the unpublished study.

Contrary to previous assumptions that recovery rates for the two iron radio isotopes used were similar, the re-analysis carried out by EFSA showed different recovery rates in this study. A second stop-the-clock procedure was applied to seek clarification from the applicant on how this study could still be used to address the previous reservations of the Panel.

A revised draft (pending the applicant's reply) will be circulated to the WG Claims for comments, prior to its submission to the NDA panel⁵ for possible adoption.

5.3. Matsutani Chemical Industry Co., Ltd - "Fibersol-2 and contributes to a normal bowel function" (Art. 13.5, 0474_DE, EFSA-Q-2018-00065)

The WG considered the data submitted in the present application. The draft scientific opinion related to the sections on characterisation of the food/constituent, the claimed effect, and the scientific substantiation of the claim were reviewed and discussed. It was considered that additional information from the applicant is needed (clarification about the food/constituent that is the subject of the claim and the claimed effect, and questions about the human studies submitted).

Therefore, a request for additional information will be sent to the applicant and a stop-the-clock procedure will be applied.

5.4. AVVA Pharmaceuticals Ltd. - "Lignin hydrolysed (Filtrum) and defence against pathogenic bacteria and viruses in the intestine" (Art. 13.5, 0468-0469_CY, EFSA-Q-2018-00004/EFSA-Q-2018-00005)

Postponed (pending the applicant's reply to the stop-the-clock letter regarding the use human intervention studies performed in individual with diagnosed/confirmed acute GI infections at baseline for substantiation of the claim).

6. Any other business

⁶ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016c. Lactobacillus plantarum 299v and an increase of non-haem iron absorption: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2016; 14(7):4550, 12 pp. doi:10.2903/j.efsa.2016.455



The next meeting of the Working Group on Claims will be held on 10-11 September 2018 in Parma (To be confirmed).



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 74th meeting of the Working Group on Claims

Web-conference, 18 May 2018

(Agreed on 21 May 2018)

Participants

• Working Group Members:

Jean-Louis Bresson, Susan Fairweather-Tait, Yolanda Sanz, Alfonso Siani (Chair), Anders Sjödin, Sean Strain and Peter Willatts.

Hearing Experts¹:

Not Applicable.

- European Commission and/or Member States representatives: Not Applicable.
- EFSA:

Nutrition Unit: Valeriu Curtui, Leng Heng, Ariane Titz.

Others:

Not Applicable.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



The Chair welcomed the participants. Apologies were received from Marina Heinonen, Ambroise Martin, Anders Sjödin and Henk van Loveren.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claim evaluations

4.1. Update on Article 13(5) and 14 applications Postponed.

5. Scientific topic(s) for discussion

5.1. Probi AB - "Lactobacillus plantarum 299v increases nonheme iron absorption" (Art. 13.5, 0466_SE, EFSA-Q-2017-00820)

The WG considered the data submitted in the present application and the applicant's response to EFSA's request for clarification. The draft scientific opinion related to the section on scientific substantiation of the claimed effect was reviewed and discussed. It will be further elaborated and discussed at the next meeting of WG Claims⁴.

5.2. AVVA Pharmaceuticals Ltd. - "Lignin hydrolysed (Filtrum) and defence against pathogenic bacteria and viruses in

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁴ The next meeting of WG Claims will be held on 5-6 June 2018



the intestine" (Art. 13.5, 0468-0469_CY, EFSA-Q-2018-00004/EFSA-Q-2018-00005

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3. Matsutani Chemical Industry Co., Ltd - "Fibersol-2 and contributes to a normal bowel function" (Art. 13.5, 0474_DE, EFSA-Q-2018-00065)

Postponed.

5.4. Han-Asiabiotech GmbH – "Symbiosal and lowering the rise of blood pressure when used as a replacement to table salt. The rising of blood pressure is a risk factor for hypertension" (Art. 14, 0467_DE, EFSA-Q-2018-00002)

Postponed.

6. Any other business

The next meeting of the Working Group on Claims will be held on 5-6 June 2018 in Parma.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In the ADoI or in the SDoI filled for the present meeting, Dr. Anders Sjödin declared the following interest: "Lactobacillus plantarum 299v increases non-heme iron absorption" (EFSA-Q-2017-00820)" (item 5.4). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁹ and the Decision of the Executive Director on Declarations of Interest¹⁰, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 5.4 by the concerned scientific group

⁹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

¹⁰http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 73rd meeting of the Working Group on Claims

Held on 14-15 March 2018, Parma (Italy)

(Agreed on 19 March 2018)

Participants

• Working Group Members:

Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Alfonso Siani (Chair), Anders Sjödin, Sean Strain and Peter Willatts.

• Hearing Experts²:

Farine Varvello & Co. S.r.l.: Corrado Finardi, Francesca Varvello, Alessandro Filippini (for item 5.3).

• European Commission and/or Member States representatives: Not Applicable.

• EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Ariane Titz, Silvia Valtueña Martínez

Others:

Not Applicable.

¹ Participated via web-conference

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



The Chair welcomed the participants. Apologies were received from Yolanda Sanz and Henk van Loveren.

Anders Sjödin did not participate in agenda point 5.4.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I.

No additional interests have been declared at the Oral Declaration of Interest (ODoI) at the beginning of this meeting.

Applicant's hearing:

Corrado Finardi, Francesca Varvello and Alessandro Filippini, on behalf of Farine Varvello & Co. S.r.l., were invited to answer to specific questions related to agenda item 5.3. They attended the meeting on 14 March 2018 from 15:30-16:00.

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, EFSA invited Corrado Finardi, Francesca Varvello and Alessandro Filippini to submit an ADoI. Their participation was limited to providing testimony, without the possibility to take on any role undertaken by members of the Panel, in accordance with the applicable legal framework⁷.

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁶ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



4. General issues on health claim evaluations

4.1. Update on Article 13(5) and 14 applications

The EFSA Unit updated the WG Members on the status of new health claim applications since the last meeting.

4.2. Updating of the guidance on the scientific requirements for health claims related to physical performance

A draft guidance document on the scientific requirements for health claims related to physical performance including muscle function, which updates the existing guidance related to physical performance published in 2011, was introduced and discussed.

The document will be further elaborated and discussed at the next meeting of WG Claims.

5. Scientific topic(s) for discussion

5.1. Unilever NV - "Black tea" and "improvement of attention "(Art. 13.5, 0461_IE, EFSA-Q-2017-00606)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁸ for possible adoption.

5.2. Han-Asiabiotech GmbH – "Symbiosal and lowering the rise of blood pressure when used as a replacement to table salt. The rising of blood pressure is a risk factor for hypertension" (Art. 14, 0467_DE, EFSA-Q-2018-00002)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3. Farine Varvello & Co. S.r.l. - "Consumption of arabinoxylan as part of a meal contributes to a reduction of the blood glucose rise after that meal" (Art. 19, 0465_IT, EFSA-Q-2017-00710)

Upon request from EFSA, the applicant was given the opportunity to answer the questions elaborated by the Working

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⁸ The next meeting of the NDA Panel will be held on 17-19 April 2018.



Group. Following discussion during the technical hearing, a number of points requiring further clarification were identified. EFSA will follow up by providing the applicant with a written summary of the points discussed with the next steps and relative timelines.

5.4. Probi AB - "Lactobacillus plantarum 299v increases nonheme iron absorption" (Art. 13.5, 0466_SE, EFSA-Q-2017-00820)

The content of the application was introduced and discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.5. Matsutani Chemical Industry Co., Ltd - "Fibersol-2 and contributes to a normal bowel function" (Art. 13.5. 0474_DE, EFSA-Q-2018-00065)

The content of the application was introduced. It will be discussed at the next meeting of WG Claims.

6. Any other business

The next meeting of the Working Group on Claims will be held on 13-14 June 2018.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In the ADoI or in the SDoI filled for the present meeting, Dr. Anders Sjödin declared the following interest: "Lactobacillus plantarum 299v increases non-heme iron absorption" (EFSA-Q-2017-00820)" (item 5.4). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁹ and the Decision of the Executive Director on Declarations of Interest¹⁰, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 5.4 by the concerned scientific group

⁹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

¹⁰ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 72nd meeting of the Working Group on Claims

Held on 17-18 January 2018, Parma (Italy)

(Agreed on 19 January 2018)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Marina Heinonen¹, Ambroise Martin, Alfonso Siani (Chair), Anders Sjödin, Sean Strain, Peter Willatts and Henk Van Loveren.

- Hearing Experts²: Not Applicable.
- European Commission and/or Member States representatives: Not Applicable.
- EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Silvia Valtueña Martínez

Others:

Not Applicable.

Participated via web-conference on 17 January.

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



The Chair welcomed the participants. Apologies were received from Yolanda Sanz.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claim evaluations

4.1. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of new health claim applications since the last meeting.

5. Scientific topic(s) for discussion: Draft Article 14 and 13.5 opinions

5.1. Unilever NV – "Black tea and improvement of attention" (Art. 13.5, 0461_IE, EFSA-Q-2017-00606)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



5.2. Specialised Nutrition Europe – "glycaemic carbohydrates and contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise" (Art. 13.5., 0462_FR, EFSA-Q-2017-00621)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁵ for possible adoption.

5.3. TA-XAN AG - "xanthohumol and maintaining the integrity of DNA", (Art. 13.5., 0463_DE, EFSA-Q-2017-00663)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁵ for possible adoption.

5.4. Farine Varvello & Co. S.r.l - "Consumption of arabinoxylan as part of a meal contributes to a reduction of the blood glucose rise after that meal" (Art. 19, 0465_IT EFSA-Q-2017-00710

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Any other business

The next meeting of the Working Group on Claims will be held on 14-15 March 2018.

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⁵ NDA Panel Plenary meeting to be held on 7-8 February 2018



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 71st meeting of the Working Group on Claims

Held on 15-16 November 2017, Parma (Italy)

(Agreed on 20 November 2017)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait¹, Marina Heinonen², Ambroise Martin, Alfonso Siani (Chair), Anders Sjödin, Sean Strain¹, Peter Willatts¹ and Henk Van Loveren.

Hearing Experts³:

Not Applicable.

• European Commission and/or Member States representatives: Not Applicable.

EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Ariane Titz, and Silvia Valtueña Martínez.

Others:

Not Applicable.

¹ Participated via web-conference

² Participated via web-conference on 16 November

³ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



The Chair welcomed the participants. Apologies were received by Yolanda Sanz

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claim evaluations

4.1. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

Postponed.

4.2. Draft technical report on the outcome of a public consultation on the draft guidance for the scientific requirements for health claim related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2017-00534)

The technical report on the outcome of public consultation on the draft guidance, which summarises the comments received from the public consultation (open from 12 July to 3 September 2017) and how the comments were addressed, was presented and discussed (see agenda item 4.3). After amendments, it will

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



be distributed to the working group for comments and presented to the next NDA plenary meeting⁶ for possible endorsement.

4.3. Draft guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2017-00094)

The draft guidance which took into consideration relevant comments received from the public consultation was presented (see agenda item 4.2). After amendments, the draft guidance will be distributed to the working group for comments and presented to the next NDA plenary meeting⁷ for possible adoption.

5. Scientific topic(s) for discussion: Draft Article 14 and 13.5 opinions

5.1. Unilever NV – "Tea flavanols and improvement of endothelium-dependent vasodilatation" (Art. 13.5, 0458_IE, EFSA-Q-2017-00419)

The draft scientific opinion was discussed and, after amendments, it will be distributed to the working group for comments and presented to the next NDA plenary meeting⁷ for possible adoption.

5.2. Newtricious R&D B.V. – "NWT-02 and reduces loss of vision" (Art 13.5, 0459_NL, EFSA-Q-2017-00539)

The draft scientific opinion was discussed and, after amendments, it will be distributed to the working group for comments and presented to the next NDA plenary meeting⁷ for possible adoption.

5.3. Lonza Ltd.- "L-carnitine and normal lipid metabolism" (Art 13.5, 0460_DE, EFSA-Q-2017-00564)

The draft scientific opinion was discussed and, after amendments, it will be distributed to the working group for comments and presented to the next NDA plenary meeting⁷ for possible adoption.

5.4. Unilever NV - "Black tea" and "improvement of attention" (Art. 13.5., 0461_IE, EFSA-Q-2017-00606)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application.

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 $^{^{6}}$ The next NDA Plenary meeting will be held on 12-14 December 2017.



Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.5. Specialised Nutrition Europe – "glycaemic carbohydrates" and "contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise" (Art. 13.5., 0462_FR, EFSA-Q-2017-00621)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.6. TA-XAN AG - "xanthohumol" and "maintaining the integrity of DNA", (Art. 13.5., 0463_DE, EFSA-Q-2017-00663

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Any other business

The next meeting of the Working Group on Claims will be held on 17-18 January 2018.



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 70th meeting of the Working Group on Claims

Held on 06 September 2017, Parma (Italy)

(Agreed on 8 September 2017)

Participants

Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Marina Heinonen, Ambroise Martin, Yolanda Sanz, Alfonso Siani (Chair), Anders Sjödin, Sean Strain¹, Peter Willatts and Henk Van Loveren.

- **Hearing Experts²:** Not Applicable.
- European Commission and/or Member States representatives: Not Applicable.

• EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Silvia Valtueña Martínez

Others:

Not Applicable.

¹ Participated via tele-conference

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claim evaluations

4.1. Feedback from the Commission

Not applicable.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of new health claim applications since the last meeting.

5. Updating of the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2017-00094)

The Unit introduced the list of comments received from public consultation on the guidance (open from 12 July to 3 September 2017).

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



The comments will be further reviewed and discussed at the next meeting of WG Claims⁵.

6. Scientific topic(s) for discussion: Draft Article 14 and 13.5 opinions

6.1. Unilever NV - "Tea flavanols and improvement of endothelium-dependent vasodilatation" (Art. 13.5, 0458_IE, EFSA-Q-2017-00419)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6.2. ENG AS – "Dietary Menaquinone-7 (MK-7) helps promote cardiovascular health via the activation of matrix Gla protein (MGP), a natural inhibitor of vascular calcification" (Art. 13.5, 0457_IE, EFSA-Q-2017-00235)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6.3. Newtricious R&D B.V. - "NWT-02 and reduces loss of vision" (Art 13.5, 0459_NL, EFSA-Q-2017-00539)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6.4. Lonza Ltd.- "L-carnitine and normal lipid metabolism" (Art 13.5, 0460_DE, EFSA-Q-2017-00564)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

7. Next meeting: 15-16 November 2017.

3

⁵ The next meeting of WG Claims will be held on 15-16 November 2017.



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 69th meeting of the Working Group on Claims

Held on 7-8 June 2017, Parma (Italy)

(Agreed on 09 June 2017)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Marina Heinonen, Ambroise Martin, Yolanda Sanz, Alfonso Siani (Chair), Anders Sjödin, Sean Strain, Peter Willatts and Henk Van Loveren¹

Hearing Experts²:

Carlo Galli (for item 6.2.)

European Commission and/or Member States representatives: Olga Goulaki (DG SANTE)

• EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Silvia Valtueña Martínez

Others:

Not Applicable

¹ Participated only on June 7

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.



The Chair welcomed the participants.

Anders Sjödin did not participate in agenda item 6.1.

2. Adoption of agenda

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

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claim evaluations

4.1. Feedback from the Commission

The Commission representative provided an update on issues related to health claims. The European Commission decisions related to health claims are published on the Commission EU Register of nutrition and health claims made on foods.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of new health claim applications since the last meeting.

 Updating of the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2017-00094)

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



The draft guidance document, which updates the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health published in 2011, was presented and discussed. After amendments, it will be circulated to the WG for comments prior to its presentation to the next NDA plenary meeting⁵ for possible endorsement for release for public consultation.

6. Scientific topic(s) for discussion: Draft Article 14 and 13.5 opinions

6.1. Biosearch Life - "Lactobacillus fermentum CECT5716 decreases the Staphylococcus load in breast milk. High Staphylococcus load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis" (Art. 14, 0447_FR, EFSA-Q-2016-00318)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁵ for possible adoption.

6.2. Cargill R&D Centre Europe – "Zerose® erythritol sugarfree hard confectionary and reduction of dental plaque which reduces the risk of caries" (Art. 14, 0452_BE, EFSA-Q-2017-00002)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁵ for possible adoption.

6.3. Loc Troi Group – "Vibigaba germinated brown rice and contributes to the maintenance of normal blood cholesterol level" (Art 13.5, 0453_NL, EFSA-Q-2017-00030)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁵ for possible adoption.

6.4. Loc Troi Group – "Vibigaba germinated brown rice and contributes to maintenance of normal blood pressure" (Art 13.5, 0454_NL, EFSA-Q-2017-00031)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁵ for possible adoption.

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⁵ The next meeting of the NDA Panel will be held on 27-29 June 2017.



6.5. Loc Troi Group – "Vibigaba germinated brown rice and contributes to weight loss" (Art 13.5, 0455_NL, EFSA-Q-2017-00032)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁶ for possible adoption.

6.6. Loc Troi Group – "Vibigaba germinated brown rice and contributes to the maintenance of normal glucose levels" (Art 13.5, 0456_NL, EFSA-Q-2017-00033)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁶ for possible adoption.

7. Next meeting: 6-7 September 2017

4

⁶ The next meeting of the NDA Panel will be held on 27-29 June 2017.



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

Dr. Anders Sjödin had the following interest: "Lactobacillus fermentum CECT5716" (EFSA-Q-2016-00318, agenda item 6.1). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interest, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This resulted in the exclusion of the expert from any discussion, voting or other processing of item 6.1 by the concerned scientific group.

⁷ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁸ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 68th meeting of the Working Group on Claims

Held on 22-23 March 2017, Parma (Italy)

(Agreed on 27 March 2017)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Marina Heinonen, Ambroise Martin, Alfonso Siani (Chair), Anders Sjödin, Sean Strain, Peter Willatts and Henk Van Loveren.

Yolanda Sanz participated via teleconference for agenda item 5.2.

Hearing Experts¹:

Carlo Galli (for item 5.5).

• European Commission and/or Member States representatives:

Olga Goulaki (DG SANTE) (participated via teleconference for item 5.1).

• EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Andrea Germini, Leng Heng, Silvia Valtueña Martínez

Others:

Not Applicable

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.



1. Welcome and apologies for absence

The Chair welcomed the participants.

Anders Sjödin did not participate in agenda item 5.2.

2. Adoption of agenda

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

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claim evaluations

4.1. Feedback from the Commission

Postponed.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of health claim applications since the last meeting.

4.3. Updating of the existing guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health⁴ (EFSA-Q-2017-00094)

The WG discussed the preparatory work regarding the NDA Panel self-task for the updating of the existing guidance on the

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁴ Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health: https://www.efsa.europa.eu/en/efsajournal/pub/2474



scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health.

5. Scientific topic(s) for discussion: Draft Article 14 and 13.5 opinions

5.1. Marks and Spencer – "Product formulated with a carbohydrate: protein ratio< 1.8. For adults with excess body weight, this helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet" (Art. 13.5, 0449_UK, EFSA-Q-2016-00436)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁵ for possible adoption.

5.2. Biosearch Life - "Lactobacillus fermentum CECT5716 decreases the Staphylococcus load in breast milk. High Staphylococcus load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis" (Art. 14, 0447_FR, EFSA-Q-2016-00318)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3. Suomen Terveysravinto Oy – "Curcumin and normal functioning of joints" (Art. 13.5, 0451_FI, EFSA-Q-2016-00856)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁵ for possible adoption.

5.4. Laboratoire Nurilia – "Condensyl®" and "decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male subfertility/infertility" (Art. 14, 0450_FR, EFSA-Q-2016-665)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁵ for possible adoption.

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⁵ The next meeting of the NDA Panel will be held on 4-6 April 2017.



5.5. Cargill R&D Centre Europe - "Zerose® erythritol sugarfree hard confectionary and reduction of dental plaque which reduces the risk of caries" (Art. 14, 0452_BE, EFSA-Q-2017-00002)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.6. Loc Troi Group – "Vibigaba germinated brown rice and contributes to the maintenance of normal blood cholesterol level" (Art 13.5, 0453_NL, EFSA-Q-2017-00030)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7. Loc Troi Group – "Vibigaba germinated brown rice and contributes to maintenance of normal blood pressure" (Art 13.5, 0454_NL, EFSA-Q-2017-00031)

Please see agenda item 5.6.

5.8. Loc Troi Group – "Vibigaba germinated brown rice and contributes to weight loss" (Art 13.5, 0455_NL, EFSA-Q-2017-00032)

Please see agenda item 5.6.

5.9. Loc Troi Group – "Vibigaba germinated brown rice and contributes to the maintenance of normal glucose levels" (Art" 13.5, 0456_NL, EFSA-Q-2017-00033)

Please see agenda item 5.6.

6. Testing applicability of "Guidance on uncertainty in EFSA scientific assessment" (EFSA-Q-2013-00738)

The WG discussed the applicability of the "Guidance on uncertainty in EFSA scientific assessment". The outcome of the testing using a case study related to soy isoflavones and maintenance of *bone mineral density* (ID 1655)⁶ was discussed, and feedback from the WG was received. It was agreed to present the outcome to the next NDA plenary meeting⁵.

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⁶ http://www.efsa.europa.eu/en/efsajournal/pub/2847



7. Next meeting: 7-8 June 2017



Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

In the SDoI filled for the present meeting, Dr Anders Sjödin declared the following interest: "Lactobacillus fermentum CECT5716" (EFSA-Q-2016-00318, agenda item 5.2). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interest⁸, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of item 5.2 by the concerned scientific group.

⁷ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 67th meeting of the Working Group on Claims

Held on 18-19 January 2017, Parma

(Agreed on 24 January 2017)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Marina Heinonen¹, Ambroise Martin, Yolanda Sanz¹, Alfonso Siani (Chair), Anders Sjödin, Sean Strain¹ and Henk Van Loveren¹.

Hearing Experts²:

Andy Hart (for item 6).

• European Commission representative:

Olga Goulaki (DG SANTE).

EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Silvia Valtueña Martínez.

SCER unit: Andrea Germini (for item 6).

Others:

Not applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Harry McArdle and Peter Willatts.

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of

¹ Participated only on 18 January.

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



Interest⁴, EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group (WG) Members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA-adopted scientific opinions on health claim applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of health claim applications since the last meeting.

5. Draft Article 14 and 13.5 opinions

5.1. Laboratoires Nutrition et Cardiométabolisme - "Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors" (Art. 13.5, 0448_FR, EFSA-Q-2016-00319)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁵ for possible adoption.

5.2. Marks and Spencer – "Product formulated with a carbohydrate: protein ratio < 1.8. For adults with excess body weight, this helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet" (Art. 13.5, 0449_UK, EFSA-Q-2016-00436)

The draft scientific opinion was discussed. It will be further elaborated and discussed at the next meeting of WG Claims⁶.

5.3. Suomen Terveysravinto Oy – "Curcumin and normal functioning of joints" (Art 13.5, 0451_FI, EFSA-Q-2016-00856)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁵ The next meeting of the NDA Panel will be held on 31 January-2 February 2017.

⁶ The next meeting of WG Claims will be held on 22-23 March 2017.



5.4. Cargill R&D Centre Europe – "Zerose® erythritol sugar-free hard confectionary and reduction of dental plaque which reduces the risk of caries" (Art. 14, 0452_BE, EFSA-Q-2017-00002)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Testing applicability of the Guidance on uncertainty in EFSA scientific assessment (EFSA-Q-2013-00738)

A sub-group⁷ of the working group discussed the case study related to 'soy isoflavones and maintenance of bone mineral density (ID 1655)' for the uncertainty exercise.

It will be reported to the next NDA plenary meeting⁸ for discussion.

7. Any other business

- In the framework of the Scientific Committee Working Group on the use of the weight of evidence approach in scientific assessments⁹, a published opinion on a health claim was used as a case study to illustrate the approach applied by the NDA Panel for the weight of evidence assessment on the substantiation of a health claim.
- A check-list for appraisal of human intervention studies adapted for health claim substantiation was presented. It was proposed to use/test the check list when evaluating studies submitted for claim substantiation, and it will be further adjusted where relevant.
- The next meeting of the Working Group on Claims will be held on 22-23 March 2017.

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Jean Louis Bresson, Sue Fairweather-Tait, Ambroise Martin, Alfonso Siani and Anders Sjödin.

 $^{^{\}rm 8}$ The next meeting of the NDA Panel will be held on 31 January-2 February 2017.

⁹ http://www.efsa.europa.eu/sites/default/files/assets/useofweight.pdf



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 66th meeting of the Working Group on Claims

WEB-conference, 20 December 2016, Parma

(Agreed on 21 December 2016)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Ambroise Martin, Alfonso Siani (Chair), Anders Sjödin and Peter Willatts.

Hearing Experts¹:

None.

• European Commission representative:

Not Applicable.

EFSA:

Nutrition Unit: Janusz Ciok, Leng Heng, Silvia Valtueña Martínez.

Others:

Not Applicable.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group (WG) Members invited for the present meeting. No Conflicts of Interest related to the

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Testing applicability of the Guidance on uncertainty in EFSA scientific assessment (EFSA-Q-2013-00738)

Participants discussed the case study related to 'soy isoflavones and maintenance of bone mineral density (ID 1655)' for the uncertainty exercise.

The case study will be further discussed at the next meeting of the Working Group on Claims.

5. Any other business

The next meeting of the Working Group on Claims will be held on 18-19 January 2017.



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 65th meeting of the Working Group on Claims

Held on 15-17 November 2016, Parma (Italy)

(Agreed on 23 November 2016)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Marina Heinonen¹, Ambroise Martin, Harry McArdle¹, Alfonso Siani (Chair), Anders Sjödin, Sean Strain¹, Henk Van Loveren¹ and Peter Willatts.

Hearing Experts²:

None.

• European Commission representative:

Olga Goulaki (DG SANTE).

EFSA:

Nutrition Unit: Valeriu Curtui, Janusz Ciok, Leng Heng, Silvia Valtueña Martínez.

SCER Unit: Andrea Germini (for item 6).

Others:

Andy Hart (for item 6).

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Yolanda Sanz.

Anders Sjödin did not participate in agenda points 5.4-5.5.

2. Adoption of the agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

¹ Participates only from 15-16 (am) November

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group (WG) Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claim evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

Postponed.

4.3. Draft Technical report on outcome of public consultation on the draft scientific and technical guidance for the preparation and presentation of a health claim application (EFSA-Q-2016-00299)

The technical report on the outcome of public consultation on the draft scientific and technical guidance for the preparation and presentation of a health claim application, which summarises the comments received from the public consultation (open from 18 July to 12 September 2016) and how the comments were addressed, was presented and discussed. After amendments, it will be distributed to the working group for comments and presented to the next NDA plenary meeting ⁵ for possible endorsement.

