

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 150<sup>th</sup> Working Group meeting on Novel Foods



8-10, 16 November 2023

14:00-18:00 / 09:00-18:00 / 09:00-13:00 / 09:00-15:00

MINUTES - Agreed on 27 November 2023

**Location:** EFSA - Parma and tele conference (on 16/11/2023)

### Attendees:

- Working Group Members:

Margarita Aguilera-Gómez, Francesco Cubadda<sup>1</sup>, Thomas Frenzel, Marina Heinonen<sup>1,2</sup>, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (co-chair)<sup>1</sup>, Inge Mangelsdorf, Harry J McArdle (co-chair)<sup>2</sup>, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona<sup>1</sup>, Josef Rudolf Schlatter, Alexandros Siskos, Henk Van Loveren.

- Hearing Experts<sup>3</sup>:

Not Applicable

- European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal, all via web conference

- EFSA:

Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Leonard Matijevic, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernández, Gabriela Precup, Pablo Rodriguez Fernandez, Ruth Roldán Torres, Annamaria Rossi, Francesco Suriano, Emanuela Turla, Ermolaos Ververis.

## I. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

## II. Adoption of agenda

The agenda was adopted without changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>5</sup> 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.

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<sup>1</sup> Participated via tele-conference

<sup>2</sup> Did not participate on day 4

<sup>3</sup> 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>

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### **IV. Agreement of the minutes of the 149<sup>th</sup> Working Group meeting held on 11-13 October 2023, via web-conference**

The [minutes of the 149th Working Group meeting](#) were agreed by written procedure on 23 October 2023.

#### **V. Feedback from the NDA Panel plenary meeting**

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

#### **VI. Feedback from the European Commission**

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

#### **VII. 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.

#### **VIII. Scientific topic(s) for discussion**

**a. 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, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 29-30/11/2023 for further discussion and possible adoption.

**b. Draft opinion isomalto-oligosaccharide as a novel food (NF 2021/2469). Applicant: BioNeutra North America Inc. ([EFSA-Q-2021-00185](#))**

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 29-30/11/2023 for further discussion and possible adoption.

**c. Draft opinion on helix complex snail mucus (HSM) as a novel food (NF 2019/1077). Applicant: HELIXPHARMA S.R.L. ([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, toxicology and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 29-30/11/2023 for further discussion and possible adoption.

**d. Draft opinion on ashitaba sap as a novel food (NF 2019/1247). Applicant: Japan Bio Science Laboratory Ltd ([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, toxicology and allergenicity. After amendments, the draft opinion will be presented at the NDA plenary meeting on 30-31 January for further discussion and possible adoption.

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**e. Draft opinion on dried *C. reinhardtii* algae as a novel food (NF 2022/8410). Applicant: Triton Algae Innovations, Ltd. (EFSA-Q-2023-00301)**

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, 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.

**f. Updated EFSA Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (EFSA-Q-2023-00442)**

The WG discussed the draft scientific Guidance document, and in particular the sections on identity, production process, compositional data, specifications, history of use of the novel food and its source, proposed uses and use levels & anticipated daily intake, nutritional information, ADME, toxicological information, and allergenicity. After amendments, the Guidance document will be presented at the next WG NF meeting for further discussion. In the meantime, specific sections of the Guidance document (identity, production process, compositional data, history of use of the novel food and its source, proposed uses and use levels & anticipated daily intake) will be presented at the next NDA plenary meeting on 29-30/11/2023 for further discussion.

## IX. Any Other Business

**o Update on *Acheta domesticus* as a novel food (NF 2018/0128). Applicant: Belgian Insect Industry Federation (BiiF) (EFSA-Q-2018-00543)**

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

**o Request for scientific and technical assistance as regards the evaluation of calcidiol monohydrate as a novel food (EFSA-Q-2023-00604)**

The WG was informed about the status and conclusions of the scientific and technical report, which will be presented at the next NDA Plenary for discussion and possible endorsement.

**o Update on the technical report for the literature review on cannabidiol**

The WG discussed the draft technical report providing the details of the literature review used to prepare the NDA Panel "Statement on safety of cannabidiol as a novel food: data gaps and uncertainties" (EFSA-Q-2021-00735). The technical report will be published as supporting publication to the NDA Panel statement.

## X. Preparatory meetings

Since the last Novel foods WG meeting, preparatory meetings chaired by EFSA staff also were held on the followings:

**• Fungi protein *Fusarium flavolapis* (NF-2021-1350). Applicant: Nature's Fynd (EFSA-Q-2021-00519)**

Date: 27/10/2023

WG members: Thomas Frenzel, Miguel Prieto Maradona

Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization, production process and proposed uses and use levels.

**• Ashitaba sap (NF 2019/1247). Applicant: Japan Bio Science Laboratory Ltd (EFSA-Q-2019-00536)**

Date: 27/10/2023

WG members: Helle Katrine Knutsen, Karen-Ildico Hirsch-Ernst, Inge Mangelsdorf, Monika Neuhäuser-Berthold, Josef Rudolf Schlatter, Henk Van Loveren.

Discussion at the meeting focused on the draft scientific opinion, and in particular on the data regarding toxicology and allergenicity.





- **Helix complex snail mucus (HSM) (NF 2019/1077). Applicant: HELIXPHARMA S.R.L (EFSA-Q-2019-00388)**  
Date: 25/10/2023      WG member: Inge Mangelsdorf  
Discussion at the meeting focused on the draft scientific opinion, and in particular on the data regarding toxicology.

## **XI. Next meeting**

The next meeting will be held on 18-20 December 2023, 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 the following experts, Francesco Cubadda and Miguel Prieto declared that their updated DoI is currently under evaluation and that no additional interests were reported in the updated DoI.

With regards to this meeting the following expert, Alexandros Siskos declared that his updated DoI is currently under evaluation and that additional interests have been reported in the updated DoI, concerning employment in the field of environmental protection and monitoring.

The interests above were not deemed to represent a Conflict of Interest (CoI) for the experts concerned.



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 149<sup>th</sup> Working Group meeting on Novel Foods



11 - 13 October 2023

14:00-18:00 / 09:00-18:00 / 09:00-13:00

MINUTES - Agreed on 23 October 2023

**Location:** Teleconference

### **Attendees:**

- Working Group Members:

Margarita Aguilera-Gómez<sup>1</sup>, Francesco Cubadda, Thomas Frenzel<sup>2</sup>, Marina Heinonen<sup>3</sup>, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Harry J McArdle, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Alexandros Siskos, Henk Van Loveren<sup>4</sup>.

- Hearing Experts<sup>5</sup>:

Not Applicable

- European Commission and/or Member States representatives:

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

- EFSA:

Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Leonard Matijević, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Francesco Suriano, Emanuela Turla, Ermolaos Ververis.

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

No apologies were received.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>7</sup> 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(s) of Interest made at the beginning of the meeting, please refer to the Annex.

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<sup>1</sup> Participated on day 1

<sup>2</sup> Participated on day 2

<sup>3</sup> Participated on day 1 and 2

<sup>4</sup> Participated on day 2 and 3

<sup>5</sup> 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>

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### IV. Agreement of the minutes of the 148<sup>th</sup> Working Group meeting held on 13-15 September 2023, via tele-conference

The [minutes of the 148<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 25 September 2023.

#### V. 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.

#### VI. Feedback from the European Commission

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

#### VII. 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.

#### VIII. Scientific topic(s) for discussion

- a. **Draft opinion on lacto-N-fucopentaose I / 2'-fucosyllactose mixture (LNFP-I / 2'-FL) as a novel food (NF 2021/2371). Applicant: Glycom ([EFSA-Q-2021-00170](#))**

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 26 October for further discussion and possible adoption.

- b. **Draft opinion on monosodium salt of L-5-methyltetrahydrofolic acid as a novel food (NF 2020/2160). Applicant: Merck & Cie ([EFSA-Q-2021-00079](#))**

The WG discussed the draft scientific opinion, and in particular assessed data regarding ADME and nutritional information. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 26th October for further discussion and possible adoption.

- c. **Draft opinion on urolithin A as a novel food (NF 2018/0538). Applicant: Amazentis ([EFSA-Q-2018-00724](#))**

The WG discussed the data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. The WG considered the need to consult the cross-cutting WG on Nanotechnologies.

- d. **Draft opinion on *Schizochytrium sp.* oil as a novel food (NF 2020/2242). Applicant: ATK Biotech Co., Ltd ([EFSA-Q-2020-00850](#))**

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 26 October for further discussion and possible adoption.

**e. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2021/2445).  
Applicant: CABIO Biotech (Wuhan) Co., Ltd. (EFSA-Q-2021-00168)**

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 26 October for further discussion and possible adoption.

**f. Draft opinion on tiger nuts oil (*Cyperus esculentus*) as a novel food (NF 2020/1746). Applicant: Tigernuts traders, S.L. (EFSA-Q-2022-00052)**

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

**g. Draft opinion on roasted sacha inchi seeds as traditional food (NF 2021/2344).  
Applicant: PROMPERU (EFSA-Q-2021-00193)**

The WG discussed the data regarding product characterization in reply to the last Clock Stop Letter. The WG considered that 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.

**h. Draft opinion on microbial protein-rich powder from *Xanthobacter* sp. SoF1 (NF 2021/1730). Applicant: Solar Foods Oy (EFSA-Q-2022-00140)**

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.

**i. Updated EFSA Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (EFSA-Q-2023-00442)**

The WG discussed the draft scientific Guidance document, and in particular the sections on identity, production process, compositional data, specifications, history of use of the novel food and its source, proposed uses and use levels & anticipated daily intake, nutritional information, ADME, toxicological information, and allergenicity. After amendments, the Guidance document will be presented at the next WG NF meeting for further discussion.

## IX. Any Other Business

**o Update on isomaltulose syrup (dried) (NF 2018/0330). Applicant: Evonik Creavis GmbH (EFSA-Q-2018-00609)**

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

## X. Preparatory meetings

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Since the last Novel foods WG meeting, preparatory meetings chaired by EFSA staff also were held on the following:

- **Tiger nuts oil (*Cyperus esculentus*) as a novel food (NF 2020/1746). Applicant: Tigernuts traders, S.L. (EFSA-Q-2022-00052)**

Date: 25/09/2023 WG member(s): Thomas Frenzel

Discussion at the meeting focused on the draft scientific opinion and additional data submitted by the applicant, and in particular on the data regarding product characterization, production process and proposed uses and use levels.

- **Isomaltulose syrup (dried) (NF 2018/0330). Applicant: Evonik Creavis GmbH (EFSA-Q-2018-00609)**

Date: 9/10/2023 WG member(s): Carmen Pelaez

Discussion at the meeting focused on the data submitted by the applicant, and in particular on the data regarding the production process.

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

Date: 22/09/2023 WG member(s): Francesco Cubadda

Discussion at the meeting focused on additional data submitted by the applicant, and in particular on the data regarding product characterization and production process.

- **Draft opinion on roasted sacha inchi seeds as traditional food (NF 2021/2344). Applicant: PROMPERU (EFSA-Q-2021-00193)**

Date: 03/10/2023 WG member(s): Thomas Frenzel

Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization.

- **Microbial protein-rich powder from *Xanthobacter* sp. SoF1 (NF 2021/1730). Applicant: Solar Foods Oy (EFSA-Q-2022-00140)**

Dates: 05/10/2023, 06/10/2023 WG member(s): Monika Neuhäuser-Berthold, Thomas Frenzel, Margarita Aguilera-Gómez, Miguel Prieto Maradona, Karen-Ildico Hirsch-Ernst

Discussion at the meeting focused on the data submitted by the applicant, and in particular on the data regarding product characterisation, production process, proposed uses and use levels, anticipated daily intake, ADME, nutritional information and toxicology.

## XI. Next meeting

The next meeting will be held on 8-10 November 2023, 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 the following experts, Helle Knutsen, Inge Mangelsdorf, Monika Neuhäuser-Berthold, Miguel Prieto and Hendrik Van Loveren declared that their updated DoI is currently under evaluation and that no additional interests were reported in the updated DoI.

In accordance with EFSA's Policy on Independence<sup>8</sup> and the Decision of the Executive Director on Competing Interest Management<sup>9</sup>, 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.

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<sup>8</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>9</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 148<sup>th</sup> Working Group meeting on Novel Foods



13 - 15 September 2023  
14:00-18:00 / 09:00-18:00 / 09:00-13:00  
MINUTES - Agreed on 25 September 2023

**Location:** Webconference

### **Attendees:**

- Working Group Members:  
Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Harry J McArdle, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Alexandros Siskos, Henk Van Loveren<sup>1</sup>.
- Hearing Experts<sup>2</sup>:  
Not Applicable
- European Commission and/or Member States representatives:  
EC: Ivona Babic, Stella D'Amore, Takis Daskaleros, Rafael Luis Perez Berbejal, all via web conference
- EFSA:  
Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Leonard Matijevic, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernandez, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Francesco Suriano, Emanuela Turla, Ermolaos Ververis.

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.  
No apologies were received.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>4</sup> 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.

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<sup>1</sup> Participated on day 2 and 3

<sup>2</sup> 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>

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### IV. Agreement of the minutes of the 147<sup>th</sup> Working Group meeting held on 12-13 July 2023, via web-conference

The [minutes of the 147<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 21 July 2023.

#### V. Feedback from the NDA Panel plenary meeting

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

#### VI. Feedback from the European Commission

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

#### VII. 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.

#### VIII. Scientific topic(s) for discussion

**a. Draft opinion on monosodium salt of L-5-methyltetrahydrofolic acid as a novel food (NF 2020/2160). Applicant: Merck & Cie ([EFSA-Q-2021-00079](#))**

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

**b. Draft opinion on oleoresin from *H. pluvialis* containing astaxanthin (NF 2022/6010). Applicant: Astareal AB ([EFSA-Q-2022-00588](#))**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product production process, specifications, toxicology, human studies. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 26<sup>th</sup> September for further discussion and possible adoption.

**c. Draft opinion on *Yarrowia lipolytica* yeast biomass as a novel food (NF 2020/1908). Applicant: Skotan S.A. ([EFSA-Q-2020-00491](#))**

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 and nutritional information. After amendments, the draft opinion will be presented at the NDA plenary meeting on 26<sup>th</sup> October for further discussion and possible adoption.

**d. Draft opinion on isomalto-oligosaccharide as a novel food (NF 2021/2469). Applicant: BioNeutra North America Inc. ([EFSA-Q-2021-00185](#))**

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

**e. Draft opinion on magnesium L-threonate as a novel food (NF 2021/2453). Applicant: AIDP Inc. ([EFSA-Q-2021-00203](#))**

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

**f. Draft opinion on 2'-Fucosyllactose as a novel food (NF 2021/1171). Applicant: Chr. Hansen A/S ([EFSA-Q-2021-00643](#))**

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 the next NDA plenary meeting on 26<sup>th</sup> September for further discussion and possible adoption.

**g. Draft opinion on 2'-Fucosyllactose as a novel food (NF 2021/2394). Applicant: Kyowa Hakko Bio Co., Ltd. ([EFSA-Q-2021-00407](#))**

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 26<sup>th</sup> September for further discussion and possible adoption.

**h. Draft opinion on HelixComplex (HSM) snail mucus (NF 2019-1077). Applicant: HelixPharma ([EFSA-Q-2019-00388](#))**

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

**i. Draft opinion on Anaerobutyricum soehngenii CH106 as novel food (NF 2021/0521). Applicant: Caelus pharmaceuticals BV ([EFSA-Q-2022-00552](#))**

The WG discussed the draft scientific opinion, and assessed data regarding identity, production process, compositional data, stability, 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.

## IX. Any Other Business

- **Novel Foods Guidance Update**

The WG received an update on the status of the activities in the different thematic areas.

