



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 118TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 07-08 January 2021

(Agreed on 15 January 2021)

Participants

■ Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren.

■ Hearing Experts¹:

Not Applicable

■ European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal

■ EFSA:

Nutrition Unit: Océane Albert, Domenico Azzollini, Paolo Colombo, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla.

■ Others:

SCER Unit: José Tarazona for agenda item 8.5

GMO Unit: Antonio Fernandez Dumont for agenda item 9.2

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies 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, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 117th Working Group meeting held on 02-04 December 2020, via web-conference.

The **minutes** of the 117th Working Group meeting were agreed by written procedure on 10 December 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that one novel food opinion was adopted at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Update on applications, new mandates

The EFSA staff provided a short introduction to one recently validated application.

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



8. Scientific topic(s) for discussion

8.1. **Draft opinion on edible *Jatropha curcas* L. kernels (Chuta) as a novel food (NF 2018/0177). Applicant: JatroSolutions GmbH (EFSA-Q-2018-00542)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology and allergenicity. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.2. **Draft opinion on Whole and ground crickets (*Acheta domesticus*) as a novel food (NF 2018/0804). Applicant: Fair Insects BV (EFSA-Q-2019-00121)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, proposed uses and use levels and toxicology. 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.

8.3. **Draft opinion on Whole and ground grasshoppers (*Locusta migratoria*) as a novel food (NF 2018/0803). Applicant: Fair Insects BV (EFSA-Q-2019-00115)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, proposed uses and use levels and toxicology. 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.

8.4. **Draft opinion on UV-treated mushrooms (*Agaricus bisporus*) as a novel food (NF 2019/1237). Applicant: MBio, Monaghan Mushrooms (EFSA-Q-2019-00550)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, ADME, human studies and allergenicity. The Experts of the WG considered that additional clarification is needed from the applicant in order to finalise the scientific assessment of this application. Therefore, a request for additional clarification will be sent to the applicant. After clarification receipt and amendments, the draft opinion will be presented at the NDA plenary meeting for further discussion and possible adoption.

8.5. **Draft opinion on Iron hydroxide adipate tartrate as a novel food (NF 2019/1417). Applicant: NEMYSIS LIMITED (EFSA-Q-2020-00200)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding absorption, metabolism and toxicology. 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.

8.6. **Draft opinion on Cellobiose as a novel food (NF 2020/1805). Applicant: SAVANNA Ingredients GmbH (EFSA-Q-2020-00465)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, ADME, toxicology, and human studies. 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.

9. Any Other Business

9.1. Update on the draft opinion on Urolithin A as a novel food (NF 2018/0538). Applicant: Amazentis SA (EFSA-Q-2018-00724)

The working group was informed about the status of the application, which is awaiting additional information from the applicant.

9.2. Update on the draft opinion on whole seeds of oilseed rape (*Brassica napus* L.) as a novel food (NF 2018/0590). Applicant: Erik Tybirk (EFSA-Q-2019-00033)

The working group was informed about the status of the application, which is awaiting additional information from the applicant.

9.3. Update on the draft opinion on Zinc L-carnosine as a novel food (NF 2019/1090). Applicant: Hamari Chemicals, Ltd. (EFSA-Q-2020-00263)

The working group was informed about the status of the application, which is awaiting additional information from the applicant.

9.4. Specifications in NF

The working group discussed the role of specifications in the safety assessment of novel foods.

10. Next meeting

The next meeting will be held on 03-05/02/2021, via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 117TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held by web-conference, 02-04 December 2020

(Agreed on 10 December 2020)

Participants

■ Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren¹.

■ Hearing Experts²:

Not Applicable

■ European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal

■ EFSA:

Nutrition Unit: Reinhard Ackerl, Fabio Alfieri, Paolo Colombo, Agnès De Sesmaisons Lecarré, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernandez, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla.

¹ Only on 2nd day

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies 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 Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, 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.

4. Agreement of the minutes of the 116th Working Group meeting held on 10-12 November 2020, via web-conference.

The minutes of the 116th Working Group meeting were agreed by written procedure on 19 November 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that four novel food opinions were adopted at the last NDA Panel plenary meeting. Furthermore, the WG was informed that a presentation providing an insight on current novel foods activities in EFSA was provided by the NUTRI Unit at the NDA plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on novel food applications received, including a short introduction to recently validated applications.

8. Scientific topic(s) for discussion

³ 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



8.1. Draft opinion on grain from perennial intermediate wheatgrass (*Thinopyrum intermedium*) (NF 2019/1468). Applicant: Patagonia Provisions, Inc (EFSA-Q-2020-00073)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process and allergenicity. 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.

8.2. Draft opinion on Schizochytrium sp. Oil (IF and FOF) (NF 2019/1213). Applicant: Bioplus Life Sciences (EFSA-Q-2019-00548)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, production process and composition. 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.

8.3. Draft opinion on mineral salt containing potassium and magnesium (NF 2018/0798). Applicant: BK Guilini GmbH (EFSA-Q-2019-00230)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, production process, composition, specifications, proposed uses and use levels. 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.

8.4. Draft opinion on iron hydroxide adipate tartrate (NF 2019/1417). Applicant: NEMYSES LIMITED (EFSA-Q-2020-00200)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization and on ADME, toxicology and human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.5. Draft opinion on *Ageratum conyzoides* L. 90% ethanolic extract from the aerial parts (NF 2019/1432). Applicant: GENCOR PACIFIC Limited (EFSA-Q-2020-00145)

The WG discussed the draft scientific opinion, and in particular assessed data regarding the production process, compositional data, specifications, history of use of the NF and toxicological information. 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.

8.6. Draft opinion on 3-Fucosyllactose (NF 2020/1620). Applicant: Jennewein Biotechnologie GmbH (EFSA-Q-2020-00309)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology. 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.



9. Any Other Business

9.1. Draft opinion on pasteurised *Akkermansia muciniphila* (NF 2019/1366). *Applicant: A-Mansia Biotech SA (EFSA-Q-2019-00767)*

The WG discussed the draft scientific opinion and the new information that had been submitted by the applicant following an EFSA request for additional information. 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.

9.2. Draft opinion on 7-hydroxymatairesinol potassium acetate complex (NF2019/0882). *Applicant: Linnea SA (EFSA-Q-2019-00147)*

The working group was informed about the status of the application which is awaiting additional information from the applicant.

9.3. Discussion on Allulose. *Applicants: CJ-Tereos Sweeteners Europe SAS (EFSA-Q-2018-00472); Petiva Europe SA (EFSA-Q-2018-00756); Samyang Corp. (EFSA-Q-2018-00797); Tate & Lyle Ingredients France SAS (EFSA-Q-2019-00584); SAVANNA Ingredients GmbH (EFSA-Q-2020-00141).*

The working group discussed the status of the applications and the strategy for the assessment.

10. Next meeting

The next meeting will be held on 07-08 January 2021, via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 116TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held via web-conference, 10-12 November 2020

(Agreed on 19 November 2020)

Participants

■ Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle¹, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter², Henk Van Loveren.

■ Hearing Experts³:

Frank Thies⁴

■ European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal

■ EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Paolo Colombo, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Eirini Kouloura, Estefanía Noriega Fernandez, Annamaria Rossi, Roman Svejstil, Emanuela Turla, Ermolaos Ververis.

¹ Did not participate on day 2 pm

² Participated only on day 1

³ 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>

⁴ Participated only for agenda item 8.4



1. Welcome and apologies for absence

The Chair welcomed the participants.

No apologies 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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management,⁶ 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. Agreement of the minutes of the 115th Working Group meeting held on 07-08 October 2020 via web-conference.

The **minutes** of the 115th Working Group meeting were agreed by written procedure on 15 October 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that one novel food opinion was adopted at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on novel food applications received, including a short introduction to recently validated applications.

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



8. Scientific topic(s) for discussion

8.1. **Draft opinion on Dried mealworms (*Tenebrio molitor*) (NF 2018/0241). Applicant: SAS EAP Group - Micronutris (EFSA-Q-2018-00262)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 24 November for further discussion and possible adoption.

8.2. **Draft opinion on Cistanche tubulosa extract (NF 2019/1318). Applicant: SINPHAR TIAN-LI PHARMACEUTICAL (EFSA-Q-2019-00812)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 24-26 November for further discussion and possible adoption.

8.3. **Draft opinion on Schizochytrium sp. Oil (NF 2019/0825). Applicant: Fermentalg (EFSA-Q-2019-00187)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 24-26 November for further discussion and possible adoption.

8.4. **Draft opinion on Schizochytrium sp. Oil (NF 2019/1046). Applicant: Fermentalg (EFSA-Q-2019-00323)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 24-26 November for further discussion and possible adoption.

8.5. **Draft opinion on 95% tetrahydrocurcuminoids from turmeric (NF 2020/1526). Applicant: Sabinsa Europe GmbH (EFSA-Q-2020-00111)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, toxicology, human studies and allergenicity. 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.

8.6. **Draft opinion on whole seeds of oilseed rape (*Brassica napus* L.) (NF 2018/0590). Applicant: Erik Tybirk (EFSA-Q-2019-00033)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.



8.7. Draft opinion on Galacto-oligosaccharide (NF 2020/1607). Applicant: Yakult Pharmaceutical Industry Co., Ltd. (EFSA-Q-2020-00211)

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels and anticipated daily intake. After amendments, the draft opinion will be presented at a forthcoming NDA plenary meeting for further discussion and possible adoption.

8.8. Draft opinion on synthetic Cannabidiol (NF 2020/1670). Applicant: Channele McCoy CBD LTD (EFSA-Q-2020-00257)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, toxicology and allergenicity. 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.

9. Any Other Business

9.1. Update on applications for allulose as a novel food. Applicants: CJ-Tereos Sweeteners Europe SAS (EFSA-Q-2018-00472), Petiva Europe SA (EFSA-Q-2018-00756), Samyang Corp. (EFSA-Q-2018-00797), Tate & Lyle Ingredients France SAS (EFSA-Q-2019-00584) and Savanna Ingredients GmbH (EFSA-Q-2020-00141)

The working group was informed about the status of the applications and discussed toxicology and human studies.

10. Next meeting

The next meeting will be held on 02-04 December 2020, via web conference.



Annex

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

With regard to this meeting, Harry McArdle and Marina Heinonen declared the following interest: both experts were nominated as member of the UK Nutrition and Health Claims Committee (UKNHCC). 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, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

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

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 115TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held via web-conference on 07-08 October 2020

(Agreed on 15 October 2020)

Participants

■ Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen¹, Miguel Prieto Maradona², Josef Rudolf Schlatter, Henk Van Loveren.

■ Hearing Experts³:

Stefaan de Henauw and Frank Thies⁴

■ European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal

■ EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Fabio Alfieri, Paolo Colombo, Agnès De Sesmaisons Lecarré, Lucien Ferreira, Wolfgang Gelbmann, Andrea Germini, Eirini Kouloura, Ruth Roldán Torres, Emanuela Turla, Ermolaos Ververis.

¹ Participated on day 2

² Participated on day 1 pm and day 2

³ 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>

⁴ Participated for agenda items 8.6 and 8.7



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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, 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.

4. Agreement of the minutes of the 114th Working Group meeting held on 08-10 September 2020, via web-conference.

The minutes of the 114th Working Group meeting were agreed by written procedure on 17 September 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that no novel food opinions were discussed at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on received novel food applications including a short introduction to recently validated applications.

8. Scientific topic(s) for discussion

8.1. Draft opinion on lacto-N-neotetraose (NF 2019/1152). Applicant: Jennewein Biotechnologie GmbH (EFSA-Q-2019-00448)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, production process, composition and specifications. After amendments, the draft



opinion will be presented at the next NDA plenary meeting on 22 October for further discussion and possible adoption.

8.2. Draft opinion on isomaltulose syrup (dried) (NF 2018/0330). Applicant: Evonik Creavis GmbH (EFSA-Q-2018-00609)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels and anticipated daily intake. 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.

8.3. Draft opinion on dried mealworms (*Tenebrio molitor*) (NF 2018/0241). Applicant: SAS EAP Group - Micronutris (EFSA-Q-2018-00262)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, specifications, proposed uses and use levels, and anticipated daily intake. 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.

8.4. Draft opinion on rhamnogalacturonan-I enriched carrot fibre (NF 2019/1172). Applicant: Nutrileads B.V. (EFSA-Q-2020-00186)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, production process, composition, specifications, production process, proposed uses and use levels, anticipated daily intake, toxicology and allergenicity. 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.

8.5. Draft opinion on Zinc L-carnosine (NF 2019/1090). Applicant: Hamari Chemicals, Ltd (EFSA-Q-2020-00263)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, production process, composition, specifications, proposed uses and use levels, anticipated daily intake, ADME and bioavailability of Zn from the source, toxicology, human studies and allergenicity. 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.

8.6. Draft opinion on *Schizochytrium* sp. Oil (NF 2019/1046). Applicant: Fermentalg (EFSA-Q-2019-00323)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, production process, composition, specifications and proposed uses/use levels. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.7. Draft opinion on *Schizochytrium* sp. Oil (NF 2019/0825). Applicant: Fermentalg (EFSA-Q-2019-00187)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, production process, composition, specifications, proposed uses/use levels and human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.



8.8. Draft opinion on turmeric extract, rich in curcuminoids (NF 2019/1466). Applicant: Naturex S.A. (EFSA-Q-2020-00108)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

8.9. Draft opinion on blend of Tamarindus indica seeds and Curcuma longa rhizome extracts (NF 2019/1283). Applicant: BOHAN & Co SA (EFSA-Q-2020-00033)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

8.10. Draft opinion on nicotinamide riboside chloride (NF 2020/1613). Applicant: ChromaDex, Inc (EFSA-Q-2020-00289)

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels, anticipated daily intake, toxicology and human studies. 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.

8.11. Draft opinion on Cistanche tubulosa extract (NF 2019/1318). Applicant: SINPHAR TIAN-LI PHARMACEUTICAL (EFSA-Q-2019-00812)

The WG discussed data regarding product characterization, history of use, proposed uses and use levels, toxicity and human studies. A draft opinion will be presented at the next WG NF meeting for further discussion.

8.12. Draft opinion on mixture of perdiethylphosphatoethyloligosilsesquioxanols absorbed on lactose monohydrate as a novel food PPST-L (NF 2019/0976). Applicant: IONTEC Sarl (EFSA-Q-2019-00549)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, production process, composition, specifications, proposed uses and use levels and bioavailability of silicon from the source. 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.

9. Next meeting

The next meeting will be held on 10-12 Nov, via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 114TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held via web-conference, 08-10 September 2020

(Agreed on 17 September 2020)

Participants

■ Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen¹, Miguel Prieto Maradona, Josef Rudolf Schlatter², Henk Van Loveren.³

■ NDA Panel members:

Frank Thies⁴ and Stefaan de Henauw⁴

■ European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore

■ EFSA:

Nutrition Unit: Reinhard Ackerl, Domenico Azzollini, Paolo Colombo, Eirini Kouloura, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Ruth Roldán Torres, Annamaria Rossi, Roman Svejstil, Emanuela Turla.

¹ On days 1 and 2

² On days 2 and 3

³ On days 2 (pm) and 3

⁴ Only for agenda item 7.6



1. Welcome and apologies for absence

The Chair welcomed the participants.

The working group welcomed the newly appointed member Miguel Prieto Maradona.

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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶ 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.

4. Agreement of the minutes of the 113th Working Group meeting held on 20 August 2020, via web-conference.

The minutes of the 113th Working Group meeting were agreed by written procedure on 27 August 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that two novel food opinions were adopted at the last NDA Panel plenary meeting.

6. Update on applications, new mandates

The EFSA staff provided a brief update on received novel food applications including a short introduction to recently validated applications.

7. Scientific topic(s) for discussion

7.1. Draft opinion on allulose as a novel food (NF 2020/1525). *Applicant: SAVANNA Ingredients GmbH (EFSA-Q-2020-00141)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. The WG considered that additional information is needed from the applicant in order to proceed with the scientific

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



assessment of this application. Therefore, a request for additional information will be sent to the applicant.

7.2. Draft opinion on synthetic cannabidiol as a novel food (NF 2019/0935). Applicant: Cibdol AG and Labocan BV (EFSA-Q-2020-00084)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels and toxicology. 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.

7.3. Draft opinion on pasteurised *Akkermansia muciniphila* as a novel food (NF 2019/1366). Applicant: A-Mansia Biotech S.A. (EFSA-Q-2019-00767)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, toxicology, human studies and allergenicity. 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.

7.4. Draft opinion on dried biomass of *Galdieria sulphuraria* (NF 2019/1342). Applicant: Fermentalg (EFSA-Q-2019-00660)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, toxicology, human studies and allergenicity. 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.

7.5. Draft opinion on powder of chitosan as a novel food (NF 2019/0908). Applicant: Cor.Con. International (EFSA-Q-2019-00324)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

7.6. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2019/1046). Applicant: Fermentalg (EFSA-Q-2019-00323)

The WG discussed the data regarding human studies. At the next WG NF meeting these data will be further discussed.

8. Any Other Business

8.1. Update on scientific opinion on water lentil powder from Lemnaceae as a novel food (NF 2018/0430). Applicant: Parabel Ltd. (EFSA-Q-2018-00995)

The working group was informed about the status of the application which is awaiting additional information from the applicant.



8.2. Update on scientific opinion on 3-fucosyllactose as a novel food (NF 2019/1321). Applicant: DuPont Nutrition & Biosciences ApS (EFSA-Q-2019-00666)

The working group was informed about the status of the application which is awaiting additional information from the applicant

8.3. WG meeting dates

The WG agreed on the proposal for the WG meeting dates in 2021.

9. Next meeting

The next meeting will be held on 07-08 Oct 2020 via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 113TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 20 August 2020 via web-conference

(Agreed on 27 August 2020)

Participants

Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Josef Rudolf Schlatter, Henk Van Loveren.

Hearing Experts¹:

Not Applicable

European Commission and/or Member States representatives:

EC: Ivona Babic

EFSA:

Nutrition Unit: Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Annamaria Rossi.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Harry J McArdle.

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>



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 114TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held via web-conference, 08-10 September 2020

(Agreed on 17 September 2020)

Participants

■ Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen¹, Miguel Prieto Maradona, Josef Rudolf Schlatter², Henk Van Loveren.³

■ NDA Panel members:

Frank Thies⁴ and Stefaan de Henauw⁴

■ European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore

■ EFSA:

Nutrition Unit: Reinhard Ackerl, Domenico Azzollini, Paolo Colombo, Eirini Kouloura, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Ruth Roldán Torres, Annamaria Rossi, Roman Svejstil, Emanuela Turla.

¹ On days 1 and 2

² On days 2 and 3

³ On days 2 (pm) and 3

⁴ Only for agenda item 7.6



1. Welcome and apologies for absence

The Chair welcomed the participants.

The working group welcomed the newly appointed member Miguel Prieto Maradona.

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 Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶ 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.

4. Agreement of the minutes of the 113th Working Group meeting held on 20 August 2020, via web-conference.

The minutes of the 113th Working Group meeting were agreed by written procedure on 27 August 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that two novel food opinions were adopted at the last NDA Panel plenary meeting.

6. Update on applications, new mandates

The EFSA staff provided a brief update on received novel food applications including a short introduction to recently validated applications.

7. Scientific topic(s) for discussion

7.1. Draft opinion on allulose as a novel food (NF 2020/1525). *Applicant: SAVANNA Ingredients GmbH (EFSA-Q-2020-00141)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. The WG considered that additional information is needed from the applicant in order to proceed with the scientific

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



assessment of this application. Therefore, a request for additional information will be sent to the applicant.

7.2. Draft opinion on synthetic cannabidiol as a novel food (NF 2019/0935). Applicant: Cibdol AG and Labocan BV (EFSA-Q-2020-00084)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels and toxicology. 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.

7.3. Draft opinion on pasteurised *Akkermansia muciniphila* as a novel food (NF 2019/1366). Applicant: A-Mansia Biotech S.A. (EFSA-Q-2019-00767)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, toxicology, human studies and allergenicity. 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.

7.4. Draft opinion on dried biomass of *Galdieria sulphuraria* (NF 2019/1342). Applicant: Fermentalg (EFSA-Q-2019-00660)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, toxicology, human studies and allergenicity. 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.

7.5. Draft opinion on powder of chitosan as a novel food (NF 2019/0908). Applicant: Cor.Con. International (EFSA-Q-2019-00324)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

7.6. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2019/1046). Applicant: Fermentalg (EFSA-Q-2019-00323)

The WG discussed the data regarding human studies. At the next WG NF meeting these data will be further discussed.

8. Any Other Business

8.1. Update on scientific opinion on water lentil powder from Lemnaceae as a novel food (NF 2018/0430). Applicant: Parabel Ltd. (EFSA-Q-2018-00995)

The working group was informed about the status of the application which is awaiting additional information from the applicant.



8.2. Update on scientific opinion on 3-fucosyllactose as a novel food (NF 2019/1321). Applicant: DuPont Nutrition & Biosciences ApS (EFSA-Q-2019-00666)

The working group was informed about the status of the application which is awaiting additional information from the applicant

8.3. WG meeting dates

The WG agreed on the proposal for the WG meeting dates in 2021.

9. Next meeting

The next meeting will be held on 07-08 Oct 2020 via web conference.



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, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 112th Working Group meeting held on 08-10 July via web-conference.

The minutes of the 112th Working Group meeting were agreed by written procedure on 17 July 2020.

5. Feedback from the NDA Panel plenary meeting

No NDA Panel plenary meeting took place since the last Novel foods WG meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on received novel food applications.

8. Scientific topics for discussion

8.1. Draft opinion on the overall dietary exposure and safety assessment for Chia seeds (*Salvia hispanica*) as a novel food. (EFSA-Q-2019-00254)

The technical report on the outcome of the public consultation⁴ was presented to the WG. The WG considered that the comment received did not have an impact on the overall risk assessment. Therefore, the draft opinion will be presented at the next NDA plenary meeting on 31 August for 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

⁴ <https://www.efsa.europa.eu/en/consultations/call/pc-draft-opinion-thermal-processed-chia-seeds>



8.2. Draft opinion on an aqueous ethanolic extract of *Labisia pumila* as a novel food (NF 2019/1337). Applicant: *Orchid Life Sdn Bhd* (EFSA-Q-2019-00694)

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology and human studies. 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.

8.3. Draft opinion on trans-Cannabidiol, synthesized as a novel food (NF 2019/1371). Applicant: *CBDepot, s.r.o.* (EFSA-Q-2019-00750)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process and toxicology. 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.

9. Any Other Business

9.1. Update on Draft opinion on dried fruits of *Synsepalum dulcificum* as a novel food (NF 2018/0709). Applicant: *Baja Food Co. (Medicinal Gardens S.L.)* (EFSA-Q-2018-01032)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

9.2. Update on Draft opinion on D-allulose (or D-psicose) as a novel food (NF 2018/0544). Applicant: *Samyang Corp.* (EFSA-Q-2018-00797)

The working group was informed about the status of the application.

10. Next meeting

The next meeting will be held on 08-10 Sep 2020, via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 112TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 08-10 July 2020 via web-conference

(Agreed on 17 July 2020)

Participants

Working Group Members:

Francesco Cubadda¹, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Josef Rudolf Schlatter, Henk Van Loveren.

Hearing Experts²:

Not Applicable

European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal

EFSA:

Nutrition Unit: Paolo Colombo, Lucien Ferreira, Eirini Kouloura, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

¹ Participated on day 1 and day 2 pm

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>



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 on Competing Interest Management⁴, 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.

4. Agreement of the minutes of the 111th Working Group meeting held on 18-19 June 2020, via web-conference.

The minutes of the 111th Working Group meeting were agreed by written procedure on 26 June 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that two novel food opinions were adopted at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Scientific topic(s) for discussion

7.1. Draft opinion on Schizochytrium sp. oil as a novel food (NF 2019/0983). *Applicant: Progress Biotech BV (EFSA-Q-2019-00306)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology. After amendments, the draft opinion will be presented at the next NDA plenary meeting on the 31st of August for further discussion and possible adoption. A request for minor clarification will be sent to the applicant in the meantime.

7.2. Draft opinion on Antrodia camphorata mycelia powder as a novel food (NF 2018/0329). *Applicant: Golden Biotechnology Corp (EFSA-Q-2019-00759)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. The WG considered that additional information is needed from the applicant in order to proceed with the scientific assessment

³ 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



of this application. Therefore, a request for additional information will be sent to the applicant.

7.3. Draft opinion on an aqueous extract of *Labisia pumila* as a novel food (NF 2019/1337). Applicant: *Orchid Life Sdn Bhd* (EFSA-Q-2019-00694)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

7.4. Draft opinion on pea and rice protein fermented by *Shiitake* mushroom (*Lentinula edodes*) mycelia as a novel food (NF 2019/1459). Applicant: *MycoTechnology, Inc.* (EFSA-Q-2020-00040)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, toxicology and allergenicity. 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.

7.5. Draft opinion on Urolithin A as a novel food (NF 2018/0538). Applicant: *Amazentis SA* (EFSA-Q-2018-00724)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

7.6. Draft opinion on *Wolffia globosa* powder as a novel food (NF 2019/1223). Applicant: *Nutraveris on behalf of Hinoman* (EFSA-Q-2019-00695)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and allergenicity. 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.

7.7. Draft opinion on HelixComplex Snail Mucus (HSM) as a novel food (NF 2019/1077). Applicant: *HELIXPHARMA SRL* (EFSA-Q-2019-00388)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization and toxicology. 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.

7.8. Draft opinion on Beta-galactosidase from *Aspergillus oryzae* as a novel food (NF 2019/0831). Applicant: *Takabio* (EFSA-Q-2019-00257)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

8. Any Other Business

8.1. Update on Request for a scientific opinion on whole and ground lesser mealworm (*Alphitobius diaperinus*) larvae products as a novel food (NF 2018/0125). Applicant: Proti-Farm Holding NV (EFSA-Q-2018-00282)

The WG was informed about the status of the application and discussed on data provided by the applicant in the areas of product characterisation, history of use, and toxicology.

8.2. Update on Request for a scientific opinion on polyphenols derived from lychee fruit (*Litchi chinensis*) and green tea leaves (*Camellia sinensis*) as a novel food (NF 2018/0443). Applicant: Amino Up Chemical Co., Ltd (EFSA-Q-2018-00556)

The WG was informed about the status of the application which is awaiting additional information from the applicant and discussed the reply of the applicant regarding toxicology. The WG decided to consult the EFSA WG on Genotoxicity.

8.3. Update on Water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* as a novel food (NF 2018/0801). Applicant: ABC Kroos BV (EFSA-Q-2019-00047)

The working group was informed about the status of the application, which is awaiting additional information from the applicant.

8.4. Update on Lacto-*N*-neotetraose as a novel food (NF 2019/1152). Applicant: Jennewein Biotechnologie GmbH (EFSA-Q-2019-00448)

The working group was informed about the status of the application, which is awaiting additional information from the applicant.

8.5. Expertise in the Working Group

The working group noted that, further to the resignation of two members earlier this year, new potential experts should be identified to support the activities in the areas of microbiology and chemistry.

9. Next meeting

The next meeting will be held on 20 August 2020, via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 111TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 18-19 June 2020 via web conference

(Agreed on 26 June 2020)

Participants

n Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Peláez, Morten Poulsen, Josef Rudolf Schlatter, Henk Van Loveren¹.

n Hearing Experts²:

Not Applicable

n European Commission and/or Member States representatives:

EC: Ivona Babic, Takis Daskaleros

n EFSA:

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Antonio Fernández Dumont, Eirini Kouloura, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Annamaria Rossi.

¹ Participated only first day in the morning

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Marina Heinonen did not participate in agenda point 8.2 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 Groups members

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, 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. Agreement of the minutes of the 110th Working Group meeting held on 27-28 May 2020, via web-conference.

The minutes of the 110th Working Group meeting were agreed by written procedure on 04 June 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that one novel food opinion was endorsed for public consultation at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on received novel food applications including a short introduction to recently validated applications.



8. Scientific topic(s) for discussion

8.1. Draft opinion on *Hovenia Dulcis* Fruit Extract (NF 2018/0328). Applicant: *Hovenia Dulcis AB* (EFSA-Q-2018-00279)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, toxicology and human studies. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 30th June for further discussion and possible adoption.

8.2. Draft opinion on rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. (NF 2018/0768). Applicant: *Avena Nordic Grain Oy* (EFSA-Q-2019-00213)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 30th June for further discussion and possible adoption.