4.4. Draft scientific and technical guidance for the preparation and presentation of a health claim application (EFSA-Q-2016-00285)

The draft guidance which took into consideration relevant comments received from the public consultation was presented (see agenda items 4.3). After amendments, the draft guidance will be distributed to the working group for comments and presented to the next NDA plenary meeting⁵ for possible adoption.

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁵ The next NDA Plenary meeting will be held on 13-15 December 2016.



5. Draft Article 14 and 13.5 opinions

5.1. Specialised Nutrition Europe (SNE, formerly IDACE) – "Vitamin C and protection of DNA, proteins and lipids from oxidative damage" (Art. 14, 0095_FR, EFSA-Q-2016-00175)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁶ for possible adoption.

5.2. Laboratoires Nutrition et Cardiométabolisme – "Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors" (Art. 13.5, 0448_FR, EFSA-Q-2016-00319)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3. Marks and Spencer – "Product formulated with a carbohydrate: protein ratio<1.8. For adults with excess body weight, this helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet" (Art 13.5, 0449_UK, EFSA-Q-2016-00436)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.4. H.J. Heinz supply chain Europe B.V. – "Nutrimune (heated treated fermented milk with *L. paracasei CBA L74*) supports the immune defence in the gastrointestinal and upper-respiratory tract of young children" (Art. 14, 0445_NL, EFSA-Q-2016-00008)

The draft scientific opinion was discussed and, after amendments, it will be circulated to WG for comments prior to its presentation to the next NDA plenary meeting⁶ for further discussion and possible adoption.

5.5. Biosearch Life – "Lactobacillus fermentum CECT5716 decreases the Staphylococcus load in breast milk. High Staphylococcus load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis" (Art. 14, 0447_FR, EFSA-Q-2016-00318)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request

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⁶ The next NDA Plenary meeting will be held on 13-15 December 2016.



for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.6. Laboratoire Nurilia – "Condensyl®" and "decreases sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index). High sperm DNA damage (sperm nuclear decondensation index and DNA fragmentation index) is a risk factor for male subfertility/infertility" (Art 14, 0450_FR, EFSA-Q-2016-00665)

Postponed – pending a completeness check of the application.

6. Testing applicability of the Guidance on uncertainty in EFSA scientific assessment (EFSA-Q-2013-00738)

A sub-group ⁷ of the working group discussed the case study related to 'soy isoflavones and maintenance of bone mineral density (ID 1655)' for the uncertainty exercise.

7. Any other business

The next meeting of the Working Group on Claims will be held on 18-19 January 2017.

⁷ Jean Louis Bresson, Sue Fairweather-Tait, Ambroise Martin, Alfonso Siani, Anders Sjödin, and Peter Willatts



Annex I

Interests and actions resulting from the screening of Specific Declarations of Interest (SDoI)

In the SDoI filled for the present meeting, Dr Anders Mikael Sjödin declared an interest for the applications related to: 'Nutrimune (heated treated fermented milk with *L. paracasei CBA L74*), EFSA-Q-2016-00008, agenda item 5.4), and 'Lactobacillus fermentum CECT5716 (EFSA-Q-2016-00318, agenda item 5.5). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on Declarations of Interests⁹, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda items 5.4 and 5.5 by the concerned scientific group.



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 64th meeting of the Working Group on Claims

Held on 6-7 September 2016, Parma (Italy)

(Agreed on 12 September 2016)

Participants

Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Marina Heinonen, Ambroise Martin, Harry McArdle, Alfonso Siani (Chair), Yolanda Sanz, Anders Sjödin, Henk Van Loveren and Peter Willatts.

Hearing Experts¹:

None.

• European Commission representative:

None.

• EFSA:

Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Leng Heng, Silvia Valtueña Martínez.

SCER Unit: Andrea Germini for item 6.1 only.

Others:

None.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Sean Strain.

Anders Sjödin did not participate in agenda points 5.1 and 5.2.

2. Adoption of the agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group (WG) Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

- 4. General issues on health claim evaluation
 - 4.1. Feedback from the European Commission

Not applicable.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

Postponed.

- 5. Draft Article 14 and 13.5 opinions submitted for discussion and/or possible adoption at the Plenary meeting in September 2016
 - **5.1.** H.J. Heinz Supply Chain Europe B.V. "Nutrimune (heat-treated fermented milk with *L. paracasei CBA L74*) supports the immune defence in the gastrointestinal and upper-respiratory tract of young children" (Art. 14, 0445_NL, EFSA-Q-2016-00008)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.2. Biosearch Life - "Lactobacillus fermentum CECT5716 decreases the Staphylococcus load in breast milk. High Staphylococcus load in breast milk is a risk factor for mammary bacterial dysbiosis/mastitis" (Art. 14, 0447_FR, EFSA-Q-2016-00318)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3. Laboratoires Nutrition et Cardiométabolisme - "Stablor® contributes to decrease visceral fat while preserving lean mass in overweight or obese subjects with abdominal fat and cardiometabolic risk factors" (Art. 13.5, 0448_FR, EFSA-Q-2016-00319)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed

http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.4. Specialised Nutrition Europe (SNE, formerly IDACE) – "Calcium is important for the development of bones" (Art. 14, 0048_FR, EFSA-Q-2008-128)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

5.5. Marks and Spencer – "Product formulated with a carbohydrate: protein ratio < 1.8. For adults with excess body weight, this helps to achieve a reduction in body weight and body fat when consumed as part of an energy restricted diet" (Art 13.5, 0449_UK, EFSA-Q-2016-00436)

Postponed – pending completeness check of the application.

5.6. Specialised Nutrition Europe (SNE, formerly IDACE) – "With Vitamin E for protection of cells against oxidative damage" (Art. 14, 0099_FR, EFSA-Q-2008-179)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

6. Any other business

6.1. Uncertainties in scientific assessment: a health claim example in pilot phase

The working group discussed about the case study on the health claim selected for the uncertainty exercise. The WG members and EFSA staff involved were identified.

6.2. **GP/EFSA/NUTRI/2014/01** - Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement.

The working group was presented with information about the grant, and about the progress and status of the grant.

6.3. Teleconference post-adoption

The Nutrition Unit informed the working group of a post-adoption teleconference with the applicant (EFSA-Q-2015-00696). The minutes of teleconference will be published in the upcoming weeks via this link: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2015-00696.

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⁴ The next meeting of the NDA Panel will be held on 21-23 September 2016.



6.4. Working Group on Claims

The next meeting of the Working Group on Claims will be held on 15-17 November 2016 (two full days meeting).



Annex I

Interests and actions resulting from the screening of Specific Declarations of Interest (SDoI)

In the SDoI filled for the present meeting, Dr Anders Mikael Sjödin declared an interest for the applications related to: 'Nutrimune (heated treated fermented milk with *L. paracasei CBA L74*), <u>EFSA-Q-2016-00008</u>, agenda item 5.1), and '*Lactobacillus fermentum* CECT5716 (<u>EFSA-Q-2016-00318</u>, agenda item 5.2). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on Declarations of Interests⁹, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda items 5.1 and 5.2 by the concerned scientific group.



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 63rd meeting of the Working Group on Claims

Held on 9-10 June 2016, Parma (Italy)

(Agreed on 13 June 2016)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Ambroise Martin¹, Harry McArdle, Alfonso Siani (Chair), Yolanda Sanz, Anders Sjödin², Sean Strain and Peter Willatts.

Hearing Experts³:

Andy Hart (Scientific Committee Working Group member, for item 6)

• European Commission representative:

Olga Goulaki (DG SANTE)4

EFSA:

Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez.

Others:

Donnell Alexander (short-term visiting Scientist, Ministry for Primary Industry, New Zealand),

Karen Wong Yoke Sim (National Pharmaceutical Control Bureau, Ministry of Health, Malaysia)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Marina Heinonen and Henk Van Loveren.

Anders Sjödin did not participate in agenda points 5.1, 5.2 and 5.5.

¹ Attended via teleconference on 10 June.

² Attended on 9 June.

³ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

⁴ Attended via teleconference on 9-10 June



2. Adoption of the agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interest⁶, EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) filled in by the working group (WG) Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claim evaluation

4.1. Feedback from the European Commission

Postponed.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

Postponed.

4.3. Draft scientific and technical guidance for the preparation and presentation of a health claim application (EFSA-Q-2016-00285)

The draft guidance document, which updates the scientific and technical guidance presentation of an application for authorisation of a health claim published in 2011^7 , was presented and discussed. After amendments, it will be circulated to the WG for comments prior to its presentation to the next NDA plenary meeting⁸ for further discussion and possible endorsement for release for public consultation.

- 5. Draft Article 14 and 13.5 opinions submitted for discussion and/or possible adoption at the Plenary meeting in June 2016
 - **5.1.** Probi AB "L. plantarum 299v increases non-haem iron absorption" (Art. 13.5, 0441_SE, EFSA-Q-2015-00696)

The draft scientific opinion was discussed and, after amendments, it will be circulated to the WG for comments prior to its presentation to the next NDA plenary meeting⁸ for further discussion and possible adoption.

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁶ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁷ Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim http://www.efsa.europa.eu/en/efsajournal/pub/2170

⁸ The next meeting of the NDA Panel will be held on 28-30 June 2016.



5.2. Granarolo Spa - "Consumption of *L. rhamnosus* GG (ATCC 53103) and fructooligosaccharides (FOS) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals" (Art. 13.5, 0439_IT, EFSA-Q-2015-00488)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁹ for further discussion and possible adoption.

5.3. Pierre Fabre Medicament – "V0137, a DHA-enriched fish oil, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function" (Art. 13.5, 0446_FR, EFSA-Q-2016-00071)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁹ for further discussion and possible adoption.

5.4. Food for Health Ireland - "FHI LFC24, a bovine milk-derived casein hydrolysate, helps to regulate blood glucose levels (Art. 13.5, 0444_IE, <u>EFSA-Q-2015-00755</u>)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁹ for further discussion and possible adoption.

5.5. H.J. Heinz supply Chain Europe B.V. - "Nutrimune (heated treated fermented milk with *L. paracasei* CBA L74) supports the immune defence in the gastrointestinal and upper-respiratory tract of young children" (Art. 14, 0445_NL, <u>EFSA-Q-2016-00008</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.6. SNE – "Iron and immune system" (Art. 14, 0066_FR, <u>EFSA-Q-2008-146</u>)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁹ for further discussion and possible adoption.

5.7. Chios Mastiha Growers Association – "Chios Mastiha contributes to the improvement of dyspepsia" (Art. 13.5, 0442_EL, <u>EFSA-Q-2015-00752</u>)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁹ for further discussion and possible adoption.

⁹ The next meeting of the NDA Panel will be held on 28-30 June 2016.



5.8. Chios Mastiha Growers Association – "Chios Mastiha contributes to the reduction of *Helicobacter pylori* which is a risk factor for the development of peptic ulcer disease" (Art. 14, 0443_EL, <u>EFSA-Q-2015-00753</u>)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting¹⁰ for further discussion and possible adoption.

6. Any other business

Scientific Committee guidance document on Uncertainties in scientific assessment – Andy Hart presented different tools and ways to assess uncertainties and how they could be tested on a case study during the trial phase using a health claim example.

Statistical analyses – Points to consider about the use of Intention-to-treat vs. per protocol analysis for claim substantiation were presented.

Working Group on Claims - The next meeting of the Working Group on Claims will be held on 6-7 September 2016.

¹⁰ The next meeting of the NDA Panel will be held on 28-30 June 2016.



Annex I

Interests and actions resulting from the screening of Specific Declarations of Interest (SDoI)

In the SDoI filled for the present meeting, **Dr Anders Mikael Sjödin** declared an interest for the application related to: 'Lactobacillus plantarum 299v' (EFSA-Q-2015-00696, agenda item 5.1), 'Lactobacillus rhamnosus GG (ATCC 53103) and fructooligosaccharides (FOS)' (EFSA-Q-2015-00488, agenda item 5.2), and 'Nutrimune (heated treated fermented milk with *L. paracasei* CBA L74)' (EFSA-Q-2016-00008, agenda item 5.5). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on Declarations of Interests⁹, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda items 5.1, 5.2 and 5.5 by the concerned scientific group.



Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 62nd meeting of the Working Group on Claims

Held on 16-17 March 2016, Parma (Italy)

(Agreed on 22 March 2016)

Participants

• Working Group Members:

Jean Louis Bresson, Sue Fairweather-Tait, Marina Heinonen, Ambroise Martin, Harry McArdle, Alfonso Siani (Chair), Yolanda Sanz, Anders Sjödin and Sean Strain¹.

Hearing Experts²:

Not applicable

• European Commission representative:

Olga Goulaki (DG SANTE)

EFSA:

Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez.

Others:

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Hendrik Van Loveren and Peter Willatts.

Sean Strain did not participate in agenda point 5.1.

Anders Sjödin did not participate in agenda points 5.2, 5.4 and 5.7.

¹ Attended via teleconference on 16-17 March.

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf



2. Adoption of the agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest SDoI filled in by the working group (WG) Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claim evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

Postponed.

5. Draft Article 14 and 13.5 opinions

5.1. DSM Nutritional Products – "DHA contributes to improved memory function" (Art. 13.5, 0438_UK, EFSA-Q-2015-00456)

The draft scientific opinion was discussed and, after amendments, it will be circulated to the NDA Panel for possible adoption by written procedure⁵.

5.2. Granarolo Spa - "Consumption of *L. rhamnosus* GG (ATCC 53103) and fructooligosaccharides (FOS) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals" (Art. 13.5, 0439_IT, EFSA-Q-2015-00488)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

⁵ The draft opinion was discussed by the NDA Panel at its plenary meetings on 28-30 October 2015 and 1-3 February 2016.



for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3. Tate & Lyle PLC - "Polydextrose contributes to an improved bowel function by increasing stool bulk" (Art. 13.5, 0440_UK, EFSA-Q-2015-00550)

The draft scientific opinion was discussed and, after amendments, it will be circulated to the WG for comments prior to its presentation to the next NDA plenary meeting 6 for further discussion and possible adoption.

5.4. Probi AB – "Lactobacillus plantarum 299v increases non-haem iron absorption" (Art. 13.5, 0441_SE, EFSA-Q-2015-00696)

The draft scientific opinion was discussed. It was decided that this draft scientific opinion will be further discussed at the next WG Claims⁷.

5.5. Pierre Fabre Medicament - "V0137, a DHA-enriched fish oil, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function" (Art. 13.5, 0446_FR, EFSA-Q-2016-00071)

The discussion of this agenda item was postponed to the next WG Claims⁷.

5.6. Food for Health Ireland - "FHI LFC24, a bovine milk-derived casein hydrolysate, helps to regulate blood glucose levels following food consumption" (Art. 13.5, 0444_IE, EFSA-Q-2015-00755)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7. H.J. Heinz supply Chain Europe B.V. - "Nutrimune (= heated treated fermented milk with L. paracasei CBA L74) supports the immune defence in the gastrointestinal and upper-respiratory tract of young children" (Art. 14, 0445_NL, EFSA-Q-2016-00008)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8. Chios Mastiha Growers Association – "Chios Mastiha contributes to the improvement of dyspepsia" (Art. 13.5, 0442_EL, EFSA-Q-2015-00752)

⁶ The next meeting of the NDA Panel will be held on 20-21 April 2016.

⁷ The next meeting of WG Claims will be held on 9-10 June 2016.



The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.9. Chios Mastiha Growers Association – "Chios Mastiha contributes to the reduction of *Helicobacter pylori* which is a risk factor for the development of peptic ulcer disease" (Art. 14, 0443_EL, EFSA-Q-2015-00753)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Any other business

The WG was provided with feedback from the EFSA webinar on scientific aspects to consider when preparing a health claim application, which was held on 10 March 2016. The recording will soon be available on the EFSA website.

The next meeting of the Working Group on Claims will be held on 9-10 June 2016.



Annex I

Interests and actions resulting from the screening of Specific Declarations of Interest (SDoI)

In the SDoI filled for the present meeting, **Prof. Sean Strain** declared an interest for the application related to 'DHA and contributes to improved memory function' (EFSA-Q-2015-00456, agenda item 5.1). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on Declarations of Interests⁹, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda item 5.1 by the concerned scientific group.

In the SDoI filled for the present meeting **Dr Anders Mikael Sjödin** declared an interest for the application related to: 'Lactobacillus rhamnosus GG (ATCC 53103) and fructooligosaccharides (FOS)' (EFSA-Q-2015-00488, agenda item 5.2), 'Lactobacillus plantarum 299v' (EFSA-Q-2015-00696, agenda item 5.4), and 'Nutrimune (heated treated fermented milk with L. paracasei CBA L74)' (EFSA-Q-2016-00008, agenda item 5.7). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁸ and the Decision of the Executive Director on Declarations of Interests⁹, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda items 5.2, 5.4 and 5.7 by the concerned scientific group.

⁸ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁹ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



Scientific Panel on Dietetic Products, Nutrition and Allergies Minute of the 61st meeting of the Working Group on Claims Held on 19-20 January 2016, Parma (Agreed on 22 January 2016)

Participants

• Working Group Members:

 Sue Fairweather-Tait, Marina Heinonen, Ambroise Martin, Harry McArdle, Alfonso Siani (Chair), Yolanda Sanz, Anders Sjödin, Sean Strain, Henk van Loveren and Peter Willatts.

Hearing Experts¹:

- Not applicable

• European Commission representative:

Olga Goulaki (DG SANTE)

EFSA:

 Nutrition Unit: Valeriu Curtui, Reinhard Ackerl, Janusz Ciok, Leng Heng, Emanuela Turla and Silvia Valtueña Martínez.

Others:

Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jean-Louis Bresson.

Sean Strain did not participate in agenda point 5.3.

Anders Sjödin did not participate in agenda points 5.6 and 5.8.

2. Adoption of the agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of Interest of Scientific Panel Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest (ADoI) and the

As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



Specific Declaration of Interest SDoI filled in by the working group (WG) Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA-adopted scientific opinions on health claim applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of health claim applications since the last meeting.

5. Draft Article 14 and 13.5 opinions submitted for discussion and/or possible adoption at the Plenary meeting in February 2016

5.1. AlzChem AG - 'Creatine contributes to the maintenance of muscle function in the elderly' (Art. 13.5, 0437_AT, EFSA-Q-2015-00437)

The draft scientific opinion was discussed and, after amendments, it will be circulated to the WG for comments prior to its presentation to the next NDA plenary meeting⁴ for further discussion and possible adoption.

5.2. Ecopharma BVBA – 'Fabenol Max' and 'reduces the absorption of carbohydrates' (Art. 13.5, 0433_BE, <u>EFSA-Q-2015-00123</u>)

The draft scientific opinion was discussed and, after amendments, it will be circulated to the WG for comments prior to its presentation to the next NDA plenary meeting⁴ for further discussion and possible adoption.

5.3. DSM Nutritional Products - 'DHA' and 'contributes to improved memory function' (Art. 13.5, 0438_UK, EFSA-Q-2015-00456)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a "stop the clock" procedure will be applied.

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⁴ The next meeting of the NDA Panel will be held on 1-3 February 2016.



5.4. Gelita AG - 'Fortigel' and 'contributes to the maintenance of joint function' (Art. 13.5, 0434A_DE, EFSA-Q-2015-00360; Art. 13.5, 0434B_DE, EFSA-Q-2015-00762)

The draft scientific opinion was discussed and, after amendments, it will be circulated to the WG for comments prior to its presentation to the next NDA plenary meeting⁵ for further discussion and possible adoption.

5.5. Tate & Lyle PLC - 'Polydextrose' and 'improved bowel function by increasing stool bulk' (Art. 13.5, 0440_UK, EFSA-Q-2015-00550)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a "stop the clock" procedure will be applied.

5.6. Probi AB - 'Lactobacillus plantarum 299v' and 'non-haem iron absorption' (Art. 13.5, 0441 SE, EFSA-Q-2015-00696)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a "stop the clock" procedure will be applied.

5.7. Chios Mastica Growers Association – 'Chios mastica' and 'improvement of dyspepsia' (Art. 13.5, 0442_EL, <u>EFSA-Q-2015-00752</u>)

The discussion of this agenda item was postponed to the next WG Claims⁶.

5.8. Granarolo Spa - "Consumption of Lactobacillus rhamnosus GG (ATCC 53103) and fructooligosaccharides (FOS) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals" (Art. 13.5, 0439_IT, EFSA-Q-2015-00488)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a "stop the clock" procedure will be applied.

5.9. Chios Mastiha Growers Association – 'Chios mastiha' and 'reduction of *Helicobacter pylori* which is a risk factor for the development of peptic ulcer disease' (Art. 14, 0443_EL, <u>EFSA-Q-2015-00753</u>)

The discussion of this agenda item was postponed to the next WG Claims⁶.

⁵ The next meeting of the NDA Panel will be held on 1-3 February 2016.

⁶ The next meeting of the WG Claims will be held on 16-17 March 2016



6. Any other business

The next meeting of the Working Group on Claims will be held on 16-17 March 2016.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)

In the SDoI filled for the present meeting, **Prof Sean Strain** declared an interest for the application related to 'DHA' and 'contributes to improved memory function' (EFSA-Q-2015-00456, agenda item 5.3). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director on Declarations of Interests⁸, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda item 5.3 by the concerned scientific group.

In the SDoI filled for the present meeting **Dr. Anders Mikael Sjödin** declared an interest for the application related to 'Lactobacillus plantarum 299v' and 'non-heme iron absorption' (EFSA-Q-2015-00696, agenda item 5.6) and "Consumption of Lactobacillus rhamnosus GG (ATCC 53103) and fructooligosaccharides (FOS) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals" (EFSA-Q-2015-00488, agenda item 5.8). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁰ and the Decision of the Executive Director on Declarations of Interests¹¹, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda items 5.6 and 5.8 by the concerned scientific group.

⁷ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁸ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 60th meeting of the Working Group on Claims Held on 24-25 November 2015, Parma (Agreed on 1 December 2015)

Participants

• Working Group Members:

Sue Fairweather-Tait, Ambroise Martin, Harry McArdle, Alfonso Siani (Chair), Yolanda Sanz, Anders Sjödin¹, Sean Strain, Henk van Loveren and Peter Willatts¹.

• Hearing Experts²:

- Not applicable

• European Commission representative:

Olga Goulaki (DG Sante)³

• EFSA:

 Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Jelena Gudelj Rakic, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez.

Others:

- Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Jean-Louis Bresson and Marina Heinonen.

Sean Strain and Anders Sjödin declared an interest for agenda items 5.5 and 5.8, respectively. However, the discussion of these two agenda items was postponed.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed. The discussion of agenda items 4.2, 4.5, 5.5, 5.6, 5.7 and 5.8 was postponed.

¹ Present only on 24 November.

² As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

³ Present via teleconference on 24 November, am.



3. Declarations of interest of Working Group Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest SDoI filled in by the working group (WG) Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The discussion of this agenda item was postponed.

4.3. Draft technical report on outcome of the public consultation on the draft general scientific guidance for stakeholders on health claim applications (EFSA-0-2015-00402)

The EFSA Unit presented the technical report on the outcome of the public consultation on the draft general scientific guidance for stakeholders on health claim applications, which summarises the comments received from the public consultation and how the comments were addressed. This technical report was discussed and after amendments, it will be distributed to WG for comments and presented to the next NDA plenary meeting for further discussion and possible endorsement.

4.4. Draft general scientific guidance for stakeholders on health claim applications (EFSA-Q-2015-00200)

The EFSA Unit presented the draft guidance which took into consideration relevant comments received from the public consultation (see agenda item 4.3). This draft guidance was discussed and after amendments, it will be distributed to WG for comments and presented to the next NDA plenary meeting 6 for further discussion and possible adoption.

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

 $^{^{6}}$ The next meeting of the NDA Panel will be held on 9-11 December 2015.



4.5. Draft technical report on outcome of the public consultation on the draft guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms (EFSA-Q-2015-00017)

The discussion of this agenda item was postponed.

4.6. Draft guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms (<u>EFSA-Q-2014-00353</u>)

The EFSA Unit presented the draft guidance which took into consideration relevant comments received from the public consultation. This draft guidance has been re-structured to avoid overlapping with the general scientific guidance for stakeholders on health claim applications, which addresses general aspects that are common to all health claims (see agenda items 4.4). After amendments, this draft guidance will be circulated to WG for comments and presented to the next NDA plenary meeting for further discussion and possible adoption.

- 5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006
 - 5.1. Anxiofit Ltd. "Anxiofit-1" and "amelioration of subthreshold and mild anxiety" (Art. 14, 0432_HU, EFSA-Q-2015-00006)

The draft scientific opinion was discussed and, after amendments, it will be circulated to WG for comments prior to its presentation to the next NDA plenary meeting⁷ for further discussion and possible adoption.

5.2. AlzChem AG - 'Creatine contributes to the maintenance of muscle function in the elderly' (Art. 13.5, 0437_AT, EFSA-Q-2015-00437)

The draft scientific opinion was discussed. It was considered that this draft scientific opinion will be further discussed at the next WG Claims⁸.

5.3. Beghin-Meiji ZI and Tereos Syral, ZI - 'short chain FOS from sucrose' and 'normal intestinal regularity' (Art. 13.5, 0436_FR, EFSA-Q-2015-00377)

The draft scientific opinion was discussed and, after amendments, it will be circulated to WG for comments prior to its presentation to the next NDA plenary meeting⁷ for further discussion and possible adoption.

⁷ The next meeting of the NDA Panel will be held on 9-11 December 2015.

⁸ The next meeting of the WG Claims will be held on 19-20 January 2016.



5.4. Ecopharma BVBA – "Fabenol Max" and "reduces the absorption of carbohydrates" (Art. 13.5, 0433_BE, <u>EFSA-Q-2015-00123</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.5. DSM Nutritional Products - 'DHA' and 'contributes to improved memory function' (Art. 13.5, 0438_UK, <u>EFSA-Q-2015-00456</u>)

The discussion of this agenda item was postponed to the next WG Claims⁹.

5.6. Gelita AG - 'collagen peptide mixture (Fortigel®)' and 'contributes to the maintenance of normal joint function' (Art. 13.5, 0434_DE, <a href="https://example.com/ersamp

The discussion of this agenda item was postponed to the next WG Claims⁹.

5.7. Tate & Lyle PLC – 'Polydextrose' and 'improved bowel function by increasing stool bulk' (Art. 13.5, 0440_UK, <u>EFSA-Q-2015-00550</u>)

The discussion of this agenda item was postponed to the next WG Claims⁹.

5.8. Probi AB – 'Lactobacillus plantarum 299v' and 'non-heme iron absorption' (Art. 13.5, 0441_SE, <u>EFSA-Q-2015-00696</u>)

The discussion of this agenda item was postponed to the next WG Claims⁹.