## X. Preparatory meetings

Since the last Novel foods WG meeting, preparatory meetings chaired by EFSA staff also were held on the following Novel food applications:

- **Corn protein NF 2021/0441**

*Applicant: Cargill R&D Centre Europe BV ([EFSA-Q-2021-00521](#))*

*Date: 26/07/2023      WG member: Rosangela Marchelli*

*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization and production process.*

- **Corn protein NF 2021/0441**

*Applicant: Cargill R&D Centre Europe BV ([EFSA-Q-2021-00521](#))*

*Date: 27/07/2023      WG member: Monika Neuhaeuser-Berthold*

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*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding proposed uses and use levels, anticipated daily intake and nutritional information.*

- **Polyphenol extract from water olive mill by-product NF 2021/1494**  
*Applicant: Extractos y Derivados S.L. ([EFSA-Q-2021-00736](#))*  
*Date(s): 31/07/2023 WG member(s): Thomas Frenzel*  
*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake, toxicology.*
- **Olive fruit dry extract standardized in hydroxytyrosol (10 or 20%) NF 2021/0287**  
*Applicant: NATAC Biotech S.L. ([EFSA-Q-2021-00271](#))*  
*Date(s): 07/08/2023 WG member(s): Thomas Frenzel*  
*Discussion at the meeting focused on the draft additional data submitted by the applicant, and in particular on the data regarding product characterization.*
- **Grain from perennial intermediate wheatgrass (*Thinopyrum intermedium*) NF 2019/1468**  
*Applicant: Patagonia Provisions, Inc. ([EFSA-Q-2020-00073](#))*  
*Date(s): 28/08/2023 WG member(s): Thomas Frenzel, Monika Neuhäuser-Berthold*  
*Discussion at the meeting focused on the draft additional data submitted by the applicant, and in particular on the data regarding product characterization, nutrition and production process.*
- **Ashitaba sap NF 2019/1247**  
*Applicant: Japan Bio Science Laboratory (JBSL)-USA, ([EFSA-Q-2019-00536](#))*  
*Date(s): 29/8/2023 WG member(s): Karen Hirsch-Ernst, Helle Knutsen, Inge Mangelsdorf, Monika Neuhäuser-Berthold, Josef Schlatter, Hendrik Van Loveren*  
*Discussion at the meeting focused on the draft scientific opinion/additional data submitted by the applicant, and in particular on the data regarding product characterization, toxicology, and allergenicity.*
- **HelixComplex (HSM) snail mucus NF 2019/1077**  
*Applicant: HelixPharma ([EFSA-Q-2019-00388](#))*  
*Date: 30.08.2023 WG member(s): Inge Mangelsdorf*  
*Discussion at the meeting focused on the draft scientific opinion/additional data submitted by the applicant, and in particular on the data regarding toxicology.*
- **HelixComplex (HSM) snail mucus NF 2019/1077**  
*Applicant: HelixPharma ([EFSA-Q-2019-00388](#))*  
*Date: 30.08.2023 WG member(s): Rosangela Marchelli*  
*Discussion at the meeting focused on the draft scientific opinion/additional data submitted by the applicant, and in particular on the data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and allergenicity.*
- **Anaerobutyricum soehngenii CH106 NF 2021-0521**  
*Applicant: Caelus pharmaceuticals BV ([EFSA-Q-2022-00552](#))*  
*Date(s): 07.09.2023 WG member(s): Thomas Frenzel*  
*Discussion at the meeting focused on the draft scientific opinion and data submitted by the applicant, and in particular on the data regarding product characterization and production process.*

## XI. Next meeting

The next meeting will be held on 11-13 October, via webconference.

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## **Annex**

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

With regard to this meeting, the following interests were declared

- Thomas Frenzel: no additional activities were reported in the updated DoI
- Harry J McArdle: additional membership of the Scientific Committee WG on biomarkers of effect was declared in the updated DoI
- Miguel Prieto Maradona: end of the activity as Head of the Institute of Food Science and Technology at the University of León was declared in the updated DoI
- Josef Rudolf Schlatter: no additional activities were reported in the updated DoI

In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a Conflict of Interest for the experts concerned.

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 147<sup>th</sup> Working Group meeting on Novel Foods



12 - 13 July 2023

14:00-18:00 / 09:00-18:00

MINUTES - Agreed on 21 July 2023

**Location:** Teleconference

### **Attendees:**

- Working Group Members:

Margarita Aguilera-Gómez, Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst<sup>1</sup>, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Harry J McArdle, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Alexandros Siskos, Henk Van Loveren.

- Hearing Experts<sup>2</sup>:

Not Applicable

- European Commission and/or Member States representatives:

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

- EFSA:

Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Leonard Matijevic, Vânia Mendes, Alejandra Muñoz, Irene Nuin, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Francesco Suriano, Emanuela Turla, Ermolaos Ververis.

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Josef Rudolf Schlatter.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>4</sup> 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.

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<sup>1</sup> Absent on day 2 PM

<sup>2</sup> 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>

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### **IV. Agreement of the minutes of the 146<sup>th</sup> Working Group meeting held on 7-9 June 2023, in Parma**

The [minutes of the 146<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 20 June 2023.

#### **V. Feedback from the NDA Panel plenary meeting**

The working group was informed that one novel food opinion was discussed at the last NDA Panel plenary meeting and that adoption is awaiting additional information from the applicant.

#### **VI. Feedback from the European Commission**

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

#### **VII. 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.

#### **VIII. Scientific topic(s) for discussion**

**a. Draft opinion on 2'-Fucosyllactose (NF 2021/1171). Applicant: Chr. Hansen A/S ([EFSA-Q-2021-00643](#))**

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

**b. Draft opinion on arachidonic acid-rich oil from the fungus *Mortierella alpina* (NF 2020/2104). Applicant: Roquette Biotech Nutritionals (Wuhan) Co., Ltd. ([EFSA-Q-2022-00315](#))**

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

**c. Draft opinion on bacterial cellulose aqueous suspension as a novel food (NF 2018/0307). Applicant: Satisfibre, S.A. ([EFSA-Q-2018-00294](#))**

The WG discussed the newly submitted information, and in particular assessed data regarding product characterization, ADME and toxicology. 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.

**d. Draft opinion on fungi protein *Fusarium* sp. *flavolapis* (NF 2021/2456). Applicant: Nature's Fynd ([EFSA-Q-2021-00519](#))**

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.

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**e. Draft opinion on rapeseed protein-fibre concentrate (NF 2022/8650). Applicant: NapiFeryn BioTech Sp. z o.o. ([EFSA-Q-2023-00160](#))**

The WG discussed the submitted information, and in particular 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.

**f. Draft opinion on Acheta domesticus powder as a novel food (NF 2020/1860). Applicant: Società Agricola Italian Cricket Farm S.r.l. ([EFSA-Q-2021-00262](#))**

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, human studies and allergenicity. 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.

## IX. Any Other Business

○ **Update on *Tenebrio molitor* protein concentrate as a novel food (NF 2020/1959). Applicant: Ynsect ([EFSA-Q-2021-00105](#))**

The WG was informed about the status of the application, discussed the additional information provided in the dossier and agreed to request further clarification from the applicant to proceed with the assessment.

○ **Update on helix complex snail mucus (HSM) as a novel food (NF 2019/1077). Applicant: HELIXPHARMA S.R.L. ([EFSA-Q-2019-00388](#))**

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

○ **Update on krill protein hydrolysate as a novel food (NF 2021/2456). Applicant: Aker BioMarine Antarctic AS ([EFSA-Q-2021-00186](#))**

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

○ **Update on vitamin D2 mushroom powder as a novel food (NF 2020/2226). Applicant: Luxidum GmbH ([EFSA-Q-2020-00849](#))**

The WG was informed about the status of the application and agreed to request further information from the applicant to proceed with the assessment.

○ **WG meeting dates 2024**

The WG was presented with the meetings plan for 2024.

## X. Preparatory meetings

Since the last Novel foods WG meeting, preparatory meetings chaired by EFSA staff also were held on the followings:

• **Arachidonic acid-rich oil from the fungus *Mortierella alpina* (NF 2020/2104)**

*Applicant: BASF ([EFSA-Q-2021-00317](#))*

*Date(s): 13/06/2023, 14/06/2023*

*WG members: Miguel Prieto Maradona, Rosangela Marchelli*

*Discussion at the meeting focused on additional data submitted by the applicant, and in particular on the data regarding product characterization and production process.*

• **Isomaltulose syrup (dried) (NF 2018/0330)**

*Applicant: Evonik Creavis GmbH ([EFSA-Q-2018-00609](#))*

*Date: 14/06/2023*

*WG member: Carmen Pelaez*

*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding the production process.*





- **Cannabidiol Isolate (NF 2021/2340)**  
Applicant: CBD Industries LLC ([EFSA-Q-2021-00282](#))  
Date: 14/06/2023  
WG member(s): Inge Mangelsdorf  
*Discussion at the meeting focused on the draft scientific opinion, and in particular on the data regarding toxicology.*
- **Rapeseed protein-fibre concentrate (NF 2022/8650)**  
Applicant: NapiFeryn BioTech Sp. z o.o. ([EFSA-Q-2023-00160](#))  
Date: 20/06/2023  
WG members: Thomas Frenzel, Monika Neuhäuser-Berthold  
*Discussion at the meeting focused on the draft scientific opinion/additional data submitted by the applicant, and in particular on the data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake.*
- **Urolithin A (NF 2018/0538)**  
Applicant: Amazentis S.A. ([EFSA-Q-2018-00724](#))  
Date: 22/06/2023  
WG member: Francesco Cubadda  
*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization.*
- **Antarctic krill protein hydrolysate (NF 2021/2456)**  
Applicant: Aker BioMarine Antarctic AS ([EFSA-Q-2021-00186](#))  
Dates: 26/06/2023, 10/07/2023  
WG members: Carmen Pelaez, Rosangela Marchelli, Inge Mangelsdorf  
*Discussion at the meetings focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization, production process, proposed uses and use levels, anticipated daily intake and toxicology.*
- **Fungi protein *Fusarium flavolapis* (NF 2021/2456).**  
Applicant: Nature's Fynd ([EFSA-Q-2021-00519](#))  
Date(s): 29/06/2023, 11/07/2023  
WG members: Thomas Frenzel, Miguel Prieto Maradona, Monika Neuhaeuser-Berthold  
*Discussion at the meeting focused on the draft scientific opinion/additional data submitted by the applicant, and in particular on the data regarding product characterization, production process, proposed uses and use levels and nutrition.*
- ***Tenebrio molitor* protein concentrate as a novel food (NF 2020/1959).**  
Applicant: Ynsect ([EFSA-Q-2021-00105](#))  
Date: 30/06/2023  
WG member: Thomas Frenzel  
*Discussion at the meeting focused on the draft scientific opinion/additional data submitted by the applicant, and in particular on the data regarding product characterization, production process, and proposed uses and use levels.*
- **Helix complex snail mucus (HSM) as a novel food (NF 2019/1077).**  
Applicant: HELIXPHARMA S.R.L. ([EFSA-Q-2019-00388](#))  
Date: 03/07/2023, 05/07/2023  
WG members: Inge Mangelsdorf, Rosangela Marchelli  
*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization and toxicology.*
- ***Acheta domesticus* powder as a novel food (NF 2020/1860).**  
Applicant: Società Agricola Italian Cricket Farm S.r.l. ([EFSA-Q-2021-00262](#))  
Date: 10/07/2023 WG member: Monika Neuhäuser-Berthold  
*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding nutritional composition.*
- **Monosodium salt of L-5-methyltetrahydrofolic acid (NF 2020/2160)**  
Applicant: Merck & Cie ([EFSA-Q-2021-00079](#))  
Date: 10/07/2023 WG member: Francesco Cubadda  
*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization.*





- **Hemp-derived IPA extract as a novel food (NF 2021/2396)**  
**Hemp-derived CO2 extract as a novel food (NF 2021/2397)**  
**THC removed hemp-derived extract as a novel food (NF 2021/2399)**  
*Applicant: Charlotte's Web, Inc. ([EFSA-Q-2021-00217](#), [EFSA-Q-2021-00218](#), [EFSA-Q-2021-00219](#))*  
*Date: 21/06/2023*  
*WG members: Karen Ildico Hirsch-Ernst, Josef Schlatter*  
*Discussion at the meeting focused on the draft scientific opinion, and in particular on the data regarding genotoxicity.*

## **XI. Next meeting**

The next meeting will be held on 22 August 2023, via teleconference.





## Annex

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

With regard to this meeting, Dr Margarita Aguilera-Gómez declared the following interest.

The expert is the consortium coordinator for the Institute of Nutrition and Food Technology University of Granada (INYTA-UGR) that was awarded a contract by EFSA in the context of GP/EFSA/NUTRI/2021/01. INYTA-UGR was requested to perform preparatory activities related to item VIII.b of the agenda, i.e. Arachidonic acid-rich oil from the fungus *Mortierella alpina* (NF 2020/2104). Applicant: *Roquette Biotech Nutritionals (Wuhan) Co., Ltd.* ([EFSA-Q-2022-00315](#)).

In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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.

For the agenda item VIII.b, Dr Margarita Aguilera-Gómez presented the outcome of the preparatory activities in the role of hearing expert as foreseen in the specific grant contract.

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 146<sup>th</sup> Working Group meeting on Novel Foods



07 - 09 June 2023

14:00-18:00 / 09:00-18:00 / 08:30-12:30

MINUTES - Agreed on 20 June 2023

**Location:** EFSA - Parma (Meeting Room 00/M07)

### **Attendees:**

- Working Group Members:

Margarita Aguilera-Gómez, Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst<sup>1</sup>, Helle Katrine Knutsen<sup>2</sup>, Inge Mangelsdorf, Rosangela Marchelli<sup>3</sup>, Harry J McArdle (chair), Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona<sup>1</sup>, Josef Rudolf Schlatter, Alexandros Siskos, Viviana Trezza<sup>4</sup>, Henk Van Loveren<sup>5</sup>.

- Hearing Experts<sup>6</sup>:

Not Applicable

- European Commission and/or Member States representatives:

EC: Ivona Babic<sup>1</sup>, Stella D'Amore<sup>1</sup>, Takis Daskaleros, Rafael Luis Perez Berbejal<sup>1</sup>.

- EFSA:

Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

No apologies were received.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>8</sup> 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.

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<sup>1</sup> Participated via web conference

<sup>2</sup> Participated on day 1 and 2

<sup>3</sup> Participated for agenda item VIII.f

<sup>4</sup> Participated for agenda item VIII.c

<sup>5</sup> Participated on day 3

<sup>6</sup> 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>

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>8</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### IV. Agreement of the minutes of the 145<sup>th</sup> Working Group meeting held on 3-5 May 2023, via web-conference

The [minutes of the 145<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 11 May 2023.

#### V. 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.

#### VI. Feedback from the European Commission

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

#### VII. 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.

#### VIII. Scientific topic(s) for discussion

- a. **Draft opinion on 3'-sialyllactose (3'-SL) sodium salt as a novel food (NF 2021/2457).**  
**Applicant: Kyowa Hakko Bio Co., Ltd. ([EFSA-Q-2021-00445](#))**

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 4-6 July for further discussion and possible adoption.

- b. **Draft opinion on vitamin D2 mushroom powder as a novel food (NF 2020/2226).**  
**Applicant: Luxidum GmbH ([EFSA-Q-2020-00849](#))**

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 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.

- c. **Draft opinion on cannabidiol isolate as a novel food (NF 2021/2340). Applicant: CBD Industries LLC ([EFSA-Q-2021-00282](#))**

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.

- d. **Draft opinion on 2'-fucosyllactose as a novel food. Applicant: Chr. Hansen A/S ([EFSA-Q-2021-00643](#))**

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 the next WG NF meeting for further discussion.

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**e. Draft opinion on *Yarrowia lipolytica* yeast biomass as a novel food (NF 2020/1908). Applicant: Skotan S.A. ([EFSA-Q-2020-00491](#))**

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

**f. Discussion on scientific matters pertaining to the risk assessment of novel foods**

The WG discussed scientific matters pertaining to the risk assessment of novel foods. In particular, recurring issues observed regarding product characterization, production process, nutrition, toxicology, human studies and allergenicity. Moreover, information was provided to the WG on new and updated cross-cutting EFSA guidance documents relevant to the risk assessment of novel foods.

## IX. Any Other Business

- **Update on on isomaltulose syrup (dried) (NF 2018/0330). Applicant: EFSA-Q-2018-00609 ([EFSA-Q-2018-00609](#))**

The WG was informed about the status of the application, for which new data was just provided.

- **Update on JRC analytical programme on process contaminants on chia seeds.**

The WG was informed about the status of the proposal for collaboration with JRC-EC on an analytical programme to assess process contaminants in products produced with chia seeds.

- **Novel foods WG meeting dates in 2024.**

The WG discussed the proposal for the WG meeting dates in 2024.

## X. Preparatory meetings

Since the last Novel foods WG meeting, preparatory meetings chaired by EFSA staff also were held on the followings:

- **Cannabidiol Isolate (NF 2021/2340)**

Applicant: CBD Industries LLC ([EFSA-Q-2021-00282](#))

Date(s): 08/05/2023, 26/05/2023, 1/06/2023 WG members: Francesco Cubbada, Rosangela Marchelli, Karen Hirsch-Ernst, Helle Knutsen, Inge Mangelsdorf, Harry J McArdle, Monika Neuhäuser-Berthold, Josef Schlatter, Viviana Trezza

*Discussion at the meetings focused on the draft scientific opinion, and in particular on the assessment of data regarding product characterization, production process and toxicology.*

- **Vitamin D2 mushroom powder as a novel food (NF 2020/2226)**

Applicant: Luxidum GmbH ([EFSA-Q-2020-00849](#))

Date: 26/05/2023 WG member: Monika Neuhäuser-Berthold

*Discussion at the meeting focused on the draft scientific opinion and in particular on the data regarding proposed uses and use levels, anticipated daily intake and nutritional information.*

- **Schizochytrium sp. oil as a novel food (NF 2021/2445)**

Applicant: CABIO Biotech (Wuhan) Co., Ltd. ([EFSA-Q-2021-00168](#))

Date(s): 26/05/2023 WG member(s): Thomas Frenzel

*Discussion at the meeting focused on the additional data submitted by the applicant, and in particular on the data regarding product characterization.*

## XI. Next meeting

The next meeting will be held on 12-14 July 2023, via web conference.