8.3. Draft opinion on Beta-galactosidase from *Aspergillus oryzae* (NF 2019/0831). Applicant: *Takabio* (EFSA-Q-2019-00257)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.4. Draft opinion on Polyphenols from *Litchi chinensis* and *Camellia sinensis* (NF 2018/0443). Applicant: *Amino Up Chemical Co., Ltd* (EFSA-Q-2018-00556)

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels, anticipated daily intake, toxicology and human studies. 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.

9. Any Other Business

9.1. Update on Helix Complex Snail Mucus (HSM) (NF 2019/1077). Applicant: *HELIXPHARMA SRL* (EFSA-Q-2019-00388)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

9.2. Update on *Jatropha curcas* kernels (Chuta) (NF 2018/0177). Applicant: *Jatro Solutions GmbH* (EFSA-Q-2018-00542)

The working group was informed about the status of the application which is awaiting additional information from the applicant.



9.3. Update on whole seeds of oilseed rape (*Brassica napus* L.) (NF 2018/0590). Applicant: Erik Tybirk (EFSA-Q-2019-00033)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

9.4. EFSA calls for scientific and technical support

The WG was informed that two calls for scientific and technical support to EFSA risk assessment activities have been published on the EFSA website.

10. Next meeting

The next meeting will be held on 08-10 July 2020, via web conference.



Annex

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

With regards to this meeting, Marina Heinonen declared the following interest: for Agenda item 8.2 owing to her past research collaboration with the applicant with the latest activities being a MSc project in 2017. 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, the interest above was deemed to represent a Conflict of Interest (CoI). This results in the exclusion of the expert from any discussion, voting or other processing of item 8.2 by the concerned scientific group.

³ 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



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 110TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference on 27-28 May 2020

(Agreed on 04 June 2020)

Participants

n Working Group Members:

Francesco Cubadda¹, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Josef Rudolf Schlatter, Henk Van Loveren.

n Hearing Experts²:

Not Applicable

n European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal

n EFSA:

Nutrition Unit: Paolo Colombo, Antonio Fernández Dumont, Lucien Ferreira, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Ruth Roldán Torres, Annamaria Rossi, Roman Svejstil, Emanuela Turla.

¹ Did not participate on 27 May am

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Marina Heinonen did not participate in agenda point 9.1 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 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. 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. Agreement of the minutes of the 109th Working Group meeting held on 22 April 2020 via web-conference

The minutes of the 109th Working Group meeting were agreed by written procedure on 28 April 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that two novel food opinions were adopted at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on received novel food applications including a short introduction to recently validated applications.

³ 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



8. Scientific topics for discussion

8.1. Draft opinion on the overall dietary exposure and safety assessment of heat-treated chia seeds (*Salvia hispanica*) as a novel food (EFSA-Q-2019-00254)

The WG discussed the draft scientific opinion, and in particular assessed information on process contaminants in heat-treated chia seeds retrieved from the literature and received from a public call for data. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 11 June 2020 for further discussion and possible endorsement prior to public consultation.

8.2. Draft opinion on *Hovenia dulcis* fruit extract as a novel food (NF 2018/0328). Applicant: *Hovenia Dulcis AB* (EFSA-Q-2018-00279)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, and toxicology. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.3. Draft opinion on polyphenols derived from lychee fruit (*Litchi chinensis*) and green tea leaves (*Camellia sinensis*) as a novel food (NF 2018/0443). Applicant: *Amino Up Chemical Co., Ltd* (EFSA-Q-2018-00556)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.4. Draft opinion on 3-fucosyllactose as a novel food (NF 2019/1321). Applicant: *DuPont Nutrition & Biosciences ApS* (EFSA-Q-2019-00666)

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, product characterization, production process, toxicology and allergenicity. 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.

8.5. Draft opinion on dried *Tetraselmis chuii* microalgae as a novel food (NF 2019/1062). Applicant: *Green Sea Bio System One S.L.* (EFSA-Q-2019-00535)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process and allergenicity. 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.

9. Any Other Business

9.1. Update on rapeseed powder from *Brassica rapa* L. and *Brassica napus* L. as a novel food (NF 2018/0768). Applicant: *Avena Nordic Grain Oy* (EFSA-Q-2019-00213)



The working group was informed about the status of the application which is awaiting additional information from the applicant.

10. Next meeting

The next meeting will be held on 18-19 June 2020, via web conference.



Annex

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

With regard to this meeting, Marina Heinonen declared the following interest: for Agenda item 9.1 owing to her past research collaboration with the applicant with the latest activities being a MSc project in 2017. 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, the interest above was deemed to represent a Conflict of Interest (CoI). This results in the exclusion of the expert from any discussion, voting or other processing of item 9.1 by the concerned scientific 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



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 109TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 22 April 2020

(Agreed on 28 April 2020)

Participants

Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Henk Van Loveren.

Hearing Experts¹:

Not Applicable

European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal

EFSA:

Nutrition Unit: Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Ermolaos Ververis.

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Josef Schlatter.

The WG was informed that Karl-Heinz Engel resigned as member of the Novel foods WG.

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 108th Working Group meeting held on 02-03 April 2020, via web-conference.

The minutes of the 108th Working Group meeting were agreed by written procedure on 08 April 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that at the last plenary meeting the NDA Panel discussed the toxicological approach for the assessment of allulose dossiers.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

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



7. Scientific topic(s) for discussion

- 7.1. Draft opinion on the overall dietary exposure and safety assessment of heat-treated chia seeds (*Salvia hispanica* L.) as a novel food (EFSA-Q-2019-00254)

The WG discussed the draft scientific opinion, and in particular, assessed information on process contaminants in heat-treated chia seeds retrieved from the literature and received from a public call for data. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

- 7.2. Draft opinion on phytosterol esters (extension of use, cooking oils) as a novel food ingredient. Applicant: Upfield (EFSA-Q-2014-00865)

The WG discussed the draft scientific opinion, and in particular assessed data regarding stability data, proposed uses and use levels, anticipated daily intake and toxicology. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 5-6 May for further discussion and possible endorsement for public consultation.

- 7.3. Draft opinion on selenite triglycerides as novel food and source of selenium. Applicant: BioSEL Sp. z o.o. (EFSA-Q-2019-00343)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 5-6 May for further discussion and possible adoption.

- 7.4. Draft opinion on allulose as novel food. Applicant: Tate & Lyle Ingredients France SAS (EFSA-Q-2019-00584)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

- 7.5. Draft opinion on UV-treated mushrooms (*Agaricus bisporus*) as a novel food. Applicant: MBio, Monaghan Mushrooms (EFSA-Q-2019-00550)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, nutrition, toxicology, human studies and allergenicity. 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.

7.6. Draft opinion on mealworm (*Tenebrio Molitor*) as a novel food. Applicant: Belgium Insect Industry Federation (BiiF) ([EFSA-Q-2018-00746](#))

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, nutrition, toxicology, and allergenicity. 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.

8. Any Other Business

8.1. Powder of chitosan as a novel food ([EFSA-Q-2019-00324](#))

The WG was informed about the status of the application.

8.2. Lesser mealworm (*Alphitobius diaperinus*) larvae products ([EFSA-Q-2018-00282](#))

The WG was informed about the status of the application.

9. Next meeting

The next meeting will be held on 27-28 May 2020, via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 108TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 01-03 April 2020, as a web-conference

(Agreed on 08 April 2020)

Participants

Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Josef Rudolf Schlatter, Henk Van Loveren¹.

Hearing Experts²:

Not Applicable

European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros , Rafael Luis Perez Berbejal.

EFSA:

Nutrition Unit: Reinhard Ackerl, Domenico Azzollini, Paolo Colombo, Agnès De Sesmaisons Lecarré, Céline Dumas, Antonio Fernández Dumont, Lucien Ferreira, Leng Heng, Eirini Kouloura, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Remigio Marano, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Roman Svejstil, Emanuela Turla, Ermolaos Ververis.

¹ Participated on day 2 and 3

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl-Heinz Engel.

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 on Competing Interest Management⁴, 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.

4. Agreement of the minutes of the 107th Working Group meeting held on 03-05 March 2020, via web-conference

The minutes of the 107th Working Group meeting were agreed by written procedure on 10 March 2020.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that four novel food opinions were adopted at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the current and new novel food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on received novel food applications including a short introduction to recently validated applications.

³ 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



8. Scientific topic(s) for discussion

8.1. Draft opinion on Schizochytrium sp. (DHA rich) oil as a novel food (NF 2019/0983). *Applicant: Progress Biotech BV (EFSA-Q-2019-00306)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization and production process. 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.

8.2. Draft opinion on phytosterol esters (extension of use, cooking oils) as a novel food ingredient. *Applicant: Upfield (EFSA-Q-2014-00865)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding stability, anticipated daily intake and toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.3. Draft opinion on Ashitaba sap. powder as a novel food (NF 2019/1247). *Applicant: Japan Bio Science Laboratory (JBSL) – USA, Inc. (EFSA-Q-2019-00536)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology. 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.

8.4. Draft opinion on selenite triglycerides used as a novel food ingredient and as a source of selenium in the manufacture of food supplements. *Applicant: BioSEL Sp. Z o.o (EFSA-Q-2015-00343)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, absorption, distribution, metabolism and excretion, and toxicology. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.5. Draft opinion on whole and ground mealworms (*Tenebrio molitor*) larvae as a novel food (NF 2018/0802). *Applicant: Fair Insects BV (A Protix Company) (EFSA-Q-2019-00101)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, specifications, nutrition, and toxicology, human studies and allergenicity. 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.

8.6. Draft opinion on Isomaltulose syrup (dried) as a novel food (NF 2018/0330). *Applicant: Evonik Creavis GmbH (EFSA-Q-2018-00609)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization and production process. 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.



9. Any Other Business

9.1. Draft opinion on whole seeds of oilseed rape (*Brassica napus* L.) as a novel food (NF 2018/0590). *Applicant: Erik Tybirk (EFSA-Q-2019-00033)*

The WG discussed the status of the application.

10. Next meeting

The next meeting will be held on 22 April 2020, via web-conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 107th MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 3-5 March 2020, via web conference¹

(Agreed on 10 March 2020)

Participants

Working Group Members:

Francesco Cubadda, Thomas Frenzel², Marina Heinonen³, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Josef Rudolf Schlatter, Henk Van Loveren.

Hearing Experts⁴:

Not Applicable

European Commission and/or Member States representatives:

EC (DG Sante): Rafael Luis Perez Berbejal, Takis Daskaleros, Ivona Babic

EFSA

Nutrition Unit: Reinhard Ackerl, Domenico Azzollini, Paolo Colombo, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Annamaria Rossi, Ermolaos Ververis.

¹ 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.

² Participated on day 1 pm and on day 2 and 3

³ Participated on day 1 and 2

⁴ 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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl-Heinz Engel.

Marina Heinonen did not participate in agenda point 7.9 due to a conflict of interest being identified for this agenda item.

2. Adoption of agenda

The agenda was adopted with changes, namely the exclusion of the agenda item related to phytosterol esters.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management,⁶ 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.

4. Agreement of the minutes of the 106th Working Group meeting held on 05 February 2020 via web conference

The **minutes of the 106th Working Group meeting** were agreed by written procedure on 11 February 2020.

5. Feedback from the NDA plenary meeting

The WG was informed that no novel food opinions were discussed at the last NDA plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the new Novel Food applications received.

7. Scientific topics for discussion

7.1. Draft opinion on 6' Sialyllactose (6'-SL) as a novel food (NF 2019/0881) - Applicant: Glycom A/S (EFSA-Q-2019-00169)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use

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



levels, anticipated daily intake, toxicology, and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting 23-25 March 2020 for further discussion and possible adoption.

7.2. Draft opinion on 3'-sialyllactose sodium salt (3'-SL) as a novel food (NF 2019/0957) - Applicant: Glycom A/S (EFSA-Q-2019-00204)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting 23-25 March 2020 for further discussion and possible adoption.

7.3. Draft opinion on an extract derived from Panax notoginseng and Astragalus membranaceus (AstraGin®) as a novel food (NF 2018/0284) - Applicant: NuLiv Science (EFSA-Q-2018-00557)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, proposed uses and use levels, toxicology and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 23-25 March 2020 for discussion and possible adoption.

7.4. Draft opinion on Helix Complex Snail Mucus (HSM) as a novel food (NF 2019/1077) - Applicant: HELIXPHARMA SRL (EFSA-Q-2019-00388)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, ADME, nutritional information, toxicology and allergenicity. 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.

7.5. Draft opinion on dried whole cell Euglena as a novel food (NF 2018/0669) - Applicant: Kemin Foods L.C. (EFSA-Q-2019-00043)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 23-25 March 2020 for discussion and possible adoption.

7.6. Draft opinion on Whole and ground Grasshoppers (*Locusta migratoria*) as a novel food (NF 2018/0803) - Applicant: Fair Insects BV (EFSA-Q-2019-00115)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, identity of the novel food, production process, proposed uses and use levels, anticipated daily intake, toxicology, specifications. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion. 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.



7.7. Draft opinion on Whole and ground crickets (*Acheta domesticus*) as a novel food (NF 2018/0804) - Applicant: Fair Insects BV (EFSA-Q-2019-00121)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process and proposed uses and use levels. 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.

7.8. Discussion on allulose dossiers

The WG discussed the strategy for toxicological assessment of allulose dossiers.

7.9. Draft opinion on Rapeseed powder from Brassica rapa L. and Brassica napus L as a novel food (NF 2018/0768) - Applicant: Avena Nordic Grain Oy (EFSA-Q-2019-00213)

The WG discussed the draft scientific opinion, and in particular assessed data regarding production process, stability of the product, proposed uses and use levels, and anticipated daily intake. 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.

8. Any Other Business

8.1. Draft opinion on EPA rich oil from Phaeodactylum tricornutum as a novel food (NF 2018/0207) - Applicant: Simris Alg AB (EFSA-Q-2018-00105)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

8.2. Draft opinion on whole and grinded lesser mealworm (*Alphitobius diaperinus*) larvae products as a novel food (NF 2018/0125) - Applicant: Proti-Farm Holding NV (EFSA-Q-2018-00282)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

8.3. Draft opinion on Dried Tetraselmis chuii microalgae as a novel food (NF 2019/1062) - Applicant: Green Sea Bio System One S.L. (EFSA-Q-2019-00535)

The working group was informed about the status of the application.

9. Next meeting

The next meeting will be held on 1-3 April 2020 via web conference.



Annex

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

With regard to this meeting, Morten Poulsen declared the following interest: for agenda item 7.7 he is part of an EFSA financed research project, where the aim is to investigate the risk-benefit balance of substituting meat with insects (crickets). 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, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

With regard to this meeting, Karen-Ildico Hirsch-Ernst declared the following interest: for agenda item 7.8 she contributed to a BfR statement that addressed the question whether use of allulose as a sugar substitute may pose a risk with respect to supporting growth of potentially pathogenic bacterial strains that are able to utilize allulose. 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, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

With regard to this meeting, Marina Heinonen declared the following interest: for Agenda item 7.9 owing to her past research collaboration with the applicant with the latest activities being a MSc project in 2017. 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, the interest above was deemed to represent a Conflict of Interest (CoI). This results in the exclusion of the expert from any discussion, voting or other processing of item 7.9 by the concerned scientific group.

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 106th MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 5 February 2020, via web conference

(Agreed on 11 February 2020)

Participants

n Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Josef Rudolf Schlatter.

n Hearing Experts¹:

Not Applicable

n European Commission and/or Member States representatives:

EC (DG Sante): Ivona Babic, Takis Daskaleros.

n EFSA

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Antonio Fernández Dumont, Lucien Ferreira, Eirini Kouloura, Andrea Germini, Annamaria Rossi, Emanuela Turla.

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl-Heinz Engel 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 the Decision of the Executive Director on Competing Interest Management, 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.

4. Agreement of the minutes of the 105th Working Group meeting held on 08-09 January 2020

The **minutes of the 105th Working Group meeting** were agreed by written procedure on 15 January 2020.

5. Feedback from the NDA plenary meeting

The WG was informed that one novel food opinion was adopted at the last NDA plenary meeting.

6. Scientific topics for discussion

- 6.1. Draft opinion on an extract derived from *Panax notoginseng* and *Astragalus membranaceus* (AstraGin®) as a novel food (NF 2018/0284)
Applicant: NuLiv Science (EFSA-Q-2018-00557)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, specifications, proposed uses and use levels, anticipated daily intake, nutritional information and toxicology. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

- 6.2. Draft opinion on 6' Sialyllactose (6'-SL) as a novel food. (NF 2019/0881)
Applicant: Glycom A/S (EFSA-Q-2019-00169)

The WG was informed about the current status of the application. The draft opinion will be presented at the next WG NF meeting for further discussion.



**6.3. Draft opinion on Lacto-*N*-neotetraose as a novel food. (NF 2019/1152)
*Applicant: Jennewein Biotechnologie GmbH (EFSA-Q-2019-00448)***

The working group was informed about the status of the application.

6.4. Draft opinion on Leaf Protein Isolate from *Cichorium endivia* as a novel food (NF 2019/1073) *Applicant: Siuker Unie (EFSA-Q-2019-00335)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels. 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.

**6.5. Draft opinion on Ashitaba sap powder as a novel food (NF 2019/1247)
*Applicant: Japan Bio Science Laboratory (JBSL)-USA, Incorporated (EFSA-Q-2019-00536)***

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

7. Next meeting

The next meeting will be held on 3-5 March 2020 in Parma.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 105th MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 8-9 January 2020, in Parma

(Agreed on 15 January 2020)

Participants

n Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen¹, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren.

n Hearing Experts²:

Not Applicable

n European Commission and/or Member States representatives:

EC (DG Sante): Rafael Perez-Berbejal.

n EFSA

Nutrition Unit: Reinhard Ackerl, Domenico Azzollini, Paolo Colombo, Céline Dumas, Antonio Fernández Dumont, Lucien Ferreira, Eirini Kouloura, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Annamaria Rossi.

¹ Participated on day 2 via web conference

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl-Heinz Engel.

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, 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 Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

4. Agreement of the minutes of the 104th Working Group meeting held on 10-11 December 2019

The **minutes of the 104th Working Group meeting** were agreed by written procedure on 19 December 2019.

5. Feedback from the NDA plenary meeting

The WG was informed that two novel food opinions were adopted at the last NDA plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the number of new Novel Food applications received.

7. Scientific topics for discussion

7.1. Draft opinion on *Yarrowia lipolytica* (chromium-enriched biomass) as a novel food. *Applicant: SKOTAN S.A (EFSA-Q-2018-00769)*

The WG discussed the draft scientific opinion, and, in particular, assessed data regarding composition, toxicology, exposure and risk characterisation. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 22-23 January for further discussion and possible adoption.



7.2. Draft opinion on β -Hydroxybutyrate salts (Sodium/Magnesium/Calcium) as a novel food. Applicant: Pruvit Ventures Inc. (EFSA-Q-2018-00343)

The WG discussed the applicant's replies following an EFSA request for additional data, and in particular assessed the data regarding toxicology, metabolism and human studies. 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.

7.3. Draft opinion on Beta-galactosidase from *Aspergillus oryzae* as a novel food. Applicant: Takabio (EFSA-Q-2019-00257)

The WG discussed data regarding characterisation of the production strain. The discussion will be continued at the future WG NF meetings.

7.4. Draft opinion on DHA oil from *Schizochytrium* as a novel food. Applicant: Bioplus life Science (EFSA-Q-2019-00548)

The WG discussed data regarding identity of the novel food, production process, compositional data, specifications and uses and use levels. 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.

8. Any Other Business

8.1. The WG was informed that Yolanda Sanz resigned as member of the WG on 16 December 2019.

8.2. The WG was informed on the toxicity studies submitted for the applications on allulose as a novel food currently under EFSA risk assessment.

8.3. Draft opinion on 6' Sialyllactose (6'-SL) as a novel food. Applicant: Glycom A/S (EFSA-Q-2019-00169)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

8.4. Draft opinion on 3' Sialyllactose sodium salt (3'-SL) as a novel food. Applicant: Glycom A/S (EFSA-Q-2019-00204)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

8.5. Draft opinion on Inulin-propionate ester as a novel food. Applicant: Imperial College Hammersmith Campus (EFSA-Q-2018-00225)

The WG was informed about the current status of the application which is awaiting additional information from the applicant.

8.6. Draft opinion on Menaquinone-7 dipropionate as a novel food. Applicant: Kappa Bioscience AS (EFSA-Q-2018-00725)

The WG was informed of about the status of the application which is awaiting additional information from the applicant.



8.7. Draft opinion on Polyphenols derived from lychee fruit (*Litchi chinensis*) and green tea leaves (*Camellia sinensis*) as a novel food. Applicant: Amino Up Chemical Co., Ltd (EFSA-Q-2018-00556)

The WG was informed of the status of the dossier and the sections under elaboration, including toxicology and compositional data.

8.8. Draft opinion on Water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* as a novel food. Applicant: ABC Kroos BV (EFSA-Q-2019-00047)

The WG was informed of the additional data provided by the applicant on the nutritional section.

8.9. Draft opinion on Whole and ground Grasshoppers (*Locusta migratoria*) as a novel food. Applicant: Fair Insects BV (A Protix Company) (EFSA-Q-2019-00115)

The WG was informed of the status of the dossier and the section under elaboration, including the nature of the novel food, compositional data and specifications.

9. Next meeting

The next meeting will be held on 5 February 2020 via web conference.



Annex

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

With regard to this meeting, Karen-Ildico Hirsch-Ernst declared the following interest related to agenda item 8.2: She contributed to a BfR statement that addressed the question whether use of allulose as a sugar substitute may pose a risk with respect to supporting growth of potentially pathogenic bacterial strains that are able to utilize allulose. 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, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

³ 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



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 104th MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 10-11 December 2019, via web conference

(Agreed on 19 December 2019)

Participants

Working Group Members:

Francesco Cubadda¹, Thomas Frenzel, Marina Heinonen², Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle³, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren³.

Hearing Experts⁴:

Not Applicable

European Commission and/or Member States representatives:

EC (DG Sante): Ivona Babic, , Panagiotis Daskaleros, Rafael Perez-Berbejal.

EFSA

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Lucien Ferreira, Wolfgang Gelbmann, Andrea Germini, Ruth Roland Torres, Annamaria Rossi, Hans Steinkellner, Emanuela Turla, Ermolaos Ververis, Domenico Azzollini.

¹ Participated on day 1 and day 2 until 13:00

² Participated on day 1

³ Participated on day 2

⁴ 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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl-Heinz Engel.

Marina Heinonen did not participate in agenda item 7.2 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 Groups members

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, 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 Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

4. Agreement of the minutes of the 103rd Working Group meeting held on 06-08 November 2019

The **minutes of the 103rd Working Group meeting** were agreed by written procedure on 13 November 2019.

5. Feedback from the NDA plenary meeting

The WG was informed that two novel food opinions were adopted at the last NDA plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the number of new Novel Food applications received.

7. Scientific topics for discussion

7.1. Draft opinion on Astaxanthin. *Requestor: European Commission* (EFSA-Q-2018-00247)

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology, exposure and risk characterisation. After amendments, the draft opinion will be



presented at the next NDA plenary meeting on 18 December for further discussion and possible adoption.

7.2. Draft opinion on Rapeseed powder from *Brassica rapa* L. and *Brassica napus* L as a novel food. *Applicant: Avena Nordic Grain Oy* (EFSA-Q-2019-00213)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, human studies and allergenicity. 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.

7.3. Draft opinion on 3' Sialyllactose sodium salt (3'-SL). *Applicant: Glycom A/S* (EFSA-Q-2019-00204)

The WG discussed the applicant's replies following an EFSA request for additional data, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology. The WG considered that additional clarification is needed from the applicant in order to proceed with the scientific assessment of this application. Therefore, a request for clarification will be sent to the applicant.

7.4. Draft opinion on 6' Sialyllactose (6'-SL). *Applicant: Glycom A/S* (EFSA-Q-2019-00169)

The WG discussed the applicant's replies following an EFSA request for additional data, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology. The WG considered that additional clarification is needed from the applicant in order to proceed with the scientific assessment of this application. Therefore, a request for clarification will be sent to the applicant.

7.5. Draft opinion on *Yarrowia lipolytica* (selenium enriched biomass). *Applicant: SKOTAN S.A* (EFSA-Q-2018-00796)

The WG revised the draft scientific opinion following the feedback from the NDA Panel plenary meeting. The revised draft will be presented at the next NDA plenary on 18 December for further discussion and possible adoption.

7.6. Draft opinion on 7-hydroxymatairesinol potassium acetate complex. *Applicant: Linnea SA* (EFSA-Q-2019-00147)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, human studies and allergenicity. 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.

7.7. Draft opinion on mineral salt consisting of potassium and magnesium. *Applicant: BK Guilini GmbH* (EFSA-Q-2019-00230)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicological studies, human studies and allergenicity. 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.

7.8. Draft opinion on Calcium Fructoborate. Applicant: VDF FutureCeuticals, Inc. (EFSA-Q-2019-00240)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicological studies, human studies and allergenicity. 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.

7.9. Draft opinion on DHA-rich oil from *Schizochytrium* sp. Applicant: Fermentalg (EFSA-Q-2019-00323)

The WG discussed the draft scientific opinion, and in particular assessed data regarding the proposed uses and use levels, anticipated daily intake and human studies. 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.

7.10. Draft opinion on Citicoline mono-sodium salt. Applicant: Interquim S.A. (EFSA-Q-2019-00368)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, human studies and allergenicity. 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.

8. Any Other Business

8.1. Update on the LEAN process in the EFSA Novel Food Team

The working group was informed of the re-organization of the working procedures of the EFSA Novel Foods team

9. Next meeting

The next meeting will be held on 08-09 January 2020 in Parma.



Annex

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

With regard to this meeting, Marina Heinonen declared the following interest: for Agenda item 7.2 owing to her past research collaboration with the applicant with the latest activities being a MSc project in 2017. 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, the interest above was deemed to represent a Conflict of Interest (CoI).

This results in the exclusion of the expert from any discussion, voting or other processing of item 7.2 by the concerned scientific 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



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 103rd MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 06-08 November 2019, Parma

(Agreed on 13 November 2019)

Participants

n Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen¹, Karen-Ildico Hirsch-Ernst, Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle (chair), Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen¹, Josef Rudolf Schlatter, Henk Van Loveren.

n Hearing Experts²:

Not Applicable

n European Commission and/or Member States representatives:

EC: Ivona Babic

n EFSA

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Agnès De Sesmaisons Lecarré, Céline Dumas, Lucien Ferreira, Eirini Kouloura, Wolfgang Gelbmann, Andrea Germini, Annamaria Rossi, Hans Steinkellner, Emanuela Turla, Ermolaos Ververis.

¹ Participated on day 2 and 3

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>



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl-Heinz Engel, Helle Katrine Knutsen and 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 Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, 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.

4. Agreement of the minutes of the 102nd Working Group meeting held on 15-16 and 24 October 2019.

The **minutes of the 102nd Working Group meeting** were agreed by written procedure on 30 October 2019.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that one novel food opinion was adopted at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the number of new Novel Food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on received Novel Food applications including a short introduction to recently validated applications.

³ 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



8. Scientific topics for discussion

8.1. Draft opinion on Selenium-enriched biomass of *Yarrowia lipolytica*. *Applicant: SKOTAN S.A. (EFSA-Q-2018-00796)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, proposed uses and use levels and anticipated daily intake. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27-29 November for further discussion and possible adoption.

8.2. Draft opinion on Dried whole cell *Euglena*. *Applicant: Kemin Foods L.C. (EFSA-Q-2018-00043)*

The WG discussed the applicant's replies following an EFSA request for additional data, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.3. Draft opinion on *Schizochytrium* sp. Oil. *Applicant: Nutraveris on behalf of Fermentalg (EFSA-Q-2019-00187)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding the identity of the producer organism, product characterization, production process, proposed uses and use levels and anticipated daily intake. 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.

8.4. Draft opinion on *Schizochytrium* sp. (DHA-rich) oil. *Applicant: Progress Biotech BV (EFSA-Q-2019-00306)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding the identity of the producer organism, product characterization, production process, proposed uses and use levels and anticipated daily intake. 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.

8.5. Draft opinion on *Calcium-L-methylfolate*. *Applicant: DSM Nutritional Products (EFSA-Q-2018-00816)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27-29 November for further discussion and possible adoption.