6. Next meeting

The next meeting of the Working Group on Claims will be held on 19-20 January 2016.

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⁹ The next meeting of the WG Claims will be held on 19-20 January 2016.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)

In the SDoI filled for the present meeting **Prof Sean Strain** declared an interest for the application related to 'DHA' and 'contributes to improved memory function' (EFSA-Q-2015-00456, agenda item 5.5). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁰ and the Decision of the Executive Director on Declarations of Interests¹¹, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda item 5.5 by the concerned scientific group.

In the SDoI filled for the present meeting **Dr. Anders Mikael Sjödin** declared an interest for the application related to 'Lactobacillus plantarum 299v' and 'non-heme iron absorption' (EFSA-Q-2015-00696, agenda item 5.8). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹⁰ and the Decision of the Executive Director on Declarations of Interests¹¹, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda item 5.8 by the concerned scientific group.

¹⁰ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

¹¹ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



NUTRITION UNIT

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 59th meeting of the Working Group on Claims Held on 7-8 October 2015, Parma (Agreed on 16 October 2015)

Participants

- Working Group Members:
 - Jean-Louis Bresson, Sue Fairweather-Tait, Ambroise Martin, Alfonso Siani (Chair), Anders Sjödin, Sean Strain, and Henk van Loveren.
- Hearing Experts¹:
 - Not applicable
- European Commission representative:
 - Olga Goulaki (DG Sante)
- EFSA:
 - Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Valeriu Curtui, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez
- Others:
 - Not applicable

1. Welcome and apologies for absence

The Chair welcomed the member of the new Standing Working Group on Claims (2015-2018).

Apologies were received from Marina Heinonen, Harry McArdle, Yolanda Sanz and Peter Willatts.

Sean Strain did not participate in agenda point 5.4 due to a Conflict of Interest being identified for this agenda item.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest of Working Group Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest (ADoI) and the

As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



Specific Declaration of Interest SDoI filled in by the working group (WG) Members invited for the present meeting.

For further details on the outcome of the screening of the ADoI or the SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of health claims applications since the last meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1. AlzChem AG - 'Creatine contributes to the maintenance of muscle function in the elderly' (Art. 13.5, 0437_AT, EFSA-Q-2015-00437)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.2. Specialised Nutrition Europe (SNE) - 'vitamin C' and 'helps to support a healthy immune system' (Art. 14, 0097_FR, <u>EFSA-Q-2008-177</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

⁴ The next meeting of the NDA Panel will be held on 28-30 October 2015.



5.4. DSM Nutritional Products - 'DHA' and 'contributes to improved memory function' (Art. 13.5, 0438_UK, EFSA-Q-2015-00456)

The draft scientific opinion was discussed. The draft opinion will be further discussed at the next WG Claims⁵.

5.5. Beghin-Meiji ZI and Tereos Syral, ZI – "short chain FOS from sucrose" and "normal intestinal regularity" (Art. 13.5, 0436_FR, EFSA-O-2015-00377)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Next meeting

The next meeting of the Working Group on Claims will be held on 24-25 November 2015.

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 $^{^{\}rm 5}$ The next meeting of the WG Claims will be held on 24-25 November 2015.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)

In the SDoI filled for the present meeting by **Prof Sean Strain** the following interest was identified: DSM Nutritional Products - 'DHA' and 'contributes to improved memory function' (EFSA-Q-2015-00456, agenda item 5.4). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interests⁷, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of agenda item 5.4 by the concerned scientific group.

⁶ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁷ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



NUTRITION UNIT

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 58th meeting of the Working Group on Claims Held on 9 September 2015, Parma (Agreed on 16 September 2015)

Participants

• Working Group Members:

 Susan Fairweather-Tait, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Mikael Sjödin, John Joseph Strain (Chair), Inge Tetens, Henk van Loveren, Hans Verhagen, Peter Willatts.

Hearing Experts¹:

Not applicable

European Commission representative:

Not applicable

EFSA:

 Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Valeriu Curtui, Jelena Gudelj Rakic, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez

Others:

- Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Carlo Agostoni, Jean-Louis Bresson and Marina Heinonen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest of Working Group Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



Declaration of interest filled in by the working group (WG) Members invited for the present meeting. At the beginning of the meeting, WG members were also asked to declare any interest related to the issues discussed in this meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

None.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of health claims applications since the last meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1. Vifor Ltd. - 'Equazen eye q[®] (EPA:DHA:GLA at a 9:3:1 ratio) improves reading ability in children' (Art. 14, 0419_UK, EFSA-Q-2014-00462)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

5.2. Anxiofit Ltd. - 'Anxiofit-1' and 'amelioration of subthreshold and mild anxiety' (Art. 14, 0432_HU, EFSA-Q-2015-00006)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3. Specialised Nutrition Europe — 'Starch' and 'limits spitting-up by thickening the product' (Art. 14, 0123_FR, EFSA-Q-2008-204)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.4. DuPont Nutrition Biosciences ApS – 'Lactitol' and 'normal bowel function' (Art. 13(5), 0435_UK, EFSA-Q-2015-00375)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

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⁴ The next meeting of the NDA Panel will be held on 23-25 September 2015.



5.5. Beghin-Meiji ZI and Tereos Syral, ZI – 'short chain FOS from sucrose' and 'normal intestinal regularity' (Art. 13(5), 0436_FR, EFSA-Q-2015-00377)

The draft scientific opinion was discussed and, after amendments, will be presented to the next WG Claims meeting⁵ for further discussion.

6. Next meeting

The next meeting of the Working Group on Claims will be held on 7-8 October 2015.

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⁵ The next meeting of the WG Claims will be held on 7-8 October 2015.



NUTRITION UNIT

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 57th meeting of the Working Group on Claims Held on 10 June 2015, Parma (Agreed on 15 June 2015)

Participants

• Working Group Members:

 Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Alfonso Siani, Anders Mikael Sjödin, John Joseph Strain (Chair), Inge Tetens, Henk van Loveren and Hans Verhagen

Hearing Experts¹:

Not applicable

• European Commission representative:

Olga Goulaki

• EFSA:

- Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Valeriu Curtui, Leng Heng, Emanuela Turla
- Data Unit: Annette Forss

Others:

 Jenny Reid (short-term visiting Scientist, Ministry for Primary Industry, New Zealand)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Carlo Agostoni, Yolanda Sanz and Peter Willatts.

2. Adoption of agenda

The agenda was adopted with the inclusion of an additional agenda item (<u>EFSA-Q-2014-00404</u>) under "Any other business".

3. Declarations of interest of Working Group Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of

¹ As defined in Article 17 of the Decision of the Executive Director on the selection of external experts: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.



Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest filled in by the working group (WG) Members invited for the present meeting. At the beginning of the meeting, WG members were also asked to declare any interest related to the issues discussed in this meeting, including the new agenda item added under "Any other business". No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of health claims applications since the last meeting.

4.3. Draft technical report on outcome of the public consultation on the draft guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms (EFSA-Q-2015-00017)

The EFSA Unit presented the draft technical report which summarised the comments received during the public consultation and reported how the comments were addressed. The draft technical report will be submitted to the NDA plenary meeting on 11-12 June for discussion.

4.4. Draft guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms (EFSA-Q-2014-00353)

A revised draft guidance, taking into account the comments received during the public consultation, will be submitted to the NDA plenary meeting on 11-12 June for discussion.

4.5. Updating of NDA Panel general guidance for stakeholders on the evaluation of Art.13.1-13.5 and 14 health claims (<u>EFSA-Q-2015-00200</u>)

A draft guidance which updates the "General guidance for stakeholders on

² <u>http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf</u>

³ <u>http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf</u>



the evaluation of Article 13.1, 13.5 and 14 health claims" was presented to the WG Members.

The draft guidance will be submitted to the next NDA plenary meeting⁴ for possible endorsement for release for public consultation.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1. IDACE - "Niacin" and "release of energy from food" (Art. 14, 0105_FR, EFSA-Q-2008-185)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

5.2. IDACE - "Biotin" and "release of energy from food" (Art. 14, 0108_FR, EFSA-Q-2008-188)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

5.3. *IDACE* – "Vitamin D" and "contributes to the normal function of natural defences" (Art. 14, 0102_FR, <u>EFSA-Q-2008-</u>182)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

5.4. Anxiofit Ltd. – "Anxiofit-1" and "amelioration of subthreshold and mild anxiety" (Art. 14, 0432_HU, <u>EFSA-Q-2015-00006</u>)

The discussion of this agenda item was postponed to the next WG meeting.

6. Any other business

6.1. Colief Cross Vetpharm Group – "Colief/lactase enzyme reduces the lactose load of the infant's feed and improves the consequences of lactose maldigestion in colicky infants unable to effectively digest all the lactose in their feed" (Art. 14, 0417_UK, EFSA-Q-2014-00404)

The draft scientific opinion was discussed and, after amendments, will be presented to the next NDA plenary meeting⁴ for further discussion and possible adoption.

7. Next meeting

The next meeting of the Working Group on Claims will be held on 09-10 September 2015.

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⁴ The next meeting of the NDA Panel will be held on 29 June – 1 July 2015



NUTRITION UNIT

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 56th meeting of the Working Group on Claims Held on 6-7 May 2015, Parma (Agreed on 12 May 2015)

Participants

- Working Group Members:
 - Carlo Agostoni¹, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Hildegard Przyrembel¹, Yolanda Sanz¹, Anders Mikael Sjödin, John Joseph Strain (Chair), Inge Tetens¹, Henk van Loveren, Peter Willatts
- Hearing Experts:
 - Not applicable
- European Commission representative:
 - Olga Goulaki
- EFSA:
 - Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Valeriu Curtui, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez
- Observers:
 - Not applicable
- Others:
 - Not applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Ambroise Martin, Alfonso Siani and Hans Verhagen.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

¹ Present only on 6 May



3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director on Declarations of Interest³, EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest filled in by the working group members 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 Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of health claims applications since the last NDA plenary meeting.

4.3. Draft technical report on outcome of the public consultation on the draft guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms (EFSA-Q-2015-00017)

The EFSA Unit presented part of the draft technical report which summarised the comments received during the public consultation and reported how the comments were addressed. The draft technical report will be submitted to the next meeting of the WG Claims for discussion prior to submission to the Panel for possible endorsement.

4.4. Draft guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms (EFSA-Q-2014-00353)

A revised draft guidance, taking into account the comments received during the public consultation, will be submitted to the next meeting of the WG Claims for discussion prior to submission to the Panel for possible adoption.

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

³ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1. Cross Vetpharm Group – "Colief/lactase enzyme reduces the lactose load of the infant's feed and improves the consequences of lactose maldigestion in colicky infants unable to effectively digest all the lactose in their feed" (Art. 14, 0417_UK, EFSA-Q-2014-00404)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.2. Vifor Ltd. – "Equazen eye q® (EPA:DHA:GLA at a 9:3:1 ratio) improves reading ability in children" (Art. 14, 0419_UK, EFSA-Q-2014-00462)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3. PowerBar Europe GmbH – "Combined intake of glucose and fructose improves performance in active individuals performing endurance exercise compared to the intake of glucose alone" (Art. 13.5, 0431_UK, EFSA-Q-2014-00927)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.4. Anxiofit Ltd. – "Anxiofit-1" and "amelioration of subthreshold and mild anxiety" (Art. 14, 0432_HU, <u>EFSA-Q-2015-00006</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.5. Han-Asiabiotech GmbH – "Symbiosal®" and "lowers the rising of blood pressure when used as a replacement of traditional table salt. The rising of blood pressure is a risk factor for hypertension." (Art. 14, 0415_DE, <u>EFSA-Q-2014-00366</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

6. Any other business

No other business was discussed.

7. Next meeting

The next meeting will be held on 10-11 June 2015.



NUTRITION UNIT

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 55th meeting of the Working Group on Claims Held on 18-19 March 2015, Parma (Agreed on 23 March 2015)

Participants

- Working Group Members:
 - Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani¹, Anders Mikael Sjödin, John Joseph Strain (Chair), Henk van Loveren², Hans Verhagen, Peter Willatts
- Hearing expert:
 - Not Applicable
- European Commission representative:
 - Agnieszka-Anna Turek
- EFSA:
 - Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Valeriu Curtui, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Inge Tetens.

Anders Sjödin did not participate in agenda points 5.1 and 5.2 due to a Conflict of Interest being identified for these agenda points.

2. Adoption of agenda

The agenda was adopted without changes.

¹ Present only on 18 March

² Present only on 18 March



3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest (SDoI) filled in by the working group members invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of health claims applications since the last NDA plenary meeting.

4.3. Public consultation on the draft Guidance on the scientific requirements for health claims related to the gastro-intestinal tract, the immune system, and defence against pathogenic microorganisms

The EFSA Unit informed WG Members that the public consultation is still open until 23 March 2015 (http://www.efsa.europa.eu/en/press/news/150 209.htm).

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1. Lallemand Health Solutions – "Bifidobacterium bifidum CNCM I-3426 increases the proportion of healthy days by maintaining normal immune function in healthy adults during everyday life events such as moderate stress" (Art. 13.5, 0429_BE, EFSA-Q-2014-00673).

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf



5.2. Synbiotec S.r.I. – "SYNBIO®, a combination of Lactobacillus rhamnosus IMC 501® and Lactobacillus paracasei IMC 502®" and "persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being" (Art. 13.5, 0425_IT, EFSA-Q-2014-00567)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3. *VAB-nutrition* – "Vitamin D" and "contribution to the normal function of the immune system" (Art. 14, 0430_FR, <u>EFSA-Q-2014-00826</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.4. Nerthus ApS – "A combination of standardized pomegranate pomace extract and greater galangal rhizome powder" and "increases the number of motile spermatozoa in semen" (Art. 13.5, 0424_DK, <u>EFSA-Q-2014-00566</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.5. WILD-Valencia SAU – "FRUIT UP®" and "induces a lower blood glucose rise than high glycaemic carbohydrates" (Art. 13.5, 0418_ES, EFSA-Q-2014-00405)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.6. Tchibo GmbH – "Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body" (Art. 13.5, 0428_DE, <u>EFSA-Q-2014-00624</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

6. Any other business

No other business was discussed.

7. Next meeting

The next meeting will be held on 6-7 May 2015.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)

In the SDoI filled for the present meeting **Dr. Anders Mikael Sjödin** declared an interest for the applications related to "**Bifidobacterium bifidum CNCM I-3426**" (EFSA-Q-2014-00673, agenda point 5.1) and "**SYNBIO**®, a combination of **L. rhamnosus IMC 501**® and **L. paracasei IMC 502**®" (EFSA-Q-2014-00567, agenda point 5.2). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director on Declarations of Interests⁶, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent Conflicts of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of points 5.1 and 5.2 by the concerned scientific group.

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁶ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 54th meeting of the Working Group on Claims Held on 21-22 January 2015, Parma (Agreed on 27 January 2015)

Participants

- Working Group Experts:
 - Carlo Agostoni, Jean-Louis Bresson¹, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel², Yolanda Sanz³, Alfonso Siani, Anders Mikael Sjödin, John Joseph Strain (Chair), Henk van Loveren, Hans Verhagen, Peter Willatts⁴
- Hearing expert:
 - Not Applicable
- European Commission:
 - Olga Goulaki
- EFSA:
 - Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Valeriu Curtui, Leng Heng, Emanuela Turla, Silvia Valtueña Martínez

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

³ Present on 21 January

¹ Present via teleconference on 21 January (pm)

² Present on 21 January

⁴ Present via teleconference on 22 January



3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁵ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁶, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. The adopted European Commission Regulations related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1. *WILD-Valencia SAU* – "FRUIT UP[®]" and "induces a lower blood glucose rise than high glycaemic carbohydrates" (Art. 13.5, 0418_ES, <u>EFSA-Q-2014-00405</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.2. Synbiotec S.r.I. – "SYNBIO[®], a combination of *Lactobacillus rhamnosus* IMC 501[®] and *Lactobacillus paracasei* IMC 502[®]" and "persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being" (Art. 13.5, 0425_IT, <u>EFSA-Q-2014-00567</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3. *Tchibo GmbH* – "Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body" (Art. 13.5, 0428_DE, <u>EFSA-Q-2014-00624</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

⁵ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁶ http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



5.4. Lycotec Ltd – "L-tug lycopene" and "lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" (Art.14, 0427 UK, EFSA-Q-2014-00590)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.5. Nerthus ApS – "A combination of standardized pomegranate pomace extract and greater galangal rhizome powder" and "increases the number of motile spermatozoa in semen" (Art. 13.5, 0424_DK, <u>EFSA-Q-2014-00566</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the next WG for further discussion.

5.6. Vifor Ltd. – "Equazen eye q® (EPA:DHA:GLA at a 9:3:1 ratio) improves reading ability in children" (Art. 14, 0419_UK, <u>EFSA-Q-2014-00462</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7. Dextro Energy GmbH & Co. – "Glucose contributes to the maintenance of normal brain function" (Art. 13.5, 0420_DE, <u>EFSA-Q-2014-00554</u>); "Glucose contributes to normal cognitive function" (Art. 13.5, 0421_DE, <u>EFSA-Q-2014-00555</u>); "Glycaemic carbohydrates contribute to the maintenance of normal brain function" (Art. 13.5, 0422_DE, <u>EFSA-Q-2014-00556</u>); "Dextrose Tablets contribute to the maintenance of normal brain function" (Art. 13.5, 0423_DE, <u>EFSA-Q-2014-00557</u>).

The draft scientific opinions were discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.8. Lallemand Health Solutions – "Bifidobacterium bifidum CNCM I-3426 increases the proportion of healthy days by maintaining normal immune function in healthy adults during everyday life events such as moderate stress" (Art. 13.5, 0429_BE, EFSA-Q-2014-00673).

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.9. Cross Vetpharm Group – "Colief/lactase enzyme reduces the lactose load of the infant's feed and improves the consequences of lactose maldigestion in colicky infants unable to effectively digest all the lactose in their feed" (Art. 14, 0417_UK, EFSA-Q-2014-00404)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.10. Han-Asiabiotech GmbH – "Symbiosal" and "lowers the rising of blood pressure when used as a replacement of traditional table salt" (Art. 14, 0415_DE, EFSA-Q-2014-00366)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.



6. Any other business

No other business was discussed.

7. Next meeting

The next meeting will be held on 18-19 March 2015.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁷

In the SDol filled for the present meeting **Dr. Anders Mikael Sjödin** declared an interest for the applications related to "**SYNBIO**®, **a combination of** *L. rhamnosus* **IMC 501**® **and** *L. paracasei* **IMC 502**®" (EFSA-Q-2014-00567, agenda item 5.2) and "*Bifidobacterium bifidum* **CNCM I-3426**" (EFSA-Q-2014-00673, agenda item 5.8). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent conflicts of Interest.

This results in the impossibility for the expert to be present when these items of the meeting (agenda items 5.2 and 5.8) were discussed, voted on or in anyway processed by that concerned scientific group.

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⁷ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 53rd meeting of the Working Group on Claims Teleconference on 16 December 2014 (14:00 – 17:00) (Agreed on 19 December 2014)

Participants

- Working Group Experts:
 - Yolanda Sanz, Henk van Loveren and Alfonso Siani (Chair)
- EFSA:
 - Nutrition Unit: Janusz Ciok and Leng Heng
- 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jean-Louis Bresson.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest (ADoI) and the 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 were identified during the screening process. Oral Declarations of interest were asked to all experts at the beginning of the meeting and no interest or additional interest was declared or at the Oral Declaration of Interest at the beginning of this meeting.

4. Updating of NDA Panel guidance on scientific requirements for health claims related to gut and immune function (<u>EFSA-Q-2014-00353</u>) and Outcome of the public consultation on the discussion paper on the revision of the guidance on the scientific requirements for health claims related to gut and immune function (<u>EFSA-Q-2014-00409</u>)

The experts were informed that the updated draft guidance was endorsed by the NDA Panel subject to editorial comments. The experts discussed specific comments addressed in the draft technical report. After amendments, the draft technical report will be presented to the NDA Panel for endorsement by written procedure.

5. Any other business

None.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 52nd meeting of the Working Group on Claims Teleconference on 01 December 2014 (11:00 – 14:00) (Agreed on 16 December 2014)

Participants

- Working Group Experts:
 - Yolanda Sanz, Henk van Loveren and Jean-Louis Bresson
- EFSA:
 - Nutrition Unit: Janusz Ciok and Leng Heng (Chair)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alfonso Siani.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest (ADoI) and the 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 were identified during the screening process. Oral Declarations of interest were asked to all experts at the beginning of the meeting and no interest or additional interest was declared³.

4. Updating of NDA Panel guidance on scientific requirements for health claims related to gut and immune function (EFSA-Q-2014-00353)

The experts discussed the draft update of the guidance document on scientific requirements for health claims related to gut and immune function, and the comments received during the public consultation for the revision of this guidance. After amendments, the draft update of this guidance will be presented to the NDA Panel for discussion and possible endorsement.

5. Any other business

The next teleconference meeting will be held on 16 December 2014 (14:00 – 17:00).

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

³ J.L. Bresson did not manage to submit his SDoI via the workflow. An ODoI was requested at the beginning of the meeting, and no conflict of interest was identified.



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 51st meeting of the Working Group on Claims Held on 26-27 November 2014, Parma (Agreed on 2 December 2014)

Participants

- Working Group Experts:
 - Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Mikael Sjödin, John Joseph Strain (Chair), Henk van Loveren¹, Hans Verhagen², Peter Willatts
- Hearing expert:
 - Not Applicable
- European Commission:
 - Agnieszka-Anna Turek
- EFSA:
 - Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Valeriu Curtui, Leng Heng, Mieke Peters, Christos Stefanidis, Emanuela Turla, Silvia Valtueña Martínez

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

¹ Present on 26 November (pm) and 27 November

² Present on 26 November



3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁴, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. All the adopted European Commission decisions related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1. Beneo – "Orafti[®] Inulin" and "improves bowel function" (Art. 13.5, 0416_BE, <u>EFSA-Q-2014-00403</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.2. Federacion Nacional de Industrias Lácteas (FeNIL) – "Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars" and "help to reduce body and visceral fat in the context of an energy restricted diet" (Art. 13.5, 0412_ES, <u>EFSA-Q-2014-00126</u>)

The draft scientific opinion was discussed and, after amendments, will be circulated to the Panel for possible adoption by written procedure.

5.3. Federacion Nacional de Industrias Lácteas (FeNIL) – "Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars" and "maintenance of lean body mass (muscle and bone)" (Art. 13.5, 0413_ES, EFSA-Q-2014-00127)

The draft scientific opinion was discussed and, after amendments, will be circulated to the Panel for possible adoption by written procedure.

5.4. Avesthagen Limited – "Teestar™" and "lowers blood glucose levels" (Art. 13.5, 0414_FR, <u>EFSA-Q-2014-00153</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



5.5. BASF SE and Stepan Lipid Nutrition – "Clarinol® or Tonalin®" and "contributes to a reduction in body fat mass" (Art. 13.5, 0426_NL, <u>EFSA-Q-2014-00580</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.6. *WILD-Valencia SAU* – "FRUIT UP[®]" and "induces a lower blood glucose rise than high glycaemic carbohydrates" (Art. 13.5, 0418_ES, <u>EFSA-Q-2014-00405</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7. Synbiotec S.r.I. – "SYNBIO[®], a combination of *Lactobacillus rhamnosus* IMC 501[®] and *Lactobacillus paracasei* IMC 502[®]" and "persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being" (Art. 13.5, 0425_IT, EFSA-Q-2014-00567)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8. *Tchibo GmbH* – "Regular consumption of Coffee C21 contributes to the maintenance of DNA integrity in cells of the body" (Art. 13.5, 0428_DE, <u>EFSA-Q-2014-00624</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.9. Lycotec Ltd – "L-tug lycopene" and "lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" (Art.14, 0427_UK, EFSA-Q-2014-00590)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.10. Nerthus ApS – "A combination of standardized pomegranate pomace extract and greater galangal rhizome powder" and "increases the number of motile spermatozoa in semen" (Art. 13.5, 0424_DK, EFSA-Q-2014-00566)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Updating of NDA Panel guidance on scientific requirements for health claims related to gut and immune function (EFSA-Q-2014-00353)

The WG discussed the draft update of the guidance document on scientific requirements for health claims related to gut and immune function which was based on the comments received during the public consultation for the revision of this guidance. After amendments, the draft update of this guidance will be presented to



the Panel for further discussion and possible endorsement for public consultation.

7. Any other business

No other business was discussed.

8. Next meeting

The next meeting will be held on 21-22 January 2015.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁵

In the SDol filled for the present meeting **Dr. Anders Mikael Sjödin** declared an interest for the applications related to "fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin **D**, and with no added sugars" (EFSA-Q-2014-00126, agenda item 5.2 and EFSA-Q-2014-00127, agenda item 5.3); and the application related to "SYNBIO®, a combination of *L. rhamnosus* IMC 501® and *L. paracasei* IMC 502®" (EFSA-Q-2014-00567, agenda item 5.7). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent conflicts of Interest.

This results in the impossibility for the expert to be present when these items of the meeting (agenda items 5.2, 5.3 and 5.7) were discussed, voted on or in anyway processed by that concerned scientific group.

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⁵ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Scientific Panel on Dietetic Products, Nutrition and Allergies Minutes of the 50th meeting of the Working Group on Claims Teleconference on 20 November 2014 (11:00 – 14:00) (Agreed on 1 December 2014)

Participants

- Working Group Experts:
 - Yolanda Sanz, Henk van Loveren and Jean-Louis Bresson
- EFSA:
 - Nutrition Unit: Janusz Ciok, Silvia Valtueña Martínez and Leng Heng (Chair)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alfonso Siani.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest (ADoI) and the 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Updating of NDA Panel guidance on scientific requirements for health claims related to gut and immune function (EFSA-Q-2014-00353)

The experts discussed the draft update of the guidance document on scientific requirements for health claims related to gut and immune function which was based on the comments received during the public consultation for the revision of this guidance. After amendments, the draft update of this guidance will be presented to the WG claims for further discussion.

5. Any other business

The next teleconference meeting will be held on 1 December 2014 (13:30 – 16:30).

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Scientific Panel on Dietetic Products, Nutrition and Allergies Minutes of the 49th meeting of the Working Group on Claims Teleconference on 12 November 2014 (9:30 – 12:30) (Agreed on 20 November 2014)

Participants

- Working Group Experts:
 - Yolanda Sanz, Henk van Loveren, Jean-Louis Bresson and Alfonso Siani (Chair)
- EFSA:
 - Nutrition Unit: Janusz Ciok, Silvia Valtueña Martínez and Leng Heng

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest (ADoI) and the 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Updating of NDA Panel guidance on scientific requirements for health claims related to gut and immune function (EFSA-Q-2014-00353)

The experts discussed sections of the revised draft guidance document and comments received from the public consultation on the discussion paper for the revision of the guidance on scientific requirements for health claims related to gut and immune function.