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## **Annex**

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

With regard to this meeting, Dr Rosangela Marchelli declared the following: while still having a valid DoI close to expire, a new annual DoI is being submitted in the system. No additional interest are being declared in the new draft DoI. In accordance with EFSA's Policy on Independence<sup>9</sup> and the Decision of the Executive Director on Competing Interest Management<sup>10</sup>, 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.

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<sup>9</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>10</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 145<sup>th</sup> Working Group meeting on Novel Foods



3 - 5 May 2023

14:00-18:00 / 09:00-18:00 / 09:00-13:00

MINUTES - Agreed on 11 May 2023

**Location:** Webconference

### **Attendees:**

- Working Group Members:

Margarita Aguilera-Gómez<sup>1</sup>, Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter<sup>1</sup>, Alexandros Siskos, Henk Van Loveren.

- European Commission and/or Member States representatives:

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

- EFSA:

Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

- Others:

FEEDCO Unit: Anna Christodoulidou

IDATA Unit: Paula Medina Pastor

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Harry J McArdle.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>3</sup> 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.

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<sup>1</sup> Participated on day 1 and 2

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### IV. Agreement of the minutes of the 144<sup>th</sup> Working Group meeting held on 12-14 April 2023, in Parma

The [minutes of the 144<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 21 April 2023.

#### V. 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.

#### VI. Feedback from the European Commission

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

#### VII. Scientific topics for discussion

**a. Draft opinion on apple fruit cell culture extract as a novel food (NF 2020/1621). Applicant: Mibelle Group Biochemistry ([EFSA-Q-2020-00488](#))**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, toxicology and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 23-24 May 2023 for further discussion and possible adoption.

**b. Draft opinion on a blend of *Tamarindus indica* seeds and *Curcuma longa* rhizome extracts as a novel food (NF 2019/1283). Applicant: BOHAN & Co AS ([EFSA-Q-2020-00033](#))**

The WG discussed the newly submitted information, and in particular assessed data regarding product characterization, stability, 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.

**c. Draft opinion on tiger nuts oil as novel food (NF 2020/1746). Applicant: TIGERNUTS TRADERS, S.L. ([EFSA-Q-2022-00052](#))**

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.

**d. Draft opinion on the ethanolic extract of the microalgae *Phaeodactylum tricornutum* dried biomass as a novel food (NF 2018/0626). Applicant: Microphyt ([EFSA-Q-2019-00091](#))**

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 23-24 May 2023 for further discussion and possible adoption.

**e. Draft opinion on fermented soy germ powder as a novel food (NF 2020/2189). Applicant: Nutrition & Santé SAS ([EFSA-Q-2021-00092](#))**

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The WG discussed the 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.

- f. Draft opinion on mineral salt containing potassium and magnesium as a novel food (NF 2018/0798). Applicant: BK Guilini GmbH (ICL ladenburg) ([EFSA-Q-2019-00230](#))**

The WG discussed the 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.

- g. Draft opinion on cannabidiol isolate as a novel food (NF 2021/2340). Applicant: CBD Industries LLC ([EFSA-Q-2021-00282](#))**

The WG discussed the 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.

- h. Draft opinion on esterified propoxylated glycerol (NF 2021/2191). Applicant: Epogee, LLC ([EFSA-Q-2022-00088](#))**

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

- i. Draft opinion on *Schizochytrium sp.* oil as a novel food (NF 2021/2445). Applicant: CABIO Biotech (Wuhan) Co., Ltd. ([EFSA-Q-2021-00168](#))**

The WG discussed the 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.

- j. Draft opinion on *Schizochytrium sp.* oil as a novel food. Applicant: ATK Biotech Co., Ltd. ([EFSA-Q-2020-00850](#))**

The WG discussed the 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.

## VIII. Any Other Business

- **Update on nicotinamide riboside chloride (min. 95%) obtained by chemical synthesis (NF 2021/1911). Applicant: Elysium Health Inc. ([EFSA-Q-2022-00007](#))**

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

- **Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings also were held for the following novel food applications

- Tiger nuts oil (*Cyperus esculentus*) (NF 2020/1746). Applicant: TIGERNUTS TRADERS, S.L. ([EFSA-Q-2022-00052](#))
- Mineral salt containing potassium and magnesium (NF 2018/0798). Applicant: BK Guilini GmbH (ICL ladenburg) ([EFSA-Q-2019-00230](#))
- Olive fruit dry extract standardized in hydroxytyrosol (10 or 20%) (NF 2021/0287). Applicant: NATAC Biotech S.L. ([EFSA-Q-2021-00271](#))





- Fermented soy germ powder (NF 2020/2189). *Applicant: Nutrition & Santé SAS* ([EFSA-Q-2021-00092](#))
- Cannabidiol isolate (NF 2021/2340). *Applicant: CBD Industries LLC* ([EFSA-Q-2021-00282](#))
- 2'-Fucosyllactose (NF 2021/2394). *Applicant: Kyowa Hakko Bio Co., Ltd.* ([EFSA-Q-2021-00407](#))
- Esterified propoxylated glycerol (NF 2021/2191). *Applicant: Epogee, LLC* ([EFSA-Q-2022-00088](#))
- Arachidonic acid-rich oil from the fungus *Mortierella alpina* (NF 2020/2104). *Applicant: BASF SE* ([EFSA-Q-2021-00317](#))

## IX. Next meeting

The next meeting will be held on 7-9 June 2023, 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, Dr Thomas Frenzel declared the following interest: an updated annual DoI was submitted, currently under assessment by EFSA, to indicate the participation as expert to the EFSA working group on Genetically modified animals. In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 144<sup>th</sup> Working Group meeting on Novel Foods



12 - 14 April 2023

14:00-18:00 / 09:00-18:00 / 08:30-12:30

MINUTES - Agreed on 24 April 2023

**Location:** EFSA - Parma (Meeting Room 00/07)

### **Attendees:**

- Working Group Members:

Margarita Aguilera-Gómez, Francesco Cubadda<sup>1</sup>, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Harry J McArdle<sup>1</sup>, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona<sup>2</sup>, Josef Rudolf Schlatter, Alexandros Siskos, Henk Van Loveren.

- Hearing Experts<sup>3</sup>:

Not Applicable

- European Commission and/or Member States representatives:

EC: Ivona Babic<sup>1</sup>, Stella D'Amore, Takis Daskaleros<sup>1</sup>, Rafael Luis Perez Berbejal

- EFSA:

Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

No apologies were received.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## **IV. Agreement of the minutes of the 143<sup>rd</sup> Working Group meeting held on 13-14 March 2023, via web-conference**

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<sup>1</sup> Participated via web conference

<sup>2</sup> Participated on day 3 and part of day 2

<sup>3</sup> 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>

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





The [minutes of the 143<sup>rd</sup> Working Group meeting](#) were agreed by written procedure on 21 March 2023.

## V. 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.

## VI. Feedback from the European Commission

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

## VII. 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.

## VIII. Scientific topics for discussion

- a. Draft opinion on 6'-Sialyllactose (6'-SL) sodium salt as a novel food (NF 2021/2458). Applicant: Kyowa Hakko Bio Co., Ltd. ([EFSA-Q-2021-00447](#))**

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 next NDA plenary meeting on 27<sup>th</sup> April for further discussion and possible adoption.

- b. Draft opinion on 3-Fucosyllactose (3-FL) as a novel food (NF 2021/2463). Applicant: Glycom A/S ([EFSA-Q-2021-00354](#))**

The WG discussed the draft scientific opinion, and in particular assessed data regarding toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27<sup>th</sup> April 2023 for further discussion and possible adoption.

- c. Draft opinion on mineral salt containing potassium and magnesium (NF 2018/0798). Applicant: BK Guilini GmbH (ICL ladenburg) ([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, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

- d. Draft opinion on mealworm (*Tenebrio molitor*) as a novel food (NF 2018/0396). Applicant: Belgian Insect Industry Federation (BiiF) ([EFSA-Q-2018-00746](#))**

The WG discussed the additional information provided in the dossier and agreed to request further clarification from the applicant to proceed with the assessment.

- e. Draft opinion on barley rice protein as a novel food (NF 2020/2195). Applicant: Evergrain, LLC ([EFSA-Q-2020-00806](#))**

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, toxicology, and allergenicity. After amendments, the draft opinion will be presented at the NDA plenary meeting on 23<sup>rd</sup> – 25<sup>th</sup> May 2023 for further discussion and possible adoption.

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**f. Draft opinion on fungi protein (NF 2021/1350) *Fusarium* sp. strain *flavolapis*.  
Applicant: Nature's Fynd ([EFSA-Q-2021-00519](#))**

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

**g. Draft opinion on algal meal and oleoresin of *Haematococcus pluvialis* containing astaxanthin as a novel food (NF 2021/2418). Applicant: AstaReal AB ([EFSA-Q-2021-00319](#))**

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 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.

**h. Draft opinion on astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae (NF-2022-6010). Applicant: AstaReal AB ([EFSA-Q-2022-00588](#))**

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.

**i. Draft opinion on bacterial cellulose aqueous suspension. Applicant: Satisfibre, S.A. ([EFSA-Q-2018-00294](#))**

The WG discussed the newly submitted information, which was provided by the applicant following an EFSA request for additional information. The WG agreed that feed-back from the EFSA cross-cutting Working Group on Nanotechnologies was needed, before proceeding with the scientific assessment of this application.

## IX. Any Other Business

**o Update on 7-hydroxymatairesinol potassium acetate complex as a novel food (NF 2019/0882). Applicant: Linnea S.A. ([EFSA-Q-2019-00147](#))**

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

**o Draft opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt ([EFSA-Q-2019-00091](#))**

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

**o Draft opinion on olive fruit dry extract standardized in hydroxytyrosol (10 or 20%). Applicant: NATAC Biotech S.L. ([EFSA-Q-2021-00271](#))**

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

**o Update of the EFSA Guidance on novel foods**

The WG discussed the activities for the update the EFSA Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283.

**o Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings also were held for the following novel food applications:





- Extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt ([EFSA-Q-2019-00091](#))
- Fungi protein *Fusarium flavolapis* (NF 2021/1350). Applicant: Nature's Fynd ([EFSA-Q-2021-00519](#))
- Inulin-propionate ester (NF 2018/0266). Applicant: Imperial College London Hammersmith Campus ([EFSA-Q-2018-00225](#))
- Vitamin D2 mushroom powder (NF 2020/2226). Applicant: Luxidum GmbH ([EFSA-Q-2020-00849](#))
- Microbiological risk assessment of applications for Cannabidiol as novel food.
- 7-hydroxymatairesinol potassium acetate complex (NF 2019/0882). Applicant: Linnea S.A. ([EFSA-Q-2019-00147](#))
- Corn protein (NF 2021/0441). Applicant: Pen & Tec Consulting S.L.U. ([EFSA-Q-2021-00521](#))

## X. Next meeting

The next meeting will be held on 3-5 May 2023, via web conference.

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# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 143<sup>rd</sup> Working Group meeting on Novel Foods



13 - 14 March 2023

14:00-18:00 / 09:00-18:00

MINUTES - Agreed on 21 March 2023

**Location:** Web conference

### **Attendees:**

- Working Group Members:

Margarita Aguilera-Gomez, Francesco Cubadda, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Harry J McArdle, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Alexandros Siskos, Henk Van Loveren.

- Hearing Experts<sup>1</sup>:

Not Applicable

- European Commission and/or Member States representatives:

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

- EFSA:

Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Leonard Matijevic, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernandez, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

- Others:

Katerina Gerazova Efremova participated as ISA (Individual Scientific Advisor) contractor (ref. EOI/EFSA/NUTR/2019/1) for agenda item 8.a.

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Thomas Frenzel.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

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<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### IV. Agreement of the minutes of the 142<sup>nd</sup> Working Group meeting held on 06 – 08 February 2023, via web-conference

The [minutes of the 142<sup>nd</sup> Working Group meeting](#) were agreed by written procedure on 16 February 2023.

#### V. 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.

#### VI. Feedback from the European Commission

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

#### VII. 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.

#### VIII. Scientific topics for discussion

**a. Draft opinion on yellow/orange tomato extract as a novel food (NF 2021/2369). Applicant: Lycored ([EFSA-Q-2021-00201](#))**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, proposed uses and use levels, anticipated daily intake, nutritional information, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting that will be held on 28-30 March 2023 for further discussion and possible adoption.

**b. Draft opinion on UV-treated powder of whole yellow mealworm (*Tenebrio molitor* larvae) (NF 2019/1142). Applicant: Nutri'Earth ([EFSA-Q-2019-00748](#))**

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, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 28-30 March 2023 for further discussion and possible adoption.

**c. Draft opinion on barley rice protein as a novel food (NF 2020/2195). Applicant: Evergrain, LLC ([EFSA-Q-2020-00806](#))**

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 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.

**d. Draft opinion on 3-fucosyllactose (3-FL) as a novel food (NF 2021/2463). Applicant: Glycom A/S ([EFSA-Q-2021-00354](#))**

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,





nutritional information, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

**e. Draft opinion on *Acheta domesticus* as a novel food (NF 2018/0128). Applicant: Belgian Insect Industry Federation (BiiF) ([EFSA-Q-2018-00543](#))**

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

**f. Draft opinion on PCR broad spectrum hemp extract 85% as a novel food (NF 2020/2248) and CBD Isolate Powder 99%+ (NF 2020/2249). Applicant: Spectrums Europe SAS ([EFSA-Q-2021-00404](#)), ([EFSA-Q-2021-00405](#))**

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.

**g. Draft opinion on glucosyl hesperidin as a novel food (NF 2021/2455). Applicant: Hayashibara Co., Ltd. ([EFSA-Q-2021-00329](#))**

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

**h. Draft opinion on isomalto-oligosaccharide as a novel food (NF 2021/2469). Applicant: BioNeutra North America Inc. ([EFSA-Q-2021-00185](#))**

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.

## IX. Any Other Business

○ **Update on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt ([EFSA-Q-2019-00091](#))**

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

○ **Update on nicotinamide riboside chloride (min. 95%) obtained by chemical synthesis as novel food (NF 2021/1911). Applicant: Elysium Health Inc. ([EFSA-Q-2022-00007](#))**

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

○ **Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings also were held for the following novel food applications

- Olive fruit dry extract standardized in hydroxytyrosol (NF 2021/0287). Applicant: NATAC Biotech S.L. ([EFSA-Q-2021-00271](#))
- Monosodium salt of L-5-methyltetrahydrofolic acid as a novel food (NF 2020/2160). Applicant: Merck & Cie ([EFSA-Q-2021-00079](#))
- 6'-Sialyllactose (6'-SL) sodium salt as a novel food (NF 2021/2458). Applicant: Kyowa Hakko Bio Co., Ltd ([EFSA-Q-2021-00447](#))
- Inulin-propionate ester as a novel food (NF 2018/0266). Applicant: Imperial College London Hammersmith Campus ([EFSA-Q-2018-00225](#))





- Cannabidiol isolate (NF 2021/2340). *Applicant: CBD Industries LLC* ([EFSA-Q-2021-00282](#))
- Protein-rich flour from fresh larvae of mealworm (*Tenebrio molitor*). *Applicant: Ynsect* ([EFSA-Q-2021-00105](#))
- Cannabidiol isolate from the *Cannabis sativa L.* plant as a novel food (NF 2020/1696). *Applicant: Mile High Labs, Inc.* ([EFSA-Q-2021-00362](#))

## **X. Next meeting**

The next meeting will be held on 12 – 14 April 2023, in Parma.



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 142<sup>nd</sup> Working Group meeting on Novel Foods



06 - 08 February 2023

14:00-18:00 / 09:00-17:00 / 09:00-12:00

MINUTES - Agreed on 16 February 2023

**Location:** Webconference

### **Attendees:**

- Working Group Members:

Margarita Aguilera Gómez, Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst<sup>1</sup>, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Monika Neuhäuser-Berthold, Carmen Pelaez,<sup>2</sup> Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren.<sup>3</sup>

- Hearing Experts<sup>4</sup>:

Not Applicable

- European Commission and/or Member States representatives:

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

EFSA:

Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Leonard Matijevic, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernandez, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

- Others:

Katerina Gerazova Efremova participated as ISA (Individual Scientific Advisor) contractor (ref. EOI/EFSA/NUTR/2019/1) for agenda items 8.d and 8.h, via web conference.

## **I. Welcome and apologies for absence**

The Chair welcomed the participants.

Apologies were received from Harry J McArdle.