8.6. Draft opinion on Water lentil powder from *Lemnaceae*. *Applicant: Parabel Ltd (EFSA-Q-2018-00995)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, and allergenicity. 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.



**8.7. Draft opinion on extract of the microalgae *Phaeodactylum tricornutum*.
Applicant: Microphyt (EFSA-Q-2019-00091)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity of the novel food, product characterization, production process, history of use, proposed uses and use levels, anticipated daily intake, toxicology, and allergenicity. 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.

9. Any Other Business

9.1. Draft opinion on Lesser mealworm larvae products. Applicant: Proti-Farm Holding NV (EFSA-Q-2018-00282)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

9.2. Draft opinion on Dried mealworm (T. Molitor). Applicant: SAS EAP Group - Micronutris (EFSA-Q-2018-00262)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

9.3. Draft opinion on Astaxanthin (EFSA-Q-2018-00247)

The working group was informed about the status of the application.

9.4. Draft opinion on Hovenia Dulcis Fruit Extract. Applicant: Hovenia Dulcis AB (EFSA-Q-2018-00279)

The working group was informed about the status of the application.

10. Next meeting

The next meeting will be held on 10-12 December 2019, via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 102ND MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 15-16-24 October 2019,

web-conference

(Agreed on 30 October 2019)

Participants

Working Group Members:

Francesco Cubadda, Karl-Heinz Engel¹, Thomas Frenzel², Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle¹, Monika Neuhäuser-Berthold³, Carmen Pelaez, Morten Poulsen, Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren⁴.

Hearing Experts⁵:

Not Applicable

European Commission and/or Member States representatives:

EC: Ivona Babic, Daskaleros Panagotis, Rafael Perez-Berbejal.

EFSA:

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Antonio Fernandez Dumont, Lucien Ferreira, Wolfgang Gelbmann, Andrea Germini, Ruth Roldán Torres, Annamaria Rossi, Hans Steinkellner.

¹ Participated the third day

² Participated the second and third day

³ Participated the first and third day

⁴ Participated the first and second day

⁵ 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>



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 with changes. These included the removal from the agenda of the discussion on lesser mealworm (EFSA-Q-2018-00282) and the inclusion of an update on bacterial cellulose (EFSA-Q-2018-00294).

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁶ and the Decision of the Executive Director on Competing Interest Management⁷, 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.

4. Agreement of the minutes of the 101st Working Group meeting held on 03-05 September 2019.

The minutes of the 101st Working Group meeting were agreed by written procedure on 11 September 2019.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that one novel food opinion was adopted at the last NDA Panel plenary meeting.

6. Scientific topics for discussion

6.1. Draft opinion on Vitamin D2 mushroom (EFSA-Q-2018-00601) Applicant: Oakshire Naturals, LP Oakshire

The WG discussed the draft scientific opinion, and in particular assessed the information received from the applicant and the sections on product characterization, proposed uses and use levels, anticipated daily intake and toxicology. The WG considered that additional information is needed from the applicant in order to proceed with the scientific assessment

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

⁷ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



of this application. Therefore, a request for additional information will be sent to the applicant. After amendments, the draft opinion will be presented at the next NF WG meeting for further discussion and finalisation.

6.2. Draft opinion on Lacto-N-tetraose (EFSA-Q-2018-00589) Applicant: Glycom A/S

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, ADME, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 30 October for further discussion and possible adoption.

6.3. Draft opinion on Chromium-enriched biomass of *Yarrowia lipolytica* (EFSA-Q-2018-00769) Applicant: SKOTAN S.A

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels. 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.

6.4. Draft opinion on Selenium-enriched biomass of *Yarrowia lipolytica* (EFSA-Q-2018-00796) Applicant: SKOTAN S.A

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels. After amendments, the draft opinion will be presented at the next NF WG meeting for further discussion.

6.5. Draft opinion on Astragin (EFSA-Q-2018-00557) Applicant: NuLiv Science

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels and toxicology. 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.

6.6. Draft opinion on Whole seeds of oilseed rape (EFSA-Q-2019-00033) Applicant: Erik Tybirk

The WG discussed the mandate received and the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.



6.7. Draft opinion on Calcdiol (EFSA-Q-2018-00514) Applicant: DSM Nutritional Products Ltd.

The WG discussed the draft scientific opinion in particular the replies received after the request for additional information regarding production process, proposed uses and use levels and toxicological information. 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.

6.8. Draft opinion on *Schizochytrium* sp. oil (EFSA-Q-2019-00187) Applicant: Nutraveris on behalf of Fermentalg

The WG discussed the draft scientific opinion, and in particular considered data regarding the source of the NF (strain FCC-3204), product characterization, production process and possible extrapolation of toxicological data performed on different strains belonging to the same genus of *Schizochytrium*. 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.

6.9. Draft opinion on *Schizochytrium* sp. (DHA-rich) oil (EFSA-Q-2019-00306) Applicant: Progress Biotech BV

The draft opinion could not be discussed due to time constraints.

7. Any Other Business

7.1. The WG was informed of the resignation of Annette Pöting

7.2. Update on Bacterial cellulose (EFSA-Q-2018-00294)

The WG was informed of the status of the consultations with the SC WG on Nanoscience.

8. Next meeting

The next meeting will be held on 6-8 November 2019 in Parma.

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 101ST MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 03-05 September 2019, Parma

(Agreed on 11 September 2019)

Participants

Working Group Members:

Francesco Cubadda, Thomas Frenzel¹, Marina Heinonen², Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Rosangela Marchelli, Harry J McArdle³, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen⁴, Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren⁵.

Hearing Experts⁶:

Not Applicable

European Commission and/or Member States representatives:

EC: Takis Daskaleros

EFSA:

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Lucien Ferreira, Eirini Kouloura, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Patricia Romero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

¹ Participated via web conference

² Participated physically on the first and second day and via web conference on the third day

³ Participated via web conference only the second and third day

⁴ Participated only the second and third day

⁵ Participated via web conference for agenda item 7.1

⁶ 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>.



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl-Heinz Engel and Inge Mangelsdorf.

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 Independence⁷ and the Decision of the Executive Director on Competing Interest Management⁸, 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.

4. Agreement of the minutes of the 100th Working Group meeting held on 9-10 July 2019, Parma

The minutes of the 100th Working Group meeting were agreed by written procedure on 16 July 2019.

5. Feedback from the European Commission

The EC provided an update on the number of new Novel Food applications received.

6. Update on applications, new mandates

The EFSA staff provided a brief update on received Novel Food applications.

7. Scientific topic(s) for discussion

7.1. Draft opinion on Lesser mealworm. Applicant: Proti-Farm Holding FV (EFSA-Q-2018-0282)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, specifications, history of use of novel food and its source, and proposed uses, use levels, and anticipated daily intake. 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.

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

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



7.2. Draft opinion on *Mycobacterium manresensis*. Applicant: Laboratorio Reig Jofre, S.A. (EFSA-Q-2018-00278)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization. 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.

7.3. Draft opinion on Lacto-N-Tetraose. Applicant: Glycom A/S (EFSA-Q-2018-00589)

The WG discussed the additional information sent by the applicant in response to a request by EFSA. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

7.4. Draft opinion on 6'-sialyllactose (6'-SL). Applicant: Glycom A/S (EFSA-Q-2019-00169)

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.

7.5. Draft opinion on 3'-sialyllactose (3'-SL). Applicant: Glycom A/S (EFSA-Q-2019-00204)

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.

7.6. Draft opinion on Water lentil protein concentrate. Applicant: ABC Kroos BV (EFSA-Q-2019-00047)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, human studies and allergenicity. 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.

7.7. Draft opinion on Dried fruits of *Synsepalum dulcificum*. Applicant: Baía Food Co. (Medicinal Gardens S.L.) (EFSA-Q-2018-01032)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterisation, production process, proposed uses, toxicology, human studies and allergenicity. 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.



7.8. Draft opinion on Allulose. Applicant: Petiva Europe SA (EFSA-Q-2018-00756)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

7.9. Draft opinion on polyphenols derived from lychee fruit (Litchi chinensis) and green tea leaves (Camellia sinensis). Applicant: Amino Up Chemical Co., Ltd (EFSA-Q-2018-00556)

The WG discussed the additional information sent by the applicant in response to a request by EFSA and in particular assessed data regarding toxicology. 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.

8. Any Other Business

8.1. Draft opinion on Eurycoma longifolia. Applicant: Biotropics Malaysia Berhad (EFSA-Q-2018-00106)

The WG was informed that the answer to the request for additional information was received.

9. Next meeting

The next meeting will be held on 15-16 October 2019 via web conference.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 100TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 9-10 July 2019, Parma

(Agreed on 16 July 2019)

Participants

Working Group Members:

Francesco Cubadda¹, Karl-Heinz Engel, Thomas Frenzel, Marina Heinonen², Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen², Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren.

Hearing Experts³:

Not Applicable

European Commission and/or Member States representatives:

EC: Rafael Luis Perez Berbejal

EFSA:

Nutrition Unit: Reinhard Ackerl, Giovanni Bernasconi, Paolo Colombo, Aikaterini Doulgeridou, Antonio Fernandez Dumont, Lucien Ferreira, Eirini Kouloura, Wolfgang Gelbmann, Andrea Germini, Ruth Roldán Torres, Annamaria Rossi, Hans Steinkellner, Ermolaos Ververis.

¹ Participated via web conference

² Participated via web conference only the first day

³ 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>.



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karen Ildico Hirsch-Ernst 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 Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, 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.

4. Agreement of the minutes of the 99th Working Group meeting held on 19, 20 and 25 June 2019, web-conference.

The **minutes of the 99th Working Group meeting** were agreed by written procedure on 28 June 2019.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that two novel food opinions were adopted at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the number of new Novel Food applications and Traditional foods notification received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on received Novel Food applications including a short introduction to recently validated applications.

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



8. Scientific topic(s) for discussion

8.1. Draft opinion on EPA rich oil from *Phaeodactylum tricornutum* Applicant Simris Alg AB (EFSA-Q-2018-00105)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, specifications, and toxicology. 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.

8.2. Draft opinion on edible *Jatropha curcas* L. kernels (Chuta) Applicant JatroSolutions GmbH (EFSA-Q-2018-00542)

The WG discussed the draft scientific opinion, and the response received from the applicant to a request of EFSA for additional data, and in particular assessed data regarding product characterization, production process, compositional data, proposed uses and use levels, toxicology and allergenicity. 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.

8.3. Draft opinion on Water Lentil powder Applicant Parabel Ltd. (EFSA-Q-2018-00995)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, toxicology and allergenicity. 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.

8.4. Draft opinion on Allulose Applicant CJ-Tereos Sweeteners Europe SAS (EFSA-Q-2018-00472)

The WG discussed the draft scientific opinion and the response received from the applicant to a request of EFSA for additional data, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, toxicology and human studies. 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.

8.5. Draft opinion on Whole cell *Euglena* Applicant Kemin Foods L.C (EFSA-Q-2019-00043)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology and allergenicity. 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.



8.6. Draft opinion on Calcium-L-methylfolate Applicant DSM Nutritional Products (EFSA-Q-2018-00816)

The WG discussed the draft scientific opinion and the draft letter requesting additional information and assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake. 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.

9. Any Other Business

9.1. Role of proprietary data in the safety assessment of applications

The working group and the EC representative discussed the handling of confidentiality and data protection for studies submitted for the safety assessment of novel foods.

9.2. Draft opinion on dried crickets Applicant SAS EAP Group – Micronutris (EFSA-Q-2018-00263)

The working group was informed about the status of the application which is awaiting additional information from the applicant.

10. Next meeting

The next meeting will be held on 3-5 September 2019, Parma.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 99TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Web-conference, 19, 20 and 25 June 2019

(Agreed on 28 June 2019)

Participants

Working Group Members:

Francesco Cubadda¹, Karl-Heinz Engel², Thomas Frenzel, Marina³ Heinonen, Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen⁴, Annette Pöting⁵, Josef Rudolf Schlatter⁶, Henk Van Loveren⁷

Hearing Experts:

Not Applicable

European Commission and/or Member States representatives:

Not Applicable

EFSA:

Nutrition Unit: Mathias Amundsen, Giovanni Bernasconi, Paolo Colombo, Agnès De Sesmaisons Lecarré, Aikaterini Doulgeridou, Céline Dumas, Antonio Fernandez Dumont, Lucien Ferreira, Wolfgang Gelbmann, Andrea Germini, Annamaria Rossi, Goumperis Tilemachos, Ermolaos Ververis

¹ Second day only am, last day only pm

² First day only am

³ Apologies the last day

⁴ First day only am; last day only am

⁵ Participated partially only the second day

⁶ Not present on the last day

⁷ First day only pm



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 Independence⁸ and the Decision of the Executive Director on Competing Interest Management⁹, 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 Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

4. Agreement of the minutes of the 98th Working Group meeting held on 21-23 May 2019, Parma.

The minutes of the 98th Working Group meeting were agreed by written procedure on 29 May 2019.

5. Scientific topics for discussion

5.1. Draft opinion on Nicotinamide Riboside Chloride Applicant ChromaDex, Inc. (EFSA-Q-2018-00480)

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 3-5 July for further discussion and possible adoption.

5.2. Draft opinion on Isomaltulose syrup Applicant Evonik Creavis GmbH (EFSA-Q-2018-00609)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology. 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.

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



5.3. Draft opinion on Embryonated eggs whipworm Applicant Enteron Science GmbH (EFSA-Q-2018-00596)

The WG discussed the draft scientific opinion and the response received from the applicant to a request of EFSA for additional data, and in particular intended uses and use levels, animal and human data. After amendments, the draft opinion will be presented at the next NDA plenary meeting on day month for further discussion and possible adoption.

5.4. Draft opinion on β -Hydroxybutyrate salts (Sodium/Magnesium/Calcium) Applicant Pruvit Ventures Inc. (EFSA-Q-2018-00343)

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels, toxicology and human studies. 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.

5.5. Draft opinion on Allulose Applicant Samyang's Corp. (EFSA-Q-2018-00797)

The WG discussed the draft scientific opinion, and in particular assessed product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. 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.

5.6. Draft opinion on Dried mealworm Applicant SAS EAP Group - MICRONUTRIS (EFSA-Q-2018-00262)

The WG discussed the draft scientific opinion, and in particular assessed data regarding production process, compositional data, specifications, history of use, proposed uses, use levels and anticipated intake, nutritional information, and allergenicity. 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.

5.7. Draft opinion on Bacterial cellulose aqueous suspension Applicant Satisfibre, S.A. (EFSA-Q-2018-00294)

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.

5.8. Draft opinion on Calcium-L-methylfolate Applicant DSM Nutritional Products (EFSA-Q-2018-00816)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, and human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.



5.9. Draft opinion on Draft opinion on phytosterols for cooking Applicant Upfield (EFSA-Q-2014-00865)

The WG discussed the additional information sent by the applicant in response to a request by EFSA, in particular data on exposure and toxicology. After amendments, the draft opinion will be presented at a next WG NF meeting for further discussion.

6. Any Other Business

6.1. Allulose Applicant CJ Tereos (EFSA-Q-2018-00472)

The WG was informed about the status of the application which is awaiting additional information from the applicant.

7. Next meeting

The next meeting will be held on 9-10 July 2019, in Parma.



Annex

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

CONFLICT OF INTEREST:

With regard to this meeting, Prof. Karl-Heinz Engel had declared (ahead of the meeting) the following interest on agenda item 5.9 (phytosterols for cooking): the expert took note of four publications submitted by the applicant on oxidative stability and in vitro digestion of phytosterol esters, of which he is a co-author. In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management 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 these publications.



NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 98TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 21-23 May 2019, Parma

(Agreed on 29 May 2019)

Participants

Working Group Members:

Francesco Cubadda, Thomas Frenzel¹, Marina Heinonen, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle², Monika Neuhäuser-Berthold³, Carmen Pelaez, Morten Poulsen, Annette Pötting⁴, Yolanda Sanz², Josef Rudolf Schlatter, Henk Van Loveren⁵

Hearing Experts⁶:

Not Applicable

European Commission and/or Member States representatives:

EC: Rafael Luis Perez Berbejal

EFSA:

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Agnès De Sesmaisons Lecarré, Celine Dumas, Antonio Fernandez Dumont, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Ruth Roldán Torres, Hans Steinkellner, Qingqing Sun, Emanuela Turla, Ermolaos Ververis.

Others:

Not applicable

¹ Participated on day 1 and 2

² Participated via web conference on day 1 and 2

³ Participated via web conference on day 1 and physically on day 2 and 3

⁴ Participated on day 2 and 3

⁵ Participated via web conference on day 1 and physically on day 2

⁶ As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the 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>.



1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl-Heinz Engel.

2. Adoption of agenda

The agenda was adopted with the addition of the draft opinion on *Hovenia Dulcis*.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁷ and the Decision of the Executive Director on Competing Interest Management⁸, 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.

4. Agreement of the minutes of the 97th Working Group meeting held on 30 April 2019, web-conference.

The minutes of the 97th Working Group meeting were agreed by written procedure on 07 May 2019.

5. Feedback from the NDA Panel plenary meeting

The working group was informed that three novel food opinions were adopted at the last NDA Panel plenary meeting.

6. Feedback from the European Commission

The EC provided an update on the number of new Novel Food applications received.

7. Update on applications, new mandates

The EFSA staff provided a brief update on received Novel Food applications including a short introduction to recently validated applications.

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

⁸ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



8. Scientific topics for discussion

8.1. Draft opinion on Inositol stabilized arginine silicate. Applicant Nutrition 21 LLC (EFSA-Q-2017-00071)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization. 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.

8.2. Draft opinion on Hovenia Dulcis. Applicant: Hovenia Dulcis AB. (EFSA-Q-2018-00279)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and toxicology. 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.

8.3. Draft opinion on Nicotinamide Riboside Chloride Applicant: ChromaDex, Inc. (EFSA-Q-2018-00480)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.4. Draft opinion on the safety of lacto-N-tetraose (LNT). Applicant Glycom A/S (EFSA-Q-2018-00589)

The WG discussed the information provided by the applicant regarding product characterization, production process and toxicology. 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.

8.5. Draft opinion on Embryonated eggs whipworm. Applicant: Enteron Science GmbH (EFSA-Q-2018-00596)

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels, toxicology and human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.6. Draft opinion on Vitamin D2 mushroom. Applicant Oakshire Naturals, LP (EFSA-Q-2018-00601)

The WG discussed the draft scientific opinion in particular the replies received after the request for additional information regarding production process, composition, specifications, proposed uses and use levels and anticipated daily intake. The updated toxicology section was also presented. The WG considered that additional information is needed from the applicant in order to proceed with the



scientific assessment of this application. Therefore, an additional request for additional information will be sent to the applicant.

8.7. Draft opinion on Urolithin A. Applicant: Amazentis SA (EFSA-Q-2018-00724)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology and human studies. 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.

8.8. Draft opinion on menaquinone-7 dipropionate. Applicant: Kappa Bioscience AS (EFSA-Q-2018-00725)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and absorption, distribution, metabolism and excretion. 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.

8.9. Draft opinion on D-Allulose. Applicant: Samyang Corp. (EFSA-Q-2018-00797)

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology and human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

8.10. Draft opinion on Theacrine. Applicant: Compound Solutions, Inc. (EFSA-Q-2018-01033)

The WG discussed the draft scientific opinion, and in particular assessed data regarding production process, specifications, composition, and toxicology of the NF. 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.

8.11. Draft opinion on Isomaltose oligosaccharide. Applicant: BioNeutra North America Inc (EFSA-Q-2019-00032)

The WG discussed the draft scientific opinion, and in particular assessed data regarding production process and toxicology. 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.



8.12. Draft opinion on lesser mealworm (*A. diaperinus* larvae) products. Applicant: Proti-Farm Holding NV (EFSA-Q-2018-00282)

The WG discussed the draft scientific opinion and the replies received after the request for additional information. In particular, the WG assessed data regarding identity, production process, composition, specifications, history of use, proposed uses and use levels and anticipated daily intake, and nutritional information. 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.

9. Any other business

The working group also discussed the following points:

- Proposal of tables to be used to summarise available toxicological data/studies
- Cross-cutting issues on the safety assessment of insects and products thereof.

10. Next meeting

The next meeting will be held on 19-20 June 2019, via web conference.

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 97TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 30 April 2019, web conference

(Agreed on 07 May 2019)

Participants

n Working Group Members:

Francesco Cubadda, Thomas Frenzel, Helle Knutsen, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Carmen Pelaez, Annette Poeting, Morten Poulsen, Yolanda Sanz and Henk Van Loveren.

n Hearing Experts¹:

Not Applicable

n European Commission and/or Member States representatives:

Panagiotis Daskaleros, Ivona Babic

n EFSA:

Nutrition Unit: Paolo Colombo, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijević, Emanuela Turla, Ermolaos Ververis.

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Karl Heinz Engel, Marina Heinonen, Harry Mcardle and Josef Rudolf Schlatter.

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 with one change, namely the postponement of the discussion on Hovenia Dulcis fruit extract (EFSA-Q-2018-00279).

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 96th Working Group meeting held on 10-11 April 2019, web-conference.

The minutes of the 96th Working Group meeting were agreed by written procedure on 16 April 2019.

5. Scientific topics for discussion

5.1. Draft opinion on "2'-FL/DFL mixture". Applicant: Glycom A/S (EFSA-Q-2018-00374)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 15-16 May for further discussion and possible adoption.

5.2. Draft opinion on Nicotinamide riboside chloride. Applicant: ChromaDex, Inc (EFSA-Q-2018-00480)

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology and human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

5.3. Draft opinion on whole and grinded lesser mealworm larvae products. Applicant: Proti-Farm Holding NV (EFSA-Q-2018-00282)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization and production process. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

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



5.4. Draft opinion on Xia powder. Applicant: ACCESS BUSINESS GROUP INTERNATIONAL LLC (EFSA-Q-2018-00373; EFSA-Q-2018-00685)

The WG discussed the draft scientific opinion and in particular assessed data regarding proposed uses and use levels, as well as anticipated daily intake. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 15-16 May for further discussion and possible adoption.

6. Next meeting

The next meeting will be held on 21-23 May 2019, Parma.

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 96TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 10-11 April 2019, web-conference

(Agreed on 16 April 2019)

Participants

n Working Group members:

Francesco Cubadda, Karl-Heinz Engel¹, Thomas Frenzel, Marina Heinonen, Helle Katrine Knutsen, Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Annette Pöting, Yolanda Sanz, Josef Rudolf Schlatter², Henk Van Loveren

n Hearing Experts³:

Not applicable

n European Commission and/or Member States representatives:

EC: Daskaleros Takis

n EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Paolo Colombo, Agnès De Sesmaisons Lecarré, Aikaterini Doulgeridou, Wolfgang Gelbmanner, Andrea Germini, Leonard Matijevic, Ruth Roldán Torres, Qingqing Sun, Emanuela Turla

n Others:

Not applicable

¹ Partially attended on 10th April

² Attended on 10th April

³ As defined in Article 17 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>.



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 Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, 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.

4. Agreement of the minutes of the 95th Working Group meeting held on 05-06 March 2019, Parma

The **minutes of the 95th Working Group meeting** were agreed by written procedure on 11 March 2019.

5. Scientific topics for discussion

5.1 Draft opinion on Phenylcapsaicin. Applicant: aXichem AB (EFSA-Q-2018-00280)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 14-16 May for further discussion and possible adoption.

5.2 Draft opinion on Nicotinamide riboside chloride. Applicant: ChromaDex Inc (EFSA-Q-2018-00480)

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

5.3 Draft opinion on Hovenia Dulcis Fruit Extract. Applicant: Hovenia Dulcis AB (EFSA-Q-2018-00279)

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



The WG discussed the draft scientific opinion, and in particular assessed data regarding production process, specifications, composition, and toxicology of the NF. 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.

**5.4 Draft opinion on Chromium-enriched biomass from *Yarrowia lipolytica*.
Applicant: SKOTAN SA (EFSA-Q-2018-00769)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels and anticipated daily intake. 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.

**5.5 Draft opinion on Selenium-enriched biomass from *Yarrowia lipolytica*.
Applicant: SKOTAN SA (EFSA-Q-2018-00796)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels and anticipated daily intake. 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.

5.6 Draft opinion on Calcidiol. Applicant: DSM Nutritional Products Ltd (EFSA-Q-2018-00514)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization and toxicology. 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.

5.7 Draft opinion on 2'-Fucosyllactose / difucosyllactose mixture. Applicant: Glycom A/S (EFSA-Q-2018-374)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

5.8 Draft opinion on *Mycobacterium manresensis* / *Nyaditum resae*. Applicant: Laboratorio Reig Jofre, S.A. (EFSA-Q-2018-00278)

The WG discussed the draft scientific opinion, and in particular assessed data regarding production process, microbiological information, and human study of the NF. 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.



6. Any Other Business

6.1 Proposal for working group meeting dates in 2020

7. Next meeting

The next meeting will be held on 30th April via web-conference.

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 95TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 05-06 March 2019, Parma

(Agreed on 11 March 2019)

Participants

n Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli¹, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Josef Rudolf Schlatter, Henk Van Loveren²

Annette Pöting, Helle Katrine Knutsen², and Harry McArdle¹ participated via web conference

n Hearing Experts:

Not Applicable

n European Commission and/or Member States representatives:

Panagiotis Daskaleros

n EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Paolo Colombo, Valeriu Curtui, Celine Dumas, Wolfgang Gelbmann, Andrea Germini, Leonard Matijević, Ruth Roldan Torres, Patricia Romero, Annamaria Rossi, Hans Steinkellner, Emanuela Turla

Feed Unit: Maria Vittoria Vettori

n Others:

Not Applicable

¹ Attended on 6th March

² Attended on 5th March pm and 6th March



1. Welcome and apologies for absence

EFSA³ welcomed the participants. Apologies were received from Karl-Heinz Engel and Yolanda Sanz.

2. Adoption of agenda

The agenda was adopted with the inclusion of one additional agenda item, namely the Draft opinion on the safety of chia seeds (agenda item 7.6).

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, 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.

4. Agreement of the minutes of the 94th Working Group meeting held on 12-14 February, Parma.

The **minutes of the 94th Working Group meeting** were agreed by written procedure on 26 February 2019.

5. Feedback from the European Commission

The EC provided an update on the number of new Novel Food applications received.

6. Update on applications, new mandates

The EFSA staff provided a brief update on received Novel Food applications including a short introduction to recently validated applications.

³ Due to unforeseen circumstances, both the Chair and vice-Chair of the WG could attend only part of the meeting and via web conference. As a consequence, EFSA chaired the meeting.

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



7. Scientific topics for discussion

7.1. Safety of astaxanthin (review of acceptable daily intake) – draft opinion (EFSA-Q-2018-00247) and call for data (EFSA-Q-2018-00595)

EFSA staff gave a brief overview on the data received from the call for data on astaxanthin, which was closed on 15 February.

7.2. Draft Opinion on betaine. Applicant: DuPont Nutrition Biosciences ApS (EFSA-Q-2018-00997)

The WG discussed the draft scientific opinion and assessed the data on the intended uses of the NF. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 13-14 March 2019 for further discussion and possible adoption.

7.3. Draft Opinion on bovine milk basic whey protein. Applicant: Armor Protéines S.A.S (EFSA-Q-2018-00996)

The WG discussed the draft scientific opinion and, in particular, assessed data regarding the intended uses of the NF. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 13-14 March 2019 for further discussion and possible adoption.

7.4. Draft Opinion on calcidiol. Applicant: DSM Nutritional Products Ltd. (EFSA-Q-2018-00514)

The WG discussed the draft scientific opinion and, in particular, assessed data regarding product characterization, intended use, nutritional information, toxicological data and allergenicity of the NF. 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.

7.5. Draft Opinion on selenite triglycerides. Applicant: BioSEL Sp. z o.o. (EFSA-Q-2015-00343)

The WG discussed the draft scientific opinion and, in particular, assessed data regarding product characterization, and toxicological data of the NF. 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.