5. Any other business

The next teleconference meeting will be held on 20 November 2014 (11:00 – 14:00).

¹ http://www.efsa.europa.e<u>u/en/keydocs/docs/independencepolicy.pdf</u>

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 48th meeting of the Working Group on Claims Teleconference on 24 October 2014 (9:30 – 12:30) (Agreed on 11 November 2014)

Participants

- Working Group Experts:
 - Yolanda Sanz, Henk van Loveren, and Alfonso Siani (Chair)
- EFSA:
 - Nutrition Unit: Janusz Ciok and Leng Heng

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jean-Louis Bresson.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest (ADoI) and the 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 were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Updating of NDA Panel guidance on scientific requirements for health claims related to gut and immune function (EFSA-Q-2014-00353)

The experts discussed sections of the revised draft guidance document and comments received from the public consultation on the discussion paper for the revision of the guidance on scientific requirements for health claims related to gut and immune function.

5. Any other business

The next teleconference meeting will be held on 12 November 2014.

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Nutrition Unit

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 47th meeting of the Working Group on Claims Held on 15-16 October 2014, Parma (Agreed on 22 October 2014)

Participants

- Working Group Experts:
 - Carlo Agostoni¹, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Mikael Sjödin, John Joseph Strain (Chair), Henk van Loveren, Hans Verhagen, Peter Willatts
- European Commission:
 - Agnieszka-Anna Turek
- EFSA:
 - Nutrition Unit: Reinhard Ackerl, Janusz Ciok, Valeriu Curtui, Leng Heng,
 Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Inge Tetens.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests³, EFSA screened the Annual Declaration of interest (ADoI) and the

¹ Present only on 15 October.

² http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications. All the adopted European Commission decisions related to health claims are available on the Commission website: http://ec.europa.eu/nuhclaims/.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 Beneo – "Orafti[®] Inulin" and "improves bowel function" (Art. 13.5, 0416_BE, EFSA-Q-2014-00403)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.2 Federacion Nacional de Industrias Lácteas (FeNIL) – "Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars" and "help to reduce body and visceral fat in the context of an energy restricted diet" (Art. 13.5, 0412_ES, <u>EFSA-Q-2014-00126</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3 Federacion Nacional de Industrias Lácteas (FeNIL) – "Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars" and "maintenance of lean body mass (muscle and bone)" (Art. 13.5, 0413 ES, EFSA-Q-2014-00127)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.4 *Specialised Nutrition Europe (formerly IDACE)* - "Prunes" and "normal bowel function" (Art. 14, 0113_FR, <u>EFSA-Q-2008-193</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.



5.5 Specialised Nutrition Europe (formerly IDACE) – "Zinc is essential for growth" (Art. 14, 0110 FR, EFSA-Q-2008-190)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.6 Specialised Nutrition Europe (formerly IDACE) – "Non-digestible Oligoand Polysaccharides" and "calcium absorption" (Art. 14, 0060_FR, EFSA-Q-2008-140)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.7 *Vifor Ltd.* – "Equazen eye q[®] (EPA:DHA:GLA at a 9:3:1 ratio) improves reading ability in children" (Art. 14, 0419_UK, <u>EFSA-Q-2014-00462</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8 Specialised Nutrition Europe (formerly IDACE) – "Selenium has an antioxidant functionality" (Art. 14, 0079_FR, <u>EFSA-Q-2008-159</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.9 Avesthagen Limited – "Teestar™" and "lowers blood glucose levels" (Art. 13.5, 0414_FR, <u>EFSA-Q-2014-00153</u>)

The discussion of this agenda item was postponed to the next meeting.

5.10 Han-Asiabiotech GmbH – "Symbiosal" and "lowers the rising of blood pressure when used as a replacement of traditional table salt" (Art. 14, 0415 DE, EFSA-Q-2014-00366)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.11 *BASF SE* and *Stepan Lipid Nutrition* – "Clarinol® or Tonalin®" and "contributes to a reduction in body fat mass" (Art. 13.5, 0426_NL, <u>EFSA-Q-2014-00580</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.12 Specialised Nutrition Europe (formerly IDACE) – "DHA and ARA contribute to immune system development of infants and young children" (Art. 14, 0116_FR, <u>EFSA-Q-2008-196</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.



6. Updating of NDA Panel guidance on scientific requirements for health claims related to gut and immune function (EFSA-Q-2014-00353)

The EFSA Unit presented to the WG Experts a compilation of comments received during the public consultation for the revision of the guidance on scientific requirements for health claims related to gut and immune function.

7. Any other business

No other business was discussed.

8. Next meeting

The next meeting will be held on 26-27 November 2014.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁴

In the SDoI filled for the present meeting **Dr. Anders Mikael Sjödin** declared an interest for the applications from *Federacion Nacional de Industrias Lácteas (FeNIL)* and related to "fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin **D**, and with no added sugars" (EFSA-Q-2014-00126, agenda item 5.2 and EFSA-Q-2014-00127, agenda item 5.3). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent conflicts of Interest.

This results in the impossibility for the expert to be present when these items of the meeting (agenda items 5.2 and 5.3) were discussed, voted on or in anyway processed by that concerned scientific group.

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⁴ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Nutrition Unit

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 46th meeting of the Working Group on Claims Held on 8-9 July 2014, Parma (Agreed on 15 July 2014)

Participants

- Working Group Experts:
 - Agostoni C.¹, Bresson J-L., Fairweather-Tait S., Sanz Y., Siani A.,
 Sjödin A., Strain J.J. (Chair), Tetens I., van Loveren H., Willatts P.²
- European Commission:
 - None
- EFSA:
 - Nutrition Unit: Ackerl R., Ciok J., Curtui V., Heng L., Titz A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Heinonen M., Martin A., Przyrembel H., Verhagen H. and from the Commission representatives.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director implementing this Policy regarding

¹ Participated via teleconference on 8 July (pm) and present on 9 July.

² Participated via teleconference on 9 July.

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



Declarations of Interests ⁴, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

- 4. General issues on health claims evaluation
 - 4.1. Feedback from the European Commission

None.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

- 5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006
 - 5.1 *E-piim production Ltd* "Lactobacillus plantarum TENSIA[®] in the semihard Edam-type "heart cheese" of Harmony™" and "maintenance of cardiovascular health through reduction of blood pressure" (Art. 13.5, 0411_EE, EFSA-Q-2014-00097)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.2 British Specialist Nutrition Association - "Carbohydrate solutions" and "contribute to the maintenance of endurance performance during prolonged endurance exercise" (Art. 13.5, 0408_UK, EFSA-Q-2014-00058)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3 Oy Karl Fazer Ab - "High-fibre sourdough rye bread" and "reduction of post-prandial glycaemic response accompanied by a reduced insulin response" (Art. 13.5, 0405_FI, EFSA-Q-2014-00012)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.4 Olygose - "AlphaGOS[®]" and "induces a lower blood glucose rise compared to sugar-containing foods or drinks" (Art. 13.5, 0407_FR, <u>EFSA-Q-2014-00044</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



5.5 Roquette Italia S.p.a. - "Nutriose®06" and "induces a lower blood glucose rise compared to high glycaemic carbohydrate-containing foods/drinks" (Art. 13.5, 0410_IT, EFSA-Q-2014-00073)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.6 *DSM Nutritional Products Ltd.* - "Preformed DHA" and "contributes to brain development" (Art. 14, 0409_UK, <u>EFSA-Q-2014-00059</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.7 Federacion Nacional de Industrias Lácteas (FeNIL) – "Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars" and "help to reduce body and visceral fat in the context of an energy restricted diet" (Art. 13.5, 0412_ES, <u>EFSA-Q-2014-00126</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8 Federacion Nacional de Industrias Lácteas (FeNIL) – "Fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin D, and with no added sugars" and "maintenance of lean body mass (muscle and bone)" (Art. 13.5, 0413_ES, EFSA-Q-2014-00127)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.9 Beneo – "Orafti[®]Inulin" and "improves bowel function" (Art. 13.5, 0416_BE, EFSA-Q-2014-00403)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.10 Specialised Nutrition Europe (formerly IDACE) – "Lactase for comfortable digestion" (Art. 14, 0068_FR, <u>EFSA-Q-2008-148</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

6. Any other business

The EFSA Secretariat informed the WG Experts that EFSA has launched a "Call for Proposal" in the framework of article 36 of Regulation (EC) No 178/2002: Ref: GP/EFSA/NUTRI/2014/01 - "Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement":

Link: http://www.efsa.europa.eu/en/art36grants/article36/gpefsanutri201401.htm

The deadline for submitting proposals is 19 September 2014.



7. Next meeting

The next meeting will be held on 15-16 October 2014.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁵

In the SDol filled for the present meeting **Dr. A. Sjödin** declared an interest for the following applications: from *E-piim production Ltd* and related to "*Lactobacillus plantarum* **TENSIA**® in the semi-hard Edam-type "heart cheese" of Harmony™" (EFSA-Q-2014-00097, agenda item 5.1), and from *Federacion Nacional de Industrias Lácteas (FeNIL)* and related to "fat-free yogurts and fermented milks with live yogurt cultures, with added vitamin **D**, and with no added sugars" (EFSA-Q-2014-00126, agenda item 5.7 and EFSA-Q-2014-00127, agenda item 5.8). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent conflicts of Interest.

This results in the impossibility for the expert to be present when these items of the meeting (agenda items 5.1, 5.7 and 5.8) were discussed, voted on or in anyway processed by that concerned scientific group.

In the SDoI filled for the present meeting **Prof. S. Strain** declared an interest for the application from *DSM Nutritional Products Ltd* and related to "**Preformed DHA**" (EFSA-Q-2014-00059, agenda item 5.6). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when this item of the meeting (agenda item 5.6) was discussed, voted on or in anyway processed by that concerned scientific group.

⁵ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Nutrition Unit

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 45th meeting of the Working Group on Claims Held on 6-7 May 2014, Tabiano Bagni (Parma) (Agreed on 15 May 2014)

Participants

- Working Group Experts:
 - Agostoni C., Bresson J-L.¹, Fairweather-Tait S., Heinonen M., Martin A., Przyrembel H., Siani A., Sjödin A., Strain J.J. (Chair), van Loveren H., Verhagen H., Willatts P.
- European Commission:
 - Turek A.
- EFSA:
 - Nutrition Unit: Ackerl R., Ciok J., Curtui V., Heng L., Titz A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Sanz Y. and Tetens I.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests³, EFSA screened the Annual Declaration of interest (ADoI) and the

¹ Only present on 7 May (am) via teleconference.

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting⁴.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

4.3. Guidance document related to gut and immune function claims

Before proceeding with the update of the guidance document on gut and immune, a brief document, which outlines the scope and the plan for the revision, will be issued for public consultation.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 *E-piim production Ltd* - "Lactobacillus plantarum TENSIA[®] in the semihard Edam-type "heart cheese" of Harmony™" and "maintenance of cardiovascular health through reduction of blood pressure" (Art. 13.5, 0411_EE, EFSA-Q-2014-00097)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.2 DoubleGood AB – "Table water containing a nutrient mix" and "contributes to the reduction of blood glucose rise when consumed together with a carbohydrate rich meal" (Art. 13.5, 0395_SE, <u>EFSA-Q-2013-00756</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3 DSM Nutritional and Kemin Foods – "Lutein together with zeaxanthin" and "helps maintain clarity and contrast of sight in bright light conditions" (Art. 13.5, 0399_FR, <u>EFSA-Q-2013-00875</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

Oral DoI was asked to J-L. Bresson before starting the discussion related to item 5.7 and no conflict of interest was identified.



5.4 *InQpharm Europe Ltd* – "PhaseLite™" and "helps to reduce body weight" (Art. 13.5, 0403 UK, EFSA-Q-2013-00973)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.5 Natural Alternatives International, Inc (NAI) - "Beta-alanine" and "increase in performance during short-duration high intensity exercise" (Art. 13.5, 0404_UK, <u>EFSA-Q-2013-00974</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.6 British Specialist Nutrition Association - "Carbohydrate solutions" and "contribute to the maintenance of endurance performance during prolonged endurance exercise" (Art. 13.5, 0408_UK, EFSA-Q-2014-00058)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7 Clasado Limited – "Regular daily consumption of 1.37g galactooligosaccharides from Bimuno®" and "may reduce abdominal discomfort" (Art. 13.5, 0406_MT, EFSA-Q-2014-00022)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8 Oy Karl Fazer Ab - "High-fibre sourdough rye bread" and "reduction of post-prandial glycaemic response accompanied by a reduced insulin response" (Art. 13(5), 0405 FI, EFSA-Q-2014-00012)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.9 Olygose - "AlphaGOS[®]" and "induces a lower blood glucose rise compared to sugar-containing foods or drinks" (Art. 13(5), 0407_FR, <u>EFSA-Q-2014-00044</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.10 Roquette Italia S.p.a. - "Nutriose®06" and "induces a lower blood glucose rise compared to high glycaemic carbohydrate-containing foods/drinks" (Art. 13(5), 0410_IT, <u>EFSA-Q-2014-00073</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.11 Specialised Nutrition Europe (formerly IDACE) – "Lactase for comfortable digestion" (Art. 14, 0068_FR, EFSA-Q-2008-148)

The discussion of this agenda item was postponed to the next meeting.



6. Next meeting

The next meeting will be held on 8-9 July 2014.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁵

In the SDol filled for the present meeting **Dr. M. Heinonen** declared an interest for the application from *Oy Karl Fazer Ab* on "**High-fibre sourdough rye bread**" and "**reduction of post-prandial glycaemic response accompanied by a reduced insulin response**" (EFSA-Q-2014-00012, agenda item 5.8). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when this item of the meeting (agenda item 5.8) was discussed, voted on or in anyway processed by that concerned scientific group.

In the SDol filled for the present meeting **Dr. A. Sjödin** declared an interest for the application from *E-piim production Ltd* on "*Lactobacillus plantarum* **TENSIA**® in the semi-hard Edam-type "heart cheese" of Harmony™" and "maintenance of cardiovascular health through reduction of blood pressure" (EFSA-Q-2014-00097, agenda item 5.1). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when this item of the meeting (agenda item 5.1) was discussed, voted on or in anyway processed by that concerned scientific group.

In the SDol filled for the present meeting **Prof. S. Strain** declared an interest for the application from *DSM Nutritional and Kemin Foods* on "**Lutein together with zeaxanthin**" (EFSA-Q-2013-00875, agenda item 5.3). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when this item of the meeting (agenda item 5.3) was discussed, voted on or in anyway processed by that concerned scientific group.

⁵ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Nutrition Unit

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 44th meeting of the Working Group on Claims Held on 5-6 March 2014, Parma (Agreed on 13 March 2014)

Participants

- Working Group Experts:
 - Agostoni C., Bresson J-L., Fairweather-Tait S.¹, Heinonen M.², Martin A.³,
 Przyrembel H., Sanz Y., Siani A., Sjödin A., Strain J.J. (Chair), Tetens I.⁴,
 van Loveren H.⁵, Verhagen H., Willatts P.⁶
- European Commission:
 - Turek A.
- EFSA:
 - Nutrition Unit: Ackerl R., Ciok J., Curtui V., Heng L., Titz A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

¹ Present via teleconference.

² Only present on 5 March (am) via teleconference.

³ Only present on 5 March (am).

⁴ Only present on 6 March (am) via teleconference.

⁵ Only present on 5 March.

⁶ Only present on 5 March via teleconference.



3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁷ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests ⁸, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 *Biocodex* - "Citrulline-malate" and "improved recovery from muscle fatigue" (Art. 13.5, 0394_BE, <u>EFSA-Q-2013-00659</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.2 Comvita New Zealand Limited - "Daily intake of supplemental olive leaf extract polyphenols" and "contributes to the reduction of the blood glucose rise after meals" (Art. 13.5, 00397_UK, <u>EFSA-Q-2013-00783</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3 Naturex SA – "Cranberry extract named Pacran" and "inhibition of adhesion of P-fimbriated *E. Coli* to urinary tract cells" (Art. 13.5, 0400_FR, <u>EFSA-Q-2013-00889</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.4 *PiLeJe* – "a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophillus* LA 104" and "reducing intestinal discomfort" (Art. 13.5, 0401_FR, <u>EFSA-Q-2013-00892</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

⁷ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

⁸ http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



5.5 PiLeJe – "a combination of B. longum LA 101, L. helveticus LA 102, L. lactis LA 103 and S. thermophillus LA 104" and "improvement of stools frequency" (Art. 13.5, 0402_FR, EFSA-Q-2013-00893)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.6 Barry Callebaut Belgium NV - "Cocoa flavanol" and "help maintain the elasticity of the blood vessels which contributes to normal blood flow" (Art. 19, 0398 BE, EFSA-Q-2013-00832)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.7 Specialised Nutrition Europe (formerly IDACE) – "Lactase for comfortable digestion" (Art. 14, 0068_FR, <u>EFSA-Q-2008-148</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8 *Specialised Nutrition Europe (formerly IDACE)* - "choline" and "development of brain" (Art. 14, 0054 FR, EFSA-Q-2008-134)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.9 Specialised Nutrition Europe (formerly IDACE) - "complex carbohydrates" and "contribution to satiety" (Art. 14, 0051_FR, EFSA-Q-2008-131)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.10 Specialised Nutrition Europe (formerly IDACE) - "non-digestible oligoand polysaccharides" and "calcium absorption" (Art. 14, 0060_FR; <u>EFSA-Q-2008-140</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.11 Clasado Limited – "Regular daily consumption of 1.37g galactooligosaccharides from Bimuno®" and "may reduce abdominal discomfort" (Art. 13.5, 0406_MT, EFSA-Q-2014-00022)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion.

5.12 DoubleGood AB – "Table water containing a nutrient mix" and "contributes to the reduction of blood glucose rise when consumed together with a carbohydrate rich meal" (Art. 13.5, 0395_SE, <u>EFSA-Q-2013-00756</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.



5.13 DSM Nutritional and Kemin Foods – "Lutein together with zeaxanthin" and "helps maintain clarity and contrast of sight in bright light conditions" (Art. 13.5, 0399_FR, EFSA-Q-2013-00875)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.14 *InQpharm Europe Ltd* – "PhaseLite™" and "helps to reduce body weight" (Art. 13.5, 0403_UK, <u>EFSA-Q-2013-00973</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.15 Jemo-pharm A/S - "CranMax®" and "prevents adhesion of E. Coli to the uroepithelial cells in women which is a risk factor for developing urinary tract infections" (Art. 14, 0391_DK, <u>EFSA-Q-2013-00649</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.16 Natural *Alternatives International, Inc (NAI)* - "Beta-alanine" and "increase in performance during short-duration high intensity exercise" (Art. 13.5, 0404_UK, EFSA-Q-2013-00974)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.17 Specialised *Nutrition Europe (Formerly IDACE)* - Zinc and "normal function of the immune system" (Art. 14, 0109_FR, <u>EFSA-Q-2008-189</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.18 *Specialised Nutrition Europe (formerly IDACE)* - - "prunes" and "normal bowel function" (Art. 14, 0113_FR, EFSA-Q-2008-193)

The discussion of this agenda item was postponed to the next meeting.

6. Next meeting

The next meeting will be held on 6-7 May 2014.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁹

In the SDol filled for the present meeting **Dr. A. Sjödin** declared an interest for the applications from PiLeJe on "a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and S. thermophillus LA 104" (EFSA-Q-2013-00892, agenda item 5.4; EFSA-Q-2013-00893, agenda item 5.5). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when those items of the meeting (agenda item 5.4 and 5.5) were discussed, voted on or in anyway processed by that concerned scientific group.

In the SDol filled for the present meeting by **Prof. S. Strain** the following interest was identified: an application from DSM Nutritional and Kemin Foods on "Lutein together with zeaxanthin" (EFSA-Q-2013-00875, agenda item 5.13). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when this item of the meeting (agenda item 5.13) was discussed, voted on or in anyway processed by that concerned scientific group.

⁹ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Nutrition Unit

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 43rd meeting of the Working Group on Claims Held on 22-23 January 2014, Parma (Agreed on 29 January 2014)

Participants

- Working Group Experts:
 - Agostoni C., Bresson J-L., Heinonen M., Martin A., Przyrembel H., Sanz Y., Siani A., Sjödin A., Strain J.J. (Chair), Tetens I., Verhagen H., Willatts P.¹
- European Commission:
 - Turek A.
- EFSA:
 - Nutrition Unit: Ackerl R., Ciok J., Curtui V., De Sesmaisons-Lecarré A., Heng L., Titz A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Fairweather-Tait S. and van Loveren H.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests³, EFSA screened the Annual Declaration of interest (ADol) and the

¹ Only present on 23 January 2014

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

4.3. Follow-up discussion from the Technical meeting on reporting of human studies (20 Nov 2013, Parma)

The EFSA Secretariat updated the WG Experts on the feed-back from the meeting on reporting of human studies.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 *SmithKline Beecham Ltd* - "Caffeine" and "helps to increase alertness" (Art 13.5, 0393_UK, <u>EFSA-Q-2013-00399</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.2 *Omikron Italia srl* - "Cytidine diphosphate-choline in oral solution as source of choline" and "contributes to the maintenance of normal function of the ophthalmic nervous structures" (Art. 13.5, 0396_IT, <u>EFSA-Q-2013-00757</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3 Hassia Mineralquellen GmbH - "Rosbacher Drive alcohol-free drink" and "helps concentration" (Art. 13.5, 0382_DE, EFSA-Q-2013-00444)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.4 *Biocodex -* "Citrulline-malate" and "improved recovery from muscle fatigue" (Art. 13.5, 0394_BE, <u>EFSA-Q-2013-00659</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the next WG claims for further discussion.

5.5 Comvita New Zealand Limited - "Daily intake of supplemental olive leaf extract polyphenols" and "contributes to the reduction of the blood glucose rise after meals" (Art. 13.5, 00397_UK, <u>EFSA-Q-2013-00783</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be



sent to the applicant and a stop the clock procedure will be applied.

5.6 Naturex SA – "Cranberry extract named Pacran" and "inhibition of adhesion of P-fimbriated *E. Coli* to urinary tract cells" (Art. 13.5, 0400_FR, EFSA-Q-2013-00889)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7 SANOFI AVENTIS - "Plant sterol esters" and "lower/reduce blood (LDL) cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" (Art 14, 0389 FR, EFSA-Q-2013-00595)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.8 Specialised Nutrition Europe (formerly IDACE) - "Beta-palmitate" and "stool consistency softening" (Art 14, 0094_FR, <u>EFSA-Q-2008-174</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.9 Specialised Nutrition Europe (formerly IDACE) – "vitamin D" and "contribution to normal bones and teeth development" (Art. 14, 0098_FR, EFSA-Q-2008-178)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.10 *Specialised Nutrition Europe (formerly IDACE)* - - "prunes" and "normal bowel function" (Art. 14, 0113 FR, EFSA-Q-2008-193)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.11 *PiLeJe* – "a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophillus* LA 104" and "reducing intestinal discomfort" (Art. 13.5, 0401_FR, <u>EFSA-Q-2013-00892</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.12 *PiLeJe* – "a combination of *B. longum* LA 101, *L. helveticus* LA 102, *L. lactis* LA 103 and *S. thermophillus* LA 104" and "improvement of stools frequency" (Art. 13.5, 0402_FR, <u>EFSA-Q-2013-00893</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.13 Barry Callebaut Belgium NV - "Cocoa flavanol" and "help maintain the elasticity of the blood vessels which contributes to normal blood flow" (Art. 19, 0398_BE, EFSA-Q-2013-00832)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific



assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Next meeting

The next meeting will be held on 5-6 March 2014.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁴

In the SDol filled for the present meeting **Prof. J-L. Bresson** declared an interest for the application from SmithKline Beecham Ltd on "**Caffeine**" (EFSA-Q-2013-00399, agenda item 5.1). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (agenda item 5.1) is discussed, voted on or in anyway processed by that concerned scientific group.

In the SDol filled for the present meeting **Prof. H. Verhagen** declared an interest for the application from Sanofi Aventis on "**Plant sterol esters**" (EFSA-Q-2013-00595, agenda item 5.7). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (agenda item 5.7) is discussed, voted on or in anyway processed by that concerned scientific group.

In the SDol filled for the present meeting **Dr. A. Sjödin** declared an interest for the applications from PiLeJe on "a combination of **B. longum LA 101**, **L. helveticus LA 102**, **L. lactis LA 103** and **S. thermophillus LA 104**" (EFSA-Q-2013-00892, agenda item 5.11; EFSA-Q-2013-00893, agenda item 5.12). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when those items of the meeting (agenda item 5.11 and 5.12) were discussed, voted on or in anyway processed by that concerned scientific group.

⁴ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests



Nutrition Unit

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 42nd meeting of the Working Group on Claims Held on 21-22 November 2013, Parma (Agreed on 6 December 2013)

Participants

- Working Group Experts:
 - Agostoni C.¹, Bresson J-L., Fairweather-Tait S., Martin A., Przyrembel H., Sanz Y., Siani A., Sjödin A., Strain J.J. (Chair), van Loveren H., Verhagen H., Willatts P.
- European Commission:
 - Raikos A.
- EFSA:
 - Nutrition Unit: Ackerl R., Ciok J., Curtui V., De Sesmaisons-Lecarré A., Heng L., Titz A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Heinonen M. and Tetens I.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests³, EFSA screened the Annual Declaration of interest (ADoI) and the

¹ Only present on 21 November 2013

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 *Omikron Italia srl* - "Flavonoid Mixture containing Diosmin, Troxerutin and Hesperidin" and "maintaining venous-capillary permeability" (Art 13.5, 0380_IT, <u>EFSA-Q-2013-00353</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.2 *Omikron Italia srl* - "Flavonoid Mixture containing Diosmin, Troxerutin and Hesperidin" and "maintaining venous tone" (Art 13.5, 0381_IT, <u>EFSA-Q-2013-00354</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3 Beneo-Orafti SA, Sensus BV and Cosucra-Groupe Warcoing SA - "Oligofructose from chicory" and "reduction of postprandial blood glucose" (Art 13.5, 0390_BE, <u>EFSA-Q-2013-00615</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.4 *SmithKline Beecham Ltd* - "Caffeine" and "helps to increase alertness" (Art 13.5, 0393 UK, EFSA-Q-2013-00399)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.5 Specialised Nutrition Europe (formerly IDACE) - "vitamin C" and "enhances non-haem iron absorption" (Art. 14, 0096_FR, <u>EFSA-Q-2008-176</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.6 Specialised Nutrition Europe (formerly IDACE) - "iron" and "blood formation" (Art. 14, 0067_FR, EFSA-Q-2008-147)

The draft scientific opinion was discussed and, after amendments, will be presented



to the Panel for further discussion and possible adoption.