## **II. Adoption of agenda**

The agenda was adopted without changes.

## **III. Declarations of Interest of Working Groups members**

In accordance with EFSA's Policy on Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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.

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<sup>1</sup> Participated on day 2 pm and day 3

<sup>2</sup> Participated for agenda items 8.e and 8.f

<sup>3</sup> Participated on day 1 and 2

<sup>4</sup> 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>

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





#### IV. Agreement of the minutes of the 141<sup>st</sup> Working Group meeting held on 11-12 January 2023, via web-conference

The [minutes of the 141<sup>st</sup> Working Group meeting](#) were agreed by written procedure on 19 January 2023.

#### V. Feedback from the NDA Panel plenary meeting

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

#### VI. Feedback from the European Commission

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

#### VII. 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.

#### VIII. Scientific topic(s) for discussion

- a. Draft opinion on water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* as a novel food (NF 2018/0801). Applicant: ABC Kroos B.V. (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, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27-28 February for further discussion and possible adoption.

- b. Draft opinion on UV-treated powder of whole yellow mealworm (*Tenebrio molitor*) larvae (NF 2019/1142). Applicant: Nutri'Earth (EFSA-Q-2019-00748)**

The WG discussed the additional information provided in the dossier and agreed to request further clarification from the applicant to proceed with the assessment.

- c. Draft opinion on *Tenebrio molitor* protein concentrate as a novel food (NF 2020/1959). Applicant: Ynsect (EFSA-Q-2021-00105)**

The WG discussed the additional information provided in the dossier and agreed to request further clarification from the applicant to proceed with the assessment.

- d. Draft opinion on Xia Powder 435 (NF 2021-1311). Applicant: Functional Products Trading Arica S.A. / BENEXIA (EFSA-Q-2021-00551)**

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 next NDA plenary meeting starting on 27-28 February for further discussion and possible adoption.

- e. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2020/2242). Applicant: ATK Biotech Co, Ltd. (EFSA-Q-2020-00850)**

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.

**f. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2021/2445). Applicant: CABIO-Biotech (Wuhan) Co, Ltd. (EFSA-Q-2021-00168)**

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.

**g. Draft opinion on paramylon as a novel food (NF 2019/1261). Applicant: Kemin Foods L.C. (EFSA-Q-2019-00593)**

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.

**h. Draft opinion on Yellow/orange tomato extract as a novel food (NF 2021/2369). Applicant: Lycored (EFSA-Q-2021-00201)**

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 WG NF meeting for further discussion.

**i. Draft opinion on Algal meal and oleoresin of *Haematococcus pluvialis* containing astaxanthin as a novel food (NF 2021/2418). Applicant: AstaReal AB (EFSA-Q-2021-00319)**

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 the next WG NF meeting for further discussion.

## IX. Any Other Business

○ **Food Enzymes used as processing aids in the NF dossier**

The WG discussed a possible strategy to evaluate Novel Foods that during the production process foresee the use of Food Enzymes not yet evaluated by EFSA and not authorised by the Commission.

○ **Discussion on EC-JRC analytical activities on process contaminants in chia products**

The WG discussed the proposal from EC-JRC to perform analytical studies on the content of acrylamide and other process contaminants in processed chia seeds products. Technical support on the objectives and design of the studies will be provided by EFSA in consultation with the WG experts.

○ **Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings also were held for the following novel food applications

- Preparatory mtg on *Schizochytrium* sp. oil (NF 2021/2445). Applicant: CABIO-Biotech (Wuhan) Co, Ltd ([EFSA-Q-2021-00168](#))
- Preparatory mtg on UV-treated powder of whole yellow mealworm (*Tenebrio molitor* larvae) (NF 2019/1142). Applicant: Nutri'Earth ([EFSA-Q-2019-00748](#))
- Preparatory mtg on water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* (NF 2018/0801). Applicant: ABC Kroos B.V. ([EFSA-Q-2019-00047](#))
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## **X. Next meeting**

The next meeting will be held on 13-15 March 2023, via web conference.



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## 141<sup>st</sup> Working Group meeting on Novel Foods

11-12 January 2023

09:00-17:00 / 09:00-12:30

MEETING MINUTES - Agreed on 19 January 2023

**Location:** Webconference

**Attendees:**

- Working Group Members:  
Margarita Aguilera Gomez, Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Harry McArdle, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Viviana Trezza<sup>1</sup>, Henk Van Loveren<sup>2</sup>.
- Hearing Experts<sup>3</sup>:  
Not Applicable
- European Commission and/or Member States representatives:  
EC: Ivona Babic, Stella D'Amore, Takis Daskaleros and Rafael Perez-Berbejal
- EFSA:  
Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernandez, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.
- Others:  
Fernando Rivero Pino participated as ISA (Individual Scientific Advisor) contractor (ref. EOI/EFSA/NUTRI/2019/1) for agenda item 7.a.  
  
Katerina Gerazova participated as ISA (Individual Scientific Advisor) contractor (ref. EOI/EFSA/NUTRI/2019/1) for agenda item 7.c.

## I. Welcome and apologies for absence

The Chair welcomed the participants.  
No apologies were received.

## II. Adoption of agenda

The agenda was adopted without changes.

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<sup>1</sup> Participated only for item 8.e.

<sup>2</sup> Participated on day 2

<sup>3</sup> 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>





### III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

### IV. Agreement of the minutes of the 140<sup>th</sup> Working Group meeting held on 05-07 December 2022, in Parma.

The [minutes](#) of the 140<sup>th</sup> Working Group meeting were agreed by written procedure on 15 December 2022.

### V. Feedback from the last NDA Panel plenary meeting

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

### VI. Feedback from the European Commission

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

### VII. Scientific topic(s) for discussion

#### a. Draft opinion on tri-betahydroxybutyrin as a novel food (NF 2019/1316). Applicant: Neuro Energy Ventures (EFSA-Q-2021-00251)

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

#### b. Draft opinion on yellow/orange tomato extract as a novel food (NF 2021/2369). Applicant: Lycored Ltd (EFSA-Q-2021-00201)

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.

#### c. Draft opinion on Nicotinamide riboside chloride (min. 95%) obtained by chemical synthesis (NF2021-1911). Applicant: Elysium Health Inc. (EFSA-Q-2022-00007)

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

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





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.

**d. Draft opinion on Fungi protein *Fusarium flavolapis*. Applicant: Nature's Fynd (EFSA-Q-2021-00519)**

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.

**e. Update on the status of the activities on CBD**

- **Draft opinion on PCR Broad Spectrum Hemp Extract 85% as a novel food. Applicant: Spectrums Europe SAS (EFSA-Q-2021-00404)**
- **Draft opinion on CBD Isolate Powder 99%+ as a novel food. Applicant: Spectrums Europe SAS (EFSA-Q-2021-00405)**
- **Draft opinion on Refined industrial hemp extract (*Cannabis sativa* L.) as a novel food. Applicant: Dun Agro Plant Products BV (EFSA-Q-2021-00360)**
- **Draft opinion on trans-cannabidiol from *Cannabis sativa* L. as a novel food. Applicant: CBDepot, s.r.o (EFSA-Q-2021-00279)**
- **Draft opinion on Cannabidiol Isolate from the *Cannabis sativa* L. plant as a novel food. Applicant: Mile High Labs (EFSA-Q-2021-00362)**

The WG discussed the risk assessment approach for applications on CBD extracted from *Cannabis sativa*. The WG discussed the draft scientific opinions, 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. Therefore, a request for additional information will be sent to the applicants.

## VIII. Any Other Business

- **Update on the request for a scientific opinion on Fermented soy germ powder (SE5-OH®) as a novel food (NF 2020/2189). Applicant: Nutrition & Santé SAS (EFSA-Q-2021-00092)**

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

- **Draft opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt (EFSA-Q-2019-00091)**

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

- **Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings also were held for the following novel food applications

- Nicotinamide riboside chloride (NF 2021/1911). Applicant: Elysium Health Inc. (EFSA-Q-2022-00007)
  - Extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt (EFSA-Q-2019-00091)
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## **IX. Next meeting**

The next meeting will be held on 06–08 February 2023, via web conference.





# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 140<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

**Held on 05-07 December 2022, Parma  
(Agreed on 15 December 2022)**

### Participants

#### ■ Working Group Members:

Margarita Aguilera Gomez, Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Morten Poulsen<sup>1</sup>, Miguel Prieto Maradona<sup>2</sup>, Josef Rudolf Schlatter, Henk Van Loveren.<sup>3</sup>

#### ■ Hearing Experts<sup>4</sup>:

Not Applicable

#### ■ European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore, Takis Daskaleros and Rafael Luis Perez Berbejal, all via web conference.

#### ■ EFSA:

Nutrition and Food Innovation Unit: Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Esther Garcia Ruiz, Wolfgang Gelbmann, Andrea Germini, Maria Glymenaki, Eirini Kouloura, Marcello Laganaro, Leonard Matijevic, Vânia Mendes, Alejandra Munoz, Irene Nuin, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

#### ■ Others:

Fernando Rivero Pino participated as ISA (Individual Scientific Advisor) contractor (ref. EOI/EFSA/NUTR/2019/1) for agenda item 8.3 and 8.4, via web conference.

<sup>1</sup> Participated on day 1 and day 2

<sup>2</sup> Participated via web conference

<sup>3</sup> Participation on day 2 was partial

<sup>4</sup> 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.

## **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<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 139<sup>th</sup> Working Group meeting held on 08-09 November 2022 via web-conference.**

The [minutes of the 139<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 18 November 2022.

## **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.

## **8. Scientific topic(s) for discussion**

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**8.1. Draft opinion on water lentil protein concentrates from a mixture of *Lemna gibba* and *Lemna minor* as a novel food (NF 2018/0801). Applicant: ABC Kroos B.V. (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 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 xia powder 435 (extension of use) (NF 2021/1311). Applicant: Functional Products Trading Arica S.A./ BENEXIA (EFSA-Q-2021-00551)**

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. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

**8.3. Draft opinion on polyphenol extract from water olive mill by product (NF 2021/1494). Applicant: Extractos y Desirados S.L (EFSA-Q-2021-00736)**

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.

**8.4. Draft opinion on tri-betahydroxybutyrin as a novel food (NF 2019/1316). Applicant: Neuro Energy Ventures (EFSA-Q-2021-00251)**

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

**8.5. Draft opinion on protein powders from the *Alphitobius diaperinus* larva as a novel food (NF 2019/1292). Applicant: Ynsect NL B.V. (EFSA-Q-2019-00690)**

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, 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 fermented soy germ powder as a novel food (NF 2020/2189). Applicant: Nutrition & Santé SAS (EFSA-Q-2021-00092)**

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





**8.7. Draft opinion on 2'-Fucosyllactose (NF 2021/1171). Applicant: Christian Hansen A/S (EFSA-Q-2021-00643)**

The WG was informed about the status of the application. 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 barley rice protein as a novel food (NF 2020/2195). Applicant: Evergrain, LLC (EFSA-Q-2020-00806)**

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

**9.2. Update on *Tenebrio molitor* concentrate as a novel food (NF 2020/1959). Applicant: Ynsect (EFSA-Q-2021-00105)**

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

**9.3. Update on UV-treated powder of whole yellow mealworm (*Tenebrio molitor*) larvae (NF 2019/1142). Applicant: Nutri'Earth (EFSA-Q-2019-00748)**

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

**9.4. Update on arginine glutamate as a nutrient source. Applicant: Ajinomoto Co., Inc. (EFSA-Q-2021-00064)**

The WG was informed that the application for arginine glutamate as nutrient source was withdrawn by the applicant.

**9.5. Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings also were held for the following novel food applications

- Glucosyl hesperidin as a novel food (NF 2021/2455) Applicant: Hayashibara Co., Ltd. (EFSA-Q-2021-00329)
- Fermented soy germ powder as a novel food (NF 2020/2189) Applicant: Nutrition & Santé SAS (EFSA-Q-2021-00092)
- Tri-betahydroxybutyrin as a novel food (NF 2019/1316) Applicant: Neuro Energy Ventures (EFSA-Q-2021-00251)
- L-Fucose as a novel food (NF 2020/1995) Applicant: Kyowa Hakko Europe GmbH (EFSA-Q-2020-00774)
- Polyphenol extract from water olive mill by product (NF 2021-1494) Applicant: Extractos y Desirados S.L (EFSA-Q-2021-00736)
- Nutritional fungi protein (NF 2021/1350) Applicant: Nature's Fynd (EFSA-Q-2021-00519)





- 6'-Sialyllactose (6'-SL) sodium salt as a novel food (NF 2021/2458) *Applicant: Kyowa Hakko Bio Co., Ltd.* (EFSA-Q-2021-00447)
- Urolithin A as a novel food (NF 2018/0538) *Applicant: Amazentis S.A.* (EFSA-Q-2018-00724)
- Isomalto-oligosaccharide as a novel food (NF 2021/2469) *Applicant: BioNeutra North America Inc.* (EFSA-Q-2021-00185)
- Water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* as a novel food (NF 2018/0801) *Applicant: ABC Kroos B.V.* (EFSA-Q-2019-00047)
- UV-treated powder of whole yellow mealworm (*Tenebrio molitor*) larvae (NF 2019/1142) *Applicant: Nutri'Earth* (EFSA-Q-2019-00748)
- Protein powders from the *Alphitobius diaperinus* larva as a novel food (NF 2019/1292) *Applicant: Protifarm Holding NV* (EFSA-Q-2019-00690)
- Nicotinamide riboside chloride (min. 95%) obtained by chemical synthesis (NF 2021/1911) *Applicant: Elysium Health Inc.* (EFSA-Q-2022-00007)
- Finalisation of the systematic review for CBD for publication

## 10. Next meeting

The next meeting will be held on 10-12 January 2023, via web conference.





# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 139<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

**Held as web-conference, 08-09 November 2022**

**(Agreed on 18 November 2022)**

### 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<sup>1</sup>, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren.

■ Hearing Experts<sup>2</sup>:

Not Applicable

■ European Commission and/or Member States representatives:

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

■ EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Antonio Fernandez Dumont, Wolfgang Gelbmann, Andrea Germini, Eirini Kouloura, Marcello Langanaro, Leonard Matijevic, Alejandra Munoz, Estefanía Noriega Fernandez, Irene Nuin, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

<sup>1</sup> Attended only for agenda item 9 on the second day

<sup>2</sup> 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>





Apologies were received from Harry J McArdle.

## 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<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 138<sup>th</sup> Working Group meeting held on 05-07 October 2022, via web-conference.

The [minutes of the 138<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 14 October 2022.

## 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 novel food applications received, including a short introduction to recently validated applications.

## 8. Scientific topic(s) for discussion

### 8.1. Draft opinion on Apple fruit cell culture extract as a novel food (NF 2020/1621). Applicant: Mibelle Group Biochemistry (EFSA-Q-2020-00488)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





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, 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 whole seeds of oilseed rape as a novel food (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. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 24 November for further discussion and possible adoption.

**8.3. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2020/2242). Applicant: ATK Biotech Co., Ltd (EFSA-Q-2020-00850)**

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.

**8.4. Draft opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt (EFSA-Q-2019-00091)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, toxicology, and specifications. 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. Discussion on the use of confidential and proprietary data across dossiers**

The WG discussed with EFSA staff and EC representative a strategy for the use of proprietary data submitted in the context of the novel food applications under risk assessment.

**9.2. Feedback on recent scientific events attended by EFSA staff**

The WG was informed about the presentations delivered by EFSA staff on recent scientific events; in particular, the WG received feedback on the status of the activities in the area of cultured cell meat and precision fermentation that were discussed at those events.

**9.3. Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings also were held for the following novel food applications





- Scientific opinion on Cannabidiol Isolate as a novel food (NF 2021/2340) *Applicant: CBD Industries LLC* ([EFSA-Q-2021-00282](#))
- Scientific opinion on Apple fruit cell culture extract as a novel food (NF 2020/1621) *Applicant: Mibelle Group Biochemistry* ([EFSA-Q-2020-00488](#))
- Scientific opinion on whole seeds of oilseed rape as a novel food (NF 2018/0590) *Applicant: Erik Tybirk* ([EFSA-Q-2019-00033](#))
- Finalisation of the systematic review for CBD for publication

## 10. Next meeting

The next meeting will be held on 05–07 December 2022, in Parma.





NUTRITION AND FOOD INNOVATION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 138<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

**Held as web-conference, 05-07 October 2022**

**(Agreed on 14 October 2022)**

### Participants

■ Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst<sup>1</sup>, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter<sup>2</sup>, Henk Van Loveren<sup>1</sup>.

■ Hearing Experts<sup>3</sup>:

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, Océane Albert, Domenico Azzollini, Paolo Colombo, Wolfgang Gelbmann, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

<sup>1</sup> Did not participate on day 1

<sup>2</sup> Did not participate on day 2

<sup>3</sup> 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 Carmen Pelaez.