7.6. Draft Opinion on chia seeds. Applicants: Majami Sp. z o.o. Sp. k., Zentis GmbH & Co. KG, Sanchis Mira SA., Naturkost Übelhör GmbH & Co. KG, The Chia Co., Materne SAS, Parry's Pots Limited (EFSA-Q-2018-00344, EFSA-Q-2018-00681, EFSA-Q-2018-00682, EFSA-Q-2018-00683, EFSA-Q-2018-00684, EFSA-Q-2018-00686, EFSA-Q-2018-00224)

A draft opinion on the safety of chia seeds and a number of proposed extensions of use of chia seeds will be presented to the Panel for discussion and possible adoption at the next NDA plenary meeting on 13-14 March 2019. This opinion covers the extensions of use proposed in EFSA-Q-2018-00344, EFSA-Q-2018-00681, EFSA-Q-2018-00682, EFSA-Q-2018-00683, EFSA-Q-2018-00686, EFSA-Q-2018-00224, and some those proposed in application EFSA-Q-2018-00684.



The WG considered that additional information on the thermal stability of foods with added chia is needed for some of the proposed extensions of use the application [EFSA-Q-2018-00684](#) submitted by The Chia Co. in order to proceed with the scientific assessment of the proposed extended uses listed below:

- Extension of use in bakery wares at a maximum level of 10 %
- Extension of use in cereal and cereal products at a maximum level of 10 %
- Extension of use in meat
- Extension of use in fish and fishery products
- Extension of use in egg products
- Extension of use in salt, spices, soups, sauces, salads and protein products at a maximum level of 10 %
- Extension of use in food intended for particular nutritional uses as defined by Directive 2009/39/EC at a maximum level of 10 %
- Extension of use in ready-to-eat savouries and snacks at a maximum level of 10 %
- Extension of use in desserts at a maximum level of 10 %
- Extension of use in processed foods not covered in categories 1 to 17, excluding food for infants and young children

Therefore, a request for additional information will be sent to this applicant. These extensions of use will be addressed in a separate output.

The remaining questions in the scope of the generic mandate on the overall dietary exposure and safety assessment for chia seeds (*Salvia hispanica*) as a novel food submitted by the EC on 16 July 2018 (amended on 4 October 2018) will be addressed in a separate output in accordance with Article 29(1) of Regulation (EC) No 178/2002.

8. Genotoxicity testing of mixtures

The Statement of the EFSA Scientific Committee from 2018 on Genotoxicity assessment of chemical mixtures and its relevance for the assessment of Novel Food applications was discussed.

9. Next meeting

The next meeting will be held on 10-11 April 2019, via web conference.

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 94TH MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 12-14 February 2019, Parma

(Agreed on 26 February 2019)

Participants

n Working Group Members:

Francesco Cubadda, Karl-Heinz Engel (12-13 February), Thomas Frenzel, Marina Heinonen, Helle Katrine Knutsen (Chair), Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Annette Pöting, Yolanda Sanz (13 February), Josef Rudolf Schlatter, Henk Van Loveren

Harry McArdle has participated via teleconference

n Hearing Experts¹:

Not Applicable

n European Commission and/or Member States representatives:

Ivona Babic

n EFSA:

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Antonio Fernandez Dumont, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijević,

Applications Desk Unit: Patricia Romero

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Morten Poulsen and Monika Neuhäuser-Berthold.

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 with a few changes (postponement of agenda item ‘Draft opinion on betaine’ and ‘genotoxicity testing on mixture’ to the next WG meeting).

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, and no interests were declared orally by the members at the beginning of this meeting.

4. Agreement of the minutes of the 93rd Working Group meeting held on 09-10 January 2019 via web-conference.

The minutes of the 93rd Working Group meeting held on 09-10 January 2019 were agreed by written procedure on 22 January 2019.

5. Feedback from the European Commission

The EC provided an update on the number of received Novel Food applications.

6. Update on applications, new mandates

Addressed under Agenda item 5.

7. Scientific topic(s) for discussion

7.1. Draft Opinion on viable embryonated eggs of the whipworm (*Trichuris suis*). Applicant: Enteron Science GmbH (EFSA-Q-2018-00596)

The WG discussed the draft scientific opinion and, in particular the information provided by the applicant on composition, production process, specifications, proposed uses, animal and human studies. 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.

7.2. Draft Opinion on extract derived from *Panax notoginseng* and *Astragalus membranaceus* (AstraGin®). Applicant: NuLiv Science (EFSA-Q-2018-00557)

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



The WG discussed the draft scientific opinion and, in particular, the information provided by the applicant on composition, production process, specifications, history of use, exposure and toxicological information. 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.

7.3. Draft Opinion on overall dietary exposure and safety assessment for Chia seeds. Applicants: Majami Sp. z o.o. Sp. k., Zentis GmbH & Co. KG, Sanchis Mira SA., Naturkost Übelhör GmbH & Co. KG, The Chia Co, Materne SAS, Parry's Pots Limited (EFSA-Q-2018-00344, EFSA-Q-2018-00681, EFSA-Q-2018-00682, EFSA-Q-2018-00683, EFSA-Q-2018-00684, EFSA-Q-2018-00686, EFSA-Q-2018-00224)

The WG discussed the draft scientific opinion and, in particular, assessed data regarding composition, production process, specifications, intended uses, human studies and allergenicity of the NF. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 13-14 March 2019 for further discussion and possible adoption.

7.4. Draft Opinion on Xia Powders. Applicant: Access Business Group International LLC (EFSA-Q-2018-00373, EFSA-Q-2018-00685)

The WG discussed the draft scientific opinion and, in particular, assessed data regarding composition, production process, specifications, intended use and allergenicity of the NF. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 13-14 March 2019 for further discussion and possible adoption.

7.5. Draft Opinion on phytosterol esters (extension of use, cooking oils). Applicant: Upfield (EFSA-Q-2014-00865)

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses. 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.

7.6. Draft Opinion on Inulin-propionate ester. Applicant: Imperial College Hammersmith Campus (EFSA-Q-2018-00225)

The WG discussed the draft scientific opinion and, in particular, assessed data regarding composition, production process, specifications, intended use, toxicological data and allergenicity of the NF. The WG considered that additional information is needed from the applicants in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant.

7.7. Draft Opinion on Betaine. Applicant: DuPont Nutrition Biosciences ApS (EFSA-Q-2018-00997)

The discussion of this agenda item has been postponed to the next WG meeting.

7.8. Draft Opinion on Nicotinamide Riboside Chloride. Applicant: ChromaDex, Inc. (EFSA-Q-2018-00480)

The WG discussed the draft scientific opinion, and in particular assessed data regarding composition, production process, specifications, intended use, toxicological data. 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.

7.9. Draft Opinion on Lacto-N-tetraose. Applicant: Glycom A/S (EFSA-Q-2018-00589)

The WG discussed a request for additional information, which 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. Therefore, a request for additional information will be sent to the applicants.

7.10. Genotoxicity testing of mixtures

The discussion of this agenda item has been postponed.

8. Any Other Business

None

9. Next meeting

The next WG meeting will be held on 05-06 March 2019 in Parma.



Annex I

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

CONFLICT OF INTEREST: With regard to this meeting, Prof. Karl-Heinz Engel had declared (ahead of the meeting) the following interest on agenda item 10 (phytosterol esters): the expert took note of four publications submitted by the applicant on oxidative stability and in vitro digestion of phytosterol esters, of which he is a co-author. 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 deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of these publications.

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 93rd meeting of the Working Group on Novel Foods

Held by web conference on 09-10 January 2019

(Agreed on 22 January 2019)

Participants

Working Group Members:

Francesco Cubadda¹, Karl-Heinz Engel, Thomas Frenzel, Marina Heinonen, Helle Katrine Knutsen (Chair), Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Carmen Pelaez¹, Morten Poulsen², Annette Pöting, Yolanda Sanz¹, Josef Rudolf Schlatter, Henk Van Loveren

Hearing expert³

Not applicable

European Commission representative:

Not applicable

EFSA:

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijević, Ruth Roldán Torres, Patricia Romero, Annamaria Rossi, Hans Steinkellner, Qingqing Sun

1. Welcome and apologies for absence

The EFSA Unit staff welcomed the participants. Apologies were received from Henk van Loveren.

¹ Participated on 09/01/2019

² Participated on 09/01/2019 a.m. and 10/01/2019

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>

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group (WG) 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.

4. Feedback from the European Commission

EFSA Unit staff updated on new applications received by the EC since the last WG meeting.

5. Update on applications, new mandates

The EFSA Unit staff updated the WG members on NF applications including those which have been received by EFSA since the last WG meeting.

6. Introduction to new applications

No new application was introduced at the meeting.

7. Draft Opinion on *Yarrowia lipolytica* yeast biomass. Applicant: Skotan S.A. (EFSA-Q-2018-00223)

The WG discussed the draft scientific opinion and, in particular, assessed data regarding composition, production process, specifications and allergenicity of the NF. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 17-18 January 2019 for further discussion and possible adoption.

8. Draft Opinion on overall dietary exposure and safety assessment for Chia seeds. Applicants: Majami Sp. z o.o. Sp. k., Zentis GmbH & Co. KG, Sanchis Mira SA., Naturkost

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

Übelhör GmbH & Co. KG, The Chia Co, Materne SAS, Parry's Pots Limited ([EFSA-Q-2018-00344](#), [EFSA-Q-2018-00681](#), [EFSA-Q-2018-00682](#), [EFSA-Q-2018-00683](#), [EFSA-Q-2018-00684](#), [EFSA-Q-2018-00686](#), [EFSA-Q-2018-00224](#))

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses. The WG considered that additional information is needed from the applicants in order to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicants.

9. Draft Opinion on Xia Powders. Applicant: Access Business Group International LLC ([EFSA-Q-2018-00373](#), [EFSA-Q-2018-00685](#))

The discussion of this agenda item has been postponed.

10. Draft Opinion on *Jatropha curcas* L. kernels. Applicant: JatroSolutions GmbH ([EFSA-Q-2018-00542](#))

The WG discussed a request for additional information, which 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.

11. Draft opinion on the safety of vitamin D2 mushroom powder. Applicant: Oakshire Naturals, LP ([EFSA-Q-2018-00601](#))

The WG discussed a request for additional information, which 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.

12. Draft opinion on Polyphenols derived from lychee fruit (*Litchi chinensis*) and green tea leaves (*Camellia sinensis*) Applicant: Amino Up Chemical Co., Ltd ([EFSA-Q-2018-00556](#))

The WG discussed a request for additional information, which 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.

13. Draft opinion on Hovenia dulcis fruit extract. Applicant: Hovenia Dulcis AB ([EFSA-Q-2018-00279](#))

The WG discussed a request for additional information, which 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.

14. Draft opinion on phytosterol esters (extension of use, cooking oils). Applicant: Upfield ([EFSA-Q-2014-00865](#))

The WG discussed the draft scientific opinion, and in particular nutritional and toxicological information.

15. Any other business

The WG discussed an item related to the application Tongkat Ali root extract ([EFSA-Q-2018-00106](#)).

The next WG will be held on 12-14 February 2019.

Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 92nd meeting of the Working Group on Novel Foods

Held on 05-06 December 2018, Parma (Italy)

(Agreed on 14 December 2018)

Participants

Working Group Members:

Francesco Cubadda, Karl-Heinz Engel, Thomas Frenzel, Marina Heinonen, Helle Katrine Knutsen (Chair), Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Annette Pöting¹, Josef Rudolf Schlatter, Henk Van Loveren²

Hearing expert³

Not applicable

European Commission representative:

Rafael Perez-Berbejal

EFSA:

Nutrition Unit: Paolo Colombo, Céline Dumas, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijević, Ruth Roldán Torres, Anna Maria Rossi, Emanuela Turla

1. Welcome and apologies for absence

The EFSA Unit staff welcomed the participants owing to an unexpected late arrival of the Chair. Apologies were received from Harry McArdle and Yolanda Sanz.

¹ Participated via web conference

² Attended the meeting on 06/12

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>

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA screened the Annual Declarations of Interest filled out by the Working Group (WG) 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.

4. Feedback from the European Commission

The European Commission representative gave an overview on the NF applications and notifications of Traditional Foods from third countries which have been submitted through the EC web-tool according to Regulation (EU) 2015/2283.

5. Update on applications, new mandates

The EFSA Unit staff updated the WG members on NF applications including those which have been received by EFSA since the last WG meeting.

6. Introduction to new applications

The content of Calcium-L-methylfolate ([EFSA-Q-2018-00816](#)) dossier was presented to the WG. The draft scientific opinion on this application will be presented at the future WG meetings.

7. Draft opinion on Bacterial cellulose. Applicant: Satisfibre, S.A. ([EFSA-Q-2018-00294](#))

The WG discussed a request for additional information, which 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.

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

8. Draft opinion on Allulose. Applicant: CJ-Tereos Sweeteners Europe SAS ([EFSA-Q-2018-00472](#))

The WG discussed the draft scientific opinion, and in particular data regarding product characterization, production process and specifications of the NF. 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.

9. Draft Opinion on *Jatropha curcas* L. kernels. Applicant: JatroSolutions GmbH ([EFSA-Q-2018-00542](#))

The WG discussed the draft scientific opinion, and in particular data regarding product characterization, production process and specifications of the NF. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

10. Draft opinion on the safety of vitamin D2 mushroom powder. Applicant: Oakshire Naturals, LP ([EFSA-Q-2018-00601](#))

The WG discussed the draft scientific opinion, and in particular product characterization, production process, specifications of the NF, toxicology, human studies and allergenicity. 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.

11. Draft Opinion on 2'-Fucosyllactose/Difucosyllactose Applicant: Glycom A/S ([EFSA-Q-2018-00374](#))

The WG discussed the draft scientific opinion, and in particular assessed the additional information provided by the applicant and the data regarding product characterization, production process, specifications of the NF and toxicology. 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.

**12. Draft opinion on *Mycobacterium setense manresensis*.
Applicant: Laboratorio Reig Jofre, S.A. ([EFSA-Q-2018-00278](#))**

The WG discussed a request for additional information, which 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.

**13. Draft opinion on Inositol-Stabilized Arginine Silicate.
Applicant: Nutrition 21 LLC ([EFSA-Q-2017-00071](#))**

The WG discussed the draft scientific opinion, and in particular assessed the additional information provided by the applicant and the data regarding product characterization. The WG considered that additional information is needed from the applicant to proceed with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant.

14. Draft opinion on Polyphenols derived from lychee fruit (*Litchi chinensis*) and green tea leaves (*Camellia sinensis*) ([EFSA-Q-2018-00556](#))

The WG discussed the draft scientific opinion and in particular product characterization, production process, specifications of the NF, and stability. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

**15. Draft opinion on Tongkat Ali root extract. Applicant:
Biotropics Malaysia Berhad. ([EFSA-Q-2018-00106](#))**

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels, anticipated daily intake and toxicology. 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.

16. Opinion templates

The EFSA Unit staff presented to the WG a proposal to use tables to summarise studies in scientific opinions on NF. The proposal will be re-discussed by the WG in future meetings.

17. Specifications

The discussion of this agenda item has been postponed.

18. Genotoxicity mixtures

The discussion of this agenda item has been postponed.

19. Any other business

A teleconference of the WG will be held on 09-10 January 2019.

Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 91st meeting of the Working Group on Novel Foods

Held on 06-08 November 2018, Parma (Italy)

(Agreed on 21 November 2018)

Participants

Working Group Members:

Francesco Cubadda¹, Karl-Heinz Engel², Thomas Frenzel³, Marina Heinonen, Helle Katrine Knutsen (Chair), Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen¹, Annette Pöting, Yolanda Sanz¹, Josef Rudolf Schlatter, Henk Van Loveren

Hearing expert⁴:

Not applicable

European Commission representative:

Rafael Perez-Berbejal

EFSA:

Nutrition Unit: Reinhard Ackerl, Paolo Colombo, Céline Dumas, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijević, Qinging Sun, Ruth Roldán Torres, Anna Maria Rossi; other EFSA staff: Antonio Fernandez-Dumon

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Harry McArdle.

¹ Participated via web conference

² Attended the meeting on 7/11 (am) and 8/11 (pm)

³ Attended the meeting on 6/11 and 7/11

⁴ 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 agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence⁵ and the Decision of the Executive Director on Competing Interest Management⁶, EFSA screened the Annual Declarations of Interest filled out by the Working Group (WG) 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. An interest was declared orally by a member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

4. Feedback from the EC

The European Commission representative gave an overview on the NF applications and notifications of Traditional Foods from third countries which have been submitted through the EC web-tool according to Regulation (EU) 2015/2283.

5. Update on applications, new mandates

The EFSA Unit staff updated the WG members on NF applications including those which have been received by EFSA since the last WG meeting.

6. Introduction to new applications

Lacto-N-Tetraose ([EFSA-Q-2018-0589](#)); Edible Jatropha curcas L. kernels (Chuta®) ([EFSA-Q-2018-0542](#)); Viable embryonated eggs of the whipworm (Trichuris suis) ([EFSA-Q-2018-0596](#)); Calcidol ([EFSA-Q-2018-0514](#)); Vit D2 – Mushroom Powder ([EFSA-Q-2018-0601](#)); Extract derived from Panax notoginseng and Astragalus membranaceus (AstraGin®) ([EFSA-Q-2018-00557](#)).

The content of the above dossiers was presented to the WG. The draft

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 opinions on these applications will be presented at the future WG meetings.

7. Draft statement on Chia seed powder 'Xia Powder 435'. Applicant: Access Business Group International LLC (EFSA-Q-2018-0685)

The WG discussed the request for additional information, which 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.

8. Draft opinion on phytosterol esters (extension of use, cooking oils). Applicant: Upfield (EFSA-Q-2014-00865)

The WG discussed the draft scientific opinion, and in particular product characterization, anticipated daily intake, toxicological and human studies, including additional information received from the applicant in response to an EFSA request.

9. Draft opinion on *Yarrowia lipolytica* yeast biomass. Applicant: Skotan S.A. (EFSA-Q-2018-00223)

The WG discussed the draft scientific opinion, and, in particular, revised the sections on the product characterization, the production process, the proposed uses and use levels, data on toxicology and allergenicity. After amendments, a revised draft opinion will be presented at the future WG NF meeting for further discussion.

10. Draft opinion on Bacterial cellulose aqueous suspension. Applicant: Satisfibre, S.A (EFSA-Q-2018-00294)

The draft scientific opinion was discussed and in particular product characterization data and toxicological data. 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.

11. Draft opinion on heat-killed bacteria *Mycobacterium setense manresensis*. Applicant: Laboratorio Reig Jofre, S.A. (EFSA-Q-2018-00278)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, toxicology,

human studies and allergenicity. The application will be discussed again at the next WG NF meeting.

12. Draft opinion on Allulose. Applicant: CJ-Tereos Sweeteners Europe SA ([EFSA-Q-2018-00472](#))

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process and toxicology. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

13. Draft opinion on Selenium triglycerides. Applicant: BioSEL Sp. z o.o. ([EFSA-Q-2015-00343](#))

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization and production process. 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.

14. Draft opinion on Inositol-Stabilized Arginine Silicate. Applicant: Nutrition 21 LLC ([EFSA-Q-2017-00071](#))

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology and human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

15. Draft opinion on Hovenia Dulcis Fruit Extract. Applicant: Hovenia Dulcis AB ([EFSA-Q-2018-00279](#))

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the future WG NF meeting for further discussion.

16. Draft opinion on Eurycoma longifolia (tongkat ali) root extract. Applicant: Biotropics Malaysia Berhad. ([EFSA-Q-2018-00106](#))

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology and human studies. 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.

17. Any other business

Draft opinion on Polyphenols derived from lychee fruit (*Litchi chinensis*) and green tea leaves (*Camellia sinensis*) (EFSA-Q-2018-00556)

The WG discussed the draft scientific opinion and in particular product characterization and production process. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

Next meetings

The teleconference of the WG, which was scheduled on the 30 October, has been replaced by a preparatory meeting.

The next WG meeting will be held on 05-06 December 2018.

Annex I

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

With regard to this meeting, Prof. Karl-Heinz Engel declared the following interest on agenda item 8 (phytosterol esters): the expert took note of four publications submitted by the applicant on oxidative stability and *in vitro* digestion of phytosterol esters, of which he is a co-author.

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, 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 these publications.

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

⁸ 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 90th meeting of the Working Group on Novel Foods

Held on 10-11 October 2018, Parma (Italy)

(Agreed on 17 October 2018)

Participants

Working Group Members:

Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Annette Pötting¹, Morten Poulsen, Josef Rudolf Schlatter and Hendrik van Loveren (Chair)

Hearing expert²:

Not applicable

European Commission representative:

Ivona Babić

EFSA:

Nutrition Unit: Mathias Amundsen, Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann, Andrea Germini, Leonard Matijević, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

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

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which

¹ joined 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/sites/default/files/efsa_rep/blobserver_assets/expertselection.pdf

the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group (WG) 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.

An interest was declared orally by a member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

4. Feedback from the last NDA Plenary on discussed NF items

The EFSA Unit staff updated the WG members on the draft Novel Foods (NF) opinions which were presented and discussed at the NDA Panel meeting held on 26-27 September. Further information is available in the minutes of the NDA Panel meeting (available [HERE](#)).

5. Update on applications, new mandates

The EFSA Unit staff updated the WG members on NF applications including those which have been received by EFSA since the last WG meeting.

6. Feedback from the EC

The European Commission representative gave an overview on the NF applications which have been submitted through the EC web-tool according to Regulation (EU) 2015/2283.

The European Commission representative also gave an overview on the notifications of Traditional Foods from third countries which have been received by the European Commission.

7. Introduction to new applications

Bacterial cellulose (EFSA-Q-2018-00294); Nicotinamide Riboside Chloride (EFSA-Q-20018-00480)

The content of these dossiers was presented to the WG. The draft

³ 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 opinions on these applications will be presented at the future WG meetings.

8. Draft statement on D-ribose. Applicant: Bioenergy Life Science, Inc. (EFSA-Q-2018-00697)

The WG discussed a draft statement related to the EFSA scientific opinion on D-ribose. The statement includes a new exposure assessment of D-ribose based on the new proposed uses and use levels provided by the applicant, following the adoption of the scientific opinion. After amendments, the draft statement will be presented at the next NDA plenary meeting on 24-25 October for further discussion and possible adoption.

9. Draft opinion on EPA-rich oil from *P. tricornutum*. Applicant: Simris Alg AB. (EFSA-Q-2018-00105)

The draft scientific opinion was discussed and in particular product characterization data and toxicological data were reviewed. 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.

10. Draft opinion on 2'-fucosyllactose/difucosyllactose. Applicant: Glycom A/S (EFSA-Q-2018-00374)

The draft scientific opinion was discussed and in particular product characterization data and toxicological data were reviewed. 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.

11. Draft opinion on olive leaf extract, Applicant: BioActor B.V. (EFSA-Q-2018-00281)

The draft scientific opinion was discussed and in particular product characterization data and toxicological data were reviewed. 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.

12. Draft opinion on allulose. Applicant: CJ-Tereos Sweeteners Europe SAS (EFSA-Q-2018-00472)

The draft scientific opinion was discussed and in particular product characterization data were reviewed. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

13. Draft opinion on tongkat ali root extract. Applicant: Biotropics Malaysia Berhad. (EFSA-Q-2018-00106)

The draft scientific opinion was discussed and in particular toxicological data was reviewed. After amendments, the draft opinion will be presented at the next WG NF meeting (teleconference) for further discussion.

14. Draft opinion on phenylcapsaicin. Applicant: aXichem AB. (EFSA-Q-2018-00280)

The draft scientific opinion was discussed and in particular product characterization data and toxicological data were reviewed. 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.

15. Draft opinion on dried crickets. Applicant: SAS EAP Group - Micronutris (EFSA-Q-2018-00263)

The draft scientific opinion was discussed and in particular data regarding characterization, production process, proposed uses and use levels, toxicology, and allergenicity were reviewed. 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.

16. Draft opinion on Inositol stabilised arginine silicate. Applicant: Nutrition 21, LLC (EFSA-Q-2017-00071)

The WG discussed the draft scientific opinion, and in particular assessed the product characterization data and the bioavailability studies. 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.

17. Selenium triglycerides.

Applicant: BioSEL Sp. z o.o. (EFSA-Q-2015-00343)

The WG discussed the additional information received. The draft opinion will be presented at the next WG NF meeting for further discussion.

18. Any other business

A teleconference of the WG will be held on 30 October 2018.

The next WG meeting will be held on 6, 7 and 8 November 2018.

Annex I

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

With regard to this meeting, Prof. Harry J McArdle declared the following interest: the expert was involved in the UK Advisory Committee on Novel Foods and Processes that on behalf of the UK Food Authority performed the initial risk assessment on 'olive leaf extract' and 'Tongkat ali root extract' (agenda items 11 and 13, respectively). 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, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

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 89th meeting of the Working Group on Novel Foods

Held on 4-5 September 2018, Parma (Italy)

(Agreed on 12 September 2018)

Participants

Working Group Members:

Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen¹, Josef Rudolf Schlatter and Hendrik van Loveren (Chair)

Hearing expert²:

Not applicable

European Commission representative:

Takis Daskaleros

EFSA:

Nutrition Unit: Wolfgang Gelbmann, Andrea Germini, Leonard Matijević Annamaria Rossi, Qingqing Sun, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Karl-Heinz Engel and Yolanda Sanz.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

¹ 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>.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group (WG) 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.

An interest was declared orally by a member before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex I.

4. Feedback from the EC

The European Commission representative gave an overview on the Novel Foods (NF) applications which have been submitted through the EC web-tool according to Regulation (EU) 2015/2283.

The European Commission representative also gave an overview on the notifications of Traditional Foods from third countries which have been received by the European Commission.

5. Update on applications, new mandates

The EFSA Unit staff updated the WG members on the NF applications which have been received by EFSA since the last WG meeting.

6. Introduction to new applications

Inositol stabilised arginine silicate, nutrient sources (EFSA-Q-2017-00071) and Allulose (EFSA-Q-2018-00472)

The content of these dossiers was presented to the WG. The draft scientific opinions on these applications will be presented at the next WG meeting.

7. Draft opinion on magnesium citrate malate as nutrient source. Applicant: *Paul Lohman GmbH KG* (EFSA-Q-2018-00066)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 26-27 September 2018

³ 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

for further discussion and possible adoption.

8. **Draft opinion on defatted chia seed powder. Applicant: *Cabinet de conseil Nutraveris on behalf of Access Business Group International* LLC. (EFSA-Q-2018-00373)**

The applicant's reply to the EFSA's request for additional information was discussed and in particular, the anticipated intake of the NF was reviewed. 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.

9. **Draft opinion on Tongkat ali root extract. Applicant: *Biotropics Malaysia Berhad*. (EFSA-Q-2018-00106)**

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG NF meeting on 10-11 October 2018 for further discussion.

10. **Draft opinion on inulin-propionate ester. Applicant: *Imperial College Hammersmith Campus* (EFSA-Q-2018-00225)**

The draft scientific opinion was discussed and, after amendments, the WG proposed to present it at the next NDA Plenary meeting on 26-27 September 2018 for further discussion.

11. **Draft opinion on 2'-Fucosyllactose/difucosyllactose. Applicant: *Glycom A/S* (EFSA-Q-2018-00374)**

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG NF meeting on 10-11 October 2018 for further discussion.

12. **Draft opinion on Whole *Alphitobius diaperinus* larvae products. Applicant: *Proti-Farm Holding NV* (EFSA-Q-2018-00282)**

The draft scientific opinion was discussed and 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. After amendments, the draft scientific opinion will be presented at the next WG meeting.

13. Draft opinion on olive leaf extract. Applicant: *BioActor B.V.* (EFSA-Q-2018-00281)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG NF meeting on 10-11 October 2018 for further discussion.

14. NF Opinion Template: mock-up on the presentation on toxicological and human data in NF Opinions

The template of scientific opinions on NF for the presentation of toxicological data was presented and discussed. After amendments, it will be presented, together with the template for presentation of human data, at the next WG NF meeting on 10-11 October 2018 for further discussion.

15. Any other business

The next WG meeting will be held on 10-11 October 2018.

Annex I

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

With regard to this meeting, Prof. Harry J McArdle declared the following interest: the expert was involved in the UK Advisory Committee on Novel Foods and Processes that on behalf of the UK Food Authority performed the initial risk assessment on 'Tongkat ali root extract' and 'olive leaf extract' (agenda items 9 and 13). 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, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

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 88th meeting of the Working Group on Novel Foods

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

(Agreed on 23 July 2018)

Participants

Working Group Members:

Karl-Heinz Engel, Marina Heinonen¹ and Rosangela Marchelli.

EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Sun Qingqing, Ermolaos Ververis.