5.7 Specialised Nutrition Europe (formerly IDACE) - "choline" and "development of brain" (Art. 14, 0054_FR, <u>EFSA-Q-2008-134</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8 *Omikron Italia srl* - "Cytidine diphosphate-choline in oral solution as source of choline" and "contributes to the maintenance of normal function of the ophthalmic nervous structures" (Art. 13.5, 0396_IT, <u>EFSA-Q-2013-00757</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.9 Specialised Nutrition Europe (formerly IDACE) - "complex carbohydrates" and "contribution to satiety" (Art. 14, 0051_FR, EFSA-Q-2008-131)

The content of this application was presented and discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.10 Specialised Nutrition Europe (formerly IDACE) - "non-digestible oligoand polysaccharides" and "calcium absorption" (Art. 14, 0060_FR; EFSA-Q-2008-140)

The content of this application was presented and discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.11 Specialised Nutrition Europe (formerly IDACE) - "Beta-palmitate" and "stool consistency softening" (Art 14, 0094 FR, EFSA-Q-2008-174)

The draft scientific opinion was discussed and, after amendments, will be presented to the next WG claims for further discussion.

5.12 Specialised Nutrition Europe (formerly IDACE) - "iodine" and "thyroid hormone production" (Art. 14, 0064_FR, <u>EFSA-Q-2008-144</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.13 Specialised Nutrition Europe (formerly IDACE) - "iodine" and "cognitive development" (Art. 14, 0065_FR, <u>EFSA-Q-2008-145</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.14 Specialised Nutrition Europe (formerly IDACE) - "milk protein" and "growth and muscle development" (Art. 14, 0078_FR, <u>EFSA-Q-2008-158</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be



sent to the applicant and a stop the clock procedure will be applied.

5.15 Institute of Cellular Pharmacology Ltd - "Padina pavonica-extract" and "maintenance of bone mineral density" (Art. 13.5, 0378_MT, EFSA-Q-2013-00249)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.16 Hassia Mineralquellen GmbH - "Rosbacher Drive alcohol-free drink" and "helps concentration" (Art. 13.5, 0382_DE, EFSA-Q-2013-00444)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.17 Biocodex - "Citrulline-malate" and "improved recovery from muscle fatigue" (Art. 13.5, 0394_BE, <u>EFSA-Q-2013-00659</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.18 Jemo-pharm A/S - "Cranberry extract named CranMax" and "prevents adhesion of E. Coli to the uroepithelial cells in women which is a risk factor for developing urinary tract infections" (Art. 14, 0391_DK, <u>EFSA-Q-2013-00649</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.19 Comvita New Zealand Limited - "Daily intake of supplemental olive leaf extract polyphenols" and "contributes to the reduction of the blood glucose rise after meals" (Art. 13.5, 00397_UK, EFSA-Q-2013-00783)

The discussion of this agenda item was postponed to the next meeting.

5.20 ITALSUR srl - "Barley soup orzotto" and "contributes to the protection of blood lipids from oxidative damage" (Art. 13.5, 0387_IT, EFSA-Q-2013-00578)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.21 SANOFI AVENTIS - "Plant sterol esters" and "lower/reduce blood (LDL) cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" (Art 14, 0389_FR, <u>EFSA-Q-2013-00595</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Next meeting

The next meeting will be held on 22-23 January 2014.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁴

In the SDol filled for the present meeting **Prof. H. Verhagen** declared an interest for the application from Sanofi Aventis on "**Plant sterol esters**" (EFSA-Q-2013-00595, agenda item 5.21). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (agenda item 5.21) is discussed, voted on or in anyway processed by that concerned scientific group.

In the SDoI filled for the present meeting **Prof. J-L. Bresson** declared an interest for the application from SmithKline Beecham Ltd on "**Caffeine**" (EFSA-Q-2013-00399, agenda item 5.4). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (agenda item 5.4) is discussed, voted on or in anyway processed by that concerned scientific group.

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⁴ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Nutrition Unit

Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 41st meeting of the Working Group on Claims Held on 25-26 September 2013, Parma (Agreed on 03 October 2013)

Participants

- Working Group Experts:
 - Agostoni C.¹, Bresson J-L., Fairweather-Tait S., Martin A., Przyrembel H., Siani A., Sjödin A., Strain J.J. (Chair), Tetens I., van Loveren H.², Verhagen H., Willatts P.
- European Commission:
 - Turek A.
- EFSA:
 - Nutrition Unit: Ackerl R., Ciok J., Curtui V., De Sesmaisons-Lecarré A., Heng L., Titz A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Heinonen M. and Sanz Y.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director implementing this Policy regarding

¹ Only present on 25 September 2013

² Only present on 25 September 2013

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



Declarations of Interests ⁴, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI, as well as the Oral Declaration of Interest at the beginning of the meeting, please refer to Annexes I and II.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 *Aptonia* - "Glycaemic carbohydrates" and "muscle glycogen repletion following strenuous exercise" (Art. 13.5, 0377_FR, <u>EFSA-Q-2013-00234</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.2 *IDACE* - "Vitamin B2" and "energy release" (Art 14, 0104_FR, <u>EFSA-Q-2008-184</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3 *IDACE* - "Pantothenic acid" and "energy release" (Art 14, 0106_FR, EFSA-Q-2008-186)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.4 Institute of Cellular Pharmacology Ltd - "Padina pavonica - extract" and "maintenance of bone mineral density" (Art. 13.5, 0378_MT, EFSA-Q-2013-00249)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.5 *Omikron Italia s.r.l.* - "Flavonoid Mixture containing 300 mg of Diosmin, 300 mg of Troxerutin and 100 mg of Hesperidin" and "maintaining physiological venous-capillary permeability" (Art 13.5, 0380_IT, <u>EFSA-Q-2013-00353</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

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⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



5.6 *Omikron Italia s.r.l.* - "Flavonoid Mixture containing 300 mg of Diosmin, 300 mg of Troxerutin and 100 mg of Hesperidin" and "maintaining physiological venous tone" (Art 13.5, 0381_IT, <u>EFSA-Q-2013-00354</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7 *ITALSUR srl.* - "Black cabbage mix" and "contributes to the protection of blood lipids from oxidative damage" (Art 13.5, 0383_IT, <u>EFSA-Q-2013-00574</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.8 *ITALSUR srl.* - "Black cabbage mix" and "maintains normal blood cholesterol concentrations" (Art 13.5, 0385_IT, <u>EFSA-Q-2013-00576</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.9 *ITALSUR srl.* - "Mix of chard, chicory and spinach" and "contributes to the protection of blood lipids from oxidative damage" (Art 13.5, 0384_IT, <u>EFSA-Q-2013-00575</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.10 *ITALSUR srl.* - "Mix of chard, chicory and spinach" and "maintains normal blood cholesterol concentrations" (Art 13.5, 0388_IT, <u>EFSA-Q-2013-00579</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.11 SANOFI AVENTIS - "Plant sterol esters" and "lower/reduce blood (LDL) cholesterol. High cholesterol is a risk factor in the development of coronary heart disease" (Art 14, 0389_FR, <u>EFSA-Q-2013-00595</u>)

The content of this application was presented and discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.12 *IDACE* - "Beta-palmitate" and "stool consistency softening" (Art 14, 0094 FR. EFSA-Q-2008-174)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.13 *VIVATECH* - "Transitech®" and "improves bowel function" (Art 13.5, 0392_FR, <u>EFSA-Q-2013-00650</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.14 *ITALSUR srl.* - "Barley soup orzotto" and "maintains normal blood cholesterol concentrations" (Art 13.5, 0386_IT, <u>EFSA-Q-2013-00577</u>)

The draft scientific opinion was discussed. It was considered that additional



information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.15 *ITALSUR srl.* - "Barley soup orzotto" and "contributes to the protection of blood lipids from oxidative damage" (Art 13.5, 0387_IT, <u>EFSA-Q-2013-00578</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.16 Beneo-Orafti, Sensus and Cosucra-Groupe Warcoing - "Oligofructose from chicory" and "reduction of postprandial blood glucose" (Art 13.5, 0390_BE, EFSA-Q-2013-00615)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.17 *SmithKline Beecham Ltd* - "Caffeine" and "helps to increase alertness" (Art 13.5, 0393_UK, <u>EFSA-Q-2013-00399</u>)

The content of this application was presented and discussed. Based on this preliminary discussion, a draft scientific opinion will be presented to the next WG claims for further discussion.

6. Next meeting

The next meeting will be held on 21-22 November 2013.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁵

In the SDol filled for the present meeting **Prof. H. Verhagen** declared an interest for the application from Sanofi Aventis on "**Plant sterol esters**" (EFSA-Q-2013-00595, agenda item 5.11). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (agenda item 5.11) is discussed, voted on or in anyway processed by that concerned scientific group.

⁵ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Annex II

Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

With regard to this meeting **Prof. J-L. Bresson** declared an interest for the application from SmithKline Beecham Ltd on "**Caffeine**" (EFSA-Q-2013-00399, agenda item 5.17). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (agenda item 5.17) is discussed, voted on or in anyway processed by that concerned scientific group.



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 40th meeting of the Working Group on Claims Held on 26-27 June 2013, Parma (Agreed on 5 July 2013)

Participants

- Working Group Experts:
 - Agostoni C., Bresson J-L., Fairweather-Tait S.¹, Martin A., Przyrembel H.,
 Sanz Y., Siani A., Sjödin A., Strain S., van Loveren H., Verhagen H.
- European Commission:
 - Raikos A. and Turek A.
- EFSA:
 - Nutrition Unit: Ackerl R., Ciok J., Curtui V., Heng L., A. Titz, Turla E., Valtueña Martínez S.
 - Scientific Assessment Support Unit: Carlos A.2, Verloo D.3

1. Welcome and apologies for absence

The Chair welcomed the participants and especially Agnieszka Turek, a new representative from the European Commission.

Apologies were received from Heinonen M., Tetens I. and Willatts P.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items will be discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making

¹ Only present on 27 June via teleconference, for agenda point 5.5

² Only present on 26 June, for agenda point 5.2

³ Only present on 26 June, for agenda point 5.2



Processes⁴ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests⁵, EFSA screened the Annual Declaration of interest and the Specific Declaration of interest 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 Oral Declaration of interest at the beginning of this meeting.

4. General issues on health claims evaluation

Feedback from the European Commission

The Commission representatives provided an update on the status of its decisionmaking process related to the EFSA adopted scientific opinions on health claims applications.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

Pharmatoka S.A.S. - "Proanthocyanidins from Urell" and "contribute to support defence against bacterial pathogens in the lower urinary tract" (Art. 13.5, 0358_FR, EFSA-Q-2012-00700)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

Laboratoire Lescuver - "Limicol" and "reduction of LDL-cholesterol concentration. High LDL-cholesterol is a risk factor in the development of coronary heart disease" (Art. 14, 0370_FR, EFSA-Q-2012-00968)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3 Rank Nutrition Ltd - "Folic acid" and "raises maternal red blood cell folate" (Art. 14, 0379_UK, EFSA-Q-2013-00265)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

Roquette Frères - "Food/drinks containing Nutriose instead of sugar" and "maintenance of tooth mineralisation" (Art. 13.5, 0374 FR, EFSA-Q-2013-00040)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.5 Institute of Cellular Pharmacology Ltd - "Padina pavonica - extract" and "maintenance of bone mineral density" (Art. 13.5, 0378_MT, EFSA-Q-2013-00249)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific

 $[\]frac{4}{5} \frac{\text{http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf}}{\text{http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf}}$



assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.6 *Aptonia* - "Glycaemic carbohydrates" and "muscle glycogen repletion following strenuous exercise" (Art. 13.5, 0377_FR, <u>EFSA-Q-2013-00234</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Next meeting

The next meeting will be held on 24-26 September 2013.



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 39th meeting of the Working Group on Claims Held on 24-25 April 2013, Parma (Agreed on 2 May 2013)

Participants

- Working Group Experts:
 - Agostoni C.¹, Bresson J-L., Fairweather-Tait S., Heinonen M., Martin A., Przyrembel H., Sanz Y., Siani A., Sjödin A., Strain S., Tetens I., van Loveren H., Verhagen H.²
- European Commission:
 - None
- EFSA:
 - Nutrition Unit: Ackerl R., Ciok J., Curtui V., Heng L., A. Titz, Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Willatts P. and from the Commission representatives.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items will be discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director implementing this Policy regarding

¹ Present only on 24 April

² Present only for one agenda item on 24 April and present on 25 April

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



Declarations of Interests⁴, EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the SDoI please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 "Lactobacillus rhamnosus GG" and "maintain normal defecation during antibiotic treatment" (Art. 13.5, 0372_FI, EFSA-Q-2013-00015)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.2 "Proanthocyanidins from Urell" and "contribute to support defence against bacterial pathogens in the lower urinary tract" (Art. 13.5, 0358_FR, EFSA-Q-2012-00700)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.3 "Collagen hydrolysate" and "maintenance of skin health" (Art. 13.5, 0366_DE, <u>EFSA-Q-2012-00839</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.4 "Transitech" and "improves transit and durably regulates it" (Art 13.5, 0375_FR, <u>EFSA-Q-2013-00087</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.5 "A combination of glucose and fructose compared to glucose alone" and "increase in endurance performance" (Art. 13.5, 0376_FR, <u>EFSA-Q-2013-00088</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

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⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



5.6 "Galactooligosaccharides from Bimuno®" and "reducing gastrointestinal discomfort" (Art 13.5, 0371_MT, <u>EFSA-Q-2012-01007</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7 "Natural extract of prickly pear cactus (TEX-OE)" and "physiological response to stress" (Art 13.5, 0373_MT, <u>EFSA-Q-2013-00021</u>)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.8 "Food/drinks containing Nutriose instead of sugar" and "maintenance of tooth mineralisation" (Art 13.5, 0374_FR, <u>EFSA-Q-2013-00040</u>)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Next meeting

The next meeting will be held on 26-27 June 2013.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)⁵

CONFLICT OF INTEREST: In his SDoI filled for the present meeting, Dr. Sjödin A. declared the following interest: application related to "Lactobacillus rhamnosus GG" (EFSA-Q-2013-00015, agenda point 5.1). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of interest.

This results in the impossibility for the expert to be present when that item of the meeting (EFSA-Q-2013-00015, agenda point 5.1) is discussed, voted on or in anyway processed by that concerned scientific group.

The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests.



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 38th meeting of the Working Group on Claims Held on 27-28 February 2013, Parma (Agreed on 08 March 2013)

Participants

- Working Group Experts:
 - Agostoni C., Bresson J-L., Fairweather-Tait S., Martin A., Przyrembel H., Sanz Y., Siani A., Sjödin A., Strain S., Tetens I., van Loveren H., Verhagen H., Willatts P.
- European Commission:
 - Athanasios Raikos
- EFSA:
 - Nutrition Unit: Ackerl R., Brönstrup A., Ciok J., Curtui V., de Sesmaisons-Lecarré A., Dumas C., Heng L., Mullee A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants and especially Valeriu Curtui, the new head of the Nutrition Unit.

Apologies were received from Heinonen M.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items will be discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



Declarations of Interests², EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, as well as the Oral Declaration of Interest (ODoI) at the beginning of the meeting, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representative provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications and the Article 13.1 health claims that were placed on hold.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 *"Lactobacillus rhamnosus* GG" and "defence against upper respiratory tract viruses" (Art. 14, 0363_FI, EFSA-Q-2012-00750)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.2 "Yestimun®" and "helps to maintain the body's defence against pathogens in the upper respiratory tract" (Art. 13.5, 0364_DE, EFSA-Q-2012-00761)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

5.3 "Proanthocyanidins from Urell" and "contribute to support defence against baterial pathogens in the lower urinary tract" (Art. 13.5, 0358_FR, EFSA-Q-2012-00700)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.4 "Eicosapentaenoic acid (EPA)" and "reduces the AA/EPA ratio in blood. A high AA/EPA ratio is a risk factor in the development of attention difficulties in children" (Art. 14, 0350_BE, EFSA-Q-2012-00573)

The draft scientific opinion was discussed and, after amendments, will be presented to the Panel for further discussion and possible adoption.

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² http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



5.5 "Collagen hydrolysate" and "maintenance of skin health" (Art. 13.5, 0366 DE, EFSA-Q-2012-00839)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.6 "Lactobacillus rhamnosus GG" and "maintain normal defecation during antibiotic treatment" (Art. 13.5, 0372_FI, EFSA-Q-2013-00015)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.7 "Limicol" and "reduction of LDL-cholesterol concentration; high LDL-cholesterol is a risk factor in the development of coronary heart disease" (Art. 14, 0370_FR, EFSA-Q-2012-00968)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8 "Transitech" and "improves transit and durably regulates it" (Art 13.5, 0375_FR, EFSA-Q-2013-00087)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Next meeting

The next meeting will be held on 24-25 April 2013.



Annex I

Interests and actions resulting from the screening of Specific Declaration of Interests (SDoI)³

CONFLICT OF INTEREST: In his SDoI filled for the present meeting, Dr. Sjödin A. declared the following interest: applications related to "*Lactobacillus rhamnosus* GG" (EFSA-Q-2012-00750, agenda point 5.1; EFSA-Q-2013-00015, agenda point 5.6). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a conflict of interest. This results in the impossibility for the expert to be present when those items of the meeting (agenda points 5.1 and 5.6) are discussed, voted on or in anyway processed by that concerned scientific group.

Dr. Sjödin A. also declared an interest for the application on "Yestimun[®]", which consists of beta-glucans that derive from microorganisms (EFSA-Q-2012-00761, agenda point 5.2). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of Interest for the expert concerned as the application relates to beta-glucans and not to microorganisms.

³ The Annual Declarations of Interests have been screened and approved before inviting the experts to the meeting, in accordance with the Decision of the Executive Director implementing the Policy on Independence regarding Declarations of Interests



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 37th meeting of the Working Group on Claims Held on 13-14 December 2012, Parma (Agreed on 7 January 2013)

Participants

- Working Group Experts:
 - Agostoni C., Fairweather-Tait S., Martin A., Sanz Y., Siani A., Sjodin A.¹,
 Strain S., Tetens I., van Loveren H., Verhagen H., Willatts P.
 - Heinonen M.² participated via teleconference in agenda point 5.4
- European Commission:
 - Athanasios Raikos, Christina Antoniou
- EFSA:
 - Nutrition Unit: Ackerl R., Brönstrup A., Ciok J., de Sesmaisons-Lecarré A., Dumas C., Heng L., Kleiner J., Mullee A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants and especially Athanasios Raikos, a new representative of the European Commission.

Apologies were received from Bresson J-L., Przyrembel H. and Turck D.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Dols)³ and the Decision of the Executive

¹ Only on 13 December 2012

² Only via teleconference on 13 December 2012

³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



Director implementing this Policy⁴, EFSA screened the Annual Declaration of interest (ADol) and the Specific Declaration of interest (SDol) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADol and SDol, as well as the Oral Declaration of Interest (ODol) at the beginning of the meeting, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claims evaluation

4.1. Feedback from the European Commission

The Commission representatives provided an update on the status of its decision-making process related to the EFSA adopted scientific opinions on health claims applications and the Article 13.1 health claims that were placed on hold.

4.2. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Secretariat updated the WG Experts on the status of health claims applications since the last NDA plenary meeting.

5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006

5.1 "ÇEFAX™" and "reduction of menstrual discomfort" (Art. 13.5, 0354_CY, EFSA-Q-2012-00591)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.2 "A combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103, *Streptococcus thermophilus* LA 104" and "reducing intestinal discomfort" (Art. 13.5, 0351_FR, EFSA-Q-2012-00588)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.3 "A combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103, *Streptococcus thermophilus* LA 104" and "improves intestinal transit" (Art. 13.5, 0352_FR, EFSA-Q-2012-00589)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.4 "Proanthocyanidins from Monurelle cranberry" and "may help to support defence against bacterial pathogens in the lower urinary tract" (Art. 13.5, 0362_NL, EFSA-Q-2012-00737)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

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⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



5.5 "Slendesta Potato Extract" and "reduction of body weight" (Art. 13.5, 0359 BE, EFSA-Q-2012-00704)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.6 "Sylvan Bio red yeast rice" and "maintenance of normal blood LDL cholesterol concentrations" (Art. 13.5, 0361_NL, EFSA-Q-2012-00736)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.7 "Daily administration of Yestimun®" and "helps to maintain the body's defence against pathogens in the upper respiratory tract" (Art. 13.5, 0364_DE, EFSA-Q-2012-00761)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.8 "Vichy Catalan water" and "reduction of post-prandial triglyceride concentrations" (Art 13.5, 0367 ES, EFSA-Q-2012-00872)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Next meeting

The next meeting will be held on 27-28 February 2013.



Annex I

INTERESTS AND ACTIONS RESULTING FROM THE SCREENING OF ANNUAL DECLARATION OF INTERESTS (ADOI) OR SPECIFIC DECLARATION OF INTERESTS (SDOI)

CONFLICT OF INTEREST: In his SDoI filled for the present meeting, Dr. Sjodin A. declared the following interest: applications related to "a combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactococcus lactis* LA 103, *Streptococcus thermophilus* LA 104" (EFSA-Q-2012-00588, agenda point 5.2; EFSA-Q-2012-00589, agenda point 5.3). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (DoIs) and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a conflict of interest. This results in the impossibility for the expert to be present when these items (agenda points 5.2 and 5.3) are discussed, voted on or in anyway processed by that concerned scientific group.

Dr. Sjodin A. also declared an interest for the application on "Yestimun[®]", which consists of beta-glucans that derive from microorganisms (EFSA-Q-2012-00761, agenda point 5.7). In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Dols) and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of Interest for the expert concerned as the application relates to beta-glucans and not to microorganisms.



Scientific Panel on Dietetic products, Nutrition and Allergies Minutes of the 36th meeting of the Working Group on Claims Held on 25-26 October 2012, Parma (Agreed on 5 November 2012)

Participants

- Working Group Experts:
 - Agostoni C., Fairweather-Tait S., Heinonen M., Martin A., Siani A., Sjodin A., Strain S., van Loveren H., Verhagen H., Willatts P.
 - Tetens I. and Turck D. participated via teleconference in agenda points
 5.8 and 5.11
- European Commission:
 - None
- EFSA:
 - Nutrion Unit: Ackerl R., Brönstrup A., de Sesmaisons-Lecarré A., Heng
 L., Kleiner J., Titz A., Turla E., Valtueña Martínez S.

1. Welcome and apologies for absence

The Chair welcomed the participants and presented the composition of the new Working Group on Claims (2012-2015).

Apologies were received from Bresson J., Przyrembel H. and Sanz Y.

Heinonen M. did not participate in agenda point 5.10

Sjodin A. did not participate in agenda points 5.10, 5.11, 5.12 and 5.13.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Dols)¹ and the Decision of the Executive

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



Director implementing this Policy², EFSA screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, please refer to Annex I.

No other conflicts of interests related to the issues discussed in this meeting were identified during the screening process or at the Oral Declaration of interest (ODoI) at the beginning of this meeting.

- 4. The minutes of the 35th Working Group meeting held on 23-25 May 2012, Parma, were agreed by written procedure on 13 June 2012
- 5. Applications pursuant to Articles 13.5 and 14 of Regulation (EC) No 1924/2006
 - 5.1 "Grape seed extract" and "contributes to promote venous circulation in the legs" (Art. 13.5, 0342_BE, EFSA-Q-2012-00387)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.2 "Grape seed extract" and "helps to decrease swollen legs" (Art. 13.5, 0343 BE, EFSA-Q-2012-00388)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption

5.3 "Grape seed extract" and "helps to drain the body in case of water accumulation" (Art. 13.5, 0347_BE, EFSA-Q-2012-00574)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.4 "OXY280" and "helps to lose weight" (Art. 13.5, 0348_BE, EFSA-Q-2012-00572)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.5 "Green tea including EGCG and Guarana including CAF extracts" and "helps to burn fat" (Art. 13.5, 0353_CY, EFSA-Q-2012-00590)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.6 "Lycopene, vitamin E, lutein, selenium" and "helps to prepare and activate tanning" (Art. 13.5, 0356_CY, EFSA-Q-2012-00593)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.7 "ÇEFAX™" and "reduction of menstrual discomfort" (Art 13.5, 0354_CY, EFSA-Q-2012-00591)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

² http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



5.8 "Slendesta potato extract" and "reduction of body weight" (Art 13.5, 0359 BE, EFSA-Q-2012-00704)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.9 "Sylvan Bio red yeast rice" and "maintenance of normal blood LDL cholesterol concentrations" (Art 13.5, 0361 NL, EFSA-Q-2012-00736)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.10 "Lactobacillus rhamnosus GG" and "defence against upper respiratory tract viruses" (Art. 14, 0363_FI, EFSA-Q-2012-00750)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.11 "Lactobacillus paracasei LP-33®" and "resistance to airborne allergens" (Art. 13.5, 00365_DK, EFSA-Q-2012-00816)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.12 "A combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactobacullus lactis* LA 103, *Streptococcus thermophillus* LA 104" and "reducing intestinal discomfort" (Art. 13.5, 0351_FR, EFSA-Q-2012-00588)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.13 "A combination of *Bifidobacterium longum* LA 101, *Lactobacillus helveticus* LA 102, *Lactobacullus lactis* LA 103, *Streptococcus thermophillus* LA 104" and "improves intestinal transit" (Art. 13.5, 0352_FR, EFSA-Q-2012-00589)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.14 "Proanthocyanidins from Monurelle cranberry" and "may help to support defence against bacterial pathogens in the lower urinary tract" (Art. 13.5, 0362 NL, EFSA-Q-2012-00737)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.



5.15 "Cynatine[®]" and "helps to support joint flexibility" (Art. 13.5, 0349_BE, EFSA-Q-2012-00570)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.16 "Original silicea-Balsam" and "contributes to the maintenance of nails, hair and the connective tissue" (Art. 13.5, 0357_DE, EFSA-Q-2012-00627)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

5.17 "EffEXT™" and "contributes to support joint flexibility" (Art. 13.5, 0339_BE, EFSA-Q-2012-00384)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

5.18 "Krill oil" and "helps to improve the comfort of sensitive joints" (Art. 13.5, 0340_BE, EFSA-Q-2012-00385)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

6. Feedback from the European Commission

No feedback was provided since Commission Services did not attend this meeting.

7. Update on Articles 13.5 and 14 applications

EFSA secretariat updated the WG Experts on the status of health claims applications since the last meeting.