## 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<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 137<sup>th</sup> Working Group meeting held on 14-16 September 2022, in Parma

The [minutes of the 137<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 23 September 2022.

## 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 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.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## 8. Scientific topic(s) for discussion

### 8.1. **Draft opinion on a blend of *Tamarindus indica* seeds and *Curcuma longa* rhizome extracts as a novel food (NF 2019/1283). Applicant: BOHAN & CO AS (EFSA-Q-2020-00033)**

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, 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.

### 8.2. **Draft opinion on urolithin A as a novel food (NF 2018/0538). Applicant: Amazentis S.A. (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.

### 8.3. **Draft opinion on cannabidiol isolate as a novel food (NF 2021/2340). Applicant: CBD Industries LLC (EFSA-Q-2021-00282)**

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

### 8.4. **Draft opinion on 6'-sialyllactose (6'-SL) as a novel food (NF 2020/1801). Applicant: Chr. Hansen A/S (EFSA-Q-2020-00623)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding 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 26<sup>th</sup> October for further discussion and possible adoption.

### 8.5. **Draft opinion on 2'-fucosyllactose (2'-FL) as a novel food (NF 2020/1825). Applicant: Advanced Protein Technologies Corp (EFSA-Q-2020-00500)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 26<sup>th</sup> October for further discussion and possible adoption.

### 8.6. **Draft opinion on mineral salt containing potassium and magnesium (NF 2018/0798). Applicant: BK Guilini GmbH (ICL Ladenburg) (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, 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 magnesium L-threonate as a novel food (NF 2021/2453). Applicant: AIDP Inc. (EFSA-Q-2021-00203)**

The WG discussed the draft scientific opinion, 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.

**8.8. Draft opinion on *Clostridium butyricum* TO-A. Applicant: TOA Biopharma Co. Ltd (EFSA-Q-2022-00010)**

The WG discussed 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.

**8.9. Draft opinion on dry cacaofruit cascara (*Theobroma cacao* L.). Applicant: Cabosse Naturals NV (EFSA-Q-2022-00005)**

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.

**8.10. Draft opinion on arginine glutamate. Applicant: Ajinomoto Co., Inc (EFSA-Q-2021-00064)**

The WG was informed about the status of the application. 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 L-fucose as a novel food (NF 2020/1995). Applicant: Setenta e Três Mil e Cem, Lda. (EFSA-Q-2020-00774)**

The WG was informed about the status of the application. 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) as a novel food (NF 2019/1077). Applicant: HELIXPHARMA S.R.L. (EFSA-Q-2019-00388)**

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





### **9.2. Interpretation of the QPS qualification on 'Acquired antimicrobial resistance genes'**

The WG was informed on the activities of the QPS (qualified presumption of safety) sub WG on 'acquired antimicrobial resistance', aimed to clarify the interpretation of the QPS qualification for all bacteria on 'absence of acquired antimicrobial resistance genes'.

### **9.3. Additional expertise for the working group**

The WG was informed that selection procedures are ongoing to identify additional experts in the area of chemistry, microbiology and nutrition.

### **9.4. Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings also were held for the following novel food applications

- Cannabidiol Isolate NF 2021/2340 *Applicant: CBD Industries LLC (EFSA-Q-2021-00282)*
- Helix Complex Snail Mucus (HSM) NF 2019/1077 *Applicant: HELIXPHARMA S.R.L. (EFSA-Q-2019-00388)*
- Whole cell heat-killed non-GMM *Mycolicibacterium aurum* DSM33539 NF 2020/1827 *Applicant: Aurum Switzerland AG (EFSA-Q-2020-00566)*
- Magnesium L-threonate NF 2021/2453 *Applicant: AIDP Inc. (EFSA-Q-2021-00203)*
- Urolithin A NF 2018/0538 *Applicant: Amazentis S.A. (EFSA-Q-2018-00724)*
- Blend of Tamarindus indica seeds and Curcuma longa rhizome extracts NF 2019/1283 *Applicant: BOHAN & Co AS (EFSA-Q-2020-00033)*
- Dry cacaofruit cascara (*Theobroma cacao* L.) NF 2021/1824 *Applicant: Cabosse Naturals NV (EFSA-Q-2022-00005)*

## **10. Next meeting**

The next meeting will be held on 08-10 November 2022, via web conference.



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 137<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

**Held on 14-16 September 2022, Parma**

**(Agreed on 23 September 2022)**

### Participants

■ Working Group Members:

Francesco Cubadda<sup>1,2</sup>, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst<sup>1</sup>, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle<sup>1</sup>, Monika Neuhäuser-Berthold, Carmen Pelaez<sup>1,3</sup>, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren.<sup>4</sup>

■ Hearing Experts<sup>5</sup>:

Not Applicable

■ European Commission and/or Member States representatives:

EC: Ivona Babic<sup>1</sup>, Stella D'Amore<sup>1</sup>, Takis Daskaleros<sup>1</sup>, Rafael Luis Perez Berbejal<sup>1</sup>

■ EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Agnès De Sesmaisons Lecarré, Antonio Fernández Dumont, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

■ Others:

<sup>1</sup> Participated via web conference

<sup>2</sup> For agenda items 8.4 and 8.5

<sup>3</sup> For agenda items 8.3 and 9.3

<sup>4</sup> Participated via web conference on day 2 and 3

<sup>5</sup> 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>





Fabio Alfieri participated as ISA expert (ref. EOI/EFSA/NUTR/2019/1) for agenda item 8.2, via web conference.

## 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 Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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 136<sup>th</sup> Working Group meeting held on 11-12 July2022, via web-conference.

The [minutes of the 136<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 20 July 2022.

## 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.

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<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## 8. Scientific topic(s) for discussion

### 8.1. **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. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 28 September 2022 for further discussion and possible adoption.

### 8.2. **Draft opinion on *Lemna minor* (and *Lemna gibba*) whole plant material as a novel food (NF 2020/1757). Applicant: Wageningen Plant Research (EFSA-Q-2020-00512)**

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 28<sup>th</sup> of September for further discussion and possible adoption.

### 8.3. **Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2021/2445). Applicant: CABIO Biotech (Wuhan) Co., Ltd. (EFSA-Q-2021-00168)**

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.

### 8.4. **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. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 28 September 2022 for further discussion and possible adoption.

### 8.5. **Draft opinion on 6'-Sialyllactose (6'-SL) as a novel food (NF 2020/1801) Applicant: Chr. Hansen A/S (EFSA-Q-2020-00623)**

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.

### 8.6. **Draft opinion on yellow/orange tomato extract as a novel food (NF 2021/2369). Applicant: Lycored Ltd (EFSA-Q-2021-00201)**

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.

### 8.7. **Draft opinion on proteins from corn (*Zea mays*) (NF 2021/0441). Applicant: Cargill R&D Centre Europe BV (EFSA-Q-2021-00521)**





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.

**8.8. Draft opinion on algal meal and oleoresin of *Haematococcus pluvialis* containing astaxanthin as a novel food (NF 2021/2418). Applicant: *AstaReal AB* (EFSA-Q-2021-00319)**

The WG discussed the draft scientific opinion on a proposed extension of use, 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.

## 9. Any Other Business

**9.1. Update draft opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: *Microphyt* (EFSA-Q-2019-00091)**

The WG was informed about the status of the application. A request for clarification will be sent to the applicant.

**9.2. Update on cannabidiol (CBD) (NF 2020/1897). Applicant: *BSPG Laboratories Ltd.* (EFSA-Q-2020-00353)**

The WG was informed that a preparatory meeting took place for this application, which is awaiting additional information from the applicant. Complementary information has been requested to the applicant.

**9.3. Update on isomalto-oligosaccharide (NF 2021/2469). Applicant: *BioNeutra North America Inc* (EFSA-Q-2021-00185)**

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

**9.4. Genotoxicity testing for microorganisms as novel foods**

The WG discussed the requirements for genotoxicity testing in case of microorganisms intended as novel foods. The WG considered that further discussion is needed to reach a conclusion.

**9.5. Preparatory meetings**

Since the last Novel foods WG meeting, preparatory meetings occurred for the following novel food applications

- L-fucose (NF 2020/1995) Applicant: *Kyowa Hakko Europe GmbH* (EFSA-Q-2020-00774)
- Powder of chitosan (NF 2019/0908). Applicant: *Cor.Con. International* (EFSA-Q-2019-00324)
- PCR Broad Spectrum Hemp Extract 85% (NF 2020/2248). Applicant: *Spectrums Europe* (EFSA-Q-2021-00404)





- Refined industrial hemp extract (*Cannabis sativa* L.). *Applicant: Dun Agro Plant Products BV* (EFSA-Q-2021-00360)
- UV-treated powder of whole yellow mealworm (*Tenebrio molitor*) larvae (NF 2019/1142). *Applicant: Nutri'Earth* (EFSA-Q-2019-00748)

The draft opinions for these applications will be discussed during the next Novel foods WG meetings.

## 10. Next meeting

The next meeting will be held on 05-07 October 2022, via web conference.



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 136<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 11-12 July 2022 as a web-conference

(Agreed on 20 July 2022)

### 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 Experts<sup>1</sup>:

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, Océane Albert, Domenico Azzollini, Paolo Colombo, Antonio Fernández Dumont, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijević, Estefanía Noriega Fernández, Gabriela Precup, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

#### Others:

Fabio Alfieri as ISA contractor for agenda items 8.7 and 9.2

### 1. Welcome and apologies for absence

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





The Chair welcomed the participants.

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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 135th Working Group meeting held on 31 May – 01 June 2022, via web-conference.

The minutes of the 135<sup>th</sup> Working Group meeting were agreed by written procedure 08 June 2022.

## 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 novel food applications received, including a short introduction to recently validated applications.

## 8. Scientific topic(s) for discussion

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**8.1. Draft opinion on iron milk proteinate (IMP) as a novel food (NF 2020/1866). Applicant: Société des Produits Nestlé S.A. (EFSA-Q-00492)**

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. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 4 August 2022 for further discussion and possible adoption.

**8.2. Draft opinion on 2'-Fucosyllactose (2'-FL) as a novel food (NF 2020/1825). Applicant: Advanced Protein Technologies Corp. (EFSA-Q-2020-00500)**

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.

**8.3. Draft opinion on partially defatted chia seed powder (Xia powder 435). Applicant: Functional Products Trading Arica S.A./BENEXIA (EFSA-Q-2021-00551)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding process contaminants (acrylamide, furan and methylfurans) formation study, specifications, proposed uses, use levels and 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.

**8.4. Draft opinion on an Aqueous ethanolic extract of *Labisia pumila* as a novel food (NF 2019/1337). Applicant: Medika Natura 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, 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. Update on draft opinion on barley rice protein as a novel food (NF 2020/2195). Applicant: Evergrain, LLC (EFSA-Q-2020-00806)**

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

**8.6. Draft opinion on *Tenebrio molitor* protein concentrate as a novel food (NF 2020/1959). Applicant: Ynsect (EFSA-Q-2021-00105)**





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

**8.7. Draft opinion on *Lemna minor* (and *Lemna gibba*) whole plant material as a novel food (NF 2020/1757). Applicant: Wageningen Plant (EFSA-Q-2020-00512)**

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

## 9. Any Other Business

**9.1. Update on Commission request for a scientific opinion on arginine glutamate. Applicant: Ajinomoto Co., Inc. (EFSA-Q-2021-00064)**

The WG was informed about the status of the application. 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 grain from perennial intermediate wheatgrass (*Thinopyrum intermedium*) as a novel food (NF 2019/1468). Applicant: Patagonia Provisions, Inc. (EFSA-Q-2020-00073)**

The WG was informed about the status of the application that is awaiting additional information from the applicant. The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, nutritional information, proposed uses and use levels, 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.

**9.3. Update on draft opinion on 6'-sialyllactose (6'-SL) sodium salt as a novel food (NF 2021/2458). Applicant: Kyowa (EFSA-Q-2021-00447)**

The WG was informed about the status of the application. 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.

**9.4. Update on draft opinion on 3'-sialyllactose (3'-SL) sodium salt as a novel food (NF 2021/2457). Applicant: Kyowa (EFSA-Q-2021-00445)**

The WG was informed about the status of the application. 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.





**9.5. Update on draft opinion on an extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt (EFSA-Q-2019-00091)**

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

**9.6. Discussion on allergenicity assessment of novel foods**

The WG discussed the current strategy for the allergenicity assessment of novel foods and the experience with recent applications. The WG decided to initiate a task force to discuss whether the current strategy for allergenicity assessment as described in the guidance document for the assessment of novel foods is still adequate to answer the mandates from the EC or requires adjustments.

**10. Next meeting**

The next meeting will be held on 14-16 September 2022, in Parma.





NUTRITION AND FOOD INNOVATION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 135<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 31 May–01 June 2022

(Agreed on 8 June 2022)

### 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<sup>1</sup>, Henk Van Loveren.

#### Hearing Experts<sup>2</sup>:

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, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Agnès De Sesmaisons Lecarré, Antonio Fernández Dumont, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijević, Estefanía Noriega Fernández, Gabriela Precup, Fernando Rivero Pino, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Participated only on day 2

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 134<sup>th</sup> Working Group meeting held on 04-06 May 2022, via web-conference.

The [minutes of the 134<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 13 May 2022.

## 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.

## 8. Scientific topic(s) for discussion

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**8.1. Draft opinion on  $\beta$ -Hydroxybutyrate salts (Sodium/Magnesium/Calcium) as a novel food (NF 2018/0291). Applicant: Pruvit Ventures, Inc. (EFSA-Q-2018-00343)**

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 29 June - 1 July 2022 for further discussion and possible adoption.

**8.2. Draft opinion on iron milk proteinate (IMP) as a novel food (NF 2020/1866). Applicant: Société des Produits Nestlé S.A. (EFSA-Q-2020-00492)**

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.

**8.3. Draft opinion on *Yarrowia lipolytica* yeast biomass as a novel food (NF 2020/1950). Applicant: Skotan S.A. (EFSA-Q-2020-00655)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, proposed uses and use levels, anticipated daily intake and nutritional information. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 29 June - 1 July 2022 for further discussion and possible adoption.

**8.4. Draft opinions on CBD as novel foods. Applicants: CBDepot (EFSA-2019-00750, EFSA-Q-2021-00279); Chanelle McCoy CBD LTD (EFSA-Q-2020-00257); Cibdol (EFSA-Q-2020-00353); Farmabios S.p.A. (EFSA-Q-2020-00831); Charlotte's Web, Inc. (EFSA-Q-2021-00217, EFSA-Q-2021-00218, EFSA-Q-2021-00219); PureForm Global Inc (EFSA-Q-2021-00243); CBD Industries LLC (EFSA-Q-2021-00282); Hempoland (EFSA-Q-2021-00335); Linnea SA (EFSA-Q-2021-00351, EFSA-Q-2021-00406); Pharmahemp (EFSA-Q-2021-00352, EFSA-Q-2021-00456); BSPG Laboratories (EFSA-Q-2021-00353); Dun Agro Plant Products (EFSA-Q-2021-00360); Spectrums Europe (EFSA-Q-2021-00404, EFSA-Q-2021-00405)**

The WG discussed the applications, and in particular assessed data regarding toxicology and human studies. The WG considered that additional information is needed from the applicants in order to proceed with the scientific assessment of these applications. Therefore, a request for additional information will be sent to the applicants.

**8.5. Draft opinion on 2'-fucosyllactose as a novel food. Applicant: Kyowa Hakko Bio Co., Ltd. (EFSA-Q-2021-00407)**

The WG was informed about the status of the application. 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 barley rice protein as a novel food (NF 2020/2195).

**Applicant:** *Evergrain, LLC* (EFSA-Q-2020-00806)

The WG was informed about the status of the application which is awaiting additional information from the applicant and on data provided by the applicant in the areas of product characterisation, production process, specifications, and nutritional information.

### 9.2. Draft opinion on *Tenebrio molitor* protein concentrate as a novel food (NF 2020/1959). **Applicant:** *Ynsect* (EFSA-Q-2021-00105)

The WG was informed about the status of the application which is awaiting additional information from the applicant and on data provided by the applicant in the areas of product characterisation, production process, proposed uses and use levels, specifications, nutritional information, and toxicology.

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

The WG was informed about the status of the application. A request for clarification will be sent to the applicant.

### 9.4. Non-novel parts of the NF

Based on the feedback received from the risk managers (EC WG meeting on novel foods), the WG was asked to create a briefing note regarding the “non-novel parts” of the NFs, the topic which was previously discussed during the 131<sup>st</sup> meeting of the WG. After amendments, the document will be delivered to the risk managers for further discussion.

### 9.5. Allergenicity assessment of NFs

The WG discussed the approach for the assessment of the allergenicity of NFs. The topic will be presented at the next WG NF meeting for further discussion.

## 10. Next meeting

The next meeting will be held on 11-13 July 2022, via web conference.