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, except for the addition of the dossier for EFSA-Q-2018-00225 that was validated shortly before the meeting, and for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the

¹ On 18th July 2018, via 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

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.

4. Feedback from the EC

The EFSA Unit staff, who attended a meeting with the European Commission, gave an overview on the Novel Foods (NF) applications which have been submitted through the EC web-tool.

5. Update on applications

The EFSA Unit staff updated the WG members on the NF applications which have been received by EFSA since the last WG meeting.

6. Introduction to new applications

The content of dossiers of new NF applications was presented. Draft scientific opinions on these new applications will be presented at the WG meeting following the validation of these dossiers.

7. Draft opinion on Tongkat ali root extract. Applicant: *Biotropics Malaysia Berhad* (EFSA-Q-2018-00106)

The working group assessed the additional information received by the applicant. The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

8. Draft opinion on *Mycobacterium setense* strain *manresensis*. Applicant: *Laboratorio Reig Jofre, S.A.* (EFSA-Q-2018-00278)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

9. Draft opinion on *Yarrowia lipolytica*. Applicant: *SKOTAN S.A.* (EFSA-Q-2018-00223)

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.

10. Draft opinion on defatted chia seed powder. Applicant: *Cabinet de conseil Nutraveris on behalf of Access Business*

Group International LLC (EFSA-Q-2018-00373)

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.

11. Draft opinion on dried mealworm. Applicant: *SAS EAP Group - Micronutris* (EFSA-Q-2018-00262)

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.

12. Draft opinion on inulin-propionate ester. Applicant: *Imperial College Hammersmith Campus* (EFSA-Q-2018-00225)

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.

13. Any other business

The next WG meeting will be held on 3-5 September 2018.

Scientific Panel on Nutrition, Novel Foods and Food Allergens

Minutes of the 87th meeting of the Working Group on Novel Foods

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

(Agreed on 16 July 2018)

Participants

Working Group Members:

Inge Mangelsdorf, Monika Neuhäuser-Berthold, Annette Pöting¹, Morten Poulsen, Hendrik van Loveren (Chair)

Hearing expert²:

Not applicable

European Commission representative:

None

EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Wolfgang Gelbmann, Leonard Matijevic, Sun Qingqing, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Harry McArdle and Josef Rudolf Schlatter.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

¹ Via web-conference

² As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest:
<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

In accordance with EFSA's Policy on Independence³ and the Decision of the Executive Director on Competing Interest Management⁴, EFSA screened the Annual Declarations of Interest filled out by the Working Group (WG) 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.

4. Feedback from the European Commission

The EFSA Unit Staff, who attended a meeting with the European Commission, gave an overview on the Novel Foods (NF) applications which have been submitted through the EC web-tool.

5. Update on applications

The EFSA Unit Staff updated the WG Members on the NF applications which have been received by EFSA since the last WG meeting.

The EFSA Unit Staff also gave an overview on the notifications of Traditional Foods from third countries which have been assessed and received by EFSA.

6. Introduction to new applications

The content of dossiers of new NF applications was presented. Draft scientific opinions on these new applications will be presented at the WG meeting following the validation of these dossiers.

7. Draft opinion on Tongkat ali root extract. Applicant: *Biotropics Malaysia Berhad* (EFSA-Q-2018-00106)

The draft scientific opinion was discussed and in particular, toxicological and human data were reviewed. After amendments, the draft scientific opinion will be presented at the next WG meeting and sections related to the composition, manufacturing process and specifications of the NF will be discussed.

8. Draft opinion on *Mycobacterium setense* strain *manresensis*. Applicant: *Laboratorio Reig Jofre, S.A.* (EFSA-Q-2018-00278)

The draft scientific opinion was discussed and in particular, toxicological, microbiological and human data were reviewed. After amendments, the draft scientific opinion will be presented at the next WG meeting and

³ 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

sections related to the composition, manufacturing process and specifications of the NF will be discussed.

9. Draft opinion on *Yarrowia lipolytica*. Applicant: *SKOTAN S.A.* (EFSA-Q-2018-00223)

The draft scientific opinion was discussed and in particular, toxicological and human data were reviewed. 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. After amendments, the draft scientific opinion will be presented at the next WG meeting and sections related to the composition, manufacturing process and specifications of the NF will be discussed.

10. Draft opinion on dried mealworm. Applicant: *SAS EAP Group - Micronutris* (EFSA-Q-2018-00262)

The draft scientific opinion was discussed and in particular, toxicological and human data were reviewed. 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. After amendments, the draft scientific opinion will be presented at the next WG meeting and sections related to the composition, manufacturing process and specifications of the NF will be discussed.

11. Draft opinion on defatted chia seed powder. Applicant: *Cabinet de conseil Nutraveris on behalf of Access Business Group International LLC* (EFSA-Q-2018-00373)

The draft scientific opinion was discussed and in particular, toxicological and human data were reviewed. After amendments, the draft scientific opinion will be presented at the next WG meeting and sections related to the composition, manufacturing process and specifications of the NF will be discussed.

12. Any other business

The next WG meeting will be held on 17-18 July 2018.

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 86th meeting of the Working Group on Novel Foods

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

(Agreed on 15 June 2018)

Participants

Working Group Members:

Karl-Heinz Engel, Marina Heinonen¹, Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Hendrik van Loveren (Chair)

Hearing expert²:

Not applicable

European Commission representative:

Ivona Babic

EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Qingqing Sun, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Yolanda Sanz and Josef Rudolf Schlatter.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

¹ Attended via web-conference on 11 June 2018

² As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 filled in by the working group (WG) Members invited for the present meeting, as well as the Oral Declaration of Interest at the beginning of this meeting.

For the Agenda item related to 'egg membrane', Morten Poulsen declared an interest. The expert was involved in the Danish Novel Food Assessment Team that on behalf of the Danish Food Authority performed the initial assessment on 'egg membrane' in 2017. The expert will not be involved in the drafting of this opinion.

With regard to the other items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Feedback from the EC

The European Commission representative gave an overview on the NF applications which have been submitted through the EC web-tool according to Regulation (EU) 2015/2283.

The European Commission representative also gave an overview on the notifications of Traditional Foods from third countries which have been received by the European Commission.

5. Update on applications

The EFSA Unit updated the WG Members on the NF applications which have been received by EFSA since the last WG meeting.

6. Introduction to new applications

No new applications were presented by the EFSA Unit.

7. Draft opinion on xylo-oligosaccharide. Applicant: *Longlive Europe Food Division Ltd.* (EFSA-Q-2017-00665)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 27-29 June 2018 for further discussion and possible adoption.

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

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

8. Draft opinion on whey protein isolate. Applicant: Armor Protéines S.A.S. (EFSA-Q-2018-00104)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 27-29 June 2018 for further discussion and possible adoption.

9. Draft opinion on Egg Membrane. Applicant: Bionova LLC. (EFSA-Q-2018-00103)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 27-29 June 2018 for further discussion and possible adoption.

10. Draft opinion on Allanblackia seed oil. Applicant: *Unilever* (EFSA-Q-2018-00226)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 27-29 June 2018 for further discussion and possible adoption.

11. Astaxanthin (call for data) (EFSA-Q-2018-00247)

The draft call for data related to astaxanthin was discussed and after amendments, it will be presented at the next NDA plenary meeting on 27-29 June 2018 for (possible) endorsement.

12. Any other business

The next WG meeting will be held on 11-12 July 2018.

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 85th meeting of the Working Group on Novel Foods

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

(Agreed on 25 May 2018)

Participants

Working Group Members:

Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Monika Neuhäuser-Berthold, Rosangela Marchelli, Annette Pöting, Morten Poulsen, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

Hearing expert¹:

Not applicable

European Commission representative:

Ivona Babic²

EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Qingqing Sun, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Harry J McArdle and Yolanda Sanz.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

² Participated via web-conference on 17 May

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 filled in by the working group (WG) Members invited for the present meeting, as well as the interests declared at the beginning of this meeting.

For the Agenda item related to 'egg membrane', Morten Poulsen declared an interest. The expert was involved in the Danish Novel Food Assessment Team that on behalf of the Danish Food Authority performed the initial assessment on 'egg membrane' in 2017. The expert will not be involved in the drafting of this opinion.

With regard to the other agenda items for this meeting, no Conflicts of Interest were identified during the screening process or at the beginning of this meeting.

4. Update on NF applications

The EFSA Unit updated the WG Members on the NF applications which have been received by EFSA since the last WG meeting.

The content of several NF applications was presented. Draft scientific opinions will be presented at the next meeting of the WG following the validation of these applications.

5. Draft opinion on xylo-oligosaccharide. Applicant: Longlive Europe Food Division Ltd (EFSA-Q-2017-00665)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

6. Draft opinion on whey protein isolate. Applicant: Armor Protéines S.A.S. (EFSA-Q-2018-00104)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

7. Draft opinion on egg membrane. Applicant: Bionova LLC (EFSA-Q-2018-00103)

The draft scientific opinion was discussed and, after amendments, will be

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

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

presented at the next WG meeting for further discussion.

8. Draft opinion on Tongkat ali root extract. Applicant: Biotropics Malaysia Berhad (EFSA-Q-2018-00106)

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.

9. Draft opinion on Allanblackia seed oil. Applicant: Unilever (EFSA-Q-2018-00226)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

10. Draft opinion on EPA-rich oil from *Phaeodactylum tricornutum*. Applicant: Simris Alg AB (EFSA-Q-2018-00105)

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.

11. Any other business

The next WG meeting will be held on 11-12 June 2018.

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 84th meeting of the Working Group on Novel Foods

Held on 22-23 March 2018, Parma (Italy)

(Agreed on 27 March 2018)

Participants

Working Group Members:

Karl-Heinz Engel, Inge Mangelsdorf, Harry J McArdle¹, Monika Neuhäuser-Berthold, Rosangela Marchelli, Annette Pötting¹, Morten Poulsen², Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

Hearing expert³:

Not applicable

European Commission representative:

Rafael Perez-Berbejal

EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Sun Qingqing, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Marina Heinonen and Yolanda Sanz.

¹ Participated via web-conference on 22 and 23 March

² Participated via web-conference on 22 March

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest:
<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

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 and the Specific Declaration of Interest 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. Draft opinion on D-Ribose. Applicant: Bioenergy Life Science Inc. (EFSA-Q-2017-00461)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 17-19 April 2018 for further discussion and possible adoption.

5. Draft opinion on shrimp peptides. Applicant: Medfiles Ltd on behalf of Marealis AS (EFSA-Q-2017-00679)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 17-19 April 2018 for further discussion and possible adoption.

6. Draft opinion on whey protein isolate. Applicant: Armor Protéines S.A.S. (EFSA-Q-2018-00104)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

7. Draft opinion on EPA-rich oil from *Phaeodactylum tricornutum*. Applicant: Simris Alg AB (EFSA-Q-2018-00105)

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

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

additional information will be sent to the applicant.

8. Approach for the evaluation of traditional foods (TF) from third countries

The WG discussed the approach for the evaluation of notifications of TF from third countries.

9. Update on organisational matters

9.1. Update from the European Commission

The European Commission representative informed the WG that the Implementing Regulation on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 has been adopted and published by the European Commission (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1521535173347&uri=CELEX:32018R0456>). The content of the Implementing Act was presented by the European Commission representative.

The European Commission also gave an overview on applications on novel foods (NF) and notifications on TF which have been received by the European Commission.

10. Status and update on other applications

The EFSA Unit updated the WG Members on the NF applications which have been received by EFSA since the last meeting.

10.1. Preparatory discussion on the request for a scientific opinion on inulin-propionate ester as a novel food. Applicant: Imperial College Hammersmith Campus (EFSA-Q-2018-00225)

The content of the dossier was presented. A draft scientific opinion will be presented at the meeting of the WG following the validation of the dossier.

11. Any other business

The next WG meeting will be held on 17-18 May 2018.

11.1. Discussion on the new mandate on astaxanthin - Article 29 of Regulation (EC) No 178/2002 (EFSA-Q-2018-00247)

The EFSA Unit informed the WG Members on the new mandate, which

was received by EFSA on 27 February 2018 from the European Commission, in relation to astaxanthin as a NF. This new Mandate was discussed by the WG Members.

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 83rd meeting of the Working Group on Novel Foods

Held on 19-20 February 2018, Parma (Italy)

(Agreed on 22 February 2018)

Participants

Working Group Members:

Karl-Heinz Engel, Inge Mangelsdorf¹, Harry J McArdle, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

Hearing expert²:

Not applicable

European Commission representative:

None

EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Marina Heinonen, Rosangela Marchelli and Yolanda Sanz.

2. Adoption of agenda

The agenda was adopted without changes.

¹ Participated via web-conference

² As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 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. Draft opinion on D-Ribose. Applicant: Bioenergy Life Science Inc. (EFSA-Q-2017-00461)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

5. Draft opinion on shrimp peptides. Applicant: Medfiles Ltd on behalf of Marealis AS (EFSA-Q-2017-00679)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

6. Preparation for 2018

The WG discussed the planning of the forthcoming meetings in order to streamline the process for the evaluation Novel Foods applications.

7. Status of other applications

The EFSA Unit updated the WG Members on the NF applications which have been received by EFSA since the last meeting.

8. Any other business

8.1. Preparatory discussion on the request for a scientific opinion on EPA rich oil from *Phaeodactylum tricornutum* as a novel food. Applicant: Simris Alg AB (EFSA-Q-2018-00105)

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

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

The content of the dossier was presented. A draft scientific opinion will be presented at the meeting of the WG following validation of the dossier.

8.2. Preparatory discussion on the request for a scientific opinion on egg membrane as a novel food. Applicant: Biova, LLC (EFSA-Q-2018-00103)

The content of the dossier was presented. A draft scientific opinion will be presented at the meeting of the WG following validation of the dossier.

8.3. Preparatory discussion on the request for a scientific opinion on Tongkat Ali root extract as a novel food. Applicant: Biotropics Malaysia Berhad (EFSA-Q-2018-00106)

The content of the dossier was presented. A draft scientific opinion will be presented at the meeting of the WG following validation of the dossier.

8.4. Proprietary data for Novel Food applications pursuant to Art 26(2)(c) of Regulation (EU) 2015/2283

The WG discussed the requirements of the NF Regulation in relation to data which are requested to be protected by applicants for Novel Food applications (i.e. whether the Novel Food could not have been assessed by EFSA without the scientific evidence or data requested to be protected by applicants).

8.5. The next WG meeting will be held on 22-23 March 2018.

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 82nd meeting of the Working Group on Novel Foods

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

(Agreed on 17 January 2018)

Participants

Working Group Members:

Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Harry J McArdle, Monika Neuhäuser-Berthold, Rosangela Marchelli, Annette Pöting, Morten Poulsen, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

Hearing expert¹:

Not applicable

European Commission representative:

Takis Daskaleros

EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Valeriu Curtui, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

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

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 (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. Draft opinion on D-Ribose. Applicant: Bioenergy Life Science Inc. (EFSA-Q-2017-00461)

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.

5. Draft opinion on xylo-oligosaccharide. Applicant: Longlive Europe Food Division Ltd (EFSA-Q-2017-00665)

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.

6. Draft opinion on shrimp peptides. Applicant: Medfiles Ltd on behalf of Marealis AS (EFSA-Q-2017-00679)

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.

7. Preparation for 2018

7.1. Update from the European Commission

The European Commission representative informed the WG that the Implementing Acts for administrative and scientific requirements on Novel Foods (NF) and Traditional Foods (TF) from third countries as referred to in Regulation (EU) 2015/2283 were adopted by the European Commission

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

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

and they were published in the European Commission website (https://ec.europa.eu/food/safety/novel_food/legislation_en). The content of the Implementing Acts was presented by the European Commission representative.

The European Commission representative outlined the number of NF applications which are probably expected to be submitted in 2018 pursuant to Regulation (EU) 2015/2283.

7.2. WG organisation, resources, flow-charts

In view of the entry into force of the NF Regulation (EU) 2015/2283, the EFSA Unit updated the WG Members on the impact of the submission of NF applications on the organisation of the WG and EFSA resources. The WG on NF will continue dealing with applications submitted under Art. 10 (NF applications) and Art. 16 (applications on TF from third countries).

The EFSA Unit informed the WG that an EFSA WG will be established in order to deal with TF notifications from third countries (Art. 14). The outputs of the WG on TF will not be subject to endorsement/adoption by the NDA Panel.

7.3. Draft approach for evaluating Art. 14 notifications of traditional food

The discussion of this agenda item was postponed to the next WG meeting.

8. Status of other applications

The EFSA Unit updated the WG Members on the NF applications which have been received by EFSA since the last meeting.

9. Any other business

The next WG meeting will be held on 19-20 February 2018.

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 81st meeting of the Working Group on Novel Foods

Held on 22-24 November 2017, Parma (Italy)

(Agreed on 4 December 2017)

Participants

Working Group Members:

Karl-Heinz Engel, Marina Heinonen¹, Inge Mangelsdorf, Monika Neuhäuser-Berthold, Rosangela Marchelli, Morten Poulsen, Annette Pöting², Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

Hearing expert³:

Not applicable

European Commission representative:

Rafael Perez-Berbejal

EFSA:

Nutrition Unit: Reinhard Ackerl, Mathias Amundsen, Valeriu Curtui, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Emanuela Turla, Ermolaos Ververis

Antonio Fernandez Dumont

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Harry J McArdle and Yolanda Sanz.

¹ Participated on 22-23 November

² Participated via web-conference

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest:
<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

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 and the Specific Declaration of Interest 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. Draft opinion on D-Ribose. Applicant: Bioenergy Life Science Inc. (EFSA-Q-2017-00461)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

5. Preparation for 2018

5.1. Update from the European Commission

The European Commission representative informed the WG that the Implementing Acts for administrative and scientific requirements on Novel Foods (NF) and Traditional Foods (TF) from third countries as referred to in Regulation (EU) 2015/2283 were voted in favour by the Member States on 17 November 2017 and will be adopted by the European Commission at the end of this year. The content of the Implementing Acts was presented by the European Commission representative.

5.2. Feed-back from the NF Network meeting with Member States

On 8-9 November 2017 the first meeting of the NF Network took place at the EFSA's premises among representatives of Member States, the European Commission and EFSA. The NF Network aimed to facilitate the collaboration in the area of NF, to promote the discussion on the approach for evaluating notifications of TF from third countries and on the submission of "duly reasoned safety objections" for TF from third

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

countries. Minutes of the NF Network will be available on the EFSA website.

5.3. (Draft) approach for evaluating Art. 14 notifications of TF from third countries

The WG discussed the approach on the evaluation of notifications of TF from third countries expected with implementation of the Regulation (EU) 2015/2283 on NF. Details on the proposed approach are available in the minutes of the NF Network.

5.4. Insects

5.4.1. Feed-back from IPIFF conference on “insects for food and feed”

The EFSA Unit provided feed-back from the IPIFF conference on “insects for food and feed” which was held in Brussels on 21 November 2017.

5.4.2. Evaluation of insect dossiers

The WG discussed points for considerations on the evaluation of dossiers on insects based on existing international and European guidelines.

6. Status of other applications

The discussion of this agenda item was postponed to the next WG meeting.

7. Any other business

The next WG meeting will be held on 11-12 January 2018.

7.1. Preparatory discussion for the draft opinion on xylo-oligosaccharide. Applicant: Longlive Europe Food Division Ltd (EFSA-Q-2017-00665)

The content of the dossier was presented. A draft scientific opinion will be presented at the next WG meeting.

7.2. Preparatory discussion for the draft opinion on shrimp peptides. Applicant: Medfiles Ltd on behalf of Marealis AS (EFSA-Q-2017-00679)

The content of the dossier was presented. A draft scientific opinion will be presented at the next WG meeting.

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 80th meeting of the Working Group on Novel Foods

Held on 10-11 October 2017, Parma (Italy)

(Agreed on 13 October 2017)

Participants

Working Group Members:

Marina Heinonen, Inge Mangelsdorf, Monika Neuhäuser-Berthold, Rosangela Marchelli, Annette Pöting, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

Hearing expert¹:

Not applicable

European Commission representative:

Ivona Babic

EFSA:

Nutrition Unit:

Reinhard Ackerl, Agnès de Sesmaisons-Lecarré, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Karl-Heinz Engel, Harry J McArdle, Morten Poulsen and Yolanda Sanz.

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

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 (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. Draft opinion on betaine. Applicant: DuPont Nutritional Biosciences ApS (EFSA-Q-2016-00287)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 24-26 October 2017 for further discussion and possible adoption.

5. Draft opinion on pyrroloquinoline quinone disodium salt. Applicant: Mitsubishi Gas Chemical Company Inc. (EFSA-Q-2016-00659)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 24-26 October 2017 for further discussion and possible adoption.

6. Draft statement on taxifolin. Applicant: Ametis JSC (EFSA-Q-2017-00554)

The draft scientific statement was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 24-26 October 2017 for further discussion and possible adoption.

7. Draft statement on L-ergothioneine. Applicant: *Tetrahedron* (EFSA-Q-2017-00448)

The draft scientific statement was discussed and, after amendments, it

² <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

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

will be presented at the next NDA plenary meeting on 24-26 October 2017 for further discussion and possible adoption.

8. Draft opinion on D-ribose. Applicant: Bioenergy Life Science Inc. (EFSA-Q-2017-00461)

The discussion of this agenda item was postponed to the next WG meeting.

9. Draft opinion on tocotrienol-rich extract from *Annatto* seeds. Applicant: American River Nutrition Inc. (EFSA-Q-2016-00519)

The discussion of this agenda item was postponed to the next WG meeting.

10. Status of other applications

The European Commission representative updated the WG on the status of the Implementing Acts for administrative and scientific requirements on novel foods and traditional foods from third countries as referred to Regulation (EU) 2015/2283 of the European Parliament and of the Council.

The EFSA Unit updated the WG Members on the Novel Foods applications which have been received by EFSA since the last meeting.

11. Any other business

The next WG meeting will be held on 22-24 November 2017.

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 79th meeting of the Working Group on Novel Foods

Web-conference, 13 September 2017

(Agreed on 13 September 2017)

Participants

Working Group Members:

Marina Heinonen, Inge Mangelsdorf, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Hendrik van Loveren (Chair)

Hearing expert¹:

Not applicable

European Commission representative:

None

EFSA:

Nutrition Unit: Reinhard Ackerl, Agnès de Sesmaisons-Lecarré, Andrea Germini, Emanuela Turla, Ermolaos Ververis

GMO Unit: Antonio Fernandez Dumont

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Karl-Heinz Engel, Rosangela Marchelli, Harry J McArdle, Josef Rudolf Schlatter and Tara Dean.

2. Adoption of agenda

The agenda was adopted without changes.

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 (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. Draft opinion on pyrroloquinoline quinone disodium salt. Applicant: Mitsubishi Gas Chemical Company Inc. (EFSA-Q-2016-00659)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

5. Draft statement on L-ergothioneine. Applicant: *Tetrahedron* (EFSA-Q-2017-00448)

The discussion of this agenda item was postponed to the next WG meeting.

6. Status of other applications

The discussion of this agenda item was postponed to the next WG meeting.

7. Any other business

The minutes of this meeting were agreed by the WG Members.

The next WG meeting will be held on 10-11 October 2017.

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

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

Scientific Panel on Dietetic Products, Nutrition and Allergies

Minutes of the 78th meeting of the Working Group on Novel Foods

Held on 4-5 September 2017, Parma (Italy)

(Agreed on 7 September 2017)

Participants

Working Group Members:

Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz¹, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

Hearing expert²:

Not applicable

European Commission representative:

Takis Daskaleros (DG Sante)

EFSA:

Nutrition Unit: Reinhard Ackerl, Wolfgang Gelbmann, Andrea Germini, Emanuela Turla

GMO Unit: Antonio Fernandez Dumont³

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Karl-Heinz Engel, Harry J McArdle and Tara Dean.

¹ Attended on 5 September.

² As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

³ Attended on 4 September.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

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 and the Specific Declaration of Interest 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. Draft opinion on methylnicotinamide chloride. Applicant: Pharmena S.A. (EFSA-Q-2016-00520)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 19-21 September 2017 for further discussion and possible adoption.

5. Draft opinion on *Hoodia parviflora*. Applicant: Desert Labs, Ltd. (EFSA-Q-2016-00091)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 19-21 September 2017 for further discussion and possible adoption.

6. Draft opinion on *Ecklonia cava* phlorotannins. Applicant: Botamedi Inc. (EFSA-Q-2016-00518)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 19-21 September 2017 for further discussion and possible adoption.

7. Draft scientific statement on L-ergothioneine. Applicant: Tetrahedron (EFSA-Q-2017-00448)

The discussion of this agenda item was postponed to the next WG meeting.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

8. Draft opinion on D-Ribose. Applicant: Bioenergy Life Science Inc (EFSA-Q-2017-00461)

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.

9. Status of other applications

The European Commission representative updated the WG on the status of the Implementing Acts for administrative and scientific requirements on novel foods and traditional foods from third countries as referred to Regulation (EU) 2015/2283 of the European Parliament and of the Council.

10. Any other business

The next WG meeting will be held on 13 September 2017 (web-conference).

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 77th meeting of the Working Group on Novel Foods

Held on 15-16 June 2017, Parma (Italy)

(Agreed on 20 June 2017)

Participants

Working Group Members:

Marina Heinonen, Karl-Heinz Engel¹, Harry J McArdle², Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Hendrik van Loveren (chair)

Hearing expert³:

Not applicable

European Commission representative:

None

EFSA:

Nutrition Unit: Reinhard Ackerl, Agnès de Sesmaisons-Lecarré, Wolfgang Gelbmann, Andrea Germini, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Yolanda Sanz and Josef Schlatter.

¹ Participation on 15 (pm) and 16 June

² Participation via tele-conference on 15 June

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

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 and the Specific Declaration of Interest 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. Draft opinion on *Hoodia parviflora* Applicant: *Desert Labs, Ltd.* (EFSA-Q-2016-00091)

The discussion of this agenda item was postponed to the next WG meeting.

5. Draft opinion on betaine. Applicant: DuPont Nutritional Biosciences ApS (EFSA-Q-2016-00287)

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.

6. Draft opinion on N-acetyl-D-neuraminic acid. Applicant: Glycom A/S. (EFSA-Q-2016-00488)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 27-29 June 2017 for further discussion and possible adoption.

7. Draft opinion on methylnicotinamide chloride. Applicant: Pharmena S.A. (EFSA-Q-2016-00520)

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

**8. Draft opinion on pyrroloquinoline quinone disodium salt.
Applicant: Mitsubishi Gas Chemical Company Inc. (EFSA-Q-2016-00659)**

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

9. Presentation on D-Ribose. Applicant: Bioenergy Life Science Inc.

The dossier was presented. The draft scientific opinion will be discussed at the next WG meeting.

10. Status of other applications

The EFSA Unit updated the WG Members on the status of Novel Foods applications since the last meeting.

11. Any other business

The next WG meeting will be held on 4-5 September 2017.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 76th meeting of the Working Group on Novel Foods

Held on 18-19 May 2017, Parma (Italy)

(Agreed on 22 May 2017)

Participants

Working Group Members:

Marina Heinonen, Harry J McArdle, Karl-Heinz Engel, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting¹, Morten Poulsen, Yolanda Sanz, Josef Rudolf Schlatter, Hendrik van Loveren (chair)

Hearing expert²:

Not applicable

European Commission representative:

Rafael Perez-Berbejal (DG Sante)

EFSA:

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui³, Wolfgang Gelbmann, Andrea Germini⁴, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean.

¹ Participated via tele-conference

² As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

³ Attended on 18 May

⁴ Attended on 19 May

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group 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 and the Specific Declaration of Interest 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. Draft opinion on *Hoodia parviflora* Applicant: *Desert Labs, Ltd.* (EFSA-Q-2016-00091)

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.

5. Draft opinion on betaine. Applicant: DuPont Nutritional Biosciences ApS (EFSA-Q-2016-00287)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

6. Draft opinion on N-acetyl-D-neuraminic acid. Applicant: Glycom A/S. (EFSA-Q-2016-00488)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

7. Draft opinion on *Ecklonia cava* phlorotannins. Applicant: Botamedi Inc. (EFSA-Q-2016-00518)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed

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

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

with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant.

8. Draft opinion on methylnicotinamide chloride. Applicant: Pharmena S.A. (EFSA-Q-2016-00520)

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.

9. Draft opinion on pyrroloquinoline quinone disodium salt. Applicant: Mitsubishi Gas Chemical Company Inc. (EFSA-Q-2016-00659)

The discussion of this agenda item was postponed to the next WG meeting.