8. Next meeting(s)

The next meeting will be held on 13-14 December 2012.



Annex I

Interests and actions resulting from the screening of Annual Declaration of Interests (ADol) OR Specific Declaration of Interests (SDol)

CONFLICT OF INTEREST: In her SDol filled for the present meeting Ms. Heinonen M. declared the following interest: application from Valio on "Lactobacillus rhamnosus GG" and "defence against upper respiratory tract viruses". In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when that item of the meeting (agenda point 5.10) is discussed, voted on or in anyway processed by that concerned scientific group.

CONFLICT OF INTEREST: In his SDoI filled for the present meeting Mr. Sjodin A. declared the following interests: applications from Valio on "Lactobacillus rhamnosus GG" and "defence against upper respiratory tract viruses", from Merck Médication Familiale & Chr. Hansen A/S on "Lactobacillus paracasei LP-33®" and "resistance to airborne allergens", from PiLeJe on "a combination of Bifidobacterium longum LA 101, Lactobacillus helveticus LA 102, Lactobacullus lactis LA 103, Streptococcus thermophillus LA 104" and "reducing intestinal discomfort", from PiLeJe on "a combination of Bifidobacterium longum LA 101, Lactobacillus helveticus LA 102, Lactobacullus lactis LA 103, Streptococcus thermophillus LA 104" and "improves intestinal transit". In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests and the Decision of the Executive Director implementing this Policy, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a conflict of Interest.

This results in the impossibility for the expert to be present when those items of the meeting (agenda points 5.10, 5.11, 5.12 and 5.13) are discussed, voted on or in anyway processed by that concerned scientific group.



Parma, 11 June 2012

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 35th meeting of the Working Group on Claims Parma, 23-25 May 2012 EFSA / Nutrition / Claims

Agreed by the WG on 13 June 2012

Participants

WG Experts: Carlo Agostoni, Albert Flynn, Ines Golly, Marina Heinonen¹, Hannu

Korhonen, Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen², Yolanda Sanz, Sean Strain³, Inge Tetens⁴,

Hendrik van Loveren, Hans Verhagen⁵.

European Commission: Francesco Felice Carlucci⁶.

EFSA: Reinhard Ackerl, Maria Astridou, Anja Brönstrup, Janusz Ciok,

Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Ilkka Ojansivu, Danai Papanastasiou, Ariane Titz, Emanuela Turla.

1. Welcome and apologies

First day of the meeting was chaired by Albert Flynn, whereas the remaining days were chaired by Sean Strain. The Chair welcomed the participants. Apologies were received from Jean-Louis Bresson and Susan Fairweather-Tait.

2. Adoption of agenda

The agenda was amended to include a new agenda item: "Saccharomyces cerevisiae var. boulardii CNCM I-3799" and "helps maintain intestinal comfort" (Art. 13(5) health claim application: 0327_FR; EFSA-Q-2012-00271). The agenda was adopted without any further changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the Annual Declarations of Interests and the Specific Declarations of Interests filled in by the experts invited at this meeting as well as the interests declared at the beginning of this

¹ Participated on 23/05 and 24/05

² Participated on 23/05 and 24/05

³ Participated on 24/05 and 25/05

⁴ Participated on 23/05 and 24/05

⁵ Participated on 24/05 and 25/05

⁶ Participated on 23/05 and 24/05



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. General issues on health claims evaluation

4.1 Feedback from the European Commission

The Commission Services informed that the list of Article 13(1) health claims was officially adopted by the European Commission and that it will be soon published in the Official Journal. The Commission Services provided feedback on the transitional measures for the rejected claims, and the status of those claims that are on hold. The Commission Services informed that the EU Register of nutrition and health claims is available to the public in the European Commission website.

The Commission Services also provided feedback on the status of the Commission Decisions related to adopted health claim opinions.

4.2 Update on Articles 13(5) and 14 applications

EFSA secretariat updated the WG Experts on the status of health claims applications since the last meeting.

4.3 Draft guidance on the scientific requirements for health claims related to neurological and psychological functions (EFSA-Q-2010-01185)

This draft guidance was discussed and after amendments it will be presented to the Panel for further discussion.

4.4 Technical report: Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to neurological and psychological functions (EFSA-Q-2011-01097)

The discussion of the technical report was postponed to the Panel meeting.

4.5 Draft guidance on the scientific requirements for health claims related to physical performance (EFSA-Q-2010-01186)

This draft guidance was discussed and after amendments it will be presented to the Panel for further discussion.

4.6 Technical report: Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to physical performance (EFSA-Q-2011-01269)

The discussion of the technical report was postponed to the Panel meeting.

5. Applications pursuant to Articles 13(5) and 14 of Regulation (EC) No 1924/2006 "OptiEFAX™" and "maintenance of normal blood LDL-cholesterol concentrations" (Art. 13(5): 0334_BE; EFSA-Q-2012-00339)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"OptiEFAX™" and "maintenance of normal blood HDL-cholesterol concentrations (Art. 13(5): 0335_BE; EFSA-Q-2012-00340)



The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"OptiEFAX™" and "maintenance of normal blood concentrations of triglycerides" (Art. 13(5): 0338_BE; EFSA-Q-2012-00383)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"Hyaluronic acid" and "helps to maintain good skin hydration" (Art. 13(5): 0337_BE; EFSA-Q-2012-00382)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"Transitech®" and "reduction of transit time" (Art. 13(5): 0328_FR; EFSA-Q-2012-00293)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Flaxseed oil and vitamin E" and "contributes to maintain skin permeability barrier function" (Art. 13(5): 0332_BE; EFSA-Q-2012-00337)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Cocoa flavanols" and "endothelium-dependent vasodilation" (Art. 13(5): 0319_BE; EFSA-Q-2012-00002)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"Rhodiola rosae" and "helps to reduce tiredness in case of stress" (Art. 13(5): 0331 BE; EFSA-Q-2012-00336)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"Grape seed extract" and "contributes to promote venous circulation in the legs" (Art. 13(5): 0342_BE; EFSA-Q-2012-00387)

The discussion of this agenda item was postponed to the next meeting.

"Grape seed extract" and "helps to decrease swollen legs" (Art. 13(5): 0343_BE; EFSA-Q-2012-00388)

The discussion of this agenda item was postponed to the next meeting.

"Wheat polar lipid extract" and "protection of the skin against dehydration" (Art. 13(5): 0315 FR; EFSA-Q-2011-01122)

The draft scientific opinion was discussed and will be subject to Panel adoption by written procedure after incorporation of the comments made at the Working Group.



"Prolibra[®]" and "reduction of body fat while preserving lean muscle" (Art. 13(5): 0318_IE; EFSA-Q-2012-00001)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Group B vitamins and pumpkin seed oil" and "maintenance of normal hair" (Art. 13(5): 0329_BE and 0330_BE; EFSA-Q-2012-00334 and EFSA-Q-2012-00335)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"Keratin, copper, zinc, group B vitamins" and "maintenance of normal hair" (Art. 13(5): 0336_BE; EFSA-Q-2012-00381)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"EffEXT™" and "contributes to support joint flexibility" (Art. 13(5): 0339_BE; EFSA-Q-2012-00384)

The discussion of this agenda item was postponed to the next meeting.

"EffEXT™" and "helps to support joint function by maintaining low levels of plasma C-reactive protein" (Art. 13(5): 0341_BE; EFSA-Q-2012-00386)

The discussion of this agenda item was postponed to the next meeting.

"Krill oil" and "helps to improve the comfort of sensitive joints" (Art. 13(5): 0340_BE; EFSA-Q-2012-00385)

The discussion of this agenda item was postponed to the next meeting.

"Saccharomyces cerevisiae var. boulardii CNCM I-3799" and "helps maintain intestinal comfort" (Art. 13(5): 0327_FR; EFSA-Q-2012-00271)

The applicant's reply to EFSA's request for additional information was discussed. After amendments the draft scientific opinion will be presented to the Panel for further discussion and possible adoption.

6. Further assessment of Article 13(1) health claims

Draft scientific opinions on some health claims eligible for further assessment (microorganisms not sufficiently characterised, and claims for which EFSA concluded that there is insufficient evidence) were discussed. After amendments the following draft opinions will be presented to the Panel for further discussion and possible adoption:

- "Soy isoflavones" and "vasomotor symptoms associated with menopause" (ID 1654 EFSA-Q-2012-00165; 1704 EFSA-Q-2012-00167; 2140 EFSA-Q-2012-00170; 3093 EFSA-Q-2012-00212; 3154 EFSA-Q-2012-00213; 3590 EFSA-Q-2012-00214) and "bone mineral density" (ID 1655 EFSA-Q-2012-00166)
- "Polyphenols in olive" and "HDL cholesterol concentrations" (ID 1639 ${\sf EFSA-Q-2012-00164})$



- "L. helveticus CNCM I-1722 and B. longum subsp. Longum CNCM I-3470" and "alleviation of stress-induced symptoms" (ID 938 EFSA-Q-2012-00130)
- "L. paracasei LPC 01 (CNCM I-1390)" and "gastrointestinal discomfort associated with bowel function" (ID 3055 EFSA-Q-2012-00208)
- "L. paracasei CNCM I 1688 and L. salivarius CNCM I 1794" and "reduction of gastrointestinal discomfort" (ID 2972 EFSA-Q-2012-00200), and "decreasing potentially pathogenic microorganisms" (ID 2972 EFSA-Q-2012-00200), and "increasing the IL-10 production" (ID 2973 EFSA-Q-2012-00201)
- "S. thermophilus BCCM/LMG P 18807" and "reduction of gastrointestinal discomfort" (ID 2974 EFSA-Q-2012-00202), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2974 EFSA-Q-2012-00202), and "reduction in CD34* cells" (ID 2975 EFSA-Q-2012-00203)
- "L. helveticus CNCM I-1722, B. infantis CNCM I-3424, B. bifidum CNCM I-3426 and FOS from sucrose" and "defence against pathogens" (ID 3016 EFSA-Q-2012-00204)
- "B. lactis BS 01 (LMG P-21384)" and "reducing transit time/abdominal bloating" (ID 2940 EFSA-Q-2012-00176)
- "L. acidophilus bar 13 (CNCM-I-3857) and B. longum bar 33 (CNCM-I-3858)" and "maintains the balance of healthy microbiota, that helps to strengthen the natural defence" (ID 2942 EFSA-Q-2012-00178)
- "L. rhamnosus CNCM I-1720, L. helveticus CNCM I-1722, B. longum CNCM I-3470 and S. boulardii CNCM I-1079" and "defence against pathogenic gastrointestinal microorganisms" (ID 3017 EFSA-Q-2012-00205)
- "Bifidobacterium breve BR 03 (DSM 16604)" and "intestinal mobility" (ID 2936 EFSA-Q-2012-00173)
- "Bifidobacterium longum BL 03 (DSM 16603)" and "intestinal mobility" (ID 2937 EFSA-Q-2012-00174)
- "Bifidobacterium breve BR03 (DSM 16604) and Lactobacillus plantarum LP01 (LMG P-21021)" and "reducing gastrointestinal discomfort associated with increased transit time" (ID 2938 EFSA-Q-2012-00175)
- "Combination of microorganisms with or without FOS" and "defence against upper respiratory tract infections" (ID 2941 EFSA-Q-2012-00177; 3047 EFSA-Q-2012-00277; 3059 EFSA-Q-2012-00210)
- "Lactobacillus acidophilus LA 02 (DSM 21717) and Lactobacillus plantarum LP 01 (LMG P-21021) " and "relieve of abdominal discomfort and pain" (ID 2944 EFSA-Q-2012-00179)
- "Lactobacillus plantarum LP 01 (LMG P-21021)" and "intestinal mobility" (ID 2965 EFSA-Q-2012-00193)
- "Lactobacillus rhamnosus LR 04 (DSM 16605)" and "balancing intestinal flora, improves skin, scalp and hair health" (ID 2968 EFSA-Q-2012-00196)



- "Lactobacillus rhamnosus LR 04 (DSM 16605)" and "reduce the daily number of bowel movements" (ID 2969 EFSA-Q-2012-00197)
- "Bifidobacterium adolescentis BA 02 (DSM 17103)" and "intestinal motility" (ID 3035 EFSA-Q-2012-00206)
- "Bifidobacterium longum W11 (LMG P-21586)" and "relieve of abdominal discomfort and bloating" (ID 3056 EFSA-Q-2012-00209)
- **"B. animalis** ssp *lactis* THT 010801" and "changes in bowel function" (ID 960 EFSA-Q-2012-00133), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 960 EFSA-Q-2012-00133), "reduction of intestinal transit time" (ID 961 EFSA-Q-2012-00134), and "stimulation of immunological responses" (ID 962 EFSA-Q-2012-00135)
- **"B. longum** ssp *infantis* THT 010201" and "changes in bowel function" (ID 967 EFSA-Q-2012-00136), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 967 EFSA-Q-2012-00136), and "stimulation of immunological responses" (ID 968 EFSA-Q-2012-00137)
- **"B. longum** ssp longum THT 010301" and "changes in bowel function" (ID 969 EFSA-Q-2012-00138), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 969 EFSA-Q-2012-00138), and "stimulation of immunological responses" (ID 970 EFSA-Q-2012-00139)
- **"B. pseudolongum ssp pseudolongum THT 010501"** and "changes in bowel function" (ID 971 EFSA-Q-2012-00140), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 971 EFSA-Q-2012-00140), and "stimulation of immunological responses" (ID 972 EFSA-Q-2012-00141)
- "L. casei THT 030401" and "changes in bowel function" (ID 975 EFSA-Q-2012-00142), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 975 EFSA-Q-2012-00142), and "stimulation of immunological responses" (ID 976 EFSA-Q-2012-00143)
- "L. gasseri THT 031301" and "changes in bowel function" (ID 983 EFSA-Q-2012-00144), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 983 EFSA-Q-2012-00144), and "stimulation of immunological responses" (ID 984 EFSA-Q-2012-00145)
- **"L. helveticus THT 031102"** and "changes in bowel function" (ID 985 EFSA-Q-2012-00146), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 985 EFSA-Q-2012-00146), and "stimulation of immunological responses" (ID 986 EFSA-Q-2012-00147)
- "L. plantarum THT 030701" and "changes in bowel function" (ID 994 EFSA-Q-2012-00148), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 994 EFSA-Q-2012-00148), and "stimulation of immunological responses" (ID 995 EFSA-Q-2012-00149)
- "L. plantarum THT 030707" and "changes in bowel function" (ID 996 EFSA-Q-2012-00150), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 996 -



- EFSA-Q-2012-00150), and "stimulation of immunological responses" (ID 997 EFSA-Q-2012-00151)
- *"L. reuteri* THT 030802" and "changes in bowel function" (ID 998 EFSA-Q-2012-00152), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 998 EFSA-Q-2012-00152), and "stimulation of immunological responses" (ID 999 EFSA-Q-2012-00153)
- "L. salivarius THT 031001" and "changes in bowel function" (ID 1006 EFSA-Q-2012-00154), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 1006 EFSA-Q-2012-00154), and "stimulation of immunological responses" (ID 1007 EFSA-Q-2012-00155)
- **"S. thermophilus THT 070102"** and "changes in bowel function" (ID 1014 EFSA-Q-2012-00158), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 1014 EFSA-Q-2012-00158) and "stimulation of immunological responses" (ID 1015 EFSA-Q-2012-00159)
- "L. crispatus BCCM/LMG P 17631" and "reduction of gastrointestinal discomfort" (ID 1030 EFSA-Q-2012-00160), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 1030 EFSA-Q-2012-00160), and "defence against vaginal pathogens" (ID 2950 EFSA-Q-2012-00183)
- "L. acidophilus BCCM/LMG P 18806" and "reduction of gastrointestinal discomfort" (ID 2946 EFSA-Q-2012-00180), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2946 EFSA-Q-2012-00180), and "reduction in numbers of circulating CD34* cells" (ID 2947 EFSA-Q-2012-00181)
- "L. delbrueckii BCCM/LMG P 18805" and "reduction of gastrointestinal discomfort" (ID 2951 EFSA-Q-2012-00184), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2951 EFSA-Q-2012-00184), and "reduction in numbers of circulating CD34* cells" (ID 2952 EFSA-Q-2012-00185)
- "L. gasseri BCCM/LMG P 17632" and "reduction of gastrointestinal discomfort" (ID 2956 EFSA-Q-2012-00186), and "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2956 EFSA-Q-2012-00186)
- "L. gasseri BCCM/LMG P 18137" and "defence against vaginal pathogens" (ID 2957 EFSA-Q-2012-00187), "reduction of gastrointestinal discomfort" (ID 2958 EFSA-Q-2012-00188), and "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2958 EFSA-Q-2012-00188)
- "L. paracasei CNCM I 1687" and "induction of cytokine production and/or enhancement of lytic activity of natural killer cells" (ID 2960 EFSA-Q-2012-00189), "reduction of gastrointestinal discomfort" (ID 2961 EFSA-Q-2012-00190), and "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2961 EFSA-Q-2012-00190)
- "L. paracasei CNCM I 1688" and "induction of cytokine production and/or enhancement of lytic activity of natural killer cells" (ID 2962 EFSA-Q-2012-00191), "reduction of gastrointestinal discomfort" (ID 2963 EFSA-Q-2012-00192), and "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2963 EFSA-Q-2012-00192)



- "L. plantarum BCCM/LMG P 17630" and "reduction of gastrointestinal discomfort" (ID 2966 EFSA-Q-2012-00194), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2966 EFSA-Q-2012-00194), and "defence against vaginal pathogens" (ID 2967 EFSA-Q-2012-00195)
- "L. salivarius CNCM I 1794" and "reduction of gastrointestinal discomfort" (ID 2970 EFSA-Q-2012-00198), "decreasing potentially pathogenic gastrointestinal microorganisms" (ID 2970 EFSA-Q-2012-00198), and "induction of cytokine production and/or enhancement of lytic activity of natural killer cells" (ID 2971 EFSA-Q-2012-00199
- "B. animalis ssp. lactis Bf-6/Bif-6/CB111 and L. johnsonii La-1/ACD-1/CLbA22 (A/B-61)" and "intestinal flora/digestive health" (ID 4231 EFSA-Q-2012-00215)

7. Next meeting date

The next meeting will be held on 3-5 October 2012.



Parma, 26 March 2012

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 34th meeting of the Working Group on Claims Parma, 21-23 March 2012 EFSA / Nutrition / Claims

Agreed by the WG on 28 March 2012

Participants

WG Experts: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait,

Albert Flynn, Ines Golly, Marina Heinonen¹, Martinus Lovik², Ambroise Martin³, Hildegard Przyrembel, Seppo Salminen⁴, Yolanda Sanz⁵, Sean Strain, Inge Tetens⁶, Hendrik van Loveren⁷,

Hans Verhagen.

European Commission: Christina Antoniou⁸, Noel Griffin⁹

EFSA: Reinhard Ackerl, Maria Astridou, Anja Brönstrup, Janusz Ciok,

Agnès de Sesmaisons-Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Ilkka Ojansivu, Danai Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez.

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Hannu Korhonen.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the Annual Declarations of Interests and the Specific Declarations of Interests filled in by the

¹ Participated on 21/03 and 22/03

² Participated on 22/03 and 23/03

³ Participated on 21/03 and 22/03

⁴ Participated on 21/03 and 22/03

⁵ Participated on 23/03 via teleconference

⁶ Participated on 21/03 and 22/03

⁷ Participated on 21/03 and 23/03

⁸ Participated on 22/03 via teleconference

⁹ Participated on 21/03 via teleconference



experts invited at this meeting as well as the interests declared at the beginning of this meeting. With regard to the specific items on the agenda for this meeting, interests were declared and actions were taken as follows:

In relation to the applications from Raisio Nutrition Ltd on "plant stanols" and "reduction of blood cholesterol" and from Unilever PLC/NV on "plant sterols and plant stanols" and "reduction of blood cholesterol", Hans Verhagen declared an interest and refrained from the discussion for these agenda items.

In relation to the application from Health Concern B.V. on "plant sterols and cholesternorm® mix" and "reduction of blood cholesterol levels", at the beginning of the meeting Hans Verhagen declared an interest and refrained from the discussion for this agenda item.

In relation to the application from Unilever PLC/NV on "plant sterols and plant stanols" and "reduction of blood cholesterol", Susan Fairweather-Tait declared an interest and refrained from the discussion for this agenda item.

In relation to the application from Raisio Nutrition Ltd on "plant stanols" and "reduction of blood cholesterol", Marina Heinonen declared an interest and refrained from the discussion for this agenda item.

In relation to the applications from Biocodex on "citrulline-malate" and "improved exercise performance and recovery", from Merck Consumer Healthcare n.v. on "glucosamine" and "normal joint cartilage" and to the draft Article 13(1) opinions on *Saccharomyces boulardii* CNCM I-1079 and *Saccharomyces boulardii* ATY-SB-101 (BCCM/MUCL 53837), Jean-Louis Bresson declared an interest and refrained from the discussion for these agenda items.

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. General issues on health claims evaluation

4.1 Feedback from the European Commission

The Commission Services provided feedback on the status of the Commission Decisions related to adopted health claim opinions. Related to Article 13(1) health claims, the Commission Services provided some feedback on the ENVI (Environment, Public Health and Food Safety) committee meeting of the European Parliament.

4.2 Update on Article 13(5) and 14 applications

EFSA secretariat updated the WG Experts on the status of health claims applications since the last meeting.

4.3 Draft guidance on the scientific requirements for health claims related to neurological and psychological functions (EFSA-Q-2010-01185)

This draft guidance was discussed and after amendments it will be presented to the Panel for further discussion.

4.4 Technical report: Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to neurological and psychological functions (EFSA-Q-2011-01097)

Feedback on the public consultation was discussed and after amendments the technical report will be presented to the Panel for further discussion.



4.5 Draft guidance on the scientific requirements for health claims related to physical performance (EFSA-Q-2010-01186)

This draft guidance was discussed and after amendments it will be presented to the Panel for further discussion.

4.6 Technical report: Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to physical performance (EFSA-Q-2011-01269)

Feedback on the public consultation was discussed and after amendments the technical report will be presented to the Panel for further discussion.

5. Applications pursuant to Articles 13(5) and 14 of Regulation (EC) No 1924/2006 "Glucosamine" and "normal joint cartilage" (Art. 13(5): 0313_BE; EFSA-Q-2011-01113)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"Citrulline-malate" and "improved exercise performance and recovery" (Art. 13(5): 0310 BE; EFSA-Q-2011-00931)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Cocoa flavanols" and "endothelium-dependent vasodilation" (Art. 13(5): 0319_BE; EFSA-Q-2012-00002)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Plant sterols and cholesternorm® mix" and "reduction of blood cholesterol levels" (Art. 14: 0239_NL and 0314_NL; EFSA-Q-2009-00237 and EFSA-Q-2011-01114)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Plant stanols" and "reduction of blood cholesterol" (Art 14: 0307_FI; EFSA-Q-2011-00851)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"Plant sterols and plants stanols" and "reduction of blood cholesterol" (Art 19: 0316_UK; EFSA-Q-2011-01241)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.



"Daidzein-rich soy germ extract" and "reduction of vasomotor symptoms associated with menopause" (Art. 13(5): 0317_AT; EFSA-Q-2011-01251)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Further assessment of Article 13(1) health claims list

Draft scientific opinions on some health claims eligible for further assessment (microorganisms not sufficiently characterised, and claims for which EFSA concluded that there is insufficient evidence) were discussed. After amendments the following draft opinions will be presented to the Panel for further discussion and possible adoption:

- "Dried prunes" and "bowel function" (ID 1164 EFSA-Q-2012-00161)
- "Lutein" and "vision" (ID 1603 EFSA-Q-2012-00162 and ID 1604 EFSA-Q-2012-00163)
- "Lactotripeptides" and "blood pressure" (ID 661-EFSA-Q-2012-00126, ID 1831 EFSA-Q-2012-00168, ID 1832 EFSA-Q-2012-00169, ID 2891 EFSA-Q-2012-00171)
- "Polyphenols in olive" and "HDL cholesterols concentrations" (ID 1639-EFSA-Q-2012-00164)
- "Soy isoflavones" and "bone mineral density" (ID 1655 EFSA-Q-2012-00166)
- "Soy isoflavones" and "vasomotor symptoms associated with menopause" (ID 1654 EFSA-Q-2012-00165; ID 1704 EFSA-Q-2012-00167; ID 2140 EFSA-Q-2012-00170; ID 3093 EFSA-Q-2012-00212; ID 3154 EFSA-Q-2012-00213; ID 3590 EFSA-Q-2012-00214)
- "Vitamin K" and "function of the heart and blood vessels" (ID 125 EFSA-Q-2012-00125): the discussion of this agenda item was postponed to the Panel meeting.
- "Saccharomyces boulardii CNCM I-1079" and "defence against gastrointestinal pathogenic microorganisms" (ID 913 EFSA-Q-2012-00127)
- "Saccharomyces boulardii ATY-SB-101 (BCCM/MUCL 53837)" and "intestinal microflora balance, and natural defence/stimule immune system" (ID 1010- EFSA-Q-2012-00156, ID 1011- EFSA-Q-2012-00157)
- "Lactobacillus rhamnosus CNCM I-1720 and Lactobacillus helveticus CNCM I-1722" and "defence against pathogenic gastrointestinal microorganisms" (ID 939 EFSA-Q-2012-00131)
- "Lactobacillus gasseri PA 16/8, Bifidobacterium bifidum M 20/5 and Bifidobacterium longum SP 07/3" and "immune defence against upper respiratory tract pathogens" (ID 931-EFSA-Q-2012-00128)
- "Lactobacillus fermentum 57A, Lactobacillus plantarum 57B and Lactobacillus gasseri 57C" and "defence against vaginal pathogens" (ID 934-EFSA-Q-2012-00129)



"Lactobacillus helveticus CNCM I-1722 and Bifidobacterium longum subsp. Longum CNCM I-3470" and "stress related to psychological and gastrointestinal symptoms" (ID 938 - EFSA-Q-2012-00130)

"Bifidobacterium breve BR 03 (DSM 16604) and Lactobacillus plantarum LP 01 (LMG P-21021)" and "gastrointestinal discomfort/transit time" (ID 2938 - EFSA-Q-2012-00175)

"Lactobacillus casei DG, CNCM I-1572" and "decreasing gastrointestinal pathogens (ID 2949 - EFSA-Q-2012-00182)

Combination of microorganisms and "defence against upper respiratory tract infections" (ID 2941 - EFSA-Q-2012-00177, ID 3047 - EFSA-Q-2012-00277, ID 3059 - EFSA-Q-2012-00210)

The discussion of some draft opinions related to various microorganisms was postponed to the Panel meeting (ID 960 - EFSA-Q-2012-00133, ID 961 - EFSA-Q-2012-00134, ID 962 - EFSA-Q-2012-00135, ID 967 - EFSA-Q-2012-00136, ID 968 - EFSA-Q-2012-00137, ID 969 - EFSA-Q-2012-00138, ID 970 - EFSA-Q-2012-00139, ID 971 - EFSA-Q-2012-00140, ID 983 - EFSA-Q-2012-00144, ID 976 - EFSA-Q-2012-00143, ID 975 -EFSA-Q-2012-00142, ID 972 - EFSA-Q-2012-00141, ID 984 - EFSA-Q-2012-00145, ID 985 -EFSA-Q-2012-00146, ID 986 - EFSA-Q-2012-00147, ID 994 - EFSA-Q-2012-00148, ID 995 -EFSA-Q-2012-00149, ID 996 - EFSA-Q-2012-00150, ID 997 - EFSA-Q-2012-00151, ID 998 -EFSA-Q-2012-00152, ID 999 - EFSA-Q-2012-00153, ID 1006 - EFSA-Q-2012-00154, ID 1007 - EFSA-Q-2012-00155, ID 1014 - EFSA-Q-2012-00158, ID 1015 - EFSA-Q-2012-00159, ID 1030 - EFSA-Q-2012-00160, ID 2946 - EFSA-Q-2012-00180, ID 2947 - EFSA-Q-2012-00181, ID 2950 - EFSA-Q-2012-00183, ID 2951 - EFSA-Q-2012-00184, ID 2952 -EFSA-Q-2012-00185, ID 2956 - EFSA-Q-2012-00186, ID 2957 - EFSA-Q-2012-00187, ID 2958 - EFSA-Q-2012-00188, ID 2960 - EFSA-Q-2012-00189, ID 2961 - EFSA-Q-2012-00190, ID 2962 - EFSA-Q-2012-00191, ID 2963 - EFSA-Q-2012-00192, ID 2966 - EFSA-Q-2012-00194, ID 2967 - EFSA-Q-2012-00195, ID 2970 - EFSA-Q-2012-00198, ID 2971 -EFSA-Q-2012-00199, ID 2972 - EFSA-Q-2012-00200, ID 2974 - EFSA-Q-2012-00202, ID 3017 - EFSA-Q-2012-00205)

7. Next meeting date

The next meeting will be held on 23-25 May 2012.