NUTRITION AND FOOD INNOVATION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 134<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 04-06 May 2022

(Agreed on 13 May 2022)

### 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, Viviana Trezza<sup>1</sup>, Henk Van Loveren<sup>2</sup>.

#### Hearing Experts<sup>3</sup>:

Not Applicable

#### European Commission and/or Member States representatives:

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

#### EFSA:

NIF Unit: Reinhard Ackerl, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernandez, Gabriela Precup, Fernando Rivero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Participated only for agenda item 9

<sup>2</sup> Participated on day 2 am and day 3.

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 133<sup>rd</sup> Working Group meeting held on 06-08 April 2022 via web-conference.

The minutes of the 133<sup>rd</sup> Working Group meeting were agreed by written procedure on 20 April 2022.

## 5. Feedback from the NDA Panel plenary meeting

The working group was informed that five novel food opinions were adopted at the last NDA Panel plenary meeting. At the same meeting the NDA Panel also adopted the Statement on the safety of cannabidiol (CBD) as a novel food.

## 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

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**8.1. Draft opinion on *Antrrodia 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. After amendments, the draft opinion will be presented at the next NDA plenary meeting for further discussion and possible adoption.

**8.2. Draft opinion on *Tenebrio molitor* (mealworm) flour as a novel food (NF 2019/1142). Applicant: Nutri'Earth (EFSA-Q-2019-00748)**

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.

**8.3. Draft opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt (EFSA-Q-2019-00091)**

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, 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 *Lemna minor* (and *Lemna gibba*) whole plant material as a novel food (NF 2020/1757). Applicant: Wageningen Plant Research (EFSA-Q-2020-00512)**

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

**8.5. Draft opinion on Olive fruit dry extract standardized in hydroxytyrosol (10 or 20%) (NF2021-0287). Applicant: NATAC Biotech S.L.(EFSA-Q-2021-00271)**

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.

**8.6. Draft opinion on Vitamin D2 mushroom powder as a novel food (NF 2020/2226). Applicant: Luxidum GmbH. (EFSA-Q-2020-00849)**

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.

**8.7. Draft opinion on mixture of perdiethylphosphatoethyloligosilsesquioxanols absorbed on lactose monohydrate as a novel food (NF 2019/0976). Applicant: IONTEC S.A.R.L. (EFSA-Q-2019-00549)**

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.

**8.8. Draft opinion on *Acheta domesticus* flour as a novel food (NF 2020/1860). Applicant: Società Agricola. (EFSA-Q-2021-00262)**

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

**8.9. Draft opinion on Clary Sage (*Salvia Sclarea*) Seed Oil as a novel food (NF 2020/1968). Applicant: Naturesage Ltd (EFSA-Q-2021-00100)**

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. Assessment of cannabidiol as novel food**

The WG discussed the implications of the NDA Panel statement on the Safety of cannabidiol (CBD) as a novel food" on the ongoing assessment of the CBD applications received. The WG identified data gaps in the current applications that will be further discussed at the next WG NF meeting.

**9.2. Update on  $\beta$ -Hydroxybutyrate salts (Sodium/Magnesium/Calcium) as a novel food (NF 2018/0291). Applicant: Pruvit Ventues, Inc. (EFSA-Q-2018-00343)**

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

## 10. Next meeting

The next meeting will be held on 30.05–01.06 2022, via web conference.





NIF UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 133<sup>RD</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 06-08 April 2022

(Agreed on 20 April 2022)

### 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<sup>1</sup>, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren.<sup>2</sup>

#### Hearing Experts<sup>3</sup>:

Not Applicable

#### European Commission and/or Member States representatives:

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

#### EFSA:

NIF Unit: Reinhard Ackerl, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Antonio Fernández Dumont, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernández, Gabriela Precup, Fernando Rivero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Partially participated day 1 and 2

<sup>2</sup> Did not participate day 1

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 132<sup>nd</sup> Working Group meeting held on 08-10 March 2022, via web-conference.

The [minutes of the 132<sup>nd</sup> Working Group meeting](#) were agreed by written procedure on 18 March 2022.

## 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 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

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**8.1. Draft opinion on whole seeds of oilseed rape as a novel food (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 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 Zinc L-carnosine as a novel food (NF 2019/1090). Applicant: Hamari Chemicals, Ltd (EFSA-Q-2020-00263)**

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 26<sup>th</sup> and 29<sup>th</sup> April for further discussion and possible adoption.

**8.3. Draft opinion on 3-Fucosyllactose (3-FL) as a novel food (NF 2020/1620). Applicant: Chr. Hansen A/S (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, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 26<sup>th</sup> and 29<sup>th</sup> April for further discussion and possible adoption.

**8.4. Draft opinion on 3'-Sialyllactose (3'-SL) (NF 2020/1794). Applicant: Chr. Hansen A/S (EFSA-Q-2020-00625)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding 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 26<sup>th</sup> and 29<sup>th</sup> April for further discussion and possible adoption.

**8.5. Draft opinion on High vitamin D2 mushroom powder as a novel food (NF 2019/1471). Applicant: Monterey Mushrooms Inc. (EFSA-Q-2020-00417)**

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 26<sup>th</sup> and 29<sup>th</sup> April for further discussion and possible adoption.

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

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, stability, specifications, 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 26<sup>th</sup> and 29<sup>th</sup> April 2022 for further discussion and possible adoption.





**8.7. 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. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

**8.8. EFSA self-mandate for a statement on the safety of cannabidiol (CBD) as a novel food. (EFSA-Q-2021-00735)**

The WG discussed the different sections of the draft statement. After amendments, the draft statement will be presented at the next NDA plenary meeting on 26<sup>th</sup> and 29<sup>th</sup> April for further discussion and possible adoption.

**8.9. Draft opinion on 2'-Fucosyllactose as a novel food (NF 2021/2460). Applicant: Amyris (EFSA-Q-2021-00415)**

The WG discussed the draft scientific opinion, 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.

**8.10. Draft opinion on *Rhizomucor pusillus* fungus biomass (NF 2020/1795) Applicant: The Protein Brewery (EFSA-Q-2020-00476)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity of the novel food, product characterization, production process, specifications, 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.

## 9. Next meeting

The next meeting will be held on 04-06 May 2022, via web conference.





NIF UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 132<sup>ND</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 08-10 March 2022  
as web-conference

(Agreed on 18 March 2022)

### Participants

#### Working Group Members:

Francesco Cubadda<sup>1</sup>, Thomas Frenzel<sup>2</sup>, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle<sup>3</sup>, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Viviana Trezza<sup>4</sup>, Henk Van Loveren.<sup>3</sup>

#### Hearing Experts<sup>5</sup>:

Not Applicable

#### European Commission and/or Member States representatives:

EC: Ivona Babic, Takis Daskaleros, Rafael Luis Perez Berbejal

#### EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Leonard Matijevic, Estefanía Noriega Fernández, Gabriela Precup, Fernando Rivero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Participated on day 1 and 2 pm.

<sup>2</sup> Participated on day 1 and 2.

<sup>3</sup> Participated on day 1 and 2 am.

<sup>4</sup> Participated for agenda item 8.4.

<sup>5</sup> 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 Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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 131<sup>st</sup> Working Group meeting held on 08-10 February 2022, via web-conference.

The [minutes of the 131<sup>st</sup> Working Group meeting](#) were agreed by written procedure on 18 February 2022

## 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 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

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<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**8.1. Draft opinion on Lacto-N-tetraose (LNT) as a novel food (NF 2020/1809).  
Applicant: Chr. Hansen A/S (EFSA-Q-2020-00630)**

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 23-25 March 2022 for further discussion and possible adoption.

**8.2. Draft opinion on 2'-Fucosyllactose as a novel food (NF 2019/1350) and on Lacto-N-neotetraose as a novel food (NF 2019/1359).  
Applicant: Glycom A/S (EFSA-Q-2021-00088) (EFSA-Q-2021-00089)**

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 the next NDA plenary meeting on 23-25 March 2022 for further discussion and possible adoption.

**8.3. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2021/2445).  
Applicant: CABIO Biotech (Wuhan) Co., Ltd. (EFSA-Q-2021-00168)**

The WG discussed the 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.

**8.4. Draft for a statement on the safety of cannabidiol (CBD) as a novel food.  
(EFSA-Q-2021-00735)**

The WG discussed the different sections of the draft statement. After amendments, the draft statement will be presented at the next NDA plenary meeting on 23-25 March for further discussion.

**8.5. Draft opinion on defatted whole cricket (*Acheta domesticus*) powder as a novel food (NF 2019/1227). Applicant: CRICKET ONE CO., LTD (EFSA-Q-2019-00589)**

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 2022 for further discussion and possible adoption.

**8.6. Draft opinion on paramylon as a novel food (NF 2019/1261). Applicant: Kemin Foods L.C. (EFSA-Q-2019-00593)**

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 3'-Sialyllactose (3'-SL) sodium salt (NF 2020/1794).  
Applicant: Chr. Hansen A/S (EFSA-Q-2020-00625)**





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.

**8.8. Draft opinion on 3-Fucosyllactose (3-FL) as a novel food (NF 2021/2463). Applicant: Glycom A/S (EFSA-Q-2021-00354)**

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. Requirements for representative samples in NF assessment**

The working group agreed that representativeness of the samples to be provided for compositional analyses of the NF pertains primarily to i) the production process used in manufacturing the samples and whether this is representative of the production process used to manufacture the novel food, and ii) the sampling procedure to select the samples provided for compositional analyses.

**9.2. Use of the term “fibre” in NF opinions**

The working group was informed about recent discussions regarding the use of the term “fibre” in ongoing NF opinions, and the possible misinterpretation of its definition between Regulation (EU) No 1169/2011 (food information to consumers) and the Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre (EFSA NDA Panel, 2010). The WG was given an overview of ongoing dossiers for which a similar issue may arise and agreed to discuss on a case-by-case basis.

## 10. Next meeting

The next meeting will be held on 06-08 April 2022, via web conference.





NIF UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 132<sup>ND</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 08-10 March 2022  
as web-conference

(Agreed on 18 March 2022)

### Participants

#### Working Group Members:

Francesco Cubadda<sup>1</sup>, Thomas Frenzel<sup>2</sup>, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle<sup>3</sup>, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Viviana Trezza<sup>4</sup>, Henk Van Loveren.<sup>3</sup>

#### Hearing Experts<sup>5</sup>:

Not Applicable

#### European Commission and/or Member States representatives:

EC: Ivona Babic, Takis Daskaleros, Rafael Luis Perez Berbejal

#### EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Leonard Matijevic, Estefanía Noriega Fernández, Gabriela Precup, Fernando Rivero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Participated on day 1 and 2 pm.

<sup>2</sup> Participated on day 1 and 2.

<sup>3</sup> Participated on day 1 and 2 am.

<sup>4</sup> Participated for agenda item 8.4.

<sup>5</sup> 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 Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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 131<sup>st</sup> Working Group meeting held on 08-10 February 2022, via web-conference.

The [minutes of the 131<sup>st</sup> Working Group meeting](#) were agreed by written procedure on 18 February 2022

## 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 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

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<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**8.1. Draft opinion on Lacto-N-tetraose (LNT) as a novel food (NF 2020/1809).  
Applicant: Chr. Hansen A/S (EFSA-Q-2020-00630)**

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 23-25 March 2022 for further discussion and possible adoption.

**8.2. Draft opinion on 2'-Fucosyllactose as a novel food (NF 2019/1350) and on Lacto-N-neotetraose as a novel food (NF 2019/1359).  
Applicant: Glycom A/S (EFSA-Q-2021-00088) (EFSA-Q-2021-00089)**

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 the next NDA plenary meeting on 23-25 March 2022 for further discussion and possible adoption.

**8.3. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2021/2445).  
Applicant: CABIO Biotech (Wuhan) Co., Ltd. (EFSA-Q-2021-00168)**

The WG discussed the 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.

**8.4. Draft for a statement on the safety of cannabidiol (CBD) as a novel food.  
(EFSA-Q-2021-00735)**

The WG discussed the different sections of the draft statement. After amendments, the draft statement will be presented at the next NDA plenary meeting on 23-25 March for further discussion.

**8.5. Draft opinion on defatted whole cricket (*Acheta domesticus*) powder as a novel food (NF 2019/1227). Applicant: CRICKET ONE CO., LTD (EFSA-Q-2019-00589)**

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 2022 for further discussion and possible adoption.

**8.6. Draft opinion on paramylon as a novel food (NF 2019/1261). Applicant: Kemin Foods L.C. (EFSA-Q-2019-00593)**

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 3'-Sialyllactose (3'-SL) sodium salt (NF 2020/1794).  
Applicant: Chr. Hansen A/S (EFSA-Q-2020-00625)**





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.

**8.8. Draft opinion on 3-Fucosyllactose (3-FL) as a novel food (NF 2021/2463). Applicant: Glycom A/S (EFSA-Q-2021-00354)**

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. Requirements for representative samples in NF assessment**

The working group agreed that representativeness of the samples to be provided for compositional analyses of the NF pertains primarily to i) the production process used in manufacturing the samples and whether this is representative of the production process used to manufacture the novel food, and ii) the sampling procedure to select the samples provided for compositional analyses.

**9.2. Use of the term “fibre” in NF opinions**

The working group was informed about recent discussions regarding the use of the term “fibre” in ongoing NF opinions, and the possible misinterpretation of its definition between Regulation (EU) No 1169/2011 (food information to consumers) and the Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre (EFSA NDA Panel, 2010). The WG was given an overview of ongoing dossiers for which a similar issue may arise and agreed to discuss on a case-by-case basis.

## 10. Next meeting

The next meeting will be held on 06-08 April 2022, via web conference.





NIF UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 131<sup>ST</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 08-10 February 2022

(Agreed on 18 February 2022)

### 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<sup>1</sup>, Henk Van Loveren<sup>2</sup>.

#### Hearing Experts<sup>3</sup>:

Viviana Trezza for agenda item 10.

#### 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, Domenico Azzollini, Paolo Colombo, Antonio Fernández Dumont, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijević, Estefanía Noriega Fernández, Gabriela Precup, Fernando Rivero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

#### Others:

ED Team: George Kass for agenda item 10.

<sup>1</sup> Participated only day 1.

<sup>2</sup> Participated only day 1 and part of day 2.

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 130<sup>th</sup> Working Group meeting held on 12-14 January 2022 via web-conference.

The minutes of the 130<sup>th</sup> Working Group meeting were agreed by written procedure on 21 January 2022.

## 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 novel food applications received, including a short introduction to recently validated applications.

## 8. Scientific topic(s) for discussion

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**8.1. Draft opinion on galacto-oligosaccharide (GOS) as a novel food (NF 2020/1606). Applicant: GLNP Life Sciences B.V (EFSA-Q-2020-00747)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 28<sup>th</sup> February for further discussion and possible adoption.

**8.2. Draft statement on the safety of cannabidiol (CBD) as a novel food (EFSA-Q-2021-00735)**

The WG discussed the development of the statement on CBD to outline the data gaps identified in the available scientific literature with regards to the safety of CBD as novel food.

**8.3. Draft opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt (EFSA-Q-2019-00091)**

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.

**8.4. 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, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 28<sup>th</sup> February 2022 for further discussion and possible adoption.

**8.5. Draft opinion on lacto-N-tetraose (LNT) as a novel food (NF 2020/1809). Applicant: Chr. Hansen A/S (EFSA-Q-2020-00630)**

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.

**8.6. Draft opinion on High vitamin D2 mushroom powder as a novel food (NF 2019/1471). Applicant: Monterey Mushrooms Inc (EFSA-Q-2020-00417)**

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 beta-lactoglobulin as a novel food (NF 2020/1707). Applicant: Arla Foods Ingredients (EFSA-Q-2020-00538)**





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 28<sup>th</sup> February 2022 for further discussion and possible adoption.

**8.8. Draft opinion on Fucoidan extract from *Cladosiphon okamuranus* as a novel food (NF 2020/2135). Applicant: H. Holstein GmbH & Co KG (EFSA-Q-2021-00141)**

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 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.

**8.9. Draft opinion on protein powders from the *Alphitobius diaperinus* larva as a novel food (NF 2019/1292). Applicant: Protifarm Holding NV (EFSA-Q-2019-00690)**

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

**8.10. 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, 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 isomalto-oligosaccharide as a novel food (NF 2021/2469). Applicant: BioNeutra North America Inc. (EFSA-Q-2021-00185)**

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. **Update on mixture of perdiethylphosphatoethyloligosilsesquioxanols absorbed on lactose monohydrate as a novel food (NF 2019/0976). Applicant: IONTEC S.A.R.L. (EFSA-Q-2019-00549)**

The working group was informed about the status of the application and the replies received from the applicant following the EFSA request for clarifications.

- 9.2. **Update on Zinc L-carnosine as a novel food (NF 2019/1090). Applicant: Hamari Chemicals (EFSA-Q-2020-00263)**

The working group was informed about the status of the application and the replies received from the applicant following the EFSA request for additional information.