10. Status of other applications

The European Commission representative provided a summary of applications which may be submitted to EFSA over the next months.

11. Any other business

The next WG meeting will be held on 15-16 June 2017.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 75th meeting of the Working Group on Novel Foods

Held on 7-8 March 2017, Parma (Italy)

(Agreed on 10 March 2017)

Participants

Working Group Members:

Marina Heinonen, Harry McArdle, Inge Mangelsdorf¹, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter², Hendrik van Loveren (chair)

Hearing expert³:

Not applicable

European Commission representative:

Rafael Perez-Berbejal (DG Sante)

EFSA:

Nutrition Unit: Reinhard Ackerl, Agnès De Sesmaisons-Lecarré⁴, Wolfgang Gelbmann, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean and Karl-Heinz Engel.

¹ Participated via teleconference

² Attended on 7 March (all day) and 8 March (afternoon)

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

⁴ Attended on 7 March

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group 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 and the Specific Declaration of Interest 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. Draft opinion on Alginate-Konjac-Polysaccharide complex. Applicant: InovoBiologic, Inc. (EFSA-Q-2015-00469)

The draft scientific opinion was discussed and, after amendments, will be presented at the next NDA plenary meeting on 4-6 April 2017 for further discussion and possible adoption.

5. Draft opinion on cranberry extract. Applicant: Ocean Spray Cranberries, Inc. (EFSA-Q-2016-00325)

The draft scientific opinion was discussed and, after amendments, will be presented at the next NDA plenary meeting on 4-6 April 2017 for further discussion and possible adoption.

6. Draft opinion on additional data on Estrog-100TM. Applicant: Naturalendo Tech Co., Ltd (EFSA-Q-2017-00040)

The draft scientific opinion was discussed and, after amendments, will be presented at the next NDA plenary meeting on 4-6 April 2017 for further discussion and possible adoption.

7. Draft opinion on Betaine. Applicant: DuPont Nutritional Biosciences ApS (EFSA-Q-2016-00287)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

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

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

8. Draft opinion on N-acetyl-D-neuraminic acid. Applicant: Glycom A/S. (EFSA-Q-2016-00488)

The draft scientific opinion was discussed and, after amendments, will be presented at the next WG meeting for further discussion.

9. Draft opinion on methylnicotinamide chloride. Applicant: Pharmena S.A. (EFSA-Q-2016-00520)

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.

10. Draft opinion on pyrroloquinoline quinone disodium salt. Applicant: Mitsubishi Gas Chemical Company Inc. (EFSA-Q-2016-00659)

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.

11. Presentation on *Hoodia parviflora* Applicant: *Desert Labs, Ltd.* (EFSA-Q-2016-00091)

Additional information provided by the applicant was discussed at the WG.

12. Status of other applications

The European Commission representative provided a summary of applications which may be submitted to EFSA over the next weeks and months.

13. Info Session on Novel Foods (6th March 2017)

WG Experts and Nutrition Unit staff shared comments and views following the Info Session on Novel Foods.

14. Any other business

The next WG meeting will be held on 18-19 May 2017.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 74th meeting of the Working Group on Novel Foods

Tele-conference on 19 January 2017 (12:00–13:50)

(Agreed on 19 January 2017)

Participants

- **Working Group Members:**

Marina Heinonen, Inge Mangelsdorf, Annette Pöting, Henk van Loveren (chair)

- **European Commission representative:**

None

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Wolfgang Gelbmann, Emanuela Turla, Ermolaos Ververis

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 Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², 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. No Conflicts of Interest related to the issues discussed in this meeting have been

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Draft opinion on hydroxytyrosol. Applicant: Seprox Biotech Inc. (EFSA-Q-2015-00749)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 31 January-2 February 2017 for further discussion and possible adoption.

5. Any other business

The next WG meeting will be held on 7–8 March 2017.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 73rd meeting of the Working Group on Novel Foods

Held on 16-17 January 2017, Parma (Italy)

(Agreed on 19 January 2017)

Participants

Working Group Members:

Karl-Heinz Engel¹, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Henk van Loveren (chair)

Hearing expert²:

Not applicable

European Commission representative:

Ivona Babic (DG Sante)

EFSA:

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Agnès de Sesmaisons-Lecarré¹, Wolfgang Gelbmann, Emanuela Turla, Ermolaos Ververis

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Harry J McArdle and Josef Schlatter.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

¹ Attended on 16 January

² As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 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. Draft opinion on *Hoodia parviflora*. Applicant: Desert Labs, Ltd. (EFSA-Q-2016-00091)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 31 January-2 February 2017 for further discussion and possible adoption.

5. Draft opinion on cranberry extract. Applicant: Ocean Spray Cranberries, Inc. (EFSA-Q-2016-00325)

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.

6. Draft opinion on hydroxytyrosol. Applicant: Seprox Biotech. (EFSA-Q-2015-00749)

The draft scientific opinion was discussed and it was decided that further discussion would take place at a dedicated teleconference meeting of the WG on 19 January 2017. It will be presented at the next NDA plenary meeting on 31 January-2 February 2017 for further discussion and possible adoption.

7. Draft opinion on *Ecklonia cava* phlorotannins. Applicant: Botamedi, Inc. (EFSA-Q-2016-00518)

The draft scientific opinion was discussed. It was considered that additional information from the applicant is needed in order to proceed

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

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

with the scientific assessment of this application. Therefore, a request for additional information will be sent to the applicant.

**8. Draft opinion on Tocotrienol-rich extract from *Annatto* seeds.
Applicant: American River Nutrition Inc. (EFSA-Q-2016-00519)**

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.

**9. New Mandate on additional data on Estrog-100™. Applicant:
Naturalendo Tech Co., Ltd (EFSA-Q-2017-00040)**

The new Mandate received by the European Commission was introduced. It will be discussed at the next WG meeting.

**10. Presentation on methylnicotinamide chloride. Applicant:
Pharmena S.A. (EFSA-Q-2016-00520)**

The content of this dossier was discussed. The draft scientific opinion will be presented at the next WG meeting.

**11. Presentation on pyrroloquinoline quinone disodium salt.
Applicant: Mitsubishi Gas Chemical Company Inc. (EFSA-Q-2016-00659)**

The content of this dossier was discussed. The draft scientific opinion will be presented at the next WG meeting.

12. Status of other applications

The European Commission representative provided a summary on applications which may come to EFSA over the next weeks and months. The WG noted that the workload in the novel foods area will increase.

13. Info Session on Novel Foods (6 March 2017)

A technical meeting with stakeholders on Novel Food applications will be held in EFSA on 6 March 2017 (information available at <https://www.efsa.europa.eu/en/events/event/170306>).

The WG together with the EFSA Unit discussed the agenda and the content of the topics to be presented during the technical meeting. The WG agreed to focus on presenting examples from past applications and the rationales for reaching certain conclusions.

14. Any other business

The next WG meetings will be held on 19 January and 7-8 March 2017.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 72nd meeting of the Working Group on Novel Foods

Held on 28-29 November 2016, Parma (Italy)

(Agreed on 1 December 2016)

Participants

Working Group Members:

Karl-Heinz Engel¹, Marina Heinonen, Harry McArdle, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

Hearing expert²:

Not applicable

European Commission representative:

Rafael Perez-Berbejal (DG Sante)

EFSA:

Nutrition Unit: Reinhard Ackerl, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean.

2. Adoption of agenda

The agenda was adopted without changes.

¹ Attended on 29 November

² As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 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. Draft opinion on Tolerase®. Applicant: DSM Food Specialties (EFSA-Q-2015-00763)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 13-15 December 2016 for further discussion and possible adoption.

5. Draft opinion on Taxifolin. Applicant: Ametis JCS (EFSA-Q-2012-00961)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 13-15 December 2016 for further discussion and possible adoption.

6. Draft opinion on Aliginate-Konjac-Xanthan Polysaccharide Complex. Applicant: InovoBiologic Inc (EFSA-Q-2015-00469)

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.

7. Draft opinion on *Hoodia parviflora*. Desert Labs, Ltd. (EFSA-Q-2016-00091)

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.

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

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

8. Draft opinion on cranberry extract. Applicant: Ocean Spray Cranberries, Inc. (EFSA-Q-2016-00325)

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.

9. Draft opinion on hydroxytyrosol. Applicant: Seprox Biotech (EFSA-Q-2015-00749)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

10. Draft opinion on betaine. Applicant: DuPont Nutritional Biosciences ApS (EFSA-Q-2016-00287)

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.

11. Draft opinion on N-Acetyl-D-neuraminic acid draft opinion. Applicant: Glycom A/S (EFSA-Q-2016-00488)

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.

12. Draft opinion on Ecklonia cava phlorotannins. Applicant: Botamedi, Inc. (EFSA-Q-2016-00518)

The discussion of this agenda item was postponed to the next WG meeting.

13. Draft opinion on Tocotrienol-rich extract from *Annatto* seeds. Applicant: American River Nutrition Inc. (EFSA-Q-2016-00519)

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.

14. Draft opinion on methylnicotinamide chloride. Applicant: Pharmena S.A. (EFSA-Q-2016-00520)

The discussion of this agenda item was postponed to the next WG meeting.

15. Status of other applications

The EFSA Unit updated the WG Members on the status of Novel Foods applications since the last meeting.

16. Any other business

The European Commission representative provided a summary on the state of play of the Novel Foods applications.

The next WG meeting will be held on 16-17 January 2017.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 71st meeting of the Working Group on Novel Foods

Tele-conference on 24 November 2016 (10:00–13:30)

(Agreed on 25 November 2016)

Participants

- **Working Group Members:**

Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Annette Pöting, Morten Poulsen, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert¹:**

Not applicable

- **European Commission representative:**

None

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Harry McArdle, Monika Neuhäuser-Berthold and Yolanda Sanz.

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-

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 (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. Draft opinion on Tolerase®. Applicant: DSM Food Specialties (EFSA-Q-2015-00763)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

5. Taxifolin. Applicant: Ametis JCS (EFSA-Q-2012-00961)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

6. Any other business

The next WG meeting will be held on 28–29 November 2016.

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

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

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 70th meeting of the Working Group on Novel Foods

Held on 11–12 October, 2016, Parma (Italy)

(Agreed on 13 October 2016)

Participants

- **Working Group Members:**

Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting¹, Morten Poulsen, Yolanda Sanz², Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert³:**

Not applicable

- **European Commission representative:**

Not applicable

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Karl-Heinz Engel and Harry McArdle.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest of Working Group members

¹ Participated via teleconference on 11–12 October

² Participated via teleconference on 11 October

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 and the Specific Declaration of Interest 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. Draft opinion on Tolerase®. Applicant: DSM Food Specialties (EFSA-Q-2015-00763)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 25–27 October 2016 for further discussion and possible adoption.

5. Draft opinion on hydroxytyrosol. Applicant: Seprox Biotech (EFSA-Q-2015-00749)

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.

6. Draft opinion on synthetic L-ergothioneine. Applicant: Tetrahedron (EFSA-Q-2015-00613)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 25–27 October 2016 for further discussion and possible adoption.

7. Taxifolin. Applicant: Ametis JCS (EFSA-Q-2012-00961)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 25–27 October 2016 for further discussion and possible adoption.

8. Tocotrienol-rich extract from Annatto seeds. Applicant: American River Nutrition Inc. (EFSA-Q-2016-00519)

The content of this dossier was introduced. The draft scientific opinion will be presented at the next WG meeting.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

9. N-Acetyl-D-neuraminic acid. Applicant: Glycom A/S (EFSA-Q-2016-00488)

The content of this dossier was introduced. The draft scientific opinion will be presented at the next WG meeting.

10. Ecklonia cava phlorotannins. Applicant: Botamedi Inc. (EFSA-Q-2016-00518)

The content of this dossier was introduced. The draft scientific opinion will be presented at the next WG meeting.

11. Methylnicotinamide chloride. Applicant: Pharmena S.A. (EFSA-Q-2016-00520)

The content of this dossier was introduced. The draft scientific opinion will be presented at the next WG meeting.

12. Status of other applications

An overview of the applications which will be probably presented at the next WG meeting was provided.

13. Any other business

The next WG meeting will be held on 28–29 November 2016.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 69th meeting of the Working Group on Novel Foods

Held on 7–9 September, 2016, Parma (Italy)

(Agreed on 13 September 2016)

Participants

- **Working Group Members:**

Karl-Heinz Engel, Marina Heinonen¹, Harry McArdle, Inge Mangelsdorf, Rosangela Marchelli², Monika Neuhäuser-Berthold³, Annette Pöting⁴, Morten Poulsen, Yolanda Sanz¹, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert⁵:**

Not applicable

- **European Commission representative:**

Rafael Perez-Berbejal (DG Sante)

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean.

¹ Attended on 7–8 September

² Attended on 8–9 September

³ Attended on 7 September

⁴ Attended on 7 and 9 September

⁵ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁶ and the Decision of the Executive Director on Declarations of Interest⁷, 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. 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. Taxifolin. Applicant: Ametis JCS (EFSA-Q-2012-00961)

The new sub-chronic toxicity study was presented and, after amendments, the draft scientific opinion will be presented at the next WG meeting for further discussion

5. Draft opinion on synthetic L-ergothioneine. Applicant: Tetrahedron (EFSA-Q-2015-00613)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

6. Draft opinion on extract of three herbal roots (EstroG-100TM). Applicant: Naturalendo Tech Co Ltd. (EFSA-Q-2015-00249)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next NDA plenary meeting on 21–23 September 2016 for further discussion and possible adoption.

7. Draft opinion on Tolerase[®]. Applicant: DSM Food Specialties (EFSA-Q-2015-00763)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

⁶ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁷ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

8. Draft opinion on Alginate-Konjac-Xanthan Polysaccharide Complex. Applicant: InovoBiologic Inc. (EFSA-Q-2015-00469)

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.

9. Draft opinion on hydroxytyrosol. Applicant: Seprox Biotech (EFSA-Q-2015-00749)

The draft scientific opinion was discussed and, after amendments, it will be presented at the next WG meeting for further discussion.

10. Draft opinion on Hoodia parviflora. Applicant: Desert Labs Ltd. (EFSA-Q-2016-00091)

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.

11. Draft opinion on Cranberry extract. Applicant: Ocean Spray Cranberries, Inc. (EFSA-Q-2016-00325)

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.

12. Betaine. Applicant: DuPont Nutritional Biosciences ApS (EFSA-Q-2016-00287)

The content of this dossier was presented. The draft scientific opinion will be presented at the next WG meeting.

13. Status of other applications

The discussion of this agenda item was postponed to the next WG meeting.

14. Novel Food draft guidance (EFSA-Q-2014-00216)

The draft guidance was revised, taking into account the comments received during the public consultation. The revised draft guidance will be presented at the NDA plenary meeting on 21–23 September 2016 for discussion and possible adoption.

15. Draft report on the public consultation of the draft novel food guidance (EFSA-Q-2016-00113)

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 presented at the NDA plenary meeting on 21–23 September 2016 for discussion and possible endorsement.

16. Draft guidance for traditional foods (EFSA-Q-2015-00108)

The draft guidance was revised, taking into account the comments received during the public consultation. The revised guidance will be presented at the NDA plenary meeting on 21–23 September 2016 for discussion and possible adoption.

17. Draft report on the public consultation of the draft guidance for traditional foods (EFSA-Q-2016-00114)

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 presented at the NDA plenary meeting on 21–23 September 2016 for discussion and possible endorsement.

18. Any other business

The European Commission representative provided a summary on applications which may come to EFSA over the next weeks and months.

19. Next meeting

The next WG meeting will be held on 11–12 October 2016.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 68th meeting of the Working Group on Novel Foods

Tele-conference on 16 June 2016 (14:00–18:00)

(Agreed on 21 June 2016)

Participants

- **Working Group Members:**

Tara Dean, Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry McArdle, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

- **European Commission representative:**

None

- **EFSA:**

Nutrition Unit: Wolfgang Gelbmann

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Marina Heinonen, Rosangela Marchelli, Harry McArdle, Morten Poulsen, Yolanda Sanz, Josef Schlatter.

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 Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Interest and the Specific Declaration of Interest 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. Draft opinion on phytosterol esters (extension of use: for cooking oils) Applicant: Unilever PLC and Unilever N.V. (EFSA-Q-2014-00865)

The draft scientific opinion on phytosterol esters was discussed and, after amendments, it will be presented to the next NDA plenary meeting³ for further discussion and possible adoption.

5. Any other business

The next WG meeting will be held on 7–9 September 2016.

³ The next meeting of the NDA Panel will be held on 28–30 June 2016

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 67th meeting of the Working Group on Novel Foods

Held on 25–27 May, 2016, Parma (Italy)

(Agreed on 13 June 2016)

Participants

- **Working Group Members:**

Tara Dean, Karl-Heinz Engel¹, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry McArdle, Monika Neuhäuser-Berthold, Annette Pöting², Morten Poulsen¹, Yolanda Sanz¹, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert³:**

Not applicable

- **European Commission representative:**

Siret Surva (DG Sante)

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Harry McArdle.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

¹ Attended on 25–26 May

² Attended by teleconference on 25–27 May

³ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

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 and the Specific Declaration of Interest 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. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: Alginate-Konjac-Xanthan Polysaccharide Complex ([EFSA-Q-2015-00469](#)), Nattokinase ([EFSA-Q-2015-294](#)), extract of three herbal roots (EstroG-100) ([EFSA-Q-2015-00249](#)), synthetic L-ergothioneine ([EFSA-Q-2015-00613](#)), hydroxytyrosol ([EFSA-Q-2015-00749](#)); proline-specific oligopeptidase ([EFSA-Q-2015-00763](#)), phytosterol esters ([EFSA-Q-2014-00865](#)) and Hoodia parviflora ([EFSA-Q-2016-00091](#)).

In addition comments received from the public consultations ([EFSA-Q-2016-00113](#), [EFSA-Q-2016-00114](#)) of the two draft guidance documents on novel foods ([EFSA-Q-2014-00216](#)) and traditional foods from third countries ([EFSA-Q-2015-00108](#)), respectively, were discussed. Also comments and proposals from the Scientific Committee's Working Group on Botanicals on these two draft guidance documents were discussed.

5. Any other business

The European Commission representative provided a short summary on applications which may come to EFSA over the next weeks and months.

6. Next meeting

The next WG meetings will be held on 16 June (tele-conference) and on 7-9 September 2016.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 66th meeting of the Working Group on Novel Foods

Held on 4–5 April, 2016, Parma (Italy)

(Agreed on 13 June 2016)

Participants

- **Working Group Members:**

Tara Dean, Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry McArdle¹, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert²:**

Not applicable

- **European Commission representative:**

Siret Surva³ (DG Sante)

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Rosangela Marchelli, Yolanda Sanz, and Josef Schlatter.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

¹ By teleconference on 5 April

² As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

³ By teleconference on 4–5 April

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 and the Specific Declaration of Interest 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. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: Nattokinase (EFSA-Q-2015-294), synthetic L-ergothioneine (EFSA-Q-2015-00613), hydroxytyrosol (EFSA-Q-2015-00749); proline-specific oligopeptidase (EFSA-Q-2015-00763) and phytosterol esters (EFSA-Q-2014-00865). In addition comments received from EFSA Units and Panels on the two draft guidance documents on novel foods (EFSA-Q-2014-00216) and traditional foods from third countries (EFSA-Q-2015-00108), respectively, were discussed.

5. Any other business

The WG also briefly discussed the upcoming stakeholder meeting on the 11 April on the two draft guidance documents.

6. Next meeting

The next meetings will be held on the 25–27 May 2016.

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 65th meeting of the Working Group on

Novel Foods

Held on 10 - 11 February, Parma, Italy

(Agreed on 26 February, 2016)

Participants

- **Working Group Members:**

Tara Dean, Karl-Heinz Engel¹, Marina Heinonen², Inge Mangelsdorf, Rosangela Marchelli, Harry McArdle, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert:**

None

- **European Commission representative:**

Siret Surva

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean, Harry McArdle, Morten Poulsen, and Yolanda Sanz.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

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 filled in by the working group members invited for the

¹ Present only on 11th February

² Present via teleconference on 10th February

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

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

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. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: Alginate-Konjac-Xanthan Polysaccharide Complex(EFSA-Q-2015-00469), extract of three herbal roots (EstroG-100; EFSA-Q-2015-00249), synthetic L-ergothioneine (EFSA-Q-2015-00613), hydroxytyrosol (EFSA-Q-2015-00749); and phytosterol esters (EFSA-Q-2014-00865).

5. AOB

The WG was informed about the scheduled date (18th February) for the launch of the public consultation of the draft guidance documents for novel food applications (EFSA-Q-2014-00216) and for notifications of traditional foods from third countries (EFSA-Q-2015-00108), respectively, and also about a stakeholder meeting on the 11th of April when EFSA will seek comments and feed-back from stakeholders on these drafts.

6. Next meeting

The next meetings will be held on 4 - 5th April and 25 - 27th May 2016.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 64th meeting of the Working Group on

Novel Foods

Held on 14 - 15 January, Parma, Italy

(Agreed on 4 February 2016)

Participants

- **Working Group Members:**

Tara Dean, Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry McArdle, Monika Neuhäuser-Berthold, Annette Pöting (by teleconference on 15th Jan), Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert:**

None

- **European Commission representative:**

Sirkku Heinimaa

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Karl-Heinz Engel (morning of 14th January) and from Josef Schlatter.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², 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 Interest related to the issues discussed in this

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: Alginate-Konjac-Xanthan Polysaccharide Complex (EFSA-Q-2015-00469) and extract of three herbal roots (EstroG-100) (EFSA-Q-2015-00249).

The WG also discussed a revised draft guidance document for novel food applications (EFSA-Q-2014-00216) and for traditional foods from third countries (EFSA-Q-2015-00108)

5. AOB

6. Next meeting

The next meetings will be held on 10-11 February 2016.

Scientific Panel on Dietetic products, Nutrition and Allergies
Minutes of the 63rd meeting of the Working Group on
Novel Foods
Held on 26 - 27 November, Parma, Italy
(Agreed on 4 February 2016)

Participants

- **Working Group Members:**

Tara Dean (by webconference), Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry McArdle, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert:**

None

- **European Commission representative:**

Sirkku Heinimaa

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

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

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², 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 Interest related to the issues discussed in this

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: synthetic *trans*-resveratrol (EFSA-Q-2014-00232) and UV treated pasteurised milk (EFSA-Q-2015-00469).

The WG also discussed a revised draft guidance document for novel food applications (EFSA-Q-2014-00216).

5. AOB

6. Next meeting

The next meetings will be held on 14-15 January 2016.

Scientific Panel on Dietetic products, Nutrition and Allergies
Minutes of the 62nd meeting of the Working Group on
Novel Foods
Held on 10 - 11 November, Parma, Italy
(Agreed on 18 November 2015)

Participants

- **Working Group Members:**

Tara Dean, Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf (by webconference), Rosangela Marchelli, Harry McArdle, Monika Neuhäuser-Berthold, Annette Pöting (by webconference on 11th Nov), Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert:**

None

- **European Commission representative:**

Sirkku Heinimaa

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. An apology was received from Josef Schlatter.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², 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 Interest related to the issues discussed in this

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: on a fermented soybean extract (Nattokinase; EFSA-Q-2015-294), taxifolin (EFSA-Q-2012-00961), synthetic *trans*-resveratrol (EFSA-Q-2014-00232), phytosterol esters (EFSA-Q-2014-00865), and Alginate-Konjac-Xanthan Polysaccharide (EFSA-Q-2015-00469).

The WG also discussed sections of a draft guidance document for novel food applications (EFSA-Q-2014-00216).

5. AOB

The European Commission informed about the next legislative steps for the proposal for a new Novel Food Regulation.

6. Next meeting

The next meetings will be held on 26-27 November 2015.

Scientific Panel on Dietetic products, Nutrition and Allergies
Minutes of the 61st meeting of the Working Group on
Novel Foods
Held on 5 - 6 October, Parma, Italy
(Agreed on 15 October 2015)

Participants

- **Working Group Members:**

Tara Dean, Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry McArdle (by tele-conference on 6th Oct), Monika Neuhäuser-Berthold, Annette Pötting (by tele-conference), Morten Poulsen, Yolanda Sanz, Josef Schlatter (by tele-conference), Hendrik van Loveren (chair)

- **Hearing expert:**

None

- **European Commission representative:**

Siret Surva

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

Apologies have been received from Tara Dean, Karl-Heinz Engel, Marina Heinonen, Inge Mangelsdorf, Morten Poulsen, and Yolanda Sanz for both days and from Harry McArdle for the 5th of October.

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Declaration of Interest 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. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: on a fermented soybean extract (Nattokinase; EFSA-Q-2015-294), extract of three herbal roots (EstroG-100; EFSA-Q-2015-00249), taxifolin (EFSA-Q-2012-00961), synthetic trans-resveratrol (EFSA-Q-2014-00232), and UV treated pasteurised milk (EFSA-Q-2015-00132).

5. AOB

The European Commission informed that EFSA will soon receive a mandate related to the two opinions on synthetic oligosaccharides (Lacto-N-neotetraose; EFSA-Q-2014-00862 and 2'-O-Fucosyllactose, EFSA-Q-2015-00052) and their use in food supplements for children.

6. Next meeting

The next meetings will be held on 10–11 and 26–27 November 2015.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 60th meeting of the Working Group on

Novel Foods

Held on 2 - 3 September, Parma, Italy

(Agreed on 11 September 2015)

Participants

- **Working Group Members:**

Monika Neuhäuser-Berthold, Paul Brantom (by tele-conference on 2nd Sept 3-5 pm); Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Rosangela Marchelli, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik van Loveren, Hans Verhagen (Chair)

- **Hearing expert:**

None

- **European Commission representative:**

Siret Surva

- **EFSA:**

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Wolfgang Gelbmann, Emanuela Turla

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted. The agenda point on UV treated pasteurised milk (EFSA-Q-2012-00132) was not discussed because the applicants response is expected by mid of September.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

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. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: taxifolin (EFSA-Q-2012-00961), synthetic *trans*-resveratrol (EFSA-Q-2014-00232), extension of use for phytosterol esters (EFSA-Q-2014-00865), extract of three herbal roots (EstroG-100; EFSA-Q-2015-00249) and on a fermented soybean extract (Nattokinase; EFSA-Q-2015-294).

The WG also discussed sections of a draft guidance document for novel food applications (EFSA-Q-2014-00216) and a first draft for a guidance for notifications of Traditional Foods from third countries (EFSA-Q-2015-00108).

5. Next meeting

The next meeting will be held on 5 – 6 October 2015.

Scientific Panel on Dietetic products, Nutrition and Allergies

Minutes of the 59th meeting of the Working Group on

Novel Foods

Held on 3 - 4 June, Parma, Italy

(Agreed on 2 September 2015)

Participants

- **Working Group Members:**

Monika Neuhäuser-Berthold, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Rosangela Marchelli, Morten Poulsen, Annette Pöting (joined by tele-conference on 3rd of June), Seppo Salminen, Josef Schlatter, Hendrik Van Loveren (3rd of June), Hans Verhagen (Chair)

- **Hearing expert:**

Not Applicable

- **European Commission representative:**

None

- **EFSA:**

- **Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Wolfgang Gelbmann, Emanuela Turla, Silvia Valtuena-Martinez**

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Henk Van Loveren and Annette Pöting, both for the 4th of June.

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Interest², 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 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. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: UV light-treated bread (EFSA-Q-2014-00836), UV treated pasteurised milk (EFSA-Q-2012-00132), two synthetic oligosaccharides Lacto-N-neotetraose (EFSA-Q-2014-00862) and 2'-O-Fucosyllactose (EFSA-Q-2015-00052), and an extension of use for phytosterol esters (EFSA-Q-2014-00865).

The WG also discussed sections of a draft guidance document for novel food applications (EFSA-Q-2014-00216) and a first draft for a guidance for notifications of Traditional Foods from third countries (EFSA-Q-2015-00108).

5. Next meeting

The next meeting will be held on 2 – 3 September 2015.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Scientific Panel on Dietetic products, Nutrition and Allergies
Minutes of the 58th meeting of the Working Group on
Novel Foods
Held on 28 - 30 April, Parma, Italy
(Agreed on 3 June 2015)

Participants

- **Working Group Members:**

Monika Neuhäuser-Berthold (vice-chair, chairing on 29 April pm and 30 April), Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Rosangela Marchelli, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)

- **Hearing expert:**

Not Applicable

- **European Commission representative:**

Siret Surva (DG SANCO)

- **EFSA:**

- **Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Wolfgang Gelbmann, Emanuela Turla**

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received from Henk Van Loveren (28 April) and Hans Verhagen (29 April, pm and 30 April) and Annette Pöting (30 April, pm).