Parma, 10 February 2012

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 33rd meeting of the Working Group on Claims Parma, 8-10 February 2012 EFSA / Nutrition / Claims

Agreed by the WG on 16 February 2012

Participants

WG Experts: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait,

Albert Flynn, Ines Golly, Marina Heinonen¹, Hannu Korhonen, Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen², Yolanda Sanz, Sean Strain, Inge Tetens, Hendrik van

Loveren, Hans Verhagen.

European Commission: Christina Antoniou³

EFSA: Reinhard Ackerl, Maria Astridou, Anja Brönstrup, Janusz Ciok,

Agnès de Sesmaisons-Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Ilkka Ojansivu, Danai Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez.

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the Annual Declarations of Interests (ADoI) and the Specific Declaration of Interests (SDoI) filled in by the experts invited at this meeting as well as the interests declared at the beginning of this meeting. With regard to the specific items on the agenda for this meeting, interests were declared and actions were taken as follows:

In relation to the applications from Raisio Nutrition Ltd on "plant stanols" and "reduction of blood cholesterol" and from Unilever PLC/NV on "plant sterols and plant stanols" and

² Participated on 08/02 and 09/02

¹ Participated on 08/02 and 09/02

³ Participated on 09/02 and 10/02



"reduction of blood cholesterol", Hans Verhagen declared an interest and refrained from the discussion for these agenda items.

In relation to the application from Unilever PLC/NV on "plant sterols and plant stanols" and "reduction of blood cholesterol", Susan Fairweather-Tait declared an interest and refrained from the discussion for this agenda item.

In relation to the application from Raisio Nutrition Ltd on "plant stanols" and "reduction of blood cholesterol", Marina Heinonen and Hannu Korhonen declared an interest and refrained from the discussion for this agenda item.

In relation to the application from Biocodex on "Citrulline-Malate" and "improved exercise performance and recovery" and to the draft Article 13(1) opinion on *Saccharomyces boulardii* CNCM I-1079, Jean-Louis Bresson declared an interest and refrained from the discussion for these agenda items.

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. Discussions

4.1 General issues on health claims

EFSA secretariat updated the WG Experts on the status of health claims applications since the last meeting.

The Commission Services provided feedback on the status of the Commission Decisions related to adopted health claim opinions. Related to Article 13(1) health claims, the Commission Services provided some feedback on the last ENVI (Environment, Public Health and Food Safety) committee meeting of the European Parliament.

4.2 Applications pursuant to Articles 13(5) and 14 of Regulation (EC) No 1924/2006

"Citrulline-Malate" and "improved exercise performance and recovery" (Art. 13(5): 0310 BE; EFSA-Q-2011-00931)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Wheat polar lipid extract" and "improved skin hydration" (Art. 13(5): 0315_FR; EFSA-Q-2011-01122)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

"Plant stanols" and "reduction of blood cholesterol" (Art 14: 0307_FI; EFSA-Q-2011-00851)

The draft scientific opinion was discussed and after amendments it will be presented to the next WG meeting for further discussion.

"Plant sterols and plants stanols" and "reduction of blood cholesterol" (Art 19: 0316 UK; EFSA-Q-2011-01241)

The draft scientific opinion was discussed and after amendments it will be presented to the next WG meeting for further discussion.



"Iron" and "maintenance of normal hair growth" (Art 13(5): 0320_FR; EFSA-Q-2012-00059)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for further discussion and possible adoption.

4.3 General issues on health claims evaluation and feedback from public consultations

Draft guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations (EFSA-Q-2010-01183)

This draft guidance was discussed and after amendments it will be presented to the Panel for further discussion.

Technical report: Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations (EFSA-Q-2011-00307)

Feedback on the public consultation was discussed and after amendments the technical report will be presented to the Panel for further discussion.

Draft guidance on the scientific requirements for health claims related to bone, joints, skin, and oral health (EFSA-Q-2010-01184)

The discussion of this agenda item was postponed to the next WG meeting.

Technical report: Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to neurological and psychological functions (EFSA-Q-2011-01097)

Feedback on the public consultation was discussed and after amendments the technical report will be presented to the next meeting of the Claims/Sub-Working Group on mental, nervous system for further discussion.

4.4 Further assessment of Article 13(1) health claims list

Draft scientific opinions on some health claims eligible for further assessment (microorganisms not sufficiently characterised, and claims for which EFSA concluded that there is insufficient evidence) were discussed. After amendments the following draft opinions will be presented to the Panel for further discussion and possible adoption:

"Dried prunes" and "bowel function" (ID 1164 - EFSA-Q-2012-00161)

"Lutein" and "vision" (ID 1603 - EFSA-Q-2012-00162 and ID 1604 - EFSA-Q-2012-00163)

"Alpha-cyclodextrin" and "post-prandial glycaemic responses" (ID 2926 - EFSA-Q-2012-00172)

"Soy isoflavones" and "vasomotor symptoms associated with menopause" (ID 1654 - EFSA-Q-2012-00165; ID 1704 - EFSA-Q-2012-00167; ID 2140 - EFSA-Q-2012-00170; 3093 - EFSA-Q-2012-00212; ID 3154 - EFSA-Q-2012-00213; ID 3590 - EFSA-Q-2012-00214)

"Soy isoflavones" and "bone mineral density" (ID 1655 - EFSA-Q-2012-00166)

"Saccharomyces boulardii CNCM I-1079" and "defence against gastrointestinal pathogenic microorganisms" (ID 913 - EFSA-Q-2012-00127)



"Lactobacillus rhamnosus CNCM I-1720 and Lactobacillus helveticus CNCM I-1722" and "defence against pathogenic gastrointestinal microorganisms" (ID 939 - EFSA-Q-2012-00131)

"Vitamin K" and "function of the heart and blood vessels" (ID 125 - EFSA-Q-2012-00125): the discussion of this agenda item was postponed to the Panel meeting.

5. Next meeting date

The next meeting will be held on 21-23 March 2012.



Nutrition Unit

Parma, 15 December 2011

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 32nd meeting of the Working Group on Claims Parma, 13-15 December 2011

EFSA / Nutrition / Claims

Agreed by the WG on 20 December 2011

Participants

WG Experts: Carlo Agostoni, Jean-Louis Bresson¹, Susan Fairweather-Tait,

Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen², Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Yolanda

Sanz, Sean Strain, Hendrik van Loveren, Hans Verhagen³.

European Commission: Francesco Felice Carlucci⁴

EFSA: Reinhard Ackerl, Maria Astridou, Anja Brönstrup, Janusz Ciok,

Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Ilkka Ojansivu, Danai Papanastasiou, Ariane Titz, Emanuela Turla,

Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Seppo Salminen and Inge Tetens.

2. Adoption of agenda

The agenda was amended to include two new items: "plant sterols and plant stanols" and "reduction of blood cholesterol" (Art. 14 health claim application: 0316_UK; EFSA-Q-2011-01241) and "wheat polar lipid extracts" and "skin hydration" (Art. 13(5) health claim application: 0315_FR; EFSA-Q-2011-01122). The agenda was adopted without any further changes except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the Annual Declarations of Interests (ADoI) and the Specific Declaration of Interests (SDoI) filled in by the experts invited at this meeting. At the beginning of the meeting, EFSA secretariat invited the experts to declare any conflict of interests and in particular any conflict

¹ Participated on 13/12 via teleconference

² Participated on 14/12 and 15/12

³ Participated on 14/12 and 15/12

⁴ Participated on 13/12 and 14/12



related to the new agenda items "plant sterols and plant stanols" and "reduction of blood cholesterol" (Art. 14 health claim application: 0316_UK; EFSA-Q-2011-01241) and "wheat polar lipid extracts" and "skin hydration" (Art. 13(5) health claim application: 0315_FR; EFSA-Q-2011-01122).

With regard to the specific items on the agenda for this meeting, interests were declared and actions were taken as follows:

In relation to the applications from Raisio Nutrition Ltd on "plant stanols" and "reduction of blood cholesterol" and from Unilever PLC/NV on "plant sterols and plant stanols" and "reduction of blood cholesterol", Marina Heinonen declared an interest and refrained from the 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. Discussions

4.1 General issues on health claims

EFSA secretariat updated the WG Experts on the status of health claims applications since the last meeting.

The Commission Services provided feedback on the status of the Commission Decisions related to adopted health claim opinions. Related to Art 13(1) health claims, the Commission Services provided feedback on the last Standing Committee on the Food Chain and Animal Health (SCFCAH) and on the procedure/timeline for those claims eligible for further assessment (probiotics not sufficiently characterised, claims for which EFSA concluded that there is insufficient evidence).

4.2 Applications pursuant to Articles 13(5) and 14 of Regulation (EC) No 1924/2006

"Glucosamine" and "normal joint cartilage" (Art. 13(5): 0313_BE; EFSA-Q-2011-01113)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Citrulline-Malate" and "improved exercise performance and recovery" (Art. 13(5): 0310_BE; EFSA-Q-2011-00931)

EFSA secretariat provided a presentation on the content of this application. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Bimuno® GOS" and "reduces enteropathogens in the gastrointestinal tract. The invasion of colonic pathogenic bacteria is a risk factor for traveller's diarrhoea" (Art. 14: 0300_UK; EFSA-Q-2011-00402)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.



"Protein-rich soybean component" and "plasma cholesterol reduction and reduction of heart disease risk" (Art 14: 0304_BE; EFSA-Q-2011-00784)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for possible adoption.

"Plant stanols" and "reduction of blood cholesterol" (Art 14: 0307_FI; EFSA-Q-2011-00851)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Plant sterols and plant stanols" and "reduction of blood cholesterol" (Art. 14: 0316_UK; EFSA-Q-2011-01241)

EFSA secretariat informed the WG Experts about this new Art. 14 health claim application for which an evaluation will be started as soon as the completeness check is performed.

"Wheat polar lipid extracts" and "skin hydration" (Art. 13(5): 0315_FR; EFSA-Q-2011-01122)

EFSA secretariat provided a presentation on the content of this application. A draft scientific opinion will be presented at the next meeting.

4.3 General issues on health claims evaluation and feedback from public consultations

Draft guidance on the scientific requirements for health claims related to bone, joints, oral health and connective tissue (EFSA-Q-2010-01184)

This draft guidance was discussed and after amendments it will be presented to the Panel for possible adoption.

Technical report: Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to bone, joints, oral health and connective tissue (EFSA-Q-2011-00308)

Feedback on the public consultation was discussed and after amendments the technical report will be presented to the Panel for possible endorsement.

Draft guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations (EFSA-Q-2010-01183)

The discussion of this agenda item was postponed to the next meeting.

Technical report: Outcome of a public consultation on the draft guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations (EFSA-Q-2011-00307)

The discussion of this agenda item was postponed to the next meeting.

4.4 Re-assessment of Art. 13(1) list

EFSA secretariat provided an overview on the Art. 13(1) health claims eligible for further reassessment (probiotics not sufficiently characterised, claims for which EFSA concluded that there is insufficient evidence).



5. Next meeting date

The next meeting will be held on 08-10 February 2012.



Nutrition Unit

Parma, 18 October 2011

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 31st meeting of the Working Group on Claims Parma, 12-14 October 2011 EFSA / Nutrition / Claims

Agreed by the WG on 24 October 2011

Participants

WG Experts: Carlo Agostoni, Jean-Louis Bresson, Albert Flynn, Ines Golly,

Marina Heinonen¹, Hannu Korhonen, Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen², Yolanda Sanz, Sean Strain, Inge Tetens³, Hendrik van Loveren⁴, Hans Verhagen.

European Commission: None

EFSA: Reinhard Ackerl, Kinga Wanda Adamaszwili, Maria Astridou, Anja

Brönstrup, Janusz Ciok, Agnès de Sesmaisons-Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Ilkka Ojansivu, Danai Papanastasiou, Ariane Titz, Emanuela Turla,

Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Susan Fairweather-Tait.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the Annual Declarations of Interests (ADoI) and the Specific Declaration of Interests (SDoI) filled in by the experts invited at this 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.

¹ Participated on 12/10 and 13/10

² Participated on 12/10 and 13/10

³ Participated on 12/10 and 13/10

⁴ Participated on 12/10



4. Discussions

4.1 General issues on health claims

EFSA secretariat informed the WG Experts about the status of health claims applications since the last meeting.

4.2 Applications pursuant to Articles 13(5) and 14 of Regulation (EC) No 1924/2006

"Bimuno[®] GOS" and "reduces enteropathogens in the gastrointestinal tract. The invasion of colonic pathogenic bacteria is a risk factor for traveller's diarrhoea" (Art. 14: 0300_UK, EFSA-Q-2011-00402)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Bimuno[®] GOS" and "reduces intestinal discomfort" (Art. 13.5: 0299_UK, EFSA-Q-2011-00401)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"CranPure™" and "reduces the adhesion of certain bacteria *E. coli* on the walls of urinary tract, a risk factor for urinary tract infections" (Art.14: 0302_FR, EFSA-Q 2011-00778)

This agenda item was deferred as no information was received in response to the clock-stop letter.

"Coffee C21" and "maintenance of DNA integrity in cells of the body" (Art. 13.5: 0303_DE, EFSA-Q-2011-00783)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for possible adoption.

"Protein-rich soybean component" and "plasma cholesterol reduction and reduction of heart disease risk" (Art. 14: 0304_BE, EFSA-Q-2011-00784)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

"Spermidine" and "prolongation of the growing phase (anagen) of hair cycle" (Art. 13.5: 0309_IT, EFSA-Q-2011-00896)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for possible adoption.



"Sugar beet fibre" and "decreasing intestinal transit time"(Art. 13.5: 0311_DK, EFSA-Q-2011-00971)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for possible adoption.

"Sugar beet fibre" and "increasing faecal bulk" (Art. 13.5: 0312_DK, EFSA-Q-2011-00972)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for possible adoption.

"Diacylglycerol (DAG)" and "reduction of body weight" (Art. 13.5: 0301_UK, EFSA-Q-2011-00751)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for possible adoption.

"Barley beta-glucan" and "lowering of blood cholesterol and reduced risk of (coronary) heart disease" (Art. 14: 0305_BE; EFSA-Q-2011-00798)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for possible adoption.

"Barley beta-glucan" and "lowering of blood cholesterol and reduced risk of (coronary) heart disease" (Art. 14: 0306 SI; EFSA-Q-2011-00799)

The draft scientific opinion was discussed and after amendments it will be presented to the Panel for possible adoption.

"Plant stanols" and "reduction of blood cholesterol" (Art 14: 0307_FI; EFSA-Q-2011-00851)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Thus, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

4.3 General issues on health claims evaluation

Draft guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (EFSA-Q-2010-01182)

Feedback on the public consultation was discussed and after amendments this draft guidance will be presented to the Panel for possible adoption.

Draft guidance on the scientific requirements for health claims related to bone, joints, oral health and connective tissue (EFSA-Q-2010-01184)

The discussion of this agenda item was postponed to the next WG meeting.

Draft guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations (EFSA-Q-2010-01183)

The discussion of this agenda item was postponed to the next WG meeting.



Draft guidance on the scientific requirements for health claims related to physical performance (EFSA-Q-2010-0118)

This draft guidance was discussed and after amendments it will be presented to the Panel for possible adoption.

5. Next meeting date

The next meeting will be held on 13-15 December 2011.



Nutrition Unit

Tabiano, 15 July 2011

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES Minutes of the 30th meeting of the Working Group on Claims Tabiano, 13-15 July 2011

(Agreed by the WG on 15 July 2011)

Participants

WG Experts: Carlo Agostoni¹, Jean-Louis Bresson, Susan Fairweather-Tait,

Albert Flynn², Ines Golly, Marina Heinonen³, Hannu Korhonen, Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Yolanda

Sanz, Sean Strain, Hendrik van Loveren, Hans Verhagen⁴.

European Commission: Francesco Felice Carlucci⁵

EFSA: Reinhard Ackerl, Maria Astridou, Anja Brönstrup, Janusz Ciok,

Agnès de Sesmaisons-Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Danai Papanastasiou,

Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Inge Tetens and Seppo Salminen.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda items were discussed.

3. Declarations of interest

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

¹ Participated on 13/07 and 14/07

² Participated on 13/07 and 14/07

³ Participated on 13/07 and 14/07

⁴ Participated on 13/07 and 14/07

⁵ Participated on 13/07 and 14/07



In relation to the draft opinion on Valio Ltd.'s application on peptides isoleucyl-prolyl-proline and valyl-prolyl-proline, Hannu Korhonen declared an interest and refrained from the discussion for this agenda item.

In relation to the draft opinion on DSM Nutritional Products Europe AG's application on Vitamin D, Sean Strain declared an interest and withdrew from the Chair and refrained from the discussion for this agenda item.

There were no other interests declared by the experts.

4. Discussions

Scientific opinions on Articles 13(5) and 14 of Regulation (EC) 1924/2006 were discussed and after amendments they will be presented to the Panel for possible adoption or rediscussion at the next working group.

5. Next meeting date

The next meeting will be held on 12-14 October 2011.



Parma, 25 February 2011

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 29th meeting of the Working Group on Claims Parma, 23-25 February 2011

(Agreed by the WG on 25 February 2011)

Participants

WG Experts:

Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen¹, Hannu Korhonen,

Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen², Yolanda Sanz, Sean Strain, Inge Tetens³, Hendrik van

Loveren, Hans Verhagen4.

European Commission:

Francesco Felice Carlucci⁵

EFSA:

Reinhard Ackerl, Maria Astridou, Anja Brönstrup, Janusz Ciok, Agnès de Sesmaisons–Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Danai Papanastasiou,

Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants.

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 secretariat screened the Annual Declarations of Interests (ADoI) and the Specific Declaration of Interests (SDoI) filled in by the experts invited at this meeting. With regard to the specific items on the agenda for this meeting, interests were declared and actions were taken as follows:

Participated on 23/02 and 24/02

² Participated on 23/02 and 24/02

³ Participated on 23/02 and 24/02

⁴ Participated on 23/02 and 24/02

⁵ Participated on 24/02 and 25/02



In relation to the draft opinion on Kraft Foods Europe's application on biscuits for breakfast, Albert Flynn declared an interest and refrained from the discussion for this agenda item.

In relation to the draft opinion on Nestlé Nutrition, Nestec Ltd's application on *Bifidobacterium animalis* subsp. *lactis* NCC 2818, Ambroise Martin and Seppo Salminen declared an interest and refrained from the discussion for this agenda item.

In relation to the draft opinion on Valio Ltd's application on *Lactobacillus GG* and to the Article 13(1) draft opinion on *Lactobacillus rhamnosus* LGG, Seppo Salminen declared an interest and refrained from the discussion for these agenda items.

In relation to the Article 13(1) draft opinion on intense sweeteners, Hans Verhagen declared an interest and refrained from the discussion for this agenda item.

There were no other interests declared by the experts.

4. Discussions

Scientific opinions on Articles 13(1), 13(5) and 14 of Regulation (EC) 1924/2006 were discussed and after amendments they will be presented to the Panel for possible adoption or re-discussion at the next working group.

5. Next meeting date

The next meeting will be on 6-8 April 2011.



Parma, 17 December 2010

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 28th meeting of the Working Group on Claims Parma, 15-17 December 2010

(Agreed by the WG on 17 December 2010)

Participants

WG Experts:

Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen¹, Yolanda Sanz, Sean Strain, Inge Tetens², Hendrik van

Loveren, Hans Verhagen³.

EFSA:

Reinhard Ackerl, Maria Astridou, Anja Brönstrup, Janusz Ciok, Agnès de Sesmaisons–Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Danai Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

Declarations of interest

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

In relation to the draft opinion on Unilever PLC's application on soy isoflavones, fish oil, lycopene, vitamin C and vitamin E, Susan Fairweather-Tait declared an interest and refrained from the discussion for this agenda item.

¹ Participated on 15/12 and 16/12

² Participated on 15/12 and 16/12

³ Participated on 15/12 and 16/12



In relation to the draft opinion on Valio Ltd's application on *Lactobacillus* GG and to the draft opinion on Article 13(1) on a combination product containing *Lactobacillus rhamnosus* GG and *Lactobacillus rhamnosus* Lc705, Seppo Salminen declared an interest and refrained from the discussion for these agenda items.

There were no other interests declared by the experts.

4. Discussions

Scientific opinions on Articles 13(1), 13(5) and 14 of Regulation (EC) 1924/2006 were discussed and after amendments they will be presented to the Panel for possible adoption or re-discussion at the next working group.

5. Next meeting date

The next meeting will be on 23-25 February 2011.



Parma, 8 October 2010

SCIENTIFIC PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 27th meeting of the Working Group on Claims Parma, 6-8 October 2010

(Agreed by the WG on 8 October 2010)

Participants

WG Experts:

Carlo Agostoni, Jean-Louis Bresson, Albert Flynn, Ines Golly, Marina Heinonen¹, Hannu Korhonen, Martinus Lovik, Ambroise Martin², Hildegard Przyrembel, Yolanda Sanz³, Sean Strain, Inge

Tetens⁴, Hendrik van Loveren, Hans Verhagen⁵.

European Commission:

Christophe Didion⁶.

FFSA:

Reinhard Ackerl, Maria Astridou, Anja Brönstrup, Janusz Ciok, Agnès de Sesmaisons – Lecarré, Céline Dumas, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Danai Papanastasiou,

Ariane Titz, Emanuela Turla, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Susan Fairweather-Tait and Seppo Salminen.

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 secretariat screened the Annual Declarations of Interests (ADoI) and the Specific Declaration of Interests (SDoI) filled in by the experts invited at this meeting. With regard to the specific items on the agenda for this meeting, interests were declared and actions were taken as follows:

¹ Participated on 06/10 and 07/10

² Participated on 06/10 and 07/10

³ Participated on 06/10

⁴ Participated on 06/10 and 07/10

⁵ Participated on 07/10 and 08/10

⁶ Participated on 07/10 and 08/10



In relation to the draft opinion on Danone's application on a fermented milk product (Actimel®), which contains *Lactobacillus casei* DN 114001/CNCM I-1518, Jean-Louis Bresson, Albert Flynn, Ambroise Martin and Yolanda Sanz declared an interest and refrained from the discussion for this agenda item.

In relation to the draft opinion on Danone's application on a fermented milk product (Actimel®), which contains *Lactobacillus casei* DN 114001/CNCM I-1518, Sean Strain declared an interest and withdrew from the Chair and refrained from discussion for this agenda item.

There were no other interests declared by the experts.

4. Discussions

Scientific opinions on Articles 13(1), 13(5) and 14 of Regulation (EC) 1924/2006 were discussed and after amendments they will be presented to the Panel for possible adoption or re-discussion at the next working group.

5. Next meeting date

The next meeting will be on 15-16 December 2010.



Parma, 25 June 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 26th meeting of the Working Group on Claims Parma, 23-25 June 2010

(Agreed by the working group on 25 June 2010)

Participants

WG Experts:

Albert Flynn, Ines Golly, Marina Heinonen¹, Hannu Korhonen², Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Seppo

Salminen³, Yolanda Sanz⁴, Sean Strain, Inge Tetens⁵, Daniel

Tomé, Hendrik van Loveren, Hans Verhagen.

European Commission:

Christina Antoniou⁶.

EFSA:

Reinhard Ackerl, Maria Astridou, Janusz Ciok, Agnes De

Sesmaisons-Lecarre, Celine Dumas, Wolfgang Gelbmann, Leng

Heng, Juliane Kleiner, Danai Papanastasiou, Ariane Titz,

Emanuela Turla, Silvia Valtueña Martínez.

Welcome and apologies

The Chair welcomed the working group members. Apologies were received from Carlo Agostoni, Jean-Louis Bresson and Susan Fairweather-Tait.

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 secretariat screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled

¹ Participated on 23/06 and 24/06

² Participated on 23/06 and 24/06

³ Participated on 23/06 and 24/06

⁴ Participated on 23/06 and 24/06

⁵ Participated via phone-conference on 24/06

⁶ Participated on 23/06 and 24/06



in by the experts invited at this meeting. With regard to the specific items on the agenda for this meeting, interests were declared and actions were taken as follows:

In relation to the draft opinion on Kellogg Europe Trading Ltd's application on ready-to-eat breakfast cereals, Albert Flynn declared an interest. However this draft opinion was not discussed at the meeting.

In relation to the draft opinion on Danone's application on fermented milk that contains the probiotic Lactobacillus casei DN 114001/CNCM I-1518 Actimel®, Albert Flynn, Ambroise Martin and Yolanda Sanz declared an interest and refrained from the discussion for this agenda item.