- 9.3. **Update on the NF choline, succinate (2:1) salt solution. Applicant: Mitocholine Ltd. (EFSA-Q-2020-00745)**

The working group discussed about the novelty of this salt, taking into account the data supplied in the application and information submitted by the applicant following EFSA's requests for supplementary information. The statement was drafted in which the WG asked EFSA to invite the EC to reconsider the status of choline, succinate (2:1) salt solution as a NF.

- 9.4. **Update on allulose applications. Applicant: Tate & Lyle (EFSA-Q-2019-00584); Savanna GmbH (EFSA-Q-2020-00141)**

The working group was informed about a clarification teleconference with the applicants to discuss additional data requested by EFSA.

- 9.5. **Update on 'non-novel' parts of the NFs**

The working group was asked to create an inclusion/exclusion list of criteria which will serve to determine when 'non-novel' compounds, used during the production process of the NFs, should be considered as a part of the NF and when not. After amendments, the draft document will be presented at the next WG NF meeting for further discussion.

## 10. Next meeting

The next meeting will be held on 08-10 March 2022, via web conference.





NIF UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 130<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web conference, 12-14 January 2022

(Agreed on 21 January 2022)

### Participants

#### Working Group Members:

Francesco Cubadda<sup>1</sup>, 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 Experts<sup>2</sup>:

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, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Agnès De Sesmaisons Lecarré, Antonio Fernández Dumont, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernández, Gabriela Precup, Fernando Rivero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Did not attend on 14 Jan.

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 129<sup>th</sup> Working Group meeting held on 01-03 December 2021, via web conference.

The **minutes of the 129<sup>th</sup> Working Group meeting** were agreed by written procedure on 13 December 2021.

## 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 novel food applications received, including a short introduction to recently validated applications.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## 8. Scientific topic(s) for discussion

### 8.1. Draft NDA Panel statement on the safety of cannabidiol (CBD) as a novel food (EFSA-Q-2021-00735)

The WG discussed the development of the statement on CBD to outline the data gaps identified in the available scientific literature with regards to the safety of CBD as novel food.

### 8.2. Draft opinion on bovine milk osteopontin as a novel food (NF 2020/1698). *Applicant: Arla Foods Ingredients* (EFSA-Q-2020-00475)

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, proposed uses and use levels, toxicology, and human studies. Provided that the applicant can provide clarification on an issue regarding specification in due time, a draft opinion will be presented at the next NDA plenary meeting on 26-27 January for further discussion and possible adoption.

### 8.3. 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, production process, proposed uses and use levels, anticipated daily intake, toxicology, and human studies. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 26-27 January for further discussion and possible adoption.

### 8.4. Draft opinion on isomalto-oligosaccharide as a novel food (NF 2021/2469). *Applicant: BioNeutra North America Inc.* (EFSA-Q-2021-00185)

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

### 8.5. Draft opinion on arachidonic acid-rich oil from the fungus *Mortierella alpina* as a novel food (NF 2020/2104). *Applicant: BASF SE* (EFSA-Q-2021-00317)

The WG discussed the draft scientific opinion, and in particular assessed data regarding production strain characterization, production process, compositional data, stability, specifications 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 defatted whole cricket (*Acheta domesticus*) powder as a novel food (NF 2019/1227). *Applicant: CRICKET ONE CO., LT* (EFSA-Q-2019-00589)

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





**8.7. Draft opinion on magnesium L-threonate as a novel food (NF 2021/2453). Applicant: AIDP (EFSA-Q-2021-00203)**

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 lacto-N-tetraose (LNT) as a novel food (NF 2019/1456). Applicant: Glycom A/S (EFSA-Q-2021-00090)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 26-27 January for further discussion and possible adoption.

**8.9. Draft opinion on 2'-Fucosyllactose / difucosyllactose mixture as a novel food (NF 2019/1457). Applicant: Glycom A/S (EFSA-Q-2021-00091)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 26-27 January for further discussion and possible adoption.

**8.10. Draft opinion on 3'-Sialyllactose (3'-SL) (NF 2020/1794). Applicant: Chr. Hansen A/S (EFSA-Q-2020-00625)**

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.

**8.11. Draft opinion on iron milk proteinate (IMP) as a novel food (NF 2020/1866). Applicant: Société des Produits Nestlé S.A. (EFSA-Q-2020-00492)**

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 and ADME. 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 yellow/orange tomato extract as a novel food (NF 2021/2369). Applicant: Lycored Ltd (EFSA-Q-2021-00201)**

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.





**8.13. Draft opinion on glucosyl hesperidin as a novel food (NF 2021/2455).  
*Applicant: Hayashibara Co. (EFSA-Q-2021-00329)***

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

**8.14. Draft opinion on krill protein hydrolysate as a novel food (NF 2021/2456).  
*Applicant: Aker BioMarine Antarctic AS (EFSA-Q-2021-00186)***

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.

**8.15. Draft opinion on beet leaf protein (*Beta vulgaris* L.) as a novel food (NF 2021/2370). *Applicant: Royal Cosun (EFSA-Q-2021-00241)***

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, 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.

## 9. Any Other Business

### 9.1. Manganese intake from NF

The WG discussed safety concerns related to the potential increase of manganese (Mn) intake from novel foods.

The WG noted that the Scientific Committee on Food (SCF) could not establish a tolerable upper intake level (UL) for Mn, concluding that '[...] the margin between oral effect levels in humans as well as experimental animals and the estimated intake from food is very low. Given the findings on neurotoxicity and the potential higher susceptibility of some subgroups in the general population, oral exposure to manganese beyond the normally present in food and beverages could represent a risk of adverse health effects without evidence of any health benefit'(SCF/NDA, 2006)<sup>1</sup>.

The WG considered that for the purpose of the assessment of NFs, intakes that lead to a significant increase of Mn intake as compared to the background diet are considered of concern. The WG notes that an assessment of an UL for Mn is ongoing (EFSA-Q-2021-00371). Based on experts' judgment and criteria set by the WHO/FAO's Codex Alimentarius Commission (2015)<sup>2</sup> for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin, the WG concludes that Mn intake above 5% as compared to the highest mean background dietary intake<sup>3</sup> is considered a significant contribution.





<sup>1</sup> SCF/NDA Panel (Scientific Committee on Food, Panel on Dietetic Products, Nutrition and Allergies), 2006. Tolerable upper intake levels for vitamins and minerals. Available online: [https://www.efsa.europa.eu/sites/default/files/efsa\\_rep/blobserver\\_assets/ndatolerableuil.pdf](https://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf)

<sup>2</sup> Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, 2015, Procedural Manual, Twenty-fourth edition, <https://www.fao.org/3/i5079e/i5079e.pdf>.

<sup>3</sup> EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on dietary reference values for manganese. EFSA Journal 2013;11(11):3419, 44 pp. <https://doi.org/10.2903/j.efsa.2013.3419>

## 10. Next meeting

The next meeting will be held on 08-10 February 2022, via web conference.





NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 129<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 01-03 December 2021

(Agreed on 13 December 2021)

### Participants

#### Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst<sup>1</sup>, Helle Katrine Knutsen (chair), Inge Mangelsdorf<sup>2</sup>, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren.

#### Hearing Experts<sup>3</sup>:

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, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Céline Dumas, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernández, Gabriela Precup, Fernando Rivero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Attended partially on day 2

<sup>2</sup> Attended partially on day 1

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 128<sup>th</sup> Working Group meeting held on 09-11 November 2021, via web-conference.

The minutes of the 128<sup>th</sup> Working Group meeting were agreed by written procedure on 18 November 2021.

## 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.

## 8. Scientific topic(s) for discussion

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





- 8.1. **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, proposed uses and use levels, anticipated daily intake, toxicology and allergenicity. After amendments, the draft opinion will be presented at a next WG NF meeting for further discussion.

- 8.2. **Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2019/1213). Applicant: *BIOPUS LIFE SCIENCES* (EFSA-Q-2019-00548)**

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 December for further discussion and possible adoption.

- 8.3. **Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2020/2242). Applicant: *ATK Biotech Co., Ltd* (EFSA-Q-2020-00850)**

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.

- 8.4. **Draft opinion on Choline succinate (2:1) salt solution as a novel food (NF 2020/2053). Applicant: *Mitocholine Ltd.* (EFSA-Q-2020-00745)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process and ADME. 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 Coffee husk (Cascara) as a novel food (NF 2018/0192). Applicant: *Panama Varietals GmbH* (EFSA-Q-2020-00229)**

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 15-16 December for further discussion and possible adoption.

- 8.6. **Draft opinion on synthetic cannabidiol as a novel food (NF 2019/1371). Applicant: *CBDepot* (EFSA-Q-2019-00750)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity and genotoxicity. 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 as a novel food (NF 2019/1256). Applicant: *Paul Mertens Molkerei GmbH & Co. KG* (EFSA-Q-2021-00166)**





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.

**8.8. Draft opinion on Galacto-oligosaccharide (GOS) as a novel food (NF 2020/1606). Applicant: GLNP Life Sciences B.V. (EFSA-Q-2020-00747)**

The WG discussed the draft scientific opinion, and in particular assessed the proposed uses and use levels and the 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. Update on the NDA Panel statement on CBD (EFSA-Q-2021-00735)**

The WG discussed the development of the statement on CBD to outline the data gaps identified in the available scientific literature with regards to the safety of CBD as novel food.

**9.2. Draft opinion on bovine osteopontin as a novel food (NF 2020/1698). Applicant: Arla Foods Ingredients (EFSA-Q-2020-00475)**

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

**9.3. Update on *Lemna minor* (and *Lemna gibba*) whole plant material as a novel food (NF 2020/1757). Applicant: Wageningen Plant Research (EFSA-Q-2020-00512)**

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

**9.4. Update on rhamnogalacturonan-I enriched carrot fibre as a novel food (NF 2019/1172). Applicant: Nutrileads B.V. (EFSA-Q-2020-00186)**

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

**9.5. Update on isomaltulose syrup (dried) (NF 2018/0330). Applicant: Evonik Creavis GmbH (EFSA-Q-2018-00609)**

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

**9.6. Margin of exposure**

The Chair provided feedback on the discussion on the use of the Margin of Exposure (MOE) that took place at the last EFSA Scientific Committee plenary meeting

## 10. Next meeting





The next meeting will be held on 12-14 January 2022, via web conference.





NUTRITION UNIT

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

### MINUTES OF THE 128<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 09-11 November 2021

(Agreed on 18 November 2021)

#### Participants

Working Group Members:

Francesco Cubadda, Thomas Frenzel<sup>1</sup>, Marina Heinonen, Karen-Ildico Hirsch-Ernst<sup>2</sup>, 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<sup>2</sup>.

Hearing Experts<sup>3</sup>:

Not Applicable

European Commission and/or Member States representatives:

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

EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Céline Dumas, Antonio Fernández Dumont, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernandez, Gabriela Precup, Fernando Rivero, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Did not participate on day 2pm

<sup>2</sup> Participated on day 1 and partially on day 2

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 127<sup>th</sup> Working Group meeting held on 05-07 October 2021, via web-conference.

The **minutes** of the 127<sup>th</sup> Working Group meeting were agreed by written procedure on 14 October 2021.

## 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 novel food applications received, including a short introduction to recently validated applications.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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, anticipated daily intake, toxicology and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 24<sup>th</sup> November for further discussion and possible adoption.

**8.2. Draft opinion on *Schizochytrium* sp. oil as a novel food (NF 2019/1213). Applicant: BIOPLUS LIFE SCIENCES (EFSA-Q-2019-00548)**

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.

**8.3. Draft opinion on beta-lactoglobulin as a novel food (NF 2020/1707). Applicant: Arla Foods Ingredients (EFSA-Q-2020-00538)**

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 *Tenebrio molitor* (mealworm) flour as a novel food (NF 2019/1142). Applicant: Nutri'Earth (EFSA-Q-2019-00748)**

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 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 protein-rich flour from fresh larvae of mealworm (*Tenebrio molitor*) as a novel food (NF 2020/1959). Applicant: Ynsect (EFSA-Q-2021-00105)**

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, 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 citicoline as a novel food (NF 2020/2110). Applicant: Kyowa Hakko Europe GmbH (EFSA-Q-2020-00775)**

The WG discussed the available data relevant to the safety assessment, and in particular assessed data regarding product characterization, ADME data, 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.

**8.7. Draft opinion on 2'-Fucosyllactose as a novel food (NF 2019/1350).  
*Applicant: Glycom A/S (EFSA-Q-2021-00088)***

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 the next WG NF meeting for further discussion.

**8.8. Draft opinion on lacto-N-neotetraose as a novel food (NF 2019/1359).  
*Applicant: Glycom A/S (EFSA-Q-2021-00089)***

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 the next WG NF meeting for further discussion.

**8.9. Draft opinion on coffee husk (Cascara) as a novel food (NF 2018/0192).  
*Applicant: Panama Varietals GmbH (EFSA-Q-2020-00229)***

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. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

## 9. Any Other Business

**9.1. Update on bovine milk osteopontin as a novel food (NF 2020/1698).  
*Applicant: Arla Foods Ingredients (EFSA-Q-2020-00475)***

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

**9.2. Update on defatted whole cricket (*Acheta domesticus*) powder as a novel food (NF 2019/1227). *Applicant: CRICKET ONE CO., LTD (EFSA-Q-2019-00589)***

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

**9.3. Update on new Genotox GD on aneugenicity.**

The EFSA Scientific Committee (SC) "Guidance on aneugenicity assessment" was presented to the working group.

**9.4. Update on assessment strategy for CBD dossiers.**

The WG further discussed the strategy on CBD assessment. The WG was informed that the NDA Panel will develop a statement to present and discuss the data gaps identified in the available scientific literature with regards to the safety of CBD as novel food.

## 10. Next meeting

The next meeting will be held on 01-03 December 2021, via web conference





NUTRITION UNIT

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

### MINUTES OF THE 127<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 05-07 October 2021

(Agreed on 14 October 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<sup>1</sup>, Josef Rudolf Schlatter, Henk Van Loveren.

**Hearing Experts<sup>2</sup>:**

Not Applicable

**European Commission and/or Member States representatives:**

EC: Ivona Babic, Takis Daskaleros, Rafael Luis Perez Berbejal

**EFSA:**

Nutrition Unit: Reinhard Ackerl, Fabio Alfieri, Paolo Colombo, Wolfgang Gelbmann, Katerina Gerazova, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernandez, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Attended partially on day 2.

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 126<sup>th</sup> Working Group meeting held on 08-10 September 2021, via web-conference.

The minutes of the 126<sup>th</sup> Working Group meeting were agreed by written procedure on 17 September 2021.

## 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 novel food applications received, including a short introduction to recently validated applications.

## 8. Scientific topic(s) for discussion

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**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, 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 paramylon as a novel food (NF 2019/1261). Applicant: Kemin Foods L.C. (EFSA-Q-2019-00593)**

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.

**8.3. Draft opinion on iron hydroxide adipate tartrate as a novel food (NF 2019/1417). Applicant: Nemysis Ltd (EFSA-Q-2020-00200)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding anticipated daily intake, toxicology and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27-29 October for further discussion and possible adoption.

**8.4. 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. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

**8.5. Draft opinion on *Eurycoma longifolia* (Tongkat Ali) root extract as a novel food (NF 2018/0169). Applicant: Biotropics Malaysia Berhad (EFSA-Q-2018-00106)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterisation and toxicology. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27-29 October for further discussion and possible adoption.

**8.6. Draft opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt (EFSA-Q-2019-00091)**

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, 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.

**8.7. Draft opinion on roasted sacha inchi seeds as traditional food (NF 2021/2344). Applicant: Promperu, Agroindustrias Osho SAC, Amazon Health Products SAC, Comercio Alternativo de Productos No**





***Tradicionales y Desarrollo para Latino América Perú (Candela) and Shanantina SAC (EFSA-Q-2021-00193)***

The WG discussed the draft scientific opinion, and in particular assessed compositional 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.

**8.8. Draft opinion on water lentil protein concentrate from a mixture of *Lemna gibba* and *Lemna minor* as a novel food (NF 2018/0801). Applicant: ABC Kroos B.V (EFSA-Q-2019-00047)**

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

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

The WG discussed the draft scientific opinion, and in particular assessed toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27-28 October for further discussion and possible adoption.

**8.10. Draft opinion on barley rice protein as a novel food (NF 2020/2195). Applicant: Intertek Health Sciences Inc on behalf of Evergrain, LLC (EFSA-Q-2020-00806)**

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, 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.