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

3. Declarations of interest of Working Group members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director on Declarations of Interest², 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 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. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: Taxifolin (EFSA-Q-2012-00961), UV light-treated bread (EFSA-Q-2014-00836), UV treated pasteurised milk (EFSA-Q-2012-00132), two synthetic oligosaccharides Lacto-N-neotetraose (EFSA-Q-2014-00862) and 2'-O-Fucosyllactose (EFSA-Q-2015-00052), and an extension of use for phytosterol esters (EFSA-Q-2014-00865).

The WG also discussed sections of a draft guidance document for novel food applications (EFSA-Q-2014-00216) and a first draft for a guidance for notifications of Traditional Foods from third countries (EFSA-Q-2015-00108).

5. Next meeting

The next meeting will be held on 3 – 4 June 2015.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

Scientific Panel on Dietetic products, Nutrition and Allergies
Minutes of the 57th meeting of the Working Group on
Novel Foods
Held on 11 - 12 March, Parma, Italy
(Agreed on 30 April 2015)

Participants

- **Working Group Members:**

Paul Brantom¹, Monika Neuhäuser-Berthold (vice-chair, chairing on 12 Feb), Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Rosangela Marchelli, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)

- **Hearing expert:**

Not Applicable

- **European Commission representative:**

Sirkku Heinimaa (DG SANCO)

- **EFSA:**

- **Nutrition Unit: Reinhard Ackerl, Wolfgang Gelbmann, Emanuela Turla**

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Seppo Salminen and Hans Verhagen, both for the 12th of March. Paul Brantom informed about his resignation from this and other EFSA working groups for private reasons, but indicated his disposition for completing of his task as a rapporteur for the application on resveratrol. The Chair expressed his and the Working Groups regrets about this resignation and thanked him for his valuable contributions in the past.

¹ Joining in the morning of 11 March on item EFSA-Q-2014-00232 by tele-conference

2. Adoption of agenda

The agenda was adopted without changes, except for the order in which the agenda points were discussed.

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 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. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: Taxifolin (EFSA-Q-2012-00961), synthetic *trans*-resveratrol (EFSA-Q-2014-00232), UV light-treated bread (EFSA-Q-2014-00836) and the two synthetic oligosaccharides: Lacto-N-neotetraose (EFSA-Q-2014-00862) and 2'-O-Fucosyllactose (EFSA-Q-2015-00052).

The WG also discussed sections of a draft guidance document for novel food applications (EFSA-Q-2014-00216) and the approach for a guidance for notifications of Traditional Foods from third countries (EFSA-Q-2015-00108).

5. Next meeting

The next meeting will be held on 28 – 30 April 2015.

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

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

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 56th Meeting of the Working Group (WG) on Novel Foods

Held on 15-16 January 2015, Parma

(Agreed on 11 March 2015)

Participants:

• **Working Group Experts:**

– Paul Brantom, Monika Neuhäuser-Berthold, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Rosangela Marchelli, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)

• **European Commission:** none

• **EFSA, Nutrition Unit:**

– Valeriu Curtui, Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Marina Heinonen (for 16 January) and Sirkku Heinimaa (EC).

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 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.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

4. Agreement of the minutes of the 55th Working Group meeting held on 6-7 November 2014 in Parma.

The minutes were agreed by the WG on 15 January 2015.

5. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: for synthetic trans-resveratrol (EFSA-Q-2014-00232), refined seeds oil of *Buglossoides arvensis* (EFSA-Q-2014-00444), UV treated bread (EFSA-Q-2014-00836) and Lacto-N-neotetraose (EFSA-Q-2014-00862).

The WG considered that the draft opinion on synthetic trans-resveratrol and on *Buglossoides arvensis* should be forwarded to the Panel for discussion and possible adoption.

The WG also discussed sections of a draft guidance document for novel food applications (EFSA-Q-2014-00216).

6. Any Other Business

None.

7. Next meeting

The next meetings will take place on 11-12 March and on 28-30 April 2015.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 55th Meeting of the Working Group (WG) on Novel Foods

Held on 6-7 November 2014, Parma

(Agreed on 15 January 2015)

Participants:

• **Working Group Experts:**

- Paul Brantom, Monika Neuhäuser-Berthold, Rosangela Marchelli, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)

• **European Commission:** none

• **EFSA, Nutrition Unit:**

- Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Sirkku Heinimaa (EC), and Josef Schlatter.

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 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.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

4. Agreement of the minutes of the 54th Working Group meeting held on 3-4 September 2014 in Parma.

The minutes were agreed by the WG on 6 November 2014.

5. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: *Arracacia xanthorrhiza* (EFSA-Q-2011-00918), pasteurised milk products fermented with *Bacteroides xylanisolvens* (EFSA-Q-2014-00295), for synthetic trans-resveratrol (EFSA-Q-2014-00232), refined seeds oil of *Buglossoides arvensis* (EFSA-Q-2014-00444), and on post-marketing data on the use of lycopene (EFSA-Q-2014-00444).

The WG considered that the draft opinions on *Arracacia xanthorrhiza*, pasteurised milk products fermented with *Bacteroides xylanisolvens*, refined seeds oil of *Buglossoides arvensis* and lycopene should be forwarded to the Panel for discussion and possible adoption. With regards to the application on resveratrol, the Working Group considered that additional data should be requested from the applicant and a clock stop should be applied.

The WG also discussed sections of a draft guidance document for novel food applications (EFSA-Q-2014-00216).

6. Any Other Business

None.

7. Next meeting

The next meetings will take place on 27 November 2014 (sub- working group) in Parma and on 15-16 January 2015 in Parma.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 54th Meeting of the Working Group (WG) on Novel Foods

Held on 3-4 September 2014, Parma

(Agreed on 6 November 2014)

Participants:

• **Working Group Experts:**

- Paul Brantom, Monika Neuhäuser-Berthold, Rosangela Marchelli, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)

• **European Commission:** none

• **EFSA, Nutrition Unit:**

- Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Sirkku Heinimaa (EC), Paul Brantom (for 4th Sept; joining by teleconference on the 3rd) Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen and Morten Poulsen (for 3rd Sept; joining by teleconference on the 4th).

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 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.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

4. Agreement of the minutes of the 53rd Working Group meeting held on 21-22 May 2014, Vienna

The minutes were agreed by the WG on 3 September 2014.

5. Scientific topics for discussion

The WG discussed and elaborated on draft opinions on the following Novel Food applications: Extension of use for DHA and EPA-rich algal oil from *Schizochytrium* ([EFSA-Q-2014-00218](#)), for synthetic *trans*-resveratrol ([EFSA-Q-2014-00232](#)), pasteurised milk products fermented with *Bacteroides xylanisolvens* ([EFSA-Q-2014-00295](#)), refined seeds oil of *Buglossoides arvensis* ([EFSA-Q-2014-00444](#)),

The WG considered that the draft opinion on DHA and EPA-rich algal oil from *Schizochytrium* should be forwarded to the Panel for discussion and possible adoption. The WG also discussed sections of a draft guidance document for novel food applications ([EFSA-Q-2014-00216](#)). The WG was briefed about the mandate EFSA has received on risk related to insects for food and feed ([EFSA-Q-2014-00444](#)). It is addressed by the Scientific Committee.

6. Any Other Business

None.

7. Next meeting

The next meeting will take place on 6-7 November 2014 in Parma.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 53rd Meeting of the Working Group (WG) on Novel Foods

Held on 21-22 May 2014, Vienna

(Agreed on 3 September 2014)

Participants:

• **Working Group Experts:**

- Paul Brantom, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Monika Neuhäuser-Berthold, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)

• **European Commission:** Sirkku Heinimaa

• **EFSA, Nutrition Unit:**

- Agnès de Sesmaisons Lecarré, Wolfgang Gelbmann

1. Welcome and apologies for absence

The Chair welcomed the participants. An apology was received from Rosangela Marchelli.

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 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.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

4. Agreement of the minutes of the 52nd Working Group meeting held on 20 March 2014, Parma

The minutes were agreed by the WG on 21 May 2014.

5. Scientific topics for discussion

The application on Cetyl Myristoleate Complex ([EFSA-Q-2014-00166](#)) was discussed by the Working Group (WG) and after amendments, will be presented at the next Panel meeting for further discussion and possible adoption.

The WG discussed and elaborated on a draft opinion on the application for an extension of use for DHA and EPA-rich algal oil from *Schizochytrium* sp. ([EFSA-Q-2014-00218](#)).

The WG also discussed sections of a draft guidance document for novel food applications ([EFSA-Q-2014-00216](#)).

6. Any Other Business

None.

7. Next meeting

The next meeting will take place on 3-4 September 2014 in Parma.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 52nd Meeting of the Working Group (WG) on Novel Foods

Held on 20 March 2014, Parma

(Agreed on 21 May 2014)

Participants:

• **Working Group Experts:**

- Hannu Korhonen, Monika Neuhäuser-Berthold, Annette Pöting, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)
- Rosangela Marchelli participated in agenda point related to [EFSA-Q-2011-00990](#)
- Paul Brantom, Morten Poulsen, Seppo Salminen have participated via tele-conference in agenda point related to [EFSA-Q-2011-00990](#)

• **European Commission:** Sirkku Heinimaa (per tele-conference)

• **EFSA, Nutrition Unit:**

- Agnès de Sesmaisons Lecarré

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Karl-Heinz Engel and Marina Heinonen.

Paul Brantom, Morten Poulsen, Rosangela Marchelli and Seppo Salminen participated to only part of the discussion on agenda point [EFSA-Q-2011-00990](#).

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

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interests², 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. Agreement of the minutes of the 51th Working Group meeting held on 9-10 January 2014, Parma

The minutes were agreed by the WG on 20 March 2014.

5. Scientific topics for discussion

The application on Astaxanthin ([EFSA-Q-2011-00990](#)) was discussed by the Working Group (WG) and after amendments, will be presented at the next Panel meeting for further discussion and possible adoption.

A new request to review the opinion on the safety of Cetyl Myristoleate Complex ([EFSA-Q-2014-00166](#)) was presented to the WG.

6. Any Other Business

None.

7. Next meeting

The next meeting will take place on 21-22 May 2014.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 51st Meeting of the Working Group (WG) on Novel Foods

Held on 9–10 January 2014, Parma

(Agreed on 20 March 2014)

Participants:

• **Working Group Experts:**

- Paul Brantom, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Monika Neuhäuser-Berthold, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik van Loveren, Hans Verhagen (Chair)

• **European Commission:** Sirkku Heinimaa

• **EFSA, Nutrition Unit:**

- Valeriu Curtui (on 10th Jan)
- Wolfgang Gelbmann
- Agnès de Sesmaisons Lecarré

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Paul Brantom and from Seppo Salminen (for 10th Jan). Annette Pöting joined both days via telephone-conference.

Since the last WG meeting, Bevan Moseley has withdrawn his membership from the WG on Novel Foods which he served as a Chair from 2003 to 2012 and since then as a regular member. The Chair and all members the Working Group and EFSA Staff expressed their appreciation and gratitude for the significant and continued work and contribution over about ten years as a Chair, expert and rapporteur for the WG on Novel Foods. The WG and EFSA wish only the very best to Bevan Moseley.

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

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interests,² EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest filled in by the experts invited for the present meeting.

For the agenda item related to Astaxanthin, Marina Heinonen repeated her declaration on an interest at the beginning of the meeting: The expert was involved in the Finnish Novel Food Board initial assessment on Astaxanthin in 2008. The interest was classified as level b interest. The expert will not be involved in the drafting of the opinion.

No other conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

For further details on the outcome of the Oral Declaration of Interests made at the beginning of the meeting, please refer to the Annex I.

4. Agreement of the minutes of the 50th Working Group meeting held on 7-8 November 2013, Parma

The minutes were agreed by the WG on 9 January 2014 upon minor editorial changes.

5. Scientific topics for discussion

5.1 Applications

The application on Taxifolin ([EFSA-Q-2012-00961](#)) and the applicant's response to an EFSA letter (dated 08/03/2013) were discussed. The WG considers that only some of the questions were addressed, but requests additional information and a completed response to its questions from 2013. A next letter will be drafted and sent to the applicant. The application remains under clock-stop.

The application on Astaxanthin ([EFSA-Q-2013-00990](#)), under clock-stop, was discussed and is expected to be finalised for submission to the Panel and possible adoption at one of the following meetings awaiting the adoption of a related opinion ([EFSA-Q-2011-01071](#)) on Astaxanthin from another source by the FEED Panel.

5.2 EC's proposal for a new Novel Food Regulation

A verbal update on the EC's proposal for a new Novel Food Regulation and on upcoming tasks were provided by the representative of the EC. The proposal is public at: http://ec.europa.eu/food/food/biotechnology/novelfood/documents/novel-cloning_com2013-894_final_en.pdf

6. Any Other Business

None.

7. Next meeting

The next meeting will take place on 19-20 March 2014.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

Annex I

Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

For the agenda item related to Astaxanthin, Marina Heinonen repeated her declaration on an interest at the beginning of the meeting: The expert was involved in the Finnish Novel Food Board initial assessment on Astaxanthin in 2008. The interest was classified as level b interest. The expert will not be involved in the drafting of the opinion.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 50th Meeting of the Working Group on Novel Foods

Held on 7–8 November 2013, Parma

(Agreed on 9 January 2014)

Participants:

• **Working Group Experts:**

- Paul Brantom, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Bevan Moseley, Monika Neuhäuser-Berthold, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)

• **European Commission:** none

• **EFSA, Nutrition Unit:**

- Wolfgang Gelbmann
- Agnès de Sesmaisons Lecarré

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Marina Heinonen (for 8th November) and from Seppo Salminen (both days).

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 Interests,² EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest filled in by the experts invited for the present meeting.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

For the agenda item related to Astaxanthin, Marina Heinonen repeated her declaration on an interest at the beginning of the meeting: The expert was involved in the Finnish Novel Food Board initial assessment on Astaxanthin in 2008. The interest was classified as level b interest. The expert will not be involved in the drafting of the opinion.

No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

For further details on the outcome of the Oral Declaration of Interests made at the beginning of the meeting, please refer to the Annex I.

4. Agreement of the minutes of the 49th Working Group meeting held on 5–6 September 2013, Helsinki

The minutes were agreed by the WG on 7 November 2013.

5. Scientific topics for discussion

5.1 Applications

The applications on Taxifolin ([EFSA-Q-2012-00961](#)) and Astaxanthin ([EFSA-Q-2013-00990](#)), both currently under clock-stop, were discussed and will be finalised at a following meeting, once EFSA will have received the applicants response.

The Working Group considered that the draft opinion on UV-treated yeast could be forwarded to the plenary provided that the intake assessment reflects the uses of the novel foods as intended by the applicant – to be clarified by the NUTRI secretary and the applicant.

5.2 EC's proposal for a new Novel Food Regulation

A verbal update on the EC's proposal for a new Novel Food Regulation was provided.

6. Any Other Business

None.

7. Next meeting

The next meeting will take place on 9 and 10 January 2014.

Annex I

Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

For the agenda item related to Astaxanthin, Marina Heinonen repeated her declaration on an interest at the beginning of the meeting: The expert was involved in the Finnish Novel Food Board initial assessment on Astaxanthin in 2008. The interest was classified as level b interest. The expert will not be involved in the drafting of the opinion.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 49th Meeting of the Working Group on Novel Foods

Held on 5–6 September 2013, Helsinki

(Agreed on 7 November 2013)

Participants:

• **Working Group Experts:**

- Paul Brantom, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Bevan Moseley, Monika Neuhäuser-Berthold, Morten Poulsen, Annette Pöting, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)

• **European Commission:** Sirkku Heinimaa

• **EFSA, Nutrition Unit:**

- Wolfgang Gelbmann
- Agnès de Sesmaisons Lecarré participated in the first day of the meeting, agenda points related to [EFSA-Q-2013-00080](#) and [EFSA-Q-2013-00232](#)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Rosangela Marchelli.

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 Interests,² EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

conflicts of interests related to the issues discussed in this meeting have been identified during the screening process.

For further details on the outcome of the Oral Declaration of Interests made at the beginning of the meeting, please refer to the Annex I.

4. Agreement of the minutes of the 48th Working Group meeting held on 5–6 June 2013, Parma

The minutes were agreed by the WG on 7 September 2013.

5. Scientific topics for discussion

5.1 Applications

The applications on Gantrez novel chewing gum ingredient ([EFSA-Q-2012-00653](#)), Citicoline ([EFSA-Q-2013-00080](#)), Rapeseed Protein ([EFSA-Q-2013-00231](#)), Coriander Seed Oil ([EFSA-Q-2013-00232](#)) were discussed by the Working Group (WG), and after amendments, will be presented to the Panel in October for further discussion and possible adoption.

The WG discussed and elaborated on draft opinions on the following Novel Food application on UV-treated yeast ([EFSA-Q-2013-00335](#)).

The discussion on Taxifolin ([EFSA-Q-2012-00961](#)) was postponed to the following meeting, awaiting additional information requested to the applicant (clock-stop).

6. Any Other Business

None.

7. Next meeting

The next meeting will take place on 7 and 8 November 2013.

Annex I

Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

With regard to this meeting, Dr. Seppo Salminen declared an interest for the application from Nestec Ltd. on Coriander Seed Oil ([EFSA-Q-2013-00232](#)). 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 the application on Coriander Seed Oil is discussed, voted on or in anyway processed by that concerned scientific group.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 48th Meeting of the Working Group on Novel Foods

Held on 5–6 June 2013, Parma

(Agreed on 5 September 2013)

Participants:

• **Working Group Experts:**

- Paul Brantom, Karl-Heinz Engel, Hannu Korhonen, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Morten Poulsen, Hendrik Van Loveren, Hans Verhagen (Chair)
- Annette Pöting participated via teleconference in agenda point related to [EFSA-Q-2012-00653](#)

• **European Commission:** None

• **EFSA, Nutrition Unit:** Wolfgang Gelbmann, Agnès de Sesmaisons Lecarré

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Seppo Salminen and Josef Schlatter.

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 Interests,² 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.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

4. Agreement of the minutes of the 47th Working Group meeting held on 10–11 April 2013, Berlin and the teleconference of a sub-Working group held on 8 May 2013

The minutes were agreed by the WG on 5 June 2013.

5. Scientific topics for discussion

5.1 Applications

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Gantrez novel chewing gum ingredient ([EFSA-Q-2012-00653](#)) and Rapeseed Protein ([EFSA-Q-2013-00231](#)).

For Coriander Seed Oil ([EFSA-Q-2013-00232](#)), it was considered that additional information from the applicant are needed in order to proceed with the scientific assessment of these applications. Therefore, a request will be sent to the applicant and a stop the clock procedure will be applied.

A new application on UV-treated yeast ([EFSA-Q-2013-00335](#)) was discussed.

6. Any Other Business

None.

7. Next meeting

The next meeting will take place on 5 and 6 September 2013.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the Tele-conference of a sub-Working Group of the Working Group on Novel Foods

Held on 8 May 2013, Parma

(Agreed on 5 June 2013)

Participants

- **Working Group Experts:**

Paul Brantom, Karl-Heinz Engel, Hannu Korhonen, Annette Pöting, Morten Poulsen, Hendrik Van Loveren, Hans Verhagen (Chair)

- **European Commission:** None

- **EFSA, Nutrition Unit:** Wolfgang Gelbmann

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 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.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

4. Scientific topics for discussion

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications:

The draft scientific opinions on Rooster Combs Extract ([EFSA-Q-2012-00613](#)) and Cetyl Myristoleate Complex ([EFSA-Q-2012-00649](#)) were discussed by the WG, and after amendments, will be presented to the Panel in May for further discussion and possible adoption.

For Gantrez novel chewing gum ingredient ([EFSA-Q-2012-00653](#)) and Rapeseed Protein ([EFSA-Q-2013-00231](#)), it was considered that additional information from the applicants are needed in order to proceed with the scientific assessment of these applications. Therefore, a request will be sent to the applicants and stop the clock procedures will be applied.

5. Any Other Business

None.

6. Next meeting

Next meeting will take place on 5 and 6 September 2013.

Scientific Panel on dietetic products, nutrition and allergies

Minutes of the 47th Meeting of the Working Group on Novel Foods

Held on 10-11 April 2013, Berlin

(Agreed on 5 June 2013)

Participants:

• **Working Group Experts:**

Paul Brantom, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen (Chair)

• **European Commission:** None

• **EFSA, Nutrition Unit:** Wolfgang Gelbmann, Agnès de Sesmaisons

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Josef Schlatter.

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 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.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

4. Agreement of the minutes of the 46th Working Group meeting held on 11 - 12 February 2013, in Amsterdam

The minutes were agreed by the WG on 10 April 2013.

5. Scientific topics for discussion

5.1 Applications

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Rooster Combs Extract ([EFSA-Q-2012-00613](#)), Cetyl Myristoleate Complex ([EFSA-Q-2012-00649](#)), Gantrez novel chewing gum ingredient ([EFSA-Q-2012-00653](#)), Citicoline ([EFSA-Q-2013-00080](#)), Rapeseed Protein ([EFSA-Q-2013-00231](#)) and Coriander Seed Oil ([EFSA-Q-2013-00232](#)).

For the applications on Gantrez novel chewing gum ingredient and Rapeseed protein, the WG identified a number of issues to be addressed by the applicants.

5.2 Update Novel Food Guidance

In anticipation of the adoption of a new Novel Food Regulation and a respective request of the European Commission to EFSA to provide an updated Guidance for applicants, the WG has started preparatory work and discussed some draft chapters for an updated guidance on Novel Foods.

6. Any Other Business

None.

7. Next meeting

The next meeting will take place on 5 and 6 June 2013.

Scientific Panel on dietetic products, nutrition and allergies
Minutes of the 46th Meeting of the Working Group on Novel Foods
Held on 11 - 12 February 2013, Amsterdam
(Agreed on 10 April 2013)

Participants:

- **WG Experts:**
 - Paul Brantom, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair)
 - Karl-Heinz Engel has participated on 11 February 2013
 - Henk van Loveren has participated on 12 February 2013
- **European Commission:** Andreas Klepsch
- **EFSA, Nutrition Unit:** Wolfgang Gelbmann

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Rosangela Marchelli and Seppo Salminen.

2. Adoption of agenda

An item was added to the agenda with respect to the application on Cetyl Myristoleate Complex ([EFSA-Q-2012-00649](http://www.efsa.europa.eu/en/keydocs/docs/independencerule.pdf)). The Chair asked the participants whether there was any interest in relation to this application. No interest was declared. The sequence of the agenda items was amended.

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 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.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

4. Agreement of the minutes of the 45th Working Group meeting held on 6 - 7 December 2012, Parma

The minutes were agreed by the WG meeting on 11 February 2013.

5. Scientific topics for discussion

5.1 Applications

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications:

For Rooster Combs Extract ([EFSA-Q-2012-00613](#)) and Taxifolin ([EFSA-Q-2012-00961](#)), it was considered that additional information from the applicants are needed in order to proceed with the scientific assessment of these applications. Therefore, a request will be sent to the applicants and stop the clock procedures will be applied.

For Cetyl Myristoleate Complex ([EFSA-Q-2012-00649](#)) (application under clock-stop), the quality of the provided 90-day sub-chronic toxicity study was discussed.

A new application on Citicoline ([EFSA-Q-2013-00080](#)) was discussed.

5.2. Update Novel Food Guidance

In anticipation of the adoption of a new Novel Food Regulation and a respective request of the European Commission to EFSA to provide an updated Guidance for applicants, the WG has started preparatory work and discussed some draft chapters for an update guidance on Novel Foods.

6. Any Other Business

Andreas Klepsch (EC) informed about new mandates related to two Novel Food applications (coriander seed oil, rapeseed protein), which would be sent to EFSA after this WG meeting.

7. Next meeting

The next meeting will take place on 10 and 11 April 2013.

Parma, 5 February 2013

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 45th Meeting of the Working Group (WG) on Novel Foods

Parma, 6 - 7 December 2012

(Adopted by the WG on 11 February 2013)

Participants:

• **WG Experts:**

Paul Brantom, Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Seppo Salminen, Josef Schlatter, Hendrik Van Loveren, Hans Verhagen (Chair);

• **European Commission (EC):** Andreas Klepsch

• **EFSA, Nutrition Unit:** Agnes De Sesmaisons-Lecarre, Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Paul Brantom, Seppo Salminen, Josef Schlatter. The sequence of the agenda items was amended.

2. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting, as well as the interests declared at the beginning of this meeting.

With regard to the items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

3. Agreement of the minutes of the 44th Working Group meeting held on 11 - 12 October 2012 in Parma

The minutes were agreed at the WG meeting on 6 December 2012.

4. Discussions

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Cetyl Myristoleate Complex (EFSA-Q-2012-00649), Astaxanthin (EFSA-Q-2011-00990), Gantrez® - novel chewing gum base ingredient (EFSA-Q-2012-00653) and Taxifolin (EFSA-Q-2012-00961).

5. **A.O.B.** none

Parma, 3rd December 2012

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 44th Meeting of the Working Group (WG) on Novel Foods

Parma, 11 - 12 October 2012

(Adopted by the WG on 6 December 2012)

Participants

- **Working Group Experts:**
 - **Karl-Heinz Engel (11.10.12), Ines Golly, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Hendrik Van Loveren and Hans Verhagen.**
- **European Commission (EC): Andreas Klepsch**
- **EFSA: Nutrition Unit: Wolfgang Gelbmann**

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Pagona Lagiou, Seppo Salminen and Karl-Heinz Engel (for 12.10.12). The sequence of the agenda items was amended.

2. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting, as well as the interests declared at the beginning of this meeting.

With regard to the items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

3. Discussions

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Rooster Combs Extract (Bioiberica, EFSA-Q-2012-00613), Cetyl Myristoleate Complex (EFSA-Q-2012-00649), Astaxanthin (Bioreal AB, EFSA-Q-2011-00990) and Gantrez® - novel chewing gum base ingredient (EFSA-Q-2012-00653).

4. A.O.B. none

Parma, 11 October 2012

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 43rd meeting of the Working Group (WG) on Novel Foods

Parma, 30 - 31 August 2012

(Adopted by the WG on 11 October 2012)

Members

WG Experts: Karl-Heinz Engel, Ines Golly, Marina Heinonen, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren and Hans Verhagen (Chair).

Ad hoc expert: -

European Commission (EC): Andreas Klepsch

EFSA: Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Pagona Lagiou, Hendrik Van Loveren, Seppo Salminen, Karl-Heinz Engel and from Andreas Klepsch (EC). The sequence of the agenda items was amended.

2. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting, as well as the interests declared at the beginning of this meeting.

With regard to the items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

3. Discussions

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Rooster Combs Extract (Bioiberica, EFSA-Q-2012-00613), Cetyl Myristoleate Complex (EFSA-Q-2012-00649), Gantrez® - novel chewing gum base ingredient (EFSA-Q-2012-00653) and Zeaxanthin (DSM, EFSA-Q-2012-00418).

4. A.O.B. none

Parma, 30 August 2012

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 42nd meeting of the Working Group (WG) on Novel Foods

Parma, 31 May – 1 June 2012

(Adopted by the WG on 30 August 2012)

Members

WG Experts: Karl-Heinz Engel, Ines Golly, Marina Heinonen, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley (Chair), Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

Ad hoc expert: -

European Commission (EC): Andreas Klepsch

EFSA: Wolfgang Gelbmann, Ilkka Ojansivu

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Pagona Lagiou, Rosangela Marchelli, Seppo Salminen and Annette Pöting (morning of 31 May). The sequence of the agenda items was amended.

2. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting, as well as the interests declared at the beginning of this meeting.

With regard to the items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

3. Discussions

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Bovine Lactoferrin (Morinaga Milk Industry Co Ltd, EFSA-Q-2011-00974), Astaxanthin (Bioreal AB, EFSA-Q-2011-00990), Dihydrocapsiate (Ajinomoto Co. Inc., EFSA-Q-2011-01155) and Zeaxanthin (DSM, EFSA-Q-2012-00418). The Working Group was informed about the new mandate "Rooster Combs Extract" (Bioiberica, EFSA-Q-2012-00613).