In relation to the draft opinion on Danone's application on fermented milk that contains the probiotic Lactobacillus casei DN 114001/CNCM I-1518 Actimel®, Sean Strain declared an interest and withdrew from the Chair and refrained from discussion for this agenda item.

In relation to the draft opinions on Nestle Nutrition, Nestec Ltd's applications on B. animalis subsp. lactis NCC 2818, Ambroise Martin and Seppo Salminen declared an interest and refrained from the discussion for these agenda items.

There were no other interests declared by the experts.

4. Discussions

Opinions on Art 13(1), 13(5) and 14 were discussed and after amendments they will be presented to the Panel for possible adoption or re-discussion at the next working group.

5. Next meeting date

The next meeting will be on 6-8 October 2010.



Parma, 21 May 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 25th meeting of the Working Group on Claims Parma, 19-21 May 2010

(Agreed by the working group on 21 May 2010)

Participants

WG Experts:

Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Ingegerd Johansson¹, Hannu Korhonen,

Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Anders Sjodin², Sean Strain, Inge Tetens³, Daniel Tomé⁴, Hendrik van

Loveren⁵, Hans Verhagen⁶.

EFSA:

Reinhard Ackerl, Maria Astridou, Janusz Ciok, Agnes De

Sesmaisons-Lecarre, Celine Dumas, Wolfgang Gelbmann, Leng

Heng, Juliane Kleiner, Danai Papanastasiou, Ariane Titz,

Emanuela Turla, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the working group members. Apologies were received from Carlo Agostoni, Martinus Lovik and Seppo Salminen.

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 secretariat screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled

¹ Participated via phone-conference on 19/05

² Participated via phone-conference on 20/05

³ Participated on 19/05 and 20/05

⁴ Participated on 19/05

⁵ Participated on 20/05 and 21/05

⁶ Participated on 19/05 and 20/05



in by the experts invited at this meeting. With regard to the specific items on the agenda for this meeting, interests were declared and actions were taken as follows:

In relation to the draft opinion on Kellogg Europe Trading Ltd's application on ready-to-eat breakfast cereals, Susan Fairweather-Tait and Albert Flynn declared an interest and refrained from the discussion for this agenda item.

In relation to the draft opinion on dietary fibre and reduction of fat absorption, Inge Tetens declared an interest and refrained from discussion for this agenda item.

In relation to the draft opinion on yoghurt cultures (live) and lactose digestion, Jean-Louis Bresson declared an interest and refrained from the discussion for this agenda item.

There were no other interests declared by the experts.

4. Discussions

Opinions on Art 13(1), 13(5) and 14 were discussed and after amendments they will be presented to the Panel for either adoption or discussion.

5. Next meeting date

The next meeting will be on 23-25 June 2010.



Parma, 29 March 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 24th meeting of the Working Group on Claims Parma, 24-26 March 2010

(Agreed by the working group on 29 March 2010)

Participants

WG Experts:

Carlo Agostoni, Susan Fairweather-Tait, Albert Flynn, Ines Golly,

Marina Heinonen¹, Martinus Lovik, Hildegard Przyrembel, Sean Strain, Inge Tetens², Hendrik van Loveren, Hans Verhagen.

European Commission:

Lars Korsholm³

EFSA:

Reinhard Ackerl, Maria Astridou, Janusz Ciok, Agnes De

Sesmaisons-Lecarre, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Danai Papanastasiou, Ariane Titz, Emanuela Turla, Silvia

Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the working group members. Apologies were received from Jean-Louis Bresson, Hannu Korhonen, Ambroise Martin, Seppo Salminen and Yolanda Sanz.

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 secretariat screened the Annual Declaration of interest (ADoI) and the Specific Declaration of interest (SDoI) filled in by the experts invited at this meeting as well as the interests declared at the beginning of this meeting. With regard to the specific items on the agenda for this meeting, interests were declared and actions were taken as follows:

² Participated 24/3 and 25/3

¹ Participated 24/3 and 25/3

³ Participated 25/3 PM and 26/3



In relation to the draft opinion on Actimel, Susan Fairweather-Tait and Albert Flynn declared an interest and refrained from the discussion for this agenda item.

In relation to the draft opinion on Actimel, Sean Strain declared an interest and withdrew from the Chair and refrained from discussion for this agenda item.

In relation to the draft opinion on Actimel, Carlo Agostoni indicated being co-author of a study cited in the Actimel application from Danone (Giovannini et al., 2007). Nevertheless Carlo Agostoni declared that he has not received any financial benefit in relation to the aforementioned study. The EFSA secretariat did not consider this interest as a conflict of interest and the expert was allowed to participate in the discussion for this agenda item.

In relation to the draft opinions on Vitamin B12, Folate and Vitamin B12_homocysteine, Susan Fairweather-Tait declared in her SDoI that she is involved in a DG Research funded project covering these nutrients. The EFSA secretariat did not consider these interests as conflicts of interests and the expert was allowed to participate in the discussion for this agenda item.

In relation to the draft opinion on Cocoa flavanols, Hans Verhagen indicated that although the first author of the study by Buijsse et al., 2006 was formally appointed by the Wageningen University, he was in fact working at the National Institute for Public Health and the Environment (RIVM), Centre for Nutrition and Health, of which Hans Verhagen is the head. Two other authors from Wageningen University were at RIVM until mid-2005. The EFSA secretariat did not consider this interest as a conflict of interest and the expert was allowed to participate in the discussion for this agenda item.

There were no other interests declared by the experts.

4. Discussions

Opinions on Art 13(1), 13(5) and 14 were discussed and after amendments they will be presented to the Panel for either adoption or discussion.

5. Next meeting date

The next meeting will be 19-21 May 2010.



Parma, 14 January 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 23nd meeting of the Working Group on Claims Parma, 12-14 January 2010

(Adopted by the working group on 14 January 2010)

Participants

WG Experts: Carlo Agostoni¹, Jean-Louis Bresson², Susan Fairweather-Tait,

Albert Flynn, Ines Golly; Marina Heinonen², Hannu Korhonen², Martinus Lovik, Ambroise Martin³, Yolanda Sanz, Wilhelm Stahl⁴, Sean Strain, Inge Tetens², Hendrik van Loveren², Hans Verhagen.

European Commission: Christina Antoniou

EFSA: Reinhard Ackerl, Maria Astridou, Ulla Bertelsen, Janusz Ciok,

Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Danai Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez.

1. Welcome and apologies

The Chair welcomed Wilhelm Stahl and the working group members. Apologies were received from Pagona Lagiou, Hildegard Przyrembel and Seppo Salminen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

EFSA secretariat screened the ADol and SDol filled in by the scientific experts invited at 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:

¹ Participated 12/1 PM, 13/1 PM and 14/1 AM

² Participated 12/1 and 13/1

³ Participated 13/1 and 14/1

⁴ Participated 13/1



In relation to the draft opinions on Actimel and Activia, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ambroise Martin and Sean Strain declared an interest and refrained from the discussion for these Agenda items.

In relation to the draft opinions on Actimel and Activia, Yolanda Sanz declared that one of her students has received a free topic scholarship from Danone Institute. The scholarship was personally for the student. The supervisor, laboratory or institute did not receive any funding. The EFSA secretariat did not consider this interest as a conflict of interest and the expert was allowed to participate in the discussion for these Agenda items.

There were no other interests declared by the experts.

4. Discussions

Opinions on Art 13(3), 13(5) and 14 were discussed and after amendments they will be presented to the Panel for either adoption or discussion.

5. Next meeting date

The next meeting will be 24-26 March 2010.



Parma, 16 November 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 22nd meeting of the Working Group on Claims Parma, 10-12 November 2009

(Adopted by the working group on 12 November 2009)

Participants

WG Experts: Carlo Agostoni, Susan Fairweather-Tait, Albert Flynn, Ines Golly;

Marina Heinonen¹, Hannu Korhonen, Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz², Sean Strain, Stephan Strobel³, Inge Tetens¹, Hendrik van Loveren.

European Commission: Lars Korsholm²

EFSA: Reinhard Ackerl, Maria Astridou, Ulla Bertelsen, Janusz Ciok,

Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Danai Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez.

1. Welcome and apologies

The Chair welcomed Stephan Strobel and the working group members. Apologies were received from Jean-Louis Bresson, Seppo Salminen and Hans Verhagen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

EFSA secretariat screened the ADol and SDol filled in by the scientific experts invited at 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:

¹ Participated on 10 and 11 November

² Participated on 11 and 12 November

³ Participated by telephone on 11 November



In relation to the draft opinions on Actimel and Immunofortis, Susan Fairweather-Tait, Albert Flynn, Ambroise Martin and Sean Strain declared an interest and refrained from the discussion for these Agenda items.

There were no other interests declared by the experts.

4. Discussions

Opinions on Art 13(3), 13(5) and 14 were discussed and after amendments they will be presented to the Panel for either adoption or discussion.

5. Next meeting date

The next meeting will be 12-14 January 2010.



Parma, 14 October 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 21st meeting of the Working Group on Claims Parma, 15-17 September 2009

(Adopted by the working group on 14 October 2009)

Participants

WG Experts: Carlo Agostoni; Jean-Louis Bresson, Susan Fairweather-Tait;

Albert Flynn, Ines Golly; Marina Heinonen, Hannu Korhonen, Susanne Krauss-Etschmann¹, Martinus Lovik, Ambroise Martin², Hildegard Przyrembel, Seppo Salminen², Yolanda Sanz, Sean Strain, Inge Tetens, Hendrik van Loveren², Hans Verhagen².

European Commission: Christoph Didion²

EFSA: Reinhard Ackerl, Maria Astridou, Ulla Bertelsen, Janusz Ciok,

Wolfgang Gelbmann, Leng Heng, Juliane Kleiner, Danai Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez.

1. Welcome and apologies

The Chair welcomed Susanne Krauss-Etschmann and the working group members. All WG members participated in the meeting.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

EFSA secretariat screened the ADol and SDol filled in by the scientific experts invited at 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:

¹ Present 17 September

² Present 16 and 17 September



In relation to the draft opinion on Immunofortis, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ambroise Martin and Sean Strain declared an interest and refrained from discussion for this Agenda item.

In relation to the draft opinions on prunes (ID 1164) and prune juice (ID 1166) Seppo Salminen informed that one of the references provided is a publication from his earlier student, and regarding the draft opinion on *Lactobacillus casei Shirota* (ID 892) Seppo Salminen informed that his group has used the *L. casei Shirota* strain in their research but not received any funding from the Yakult company. The EFSA secretariat did not consider these interests as conflict of interests and the expert was allowed to participate in the discussion for these Agenda items.

There were no other interests declared by the experts.

4. Discussions

Opinions on Art 13(3), 13(5) and 14 were discussed and after amendments they will be presented for the Panel for either adoption or discussion.

5. Next meeting date

The next meeting will be 10-12 November 2009.



Parma, 10 June 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the Working Group on Claims Parma, 3-5 June 2009

(Adopted by the working group on 5 June 2009)

Participants

WG Experts: Jean-Louis Bresson, Albert Flynn, Mariette Gerber^{1,} Marina

Heinonen, Hannu Korhonen, Martinus Lovik, Ambroise Martin², Hildegard Przyrembel, Sean Strain, Inge Tetens, Hendrik van

Loveren², Hans Verhagen².

European Commission: Christoph Didion

EFSA: Reinhard Ackerl, Maria Astridou, Ulla Bertelsen, Janusz Ciok, Ellie

Daguet, Wolfgang Gelbmann, Juliane Kleiner, Danai

Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez.

1. Welcome and apologies

The Chair welcomed Mariette Gerber and the working group members. Apologies were received from Seppo Salminen and Henk van den Berg.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

EFSA secretariat screened the ADol and SDol filled in by the scientific experts invited at 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:

In relation to the draft opinions on Immunofortis and Danacol, Jean-Louis Bresson, Albert Flynn, Ambroise Martin and Sean Strain declared an interest and refrained from discussion for these Agenda items.

¹ Present 3 June AM

² Present 3 and 4 June



In relation to the draft opinions on catechins and ALA, Hans Verhagen declared an interest and refrained from the discussion of catechins, the discussion of the draft opinion on ALA was postponed to the next meeting.

In relation to the draft opinions on vitamin E, selenium and folic acid, Sean Strain indicated intellectual interest and was allowed to participate in the discussion for these Agenda items.

There were no other interests declared by the experts.

4. Discussions

Opinions on Art 13(3), 13(5) and 14 were discussed and after amendments they will be presented for the Panel for either adoption or discussion.



Parma, 3 April 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 19th meeting of the Working Group on Claims Parma, 1-2 April 2009

Participants

WG Experts: Jean-Louis Bresson, Albert Flynn, Hannu Korhonen, Susanne

Krauss-Etschmann¹, Martinus Lovik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Sean Strain, Hans van den Berg,

Hendrik van Loveren, Hans Verhagen.

European Commission: Lars Korsholm²

EFSA: Reinhard Ackerl, Maria Astridou, Ulla Bertelsen, Janusz Ciok, Ellie

Daguet, Wolfgang Gelbmann, Juliane Kleiner, Danai

Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez, Leng Heng.

1. Welcome and apologies

The Chair welcomed the working group members and Susanne Krauss-Etschmann. Apologies were received from Marina Heinonen and Inge Tetens.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

EFSA secretariat screened the ADol and SDol filled in by the scientific experts invited at 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:

In relation to the draft opinions on Activia and Actimel, Sean Strain, Albert Flynn, Ambroise Martin and Jean-Louis Bresson declared an interest and refrained from discussion for these Agenda items.

-

¹ Present on 1st April (am)

² Present on 2 April.



In relation to the draft opinions on DHA/EPA, iodine, iron, zinc and copper, Sean Strain indicated research funding and intellectual interest and was allowed to participate in the general discussion for these Agenda items.

There were no other interests declared by the experts.

4. Discussions

Opinions on Art 13(3), 13(5) and 14 were discussed and after amendments they will be presented for the Panel for either adoption or discussion.



Parma, 17 February 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 18th meeting of the Working Group on Claims Parma, 12-13 February 2009

Participants

WG Experts: Carlo Agostoni, Jean-Louis Bresson, Albert Flynn, Miguel

Gueimonde, Hannu Korhonen, Martinus Lovik, Ambroise Martin, Andreu Palou, Hildegard Przyrembel, Seppo Salminen, Sean Strain, Hendrik van Loveren, Inge Tetens. Henk van den Berg,

Hans Verhagen.

European Commission: Lars Korsholm

EFSA: Reinhard Ackerl, Maria Astridou, Ulla Bertelsen, Janusz Ciok, Ellie

Daguet, Wolfgang Gelbmann, Juliane Kleiner, Danai

Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez.

1. Welcome and apologies

The Chair welcomed the working group members and Carlo Agostoni and Miguel Gueimonde. Apologies were received from Marina Heinonen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

EFSA secretariat screened the ADol and SDol filled in by the scientific experts invited at 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:

In relation to the draft Art. 13(3) opinion on DHA and Art. 14 opinions on DHA/ARA, LIPIL® and Enfamil® Premium, Seppo Salminen declared an interest and refrained from the discussion for these agenda points. Also, Carlo Agostoni declared an interest and did not participate in the decision process.

In relation to the draft Art. 13(5) opinion on *Probi AB* - Lactobacillus plantarum 299v, Inge Tetens declared an interest and refrained from discussion for this Agenda item.



In relation to the draft Art. 14 opinion on ALA, Albert Flynn declared an interest and withdrew from the chair and refrained from the discussion for this agenda point.

In relation to the draft opinions on fatty acids and micronutrients, Sean Strain indicated public research funding and intellectual interest and was allowed to participate in the general discussion for these Agenda items.

There were no other interests declared by the experts.

4. Discussions

The Working group discussed Article 13 and 14 draft opinions and after amendments they will be presented at the next Panel meeting for either adoption or discussion.



Parma, 14 January 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 17th meeting of the Working Group on Claims Parma, 8-9 January 2009

Participants

WG Experts: Antti Aro, Albert Flynn, Marina Heinonen, Hannu Korhonen,

Martinus Lovik, Ambroise Martin, Andreu Palou, Hildegard

Przyrembel, Seppo Salminen, Sean Strain, Hendrik van Loveren,

Hans Verhagen

EFSA: Reinhard Ackerl, Maria Astridou, Ulla Bertelsen, Janusz Ciok, Ellie

Daguet, Wolfgang Gelbmann, Juliane Kleiner, Danai

Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez.

1. Welcome and apologies

The Chair welcomed the working group members and Antti Aro. Apologies were received from Jean-Louis Bresson, Inge Tetens, Henk van den Berg and Lars Korsholm.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In relation to the draft Art. 14 opinion on dairy fresh cheese, Albert Flynn, Ambroise Martin and Sean Strain declared an interest and refrained from discussion for these agenda items.

In relation to the draft Art. 13(3) opinion on DHA and Art. 14 opinions on DHA/ARA, LIPIL® and Enfamil® Premium, Seppo Salminen declared an interest and refrained from the discussion for these agenda points.

There were no other interests declared by the experts.

4. Discussions

The Working group discussed Article 13 and 14 draft opinions and after amendments they will be presented for the Panel for either adoption or discussion.



Parma, 21 November 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 16th meeting of the Working Group on Claims Parma, 18-19 November 2008

Participants

WG Experts: Carlo Agostoni, Jean-Louis Bresson¹, Albert Flynn, Susanne

Krauss-Etschmann, Ambroise Martin, Hildegard Przyrembel, Andreu Palou, Seppo Salminen, Barbara Stewart-Knox, Sean Strain, Inge Tetens, Henk van den Berg, Hendrik van Loveren,

Hans Verhagen

European Commission: Lars Korsholm

EFSA: Reinhard Ackerl, Maria Astridou, Ulla Bertelsen, Janusz Ciok, Ellie

Daguet, Wolfgang Gelbmann, Juliane Kleiner, Danai

Papanastasiou, Ariane Titz, Emanuela Turla, Silvia Valtueña

Martínez..

1. Welcome and apologies

The Chair welcomed the working group members and Carlo Agostoni, Susanne Krauss-Etschmann and Barbara Stewart-Knox. Apologies were received from Marina Heinonen and Hannu Korhonen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In relation to the draft Art. 13(5) opinion on black tea, Hans Verhagen declared an interest and refrained from discussion for this Agenda item.

In relation to the draft Art. 14 opinion on dairy fresh cheese, Albert Flynn, Ambroise Martin and Sean Strain declared an interest and refrained from discussion for this Agenda item.

In relation to the draft Art. 14 opinions on Bifidobacterium lactis, Seppo Salminen indicated an intellectual interest and was allowed to participate in the general discussion for these Agenda items.

¹ Participated by telephone conference



There were no other interests declared by the experts.

4. Discussions

The Working group discussed Article 13 and 14 draft opinions and after amendments they will be presented at the next Panel meeting for either adoption or discussion.

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Parma, 8 October 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 15th meeting of the Working Group on Claims Parma, 2-3 October 2008

Participants

WG Experts: Niels-Georg Asp¹, Jean-Louis Bresson, Albert Flynn, Marina

Heinonen, Hannu Korhonen, Ambroise Martin, Hildegard

Przyrembel, Andreu Palou, Jacques Rigo¹, Barbara Stewart-Knox¹,

Sean Strain, Inge Tetens, Henk van den Berg, Hendrik van

Loveren, Hans Verhagen

European Commission: Lars Korsholm

EFSA: Reinhard Ackerl, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner,

Emanuela Turla, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the working group members and Niels-Georg Asp, Jacques Rigo and Barbara Stewart-Knox. Apology was received from Seppo Salminen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In relation to the draft Art. 13(5) opinion on black tea, Hans Verhagen declared an interest and refrained from discussion for this Agenda item.

In relation to the draft Art. 14 opinion on dairy fresh cheese, Albert Flynn, Ambroise Martin and Sean Strain declared an interest and refrained from discussion for this Agenda item.

There were no other interests declared by the experts.

¹Participated via telephone conference



4. Discussions

The Working group discussed Art. 13(5) and Art. 14 draft opinions which after amendments will be presented at the next Panel meeting for discussion/adoption.



Parma, 19 September 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 14th meeting of the Working Group on Claims Parma, 15-17 September 2008

Participants

WG Experts: Christoph Baumgaertel¹, Jean-Louis Bresson, Albert Flynn,

Francisco Guarner¹, Marina Heinonen, Ingegerd Johansson², Hannu Korhonen, Ambroise Martin, Hildegard Przyrembel, Andreu Palou, Maria Saarela¹, Seppo Salminen, Barbara Stewart-Knox³,

Sean Strain, Hendrik van Loveren, Hans Verhagen

European Commission: Lars Korsholm

EFSA: Reinhard Ackerl, Wolfgang Gelbmann, Leng Heng, Juliane Kleiner,

Emanuela Turla, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the working group members and Maria Saarela, Barara Stewart-Knox, Christoph Baumgaertel and Francisco Guarner. Apologies were received from Inge Tetens and Henk van den Berg.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In relation to the draft Art. 13(5) opinion on black tea, Hans Verhagen declared an interest and refrained from discussion for this Agenda item.

In relation to the draft Art. 14 opinion on dairy fresh cheese, Albert Flynn, Ambroise Martin and Sean Strain declared an interest and refrained from discussion for thisese Agenda item.

In relation to the draft Art. 13(5) and 14 opinions on Evolus, Hannu Korhonen and Maria Saarela declared an interest and refrained from discussion for these Agenda items.

There were no other interests declared by the experts.

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¹ Present on the first day

² Present on the second day

³ Present on the second and third day



4. Discussions

The Working group discussed management and approach for Art 13(3) claims and discussed Art. 13(5) and Art. 14 draft opinions which after amendments will be presented at the next Panel meeting for discussion/adoption.



Parma, 11 July 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 13th meeting of the Working Group on Claims Parma, 8 July 2008

Participants

WG Experts: Jean-Louis Bresson, Albert Flynn, Hannu Korhonen, Ambroise

Martin, Andreu Palou, Hildegard Przyrembel, Seppo Salminen, Sean Strain, Inge Tetens, Henk van den Berg, Hendrik van

Loveren, Hans Verhagen.

European Commission: Lars Korsholm

EFSA: Leng Heng, Juliane Kleiner, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants. Apology was received from Marina Heinonen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

There were no specific interests declared for the agenda points of this meeting.

4. Discussions

The Working group discussed management and approach for assessment of Art 13(3) claims.



Parma, 27 June 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 12th meeting of the Working Group on Claims Parma, 24-25 June 2008

Participants

WG Experts: Jean-Louis Bresson, Albert Flynn, Ambroise Martin, Andreu Palou,

Seppo Salminen, Sean Strain, Henk van den Berg, Hendrik van

Loveren, Hans Verhagen.

European Commission: Lars Korsholm

EFSA: Leng Heng, Juliane Kleiner, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Hannu Korhonen, Hildegard Przyrembel and Inge Tetens.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

There were no other interests declared by the experts.

4. Discussions

The Working group discussed management and approach for Art 13(3) claims and discussed Art. 14 draft opinions which after amendments will be presented at the next Panel meeting for discussion/adoption.



Parma, 27 May 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 11th meeting of the Working Group on Claims Amsterdam, 20-21 May 2008

Participants

WG Experts: Jean-Louis Bresson, Albert Flynn, Ambroise Martin, Andreu Palou,

Seppo Salminen, Sean Strain, Henk van den Berg, Hendrik van

Loveren, Hans Verhagen.

European Commission: Lars Korsholm

EFSA: Leng Heng, Juliane Kleiner, Silvia Valtueña Martínez.

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Hannu Korhonen, Hildegard Przyrembel and Inge Tetens.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In relation to the draft Art. 14 opinions on Plant sterols and Alpha-linolenic acid and linoleic acid, Hannu Korhonen and Hans Verhagen declared an interest and refrained from discussion for these Agenda items.

There were no other interests declared by the experts.

4. Discussions

The Working group discussed management and approach for Art 13(3) claims and discussed Art. 14 draft opinions which after amendments will be presented again for the next WG meeting for discussion.



Parma, 9 April 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 10th meeting of the Working Group on Claims Parma, 8-9 April 2008

Participants

WG Experts: Jean-Louis Bresson, Albert Flynn, Hannu Korhonen, Ambroise

Martin, Andreu Palou, Hildegard Przyrembel, Seppo Salminen, Sean Strain, Henk van den Berg, Hendrik van Loveren, Inge

Tetens, Hans Verhagen

European Commission: Christophe Didion (via teleconference)

EFSA: Juliane Kleiner, Wolfgang Gelbman, Silvia Valtueña Martínez,

Maria Skarp, Leng Heng

1. Welcome and apologies

The Chair welcomed the participants. Apology was received from Marina Heinonen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In relation to the draft Art. 14 opinions on Plant sterols and Alpha-linolenic acid and linoleic acid, Hannu Korhonen and Hans Verhagen declared an interest and refrained from discussion for these Agenda items.

There were no other interests declared by the experts.

4. Discussions

The Working group discussed management and approach for Art 13(3) claims and discussed Art. 14 draft opinions which after amendments will be presented will be presented at the next Panel meeting for discussion/adoption.

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1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Yolanda Sanz.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest (SDoI) filled in by the working group members invited for the present meeting.

No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. General issues on health claim evaluations

4.1. Update on applications pursuant to Articles 13.5 and 14 of Regulation (EC) no 1924/2006

The EFSA Unit updated the WG Members on the status of new health claim applications since the last meeting.

5. Scientific topic(s) for discussion: Draft Article 14 and 13.5 opinions

5.1. Unilever NV – "Black tea and improvement of attention" (Art. 13.5, 0461_IE, EFSA-Q-2017-00606)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

⁴ http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf

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³ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



5.2. Specialised Nutrition Europe – "glycaemic carbohydrates and contribute to the improvement of physical performance during a high-intensity and long-lasting physical exercise" (Art. 13.5., 0462_FR, EFSA-Q-2017-00621)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁵ for possible adoption.

5.3. TA-XAN AG - "xanthohumol and maintaining the integrity of DNA", (Art. 13.5., 0463_DE, EFSA-Q-2017-00663)

The draft scientific opinion was discussed and, after amendments, it will be presented to the next NDA plenary meeting⁵ for possible adoption.

5.4. Farine Varvello & Co. S.r.l - "Consumption of arabinoxylan as part of a meal contributes to a reduction of the blood glucose rise after that meal" (Art. 19, 0465_IT EFSA-Q-2017-00710

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant and a stop the clock procedure will be applied.

6. Any other business

The next meeting of the Working Group on Claims will be held on 14-15 March 2018.

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⁵ NDA Panel Plenary meeting to be held on 7-8 February 2018