4. A.O.B. none

Parma, 31 May 2012

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 41st meeting of the Working Group (WG) on Novel Foods

Parma, 29 - 30 March 2012

(Adopted by the WG on 31 May – 1 June 2012)

Members

WG Experts: Karl-Heinz Engel, Ines Golly, Marina Heinonen, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

Ad hoc expert: -

European Commission (EC): Andreas Klepsch

EFSA: Agnes de Sesmaisons – Lecarré, Wolfgang Gelbmann, Ilkka Ojansivu

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Pagona Lagiou, Annette Pöting (morning of 29 March), Karl-Heinz Engel and Seppo Salminen (30 March). The sequence of the agenda items was amended.

2. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting, as well as the interests declared at the beginning of this meeting.

For the Agenda item related to Astaxanthin, Marina Heinonen declared an interest. The expert was involved in the Finnish Novel Food Board initial assessment on Astaxanthin in 2008. The expert will not be involved in the drafting of the opinion.

With regard to the other items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

3. Discussions

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Bovine Lactoferrin (Morinaga Milk Industry Co Ltd, EFSA-Q-2011-

00974; Friesland Campina Domo B.V., EFSA-Q-2010-01269), Astaxanthin (Bioreal AB, EFSA-Q-2011-00990) and Dihydrocapsiate (Ajinomoto Co. Inc., EFSA-Q-2011-01155).

4. A.O.B. none

Parma, 29 March 2012

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 40th meeting of the Working Group (WG) on Novel Foods

Parma, 16 - 17 February 2012

(Adopted by the WG on 29 - 30 March 2012)

Members

WG Experts: Karl-Heinz Engel, Ines Golly, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

Ad hoc expert: -

European Commission (EC): Andreas Klepsch

EFSA: Agnes de Sesmaisons – Lecarré, Wolfgang Gelbmann, Ilkka Ojansivu

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Pagona Lagiou and Annette Pöting (morning of 16 March). The sequence of the agenda items was amended.

2. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting, as well as the interests declared at the beginning of this meeting.

For the Agenda item related to Astaxanthin, Marina Heinonen declared an interest. The expert was involved in the Finnish Novel Food Board initial assessment on Astaxanthin in 2008. The expert will not be involved in the drafting of the opinion.

With regard to the other items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

3. Discussions

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Bovine Lactoferrin (Morinaga Milk Industry Co Ltd, EFSA-Q-2011-

00974; Friesland Campina Domo B.V., EFSA-Q-2010-01269), Astaxanthin (Bioreal AB, EFSA-Q-2011-00990) and Dihydrocapsiate (Ajinomoto Co. Inc., EFSA-Q-2011-01155).

The Working Group (WG) had a general discussion on intake assessment methodologies.

4. A.O.B. none

Parma, 16 February 2012

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 39th meeting of the Working Group (WG) on Novel Foods

Parma, 1-2 December 2011

(Adopted by the WG on 16-17 February 2012)

Members

WG Experts: Karl-Heinz Engel, Ines Golly, Marina Heinonen, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

Ad hoc expert: -

European Commission (EC): Andreas Klepsch

EFSA: Céline Dumas, Wolfgang Gelbmann, Ilkka Ojansivu

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Pagona Lagiou and Seppo Salminen. The sequence of the agenda items was amended.

2. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting, as well as the interests declared at the beginning of this meeting.

For the Agenda item related to Astaxanthin, Marina Heinonen declared an interest. The expert was involved in the Finnish Novel Food Board initial assessment on Astaxanthin in 2008. The expert will not be involved in the drafting of the opinion.

With regard to the other items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

3. Discussions

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Bovine Lactoferrin (Moringa Milk Industry Co Ltd, EFSA-Q-2011-00974; Friesland Campina Domo B.V., EFSA-Q-2010-01269), Astaxanthin (Bioreal AB, EFSA-Q-2011-00990) and *Arracacia xanthorrhiza* (Euroandina Importaciones S.L., EFSA-Q-2011-

00918). The Working Group (WG) had a general discussion on intake assessment methodologies.

4. A.O.B. none

Parma, 1-2 December 2011

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 38th meeting of the Working Group (WG) on Novel Foods

Parma, 29-30 September 2011

(Adopted by the WG on 1-2 December 2011)

Members

WG Experts: Karl-Heinz Engel, Ines Golly, Marina Heinonen, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

Ad hoc expert: -

European Commission (EC): Andreas Klepsch

EFSA: Agnes de Sesmaisons - Lecarré, Wolfgang Gelbmann, Ilkka Ojansivu

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen (29/09/11), Pagona Lagiou, Karl-Heinz Engel and Seppo Salminen (29-30/09/11). The sequence of the agenda items was amended.

2. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting, as well as the interests declared at the beginning of this meeting.

For the Agenda item related to Astaxanthin, Marina Heinonen declared an interest at the beginning of the meeting. The interest was classified as level b interest. The expert was involved in the Finnish Novel Food Board initial assessment on Astaxanthin in 2008. The expert will not be involved in the drafting of the opinion.

With regard to the other items on the agenda for this meeting, no conflicts of interests have been identified during the screening process or at the beginning of this meeting.

3. Discussions

The Working Group (WG) discussed a draft statement of the NDA Panel on a potential interaction between glucosamine and coumarin anticoagulants (EFSA-Q-2011-00770, self-

tasking mandate). The WG discussed and elaborated on draft opinions on the following Novel Food applications: Bovine Lactoferrin (Moringa Milk Industry Co Ltd; EFSA-Q-2011-00974), Astaxanthin (Bioreal AB; EFSA-Q-2011-00990) and *Arracacia xanthorrhiza* (Euroandina Importaciones S.L.; EFSA-Q-2011-00918). Rapporteurs were appointed in agreement with the WG Chair. The WG received EFSA presentations on the EFSA Comprehensive Food Consumption Database, an EFSA report on the procedures currently used at EFSA for the assessment of dietary exposure to different chemical substances, and on the concept of 'traditional use', in relation to a new EFSA Guidance for Novel Food applicants.

4. **A.O.B.** none

Helsinki, 8th July 2011

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 37th meeting of the Working Group (WG) on Novel Foods

Parma, 26 May 2011

(Adopted by the WG on 08 July 2011)

Members

WG Experts: Karl-Heinz Engel, Ines Golly, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

Ad hoc expert: -

European Commission (EC): Andreas Klepsch

EFSA: Agnes De Sesmaisons - Lecarre, Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Pagona Lagiou, Seppo Salminen and Andreas Klepsch (EC). The sequence of the agenda items was amended.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on draft opinions on the following Novel Food applications: Glavonoid (Kaneka Pharma; EFSA-Q-2009-00749) and Bovine Lactoferrin (Friesland Campina Domo B.V.; EFSA-Q-2010-01269). The WG also discussed a draft letter of the NDA Panel to the Executive Director to initiate a self-taking mandate for a statement of the NDA Panel on a potential interaction between glucosamine and coumarin anticoagulants (EFSA-Q-2011-00770). The WG discussed also an outline for new EFSA Guidance for Novel Food applicants.

4. A.O.B. none

Parma, 26th May 2011

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 36th meeting of the Working Group (WG) on Novel Foods

Parma, 12 January 2011

(Adopted by the WG on 26 May 2011)

Members

WG Experts: Karl-Heinz Engel, Ines Golly, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Hendrik Van Loveren, Hans Verhagen.

Ad hoc expert: -

European Commission (EC): Andreas Klepsch

EFSA: Agnes De Sesmaisons - Lecarre, Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen and Pagona Lagiou. The sequence of the agenda items was amended.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Glavonoid (Kaneka Pharma; EFSA-Q-2009-00749), Yeast β -Glucans (Biothera; EFSA-Q-2009-00952), the fermented black bean extract "Touchi" (CBC Co. Ltd.; EFSA-Q-2009-00765), a novel chewing gum base "Rev-7" (Revolymmer Ltd., EFSA-Q-2009-00749) and an overview about the most recent application (bovine Lactoferrin, EFSA-Q-2010-01269) was given.

4. A.O.B.

The WG discussed and fixed the WG dates for 2011.

Parma, 12th January 2011

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 35th meeting of the Working Group (WG) on Novel Foods

Amsterdam, 25-26 November 2010

(Adopted by the WG on 12 January 2011)

Participants

WG Experts: Karl-Heinz Engel, Ines Golly, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pötting, Hendrik Van Loveren, Hans Verhagen.

Ad hoc expert: Ivonne Rietjens

European Commission (EC): Andreas Klepsch

EFSA: Angès De Sesmaisons - Lecarre, Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Karl-Heinz Engel (both days), Marina Heinonen (26 November), Pagona Lagiou (both days), Seppo Salminen (for both days) and Hendrik Van Loveren (25 November). The sequence of the agenda items was amended.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Glavonoid (Kaneka Pharma; EFSA-Q-2009-00749), Yeast β -Glucans (Biothera; EFSA-Q-2009-00952), the fermented black bean extract "Touchi" (CBC Co. Ltd.; EFSA-Q-2009-00765), a novel chewing gum base "Rev-7" (Revolymmer Ltd., EFSA-Q-2009-00749). Andreas Klepsch (EC) informed about new mandate (bovine Lactoferrin, EFSA-Q-2010-01269). The WG also discussed new *in vitro* hydrolysis data sent from Myrisana on Cetylmyristate and Cetylmyristoleate. The WG was of the opinion that these data do not

address the concerns expressed in the opinion on Cetyl Myristoleate Complex (EFSA-Q-2009-00529).

4. A.O.B.

The WG discussed the WG dates for 2011.

Parma, 25th November 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 34th meeting of the Working Group (WG) on Novel Foods

Paris, 16-17 September 2010

(Adopted by the WG on 25 November 2010)

Participants

WG Experts: Karl-Heinz Engel, Ines Golly, Pagona Lagiou, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pötting, Hendrik Van Loveren, Hans Verhagen.

European Commission: Andreas Klepsch (apologized)

EFSA: Anges De Sesmaisons - Lecarre, Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Rosangela Marchelli, Seppo Salminen (for both days) and from Annette Pötting and Hans Verhagen (for 16th September). The sequence of the agenda items was amended.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Glavonoid (Kaneka Pharma; EFSA-Q-2009-00749), Yeast β -Glucans (Biothera; EFSA-Q-2009-00952), a novel chewing gum base "Rev-7" (Revolymmer Ltd., EFSA-Q-2009-00749). The Working Group discussed items of the present SCF Guidance for Novel Foods (1997) which should be updated in the framework of a new EFSA Guidance on Novel Foods and made some preparatory work for a template and structure of such a guidance.

4. A.O.B.

None

Parma, 16th Sept 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 33rd meeting of the Working Group (WG) on Novel Foods

Parma, 1-2 July 2010

(Adopted by the WG on 16-17 September 2010)

Participants

WG Experts:	Karl-Heinz Engel, Ines Golly, Marina Heinonen, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.
European Commission:	Andreas Klepsch
EFSA:	Anges De Sesmaisons - Lecarre, Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from, Pagona Lagiou, Annette Pöting (1 July). The agenda was adopted without changes.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Cetyl-Myristoleate (Myrisana; EFSA-Q-2009-00529), Sardine Peptides (Cantox/Senmi Ekisu Co.; EFSA-Q-2009-00766), Chitin-glucan (KitoZyme; EFSA-Q-2009-00762), Glavanoid (Kaneka Pharma; EFSA-Q-2009-00749), Lentinus edodes extract (GlycaNova; EFSA-Q-2009-00833), Phosphated di-starch phosphate (National Starch Food Innovation; EFSA-Q-2010-00127)

4. A.O.B.

None

Parma, 16th Sept 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 32nd meeting of the Working Group (WG) on Novel Foods

Parma, 27-28 May 2010

(Adopted by the WG on 16-17 September 2010)

Participants

WG Experts: Karl-Heinz Engel, Ines Golly, Marina Heinonen, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pöting, Hendrik Van Loveren, Hans Verhagen.

European Commission: Andreas Klepsch

EFSA: Anges De Sesmaisons - Lecarre, Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from, Pagona Lagiou, Seppo Salminen. The agenda was adopted without changes.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Fermented Black Bean Extract (EFSA-Q-2009-00765), Sardine Peptides (Cantox/Senmi Ekisu Co.; EFSA-Q-2009-00766), Chitin-glucan (KitoZyme; EFSA-Q-2009-00762), Glavanoid (Kaneka Pharma; EFSA-Q-2009-00749), Lentinus edodes extract (GlycaNova; EFSA-Q-2009-00833), Phosphated di-starch phosphate (National Starch Food Innovation; EFSA-Q-2010-00127)

In addition an overview was presented on the reasons for clock stop procedures and request by EFSA to the applicant for additional information/clarification.

4. A.O.B.

None

Parma, 27th May 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 31st meeting of the Working Group (WG) on Novel Foods

Parma, 18-19 March 2010

(Adopted by the WG on 27th May 2010)

Participants

WG Experts: Karl-Heinz Engel (18 March), Ines Golly, Rosangela Marchelli, Bevan Moseley, Monika Neuhäuser-Berthold, Annette Pötting (18 March), Hendrik Van Loveren, Hans Verhagen (18 March).

European Commission: Andreas Klepsch

EFSA: Anges De Sesmaisons - Lecarre, Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Pagona Lagiou, and Seppo Salminen. The agenda was adopted without changes.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Sardine Peptides (Cantox/Senmi Ekisu Co.; EFSA-Q-2009-00766), Chitin-glucan (KitoZyme; EFSA-Q-2009-00762), Glavanoid (Kaneka Pharma; EFSA-Q-2009-00749), Lentinus edodes extract (GlycaNova; EFSA-Q-2009-00833). In addition the draft report on the Scientific Colloquium was briefly discussed and Hans Verhagen presented a model on how to set maximum safe intake levels.

4. A.O.B.

None

Parma, 18th March 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 30th meeting of the Working Group on Novel Foods

Brussels, 7th January 2010

(Adopted by the WG on 18th March 2010)

Participants

WG Experts: Karl-Heinz Engel, Ines Golly, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pötting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

European Commission: Andreas Klepsch

EFSA: Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Pagona Lagiou and Bevan Moseley (Chair). Mr. Van Loveren, Vice-chair, was leading the meeting. The agenda was adopted with changes on the sequence of the agenda points. The discussion on the application for an extract from *Lentinus edodes* (Glyca Nova A.S., EFSA-Q-2009-00833) was limited to the status of the application.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Sardine Peptides (Cantox/Senmi Ekisu Co., EFSA-Q-2009-00766), Cetyl-Myristoleate (Myrisana; EFSA-Q-2009-00529), Glavanoid (Kaneka Pharma, EFSA-Q-2009-00749).

4. A.O.B.

A power point presentation related to the approach of safe maximum levels, prepared by Hans Verhagen was postponed to the following WG meeting.

Parma, 7th January 2010

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 29th meeting of the Working Group on Novel Foods

Amsterdam, 18th November 2009

(Adopted by the WG on 7th January 2010)

Participants

WG Experts: Karl-Heinz Engel, Ines Golly, Rosangela Marchelli, Bevan Moseley (Chair), Monika Neuhäuser-Berthold, Annette Pöting, Seppo Salminen, Hendrik Van Loveren.

EFSA: Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Pagona Lagiou, Hans Verhagen and Andreas Kleppsch (European Commission). The agenda was adopted without changes.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Fermented Black Bean Extract (EFSA-Q-2009-00765), Conjugated Linoleic Acid from Cognis (EFSA-Q-2009-00750), and Glavanoid (CBC Ltd) (EFSA-Q-2009-00749).

4. A.O.B.

The Working Group discussed organisational matters of the Scientific Colloquium on Novel Foods held on 19-20 November 10.

Parma, 18th November 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 28th meeting of the Working Group on Novel Foods

Brussels, 9th October 2009

(Adopted by the WG on 18th November 2009)

Participants

WG Experts: Karl-Heinz Engel, Ines Golly, Marina Heinonen, Rosangela Marchelli, Bevan Moseley (chair), Monika Neuhäuser-Berthold, Annette Pöting, Hendrik Van Loveren, Hans Verhagen.

Ad hoc Expert: Ambroise Martin

European Commission (EC): Andreas Klepsch

EFSA: Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from, Pagona Lagiou, Seppo Salminen. The agenda was adopted without changes.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Conjugated Linoleic Acid from Lipid Nutrition (EFSA-Q-2008-745), and Glavanoid (CBC Ltd) (EFSA-Q-2009-00749).

4. A.O.B.

None

Parma, 9th October 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 27th meeting of the Working Group on Novel Foods

Munich, 27th August 2009

(Adopted by the WG on 9th October 2009)

Participants

WG Experts: Karl-Heinz Engel, Ines Golly, Marina Heinonen, Bevan Moseley (chair), Monika Neuhäuser-Berthold, Annette Pöting, Hendrik Van Loveren, Hans Verhagen.

Ad hoc Expert: Ambroise Martin

European Commission (EC): Andreas Klepsch

EFSA: Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from, Pagona Lagiou, Rosangela Marchelli, Seppo Salminen, and from Andreas Klepsch (EC).

The agenda was adopted without changes.

2. Declarations of interest

EFSA secretariat screened the annual declarations of interests (aDoI) and specific declaration of interest (sDoI) filled in by the scientific experts invited at this meeting in accordance with EFSA's Policy on Declarations of Interests.

With regard to the aDoI, sDoI and this meeting no other interest than those already declared in the aDoI or in a previous sDoI and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Conjugated Linoleic Acid from Lipid Nutrition (EFSA-Q-2008-745), Conjugated Linoleic from Cognis (EFSA-Q-2009-00750) and Cetyl Myristoleate from Myrisana (EFSA-Q-2009-00529).

The WG concluded to ask the applicant of EFSA-Q-2009-00529 for additional information and clarification on issues related to the safety of the product.

4. A.O.B.

None

Parma, 4th May 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 26th meeting of the Working Group on Novel Foods

Parma, 23rd April 2009

(Adopted by the WG on 4th May 2009 by written procedure)

Participants

WG Experts: Karl-Heinz Engel, Marina Heinonen, Pagona Lagiou, Bevan Moseley (chair), Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

European Commission: Andreas Klepsch

EFSA: Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Marina Heinonen, Pagona Lagiou, Annette Pöting, Seppo Salminen and Hans Verhagen.

The agenda was adopted without changes.

2. 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 ADol, SDol and this meeting no other interest than those already declared in the ADol or in a previous SDol and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

3. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Glucosamine – HCl from *Aspergillus niger* (EFSA-Q-2008-306) and Conjugated Linoleic Acid (EFSA-Q-2008-745).

The WG agreed to forward Glucosamine – HCl from *Aspergillus niger* (EFSA-Q-2008-306) to the NDA Panel for discussion and possible adoption at its Plenary on 13-15 May 09.

4. A.O.B.

None

Parma, 23rd April 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 25th meeting of the Working Group on Novel Foods

Parma, 11th February 2009

(Adopted by the WG on 23rd April 2009)

Participants

WG Experts: Karl-Heinz Engel, Marina Heinonen, Pagona Lagiou, Bevan Moseley (chair), Andreu Palou, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.

European Commission: Andreas Klepsch

EFSA: Wolfgang Gelbmann

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Pagona Lagiou, Andreu Palou and Andreas Klepsch.

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 ADol, SDol and this meeting no other interest than those already declared in the ADol or in a previous SDol and screened by EFSA in accordance with its Policy on Declarations of Interests and implementing documents thereof was declared by the experts.

4. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Noni Puree and concentrate (EFSA-Q-2007-181), Alfalfa (EFSA-Q-2008-031), Chia seeds and ground whole Chia seeds (EFSA-Q-2008-008) and Glucosamine – HCl from *Aspergillus niger* (EFSA-Q-2008-306).

The WG agreed to forward Noni Puree and concentrate (EFSA-Q-2007-181), Alfalfa (EFSA-Q-2008-031) and Chia seeds and ground whole Chia seeds (EFSA-Q-2008-008) to the NDA Panel for discussion and possible adoption at its Plenary on 11-13 March 09.

5. A.O.B.

None

Parma, 11th February 2009

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 24th meeting of the Working Group (WG) on Novel Foods

Parma, 7th November 2008

(Adopted by the WG on 11th February 2009)

Participants

WG Experts: **Karl-Heinz Engel, Marina Heinonen, Pagona Lagiou, Bevan Moseley (chair), Andreu Palou, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.**

European Commission: -

EFSA: **Wolfgang Gelbmann**

1. Welcome and apologies

The Chair welcomed the participants. Apologizes were received from Seppo Salminen (WG) and Andreas Klepsch (DG Sanco).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

Members were invited to declare possible interests by filling and signing a form linked to items included on the Agenda at the beginning of the meeting. There were no specific interests declared.

4. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Noni Puree and concentrate (EFSA-Q-2007-181), Alfalfa (EFSA-Q-2008-031), Chia seeds and ground whole Chia seeds (EFSA-Q-2008-008), Lipid extract from *Euphausia superba* as food ingredient, Krill Oil (EFSA-Q-2008-027), Glucosamine – HCl from *Aspergillus niger* (EFSA-Q-2008-306) and Lycopene from *Blakeslea t. Cold Water* Dispersible (EFSA-Q-2008-697).

The WG has agreed to forward and to propose the draft opinions on Noni Puree and concentrate (EFSA-Q-2007-181), Chia seeds and ground whole Chia seeds (EFSA-Q-2008-008), Lipid extract from *Euphasia superba* as food ingredient, Krill Oil (EFSA-Q-2008-027), and Lycopene from *Blakeslea t. Cold Water Dispersible* (EFSA-Q-2008-697) to the Panel for possible adoption at its Plenary on 2nd - 4th December 08.

5. A.O.B.

Next WG Meetings:

11 February 2009, Parma

23/24 April 2009 (23 April fixed, 24 if needed), Parma

24/25 June 2009 (25 fixed, 24 if needed), location to be decided.

Parma, 7th November 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 23rd meeting of the Working Group on Novel Foods

Parma, 18 September 2008

(Adopted by the WG on 7th November 2008)

Participants

WG Experts: **Jean-Louis Bresson, Karl-Heinz Engel, Marina Heinonen, Pagona Lagiou, Bevan Moseley (chair), Andreu Palou, Annette Pötting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.**

European Commission: **Andreas Klepsch (DG Sanco)**

EFSA: **Wolfgang Gelbmann,**

1. Welcome and apologies

The Chair welcomed the participants. Apologizes were received from Seppo Salminen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

Members were invited to declare possible interests by filling and signing a form linked to items included on the Agenda at the beginning of the meeting. There were no specific interests declared.

4. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Vitamin K2 (EFSA Q-2005-179), Noni Puree and concentrate (EFSA-Q-2007-181), Alfalfa (EFSA-Q-2008-031), Chia seeds and ground whole Chia (EFSA-Q-2008-008), Lipid extract from *Euphasia superba* as food ingredient, Krill Oil (EFSA-Q-2008-027), Glucosamine –HCl from *Aspergillus niger* (EFSA-Q-2008-306).

The WG has agreed to forward and to propose the draft opinions on Vitamin K2 (EFSA Q-2005-179) to the Panel for adoption at its Plenary on 30th September – 2 October 08. Related

to the application of Noni Puree and concentrate, the WG discussed the information received from the Finnish Food Safety Authority on two recent cases of hepatotoxicity that have been suspected to be related to the consumption of a Noni Juice product from an unidentified source. It was agreed to provide an updated overview on case reports of adverse effects suspected to be related with the consumption of Noni Juice to the NDA Panel. Further revisions were proposed to the other draft opinions.

5. A.O.B.

Next WG Meetings:

07 November 2008, Amsterdam

10/11 February 2009 (11 February fixed, 10 only if needed), Parma

23/24 April 2009 (23 April fixed, 24 if needed), Parma

24/25 June 2009 (25 fixed, 24 if needed), location to be decided.

Parma, 18 September 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 22nd meeting of the Working Group on Novel Foods

Parma, 5-6 June 2008

(Adopted by the WG on 18/19 September 2008)

Participants

WG Experts: **Jean-Louis Bresson, Karl-Heinz Engel, Marina Heinonen, Pagona Lagiou, Bevan Moseley (chair), Andreu Palou, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.**

European Commission: **Andreas Klepsch (DG Sanco)**

EFSA: **Wolfgang Gelbmann,**

1. Welcome and apologies

The Chair welcomed the participants. Apologizes were received from Pagona Lagiou, Annette Pöting (for 5 June), Seppo Salminen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

Members were invited to declare possible interests by filling and signing a form linked to items included on the Agenda at the beginning of the meeting. In relation to the draft opinion on Ice Structuring Protein (EFSA-Q-2008-073), Hans Verhagen, declared having been employed by Unilever until mid-May 2005 and refrained from the discussion for this agenda item.

4. Discussions

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Fungal Oil (EFSA-Q-2007-123), Vitamin K2 (EFSA Q-2005-179), Noni leaves (EFSA-Q-2006-185), Noni Puree and concentrate (EFSA-Q-2007-181), Alfalfa (EFSA-Q-

2008-031), Ice Structuring Protein (EFSA-Q-2008-073), Chia seeds and ground whole Chia (EFSA-Q-2008-008).

The WG has agreed to forward and to propose the draft opinions on Noni leaves (EFSA-Q-2006-185) and on Fungal Oil (EFSA-Q-2007-123), Vitamin K2 (EFSA Q-2005-179) to the Panel for adoption at its July Plenary. A revision of the draft opinion on Noni Puree and concentrate (EFSA-Q-2007-181) is aimed to circulate within the WG and if feasible also to forward and to propose to the Panel for adoption at its July Plenary. Regarding Ice Structuring Protein (EFSA-Q-2008-073), this draft opinion requires co-adoption by the GMO Panel and the NDA Panel. Without anticipating the conclusions of the GMO Panel, the draft opinion can be forwarded to the NDA Panel for co-adoption.

Further revisions were proposed to the other draft opinions.

5. A.O.B.

Next WG Meetings:

18 September 2008, Parma

07 November 2008, Amsterdam

10/11 February 2009 (11 February fixed, 10 only if needed), Parma

23/24 April 2009 (23 April fixed, 24 if needed), Parma

24/25 June 2009 (25 fixed, 24 if needed), location to be decided.

Parma, 05 June 2008

PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES

Minutes of the 21st meeting of the Working Group on Novel Foods

Parma, 14-15 April 2008

(Adopted by the WG on 5 June 2008)

Participants

WG Experts: **Jean-Louis Bresson, Karl-Heinz Engel, Marina Heinonen, Pagona Lagiou, Bevan Moseley (chair), Andreu Palou, Annette Pöting, Seppo Salminen, Hendrik Van Loveren, Hans Verhagen.**

European Commission: **Jean-Francois Roch (DG Sanco)**

EFSA: **Wolfgang Gelbmann, Juliane Kleiner**

1. Welcome and apologies

The Chair welcomed the participants. Apologizes were received from Jean-Louis Bresson, Marina Heinonen (15 April), Andreu Palou (14 April), Seppo Salminen, Hans Verhagen (14 April).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

Members were invited to declare possible interests by filling and signing a form linked to items included on the Agenda at the beginning of the meeting. In relation to the draft opinion on Ice Structuring Protein (EFSA-Q-2008-073), Hans Verhagen, declared having been employed by Unilever until mid-May 2005 and refrained from the discussion for this agenda item.

4. Discussions

The representative from the European Commission presented an overview on the major changes as proposed by the European Commission for a Revision of the Novel Food Regulation. The discussion focused on the concept of "history of safe use" for "traditional

foods”, the centralized procedure of a notification procedure and the upcoming tasks and workload coming to EFSA if such changes in the Novel Food regulation would be applied.

The Working Group (WG) discussed and elaborated on the following Novel Food applications: Fungal Oil (EFSA-Q-2007-123), synthetic Zeaxanthin (EFSA-Q-2007-078), Vitamin K2 (EFSA Q-2005-179), Noni leaves (EFSA-Q-2006-185), Noni Puree and concentrate (EFSA-Q-2007-181), Chia seeds (EFSA-Q-2008-008), Alfalfa (EFSA-Q-2008-031), Ice Structuring Protein (EFSA-Q-2008-073).

The WG has agreed to forward and to propose the draft opinions on Zeaxanthin (EFSA-Q-2007-078) and on Fungal Oil (EFSA-Q-2007-123) to the Panel for adoption. Further revisions were proposed to the other draft opinions.

5. A.O.B.

Next WG Meetings:

5-6 June 2008, Parma

18 September 2008, Parma