**8.11. Draft opinion on synthetic CBD as a novel food (NF 2020/2116). Applicant: PureForm Global Inc, PureForm International Limited (EFSA-Q-2021-00243)**

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. 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 *Schizochytrium* sp. oil as a novel food (NF 2021/2445). Applicant: CABIO Biotech (Wuhan) Co., Ltd. (EFSA-Q-2021-00168)**

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





**8.13. Draft opinion on lacto-N-fucopentaose I / 2'-fucosyllactose mixture.**

***Applicant: Glycom A/S (EFSA-Q-2021-00170)***

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels 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 mixture of perdiethylphosphatoethyloligosilsesquioxanols absorbed on lactose monohydrate as a novel food (NF 2019/0976).**

***Applicant: IONTEC S.A.R.L. (EFSA-Q-2019-00549)***

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

**9.2. Update on *Lemna minor* (and *Lemna gibba*) whole plant material as a novel food (NF 2020/1757). *Applicant: Wageningen Plant Research (EFSA-Q-2020-00512)***

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 09-11 November 2021, via web conference.





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 126<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 08-10 September 2021

(Agreed on 17 September 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<sup>1</sup>, Miguel Prieto Maradona, Josef Rudolf Schlatter<sup>2</sup>, Henk Van Loveren.

#### Hearing Experts<sup>3</sup>:

Not Applicable

#### European Commission and/or Member States representatives:

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

#### EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Fabio Alfieri, Domenico Azzollini, Paolo Colombo, Agnès De Sesmaisons Lecarré, Céline Dumas, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernandez, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Fernando Rivero, Hans Steinkellner, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Did not attend 10.09.21

<sup>2</sup> Did not attend 08.09.21

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 125<sup>th</sup> Working Group meeting held on 23 August 2021, via web-conference.

The **minutes** of the 125<sup>th</sup> Working Group meeting were agreed by written procedure on 27 August 2021.

## 5. Feedback from the European Commission

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

## 6. 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.

## 7. Scientific topic(s) for discussion

### 7.1. Draft opinion on tetrahydrocurcuminoids from turmeric (*Curcuma longa* L.) as a novel food (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 and toxicology. After amendments, the draft opinion will be

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





presented at the NDA plenary meeting on 27-28 October for further discussion and possible adoption.

**7.2. Draft opinion on Fermented soy germ powder (SE5-OH®) as a novel food (NF 2020/2189). Applicant: Nutrition & Santé SAS, Otsuka Pharmaceutical Co LTD (EFSA-Q-2021-00092)**

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.

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

The WG discussed the draft scientific opinion, and in particular assessed 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 14-15 September for further discussion and possible adoption.

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

The WG discussed the draft scientific opinion, and in particular assessed 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 27-28 October for further discussion and possible adoption.

**7.5. Draft opinion on iron milk proteinate (IMP) as a novel food (NF 2020/1866). Applicant: Société des Produits Nestlé S.A. (EFSA-Q-2020-00492)**

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

**7.6. Draft opinion on Mung bean protein as a novel food (NF 2020/1651). Applicant: Eat Just, Inc. (EFSA-Q-2020-00284)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding proposed uses and use levels, anticipated daily intake and nutrition. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 14-15 September for further discussion and possible adoption.

**7.7. 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 was informed about the status of the application and discussed the additional data provided by the applicant. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.





**7.8. Draft opinion on *Yarrowia lipolytica* yeast biomass as a novel food (NF 2020/1908) and (NF 2020/1950). Applicant: Skotan S.A. (EFSA-Q-2020-00491, EFSA-Q-2020-00655)**

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

**7.9. Draft opinion on arginine glutamate as a nutrient source. Applicant: Ajinomoto Co., Inc. (EFSA-Q-2021-00064)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, 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. Any Other Business

**8.1. Update on assessment strategy for CBD dossiers.**

The working group further discussed the literature search on cannabidiol and the assessment strategy for the assessment of the novel food dossiers received.

**8.2. Update on *Eurycoma longifolia* (tongkat ali) root extract as a novel food (NF 2018/0169). Applicant: Biotropics Malaysia Berhad (EFSA-Q-2018-00106)**

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

## 9. Next meeting

The next meeting will be held on 05-07 October 2021, via web conference.





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 125<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 23 August 2021

(Agreed on 27 August 2021)

### Participants

#### Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Rosangela Marchelli, Harry J McArdle, Inge Mangelsdorf<sup>1</sup>, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren.

#### Hearing Experts<sup>2</sup>:

Not Applicable

#### European Commission and/or Member States representatives:

Takis Daskaleros

#### EFSA:

Nutrition Unit: Océane Albert, Agnès De Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann, Andrea Germini, Leonard Matijevic, Annamaria Rossi.

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

<sup>1</sup> Partially participated to the meeting.

<sup>2</sup> 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>





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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 124<sup>th</sup> Working Group meeting held on 12-14 July 2021, via web-conference.

The minutes of the 124<sup>th</sup> Working Group meeting were agreed by written procedure on 21 July 2021.

## 5. Scientific topic(s) for discussion

### 5.1. Draft opinion on monosodium salt of 5-methyltetrahydrofolate as a novel food (NF 2020/2160). *Applicant: Merck & Cie* (EFSA-Q-2021-00079)

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.

### 5.2. Draft opinion on nicotinamide riboside chloride as a novel food (NF 2020/1613). *Applicant: ChromaDex, Inc.* (EFSA-Q-2020-00289)

The WG discussed the draft scientific opinion, and in particular assessed data regarding benchmark dose (BMD) modelling. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 14-16 September for further discussion and possible adoption.

## 6. Any Other Business

### 6.1. Update on Helix Complex Snail Mucus (HSM) as a novel food (NF 2019/1077). *Applicant: HELIXPHARMA* (EFSA-Q-2019-00388)

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

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**6.2. Update on *Eurycoma longifolia* (tongkat ali) root extract as a novel food (NF 2018/0169). Applicant: Biotropics Malaysia Berhad (EFSA-Q-2018-00106)**

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

**6.3. Technical meeting on CBD with FDA**

The working group was informed that EFSA was invited by FDA to a technical meeting to discuss the state of play of CBD assessment. Participants discussed data publicly available in the literature and current data gaps identified for the safety assessment of CBD. Both parties agreed to further collaborate in this area of mutual interest.

## **7. Next meeting**

The next meeting will be held on 08-10 September 2021, via web conference.





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 124<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 12-14 July 2021

(Agreed on 21 July 2021)

### Participants

#### Working Group Members:

Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Karen Ildico Hirsch-Ernst<sup>1</sup>, 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<sup>1</sup>.

#### Hearing Experts<sup>2</sup>:

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, Océane Albert, Domenico Azzollini, Paolo Colombo, Céline Dumas, Andrea Germini, Eirini Kouloura, Estefanía Noriega Fernandez, Gabriela Precup, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis, Panagiota Zakidou.

<sup>1</sup> Did not attend 13/07/21 in the morning

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 123<sup>rd</sup>th Working Group meeting held on 10 & 16-18 June 2021, via web-conference.

The [minutes](#) of the 123<sup>rd</sup> Working Group meeting were agreed by written procedure on 24 June 2021

## 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 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.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## 8. Scientific topic(s) for discussion

### 8.1. Draft opinion on water lentil powder from Lemnaceae as a novel food (NF 2018/0430). 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. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

### 8.2. Draft opinion on *Wolffia globosa* powder as a novel food (NF 2019/1223). Applicant: *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. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

### 8.3. 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, 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.

### 8.4. Draft opinion on galacto-oligosaccharide (NF 2019/1154). Applicant: *Dairy Crest Ltd* (EFSA-Q-2020-00466)

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 the next NDA plenary meeting on 14-16 September for further discussion and possible adoption.

### 8.5. Draft opinion on tetrahydrocurcuminoids from turmeric (*Curcuma longa*) as a novel food (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, 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.

### 8.6. Draft opinion on turmeric extract as a novel food (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.

**8.7. Draft opinion on synthetic cannabidiol as a novel food (NF 2020/2174).  
Applicant: FARMABIOS S.p.A. (EFSA-Q-2020-00831)**

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. 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 *Tenebrio molitor* (mealworm) flour as a novel food (NF 2019/1142). Applicant: Nutri'Earth (EFSA-Q-2019-00748)**

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

**8.9. Draft opinion on defatted whole cricket (*Acheta domesticus*) powder as a novel food (NF 2019/1227). Applicant: CRICKET ONE CO., LTD (EFSA-Q-2019-00589)**

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. 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 Schizochytrium sp. oil as a novel food (NF 2020/2242).  
Applicant: TK Biohealth Co., Ltd. (EFSA-Q-2020-00850)**

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.

## 9. Any Other Business

### 9.1. Update on Novel foods WG renewal

The working group was informed that the NDA Panel confirmed, during its last plenary meeting 6-8 July, the need for the existing Novel foods working groups to assist the Panel in undertaking all necessary preparatory tasks in relation to draft scientific outputs falling under its remit. In particular the Panel confirmed the current members of the working group with no change to its composition, including chairmanship (Helle Katrine Knutsen).

### 9.2. Strategy for toxicological assessment of cannabidiol

The working group further discussed the strategy for the toxicological assessment of novel food dossiers related to cannabidiol.





## 10. Next meeting

The next meeting will be held on 23 August 2021, via web conference.



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 123<sup>RD</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 10 & 16-18 June 2021

(Agreed on 24 June 2021)

### Participants

#### Working Group Members:

Francesco Cubadda, Thomas Frenzel<sup>1</sup>, 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<sup>1</sup>, Henk Van Loveren<sup>2</sup>.

#### Hearing Experts<sup>3</sup>:

Not Applicable

#### European Commission and/or Member States representatives:

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

#### EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Paolo Colombo, Agnès De Sesmaisons Lecarré, Céline Dumas, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Eirini Kouloura, Estefanía Noriega Fernández, Emanuela Turla, Ermolaos Ververis.

<sup>1</sup> Did not attend 17/6 am

<sup>2</sup> Did not attend 16/6 pm and 17/6 am

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup> 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 122<sup>nd</sup> Working Group meeting held on 03-05 May 2021, via web-conference.

The minutes of the 122<sup>nd</sup> Working Group meeting were agreed by written procedure on 12 May 2021.

## 5. Feedback from the NDA Panel plenary meeting

The working group was informed that five 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 novel food applications received, including a short introduction to recently validated applications.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## 8. Scientific topic(s) for discussion

**8.1. 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, specifications, anticipated daily intake, toxicology and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 06-08 July for further discussion and possible adoption.

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

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, toxicology, and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 06-08 July 2021 for further discussion and possible adoption.

**8.3. Draft opinion on whole cell heat-killed non-GMM *Mycolicibacterium aurum* DSM33539 (NF 2020/1827). Applicant: Aurum Switzerland AG (EFSA-Q-2020-00566)**

The WG discussed the draft scientific opinion, 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.

**8.4. Draft opinion on nicotinamide riboside chloride as a novel food (NF 2020/1613). Applicant: ChromaDex Inc. (EFSA-Q-2020-00289)**

The WG discussed the draft scientific opinion, and in particular reviewed the discussion and conclusions. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 6-8 July for further discussion and possible adoption.

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

The WG discussed the draft scientific opinion, and in particular assessed data regarding 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 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, anticipated daily intake, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 6-8 July for further discussion and possible adoption.





**8.7. Draft opinion on mung bean protein as a novel food (NF 2020/1651).**

***Applicant: Eat Just, Inc (EFSA-Q-2020-00284)***

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, nutrition 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.

**8.8. Draft opinion on apple fruit cell culture extract as a novel food (NF 2020/1621). *Applicant: Mibelle Group Biochemistry (EFSA-Q-2020-00488)***

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.

**8.9. Draft opinion on roasted sacha inchi seeds. *Applicant: Promperu (EFSA-Q-2021-00193)***

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.

**8.10. Draft opinion on bovine milk osteopontin as a novel food (NF 2020/1698). *Applicant: Arla Foods Ingredients Group P/S. (EFSA-Q-2020-00475)***

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.

**8.11. Draft opinion on black yeast beta-glucan as a novel food (NF 2018/0741). *Applicant: Glucan Corporation (EFSA-Q-2020-00264)***

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.

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

The WG discussed the draft scientific opinion, and in particular assessed data regarding 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. **Update 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.

- 9.2. **Update on *Wolffia globosa* powder as a novel food (NF 2019/1223). Applicant: Hinoman (EFSA-Q-2019-00695)**

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

- 9.3. **Update on PPST- mixture of perdiethylphosphatoethyloligo-silsesquioxanols absorbed on lactose monohydrate as a novel food (NF 2019/0976). Applicant: IONTEC Sarl (EFSA-Q-2019-00549)**

The working group was informed about the status of the application under assessment and the additional information submitted. A request for clarification will be sent to the applicant.

## 10. Next meeting

The next meeting will be held on 12-14 July 2021, via web conference.





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 122<sup>ND</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference on 03-05 May 2021

(Agreed on 12 May 2021)

### Participants

#### Working Group Members:

Francesco Cubadda, Thomas Frenzel<sup>1</sup>, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle<sup>2</sup>, Monika Neuhäuser-Berthold, Carmen Peláez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren<sup>3</sup>.

#### Hearing Experts<sup>4</sup>:

Not Applicable

#### European Commission representatives:

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

#### EFSA:

Nutrition Unit: Reinhard Ackerl, Océane Albert, Domenico Azzollini, Paolo Colombo, Agnès De Sesmaisons Lecarré, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Estefanía Noriega Fernández, Ruth Roldán Torres, Annamaria Rossi, Emanuela Turla, Ermolaos Ververis.

<sup>1</sup> Attended partially day 1 and 2, attended day 3

<sup>2</sup> Did not attend day 1

<sup>3</sup> Attended day 1 and 3, and attended partially day 2

<sup>4</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 121<sup>st</sup> Working Group meeting held on 12-14 April 2021 or via web-conference.

The **minutes** of the 121<sup>st</sup> Working Group meeting were agreed by written procedure on 22 April 2021.

## 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 the expected workplan for the working group and on novel food applications received, including a short introduction to recently validated applications.

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## 8. Scientific topic(s) for discussion

### 8.1. Draft opinion on cetylated fatty acids as a novel food (NF 2020/1828). *Applicant: Pharmanutra S.p.A (EFSA-Q-2020-00422)*

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

### 8.2. 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, toxicology and human studies. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

### 8.3. Draft opinion on Calcdiol as a novel food (NF 2018/0402). *Applicant: DSM Nutritional Products Ltd. (EFSA-Q-2018-00514)*

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

### 8.4. Draft opinion on Nicotinamide Riboside chloride as a novel food (NF 2020/1613). *Applicant: Andrew Shao, ChromaDex, Inc. (EFSA-Q-2020-00289)*

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.

### 8.5. Draft opinion on whole cell heat-killed non-GMM *Mycolicibacterium aurum* Aogashima DSM33539 as a novel food (NF 2020/1827). *Applicant: Aurum Switzerland AG (EFSA-Q-2020-00566)*

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

### 8.6. Draft opinion on *Rhizomucor pusillus* fungus biomass (NF 2020/1795). *Applicant: The Protein Brewery B.V. (EFSA-Q-2020-00476)*

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, productions process, product characterization, specifications, proposed uses and use levels, nutritional information, toxicology, and genotoxicity. 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 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 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 for further discussion and possible adoption.

**8.8. Draft opinion on Calcium Fructoborate as a novel food (NF 2019/0998). 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, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting for further discussion and possible adoption.

**8.9. Draft opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626). Applicant: Microphyt (EFSA-Q-2019-00091)**

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, 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.

**8.10. 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, production process, proposed uses and use levels, toxicology, and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting for further discussion and possible adoption.

## 9. Any Other Business

**9.1. Update on Lacto-N-tetraose (LNT) (NF 2020/1809). Applicant: Chr. Hansen A/S (EFSA-Q-2020-00630)**

The working group was informed about the status of the application. A request for additional information will be sent to the applicant.

**9.2. Update on high vitamin D2 mushroom powder (NF 2019/1471). Applicant: Monterey Mushrooms Inc (EFSA-Q-2020-00417)**

The working group was informed about the status of the application. A request for additional information will be sent to the applicant.





**9.3. Update on allulose. Applicants: Samyang Corp. (EFSA-Q-2018-00797); SAVANNA Ingredients GmbH (EFSA-Q-2020-00141)**

The working group was informed about the status of the applications on allulose under assessment and additional information submitted by the applicants.

**9.4. Update on whole seeds of oilseed rape 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.

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

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 16-18 June 2021, via web conference.





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 121<sup>ST</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 12-14 April 2021 via  
web-conference

(Agreed on 22 April 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<sup>1</sup>, Henk Van Loveren.

#### Hearing Experts<sup>2</sup>:

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, Océane Albert, Domenico Azzollini, Paolo Colombo, Agnès De Sesmaisons Lecarré, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leonard Matijevic, Estefanía Noriega Fernández, Gabriela Precup, Ruth Roldán Torres, Roman Svejstil, Emanuela Turla, Ermolaos Ververis.

<sup>1</sup> Did not attend on day 3.

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 120<sup>th</sup> Working Group meeting held on 03-05 March 2021 or via web-conference.

The [minutes](#) of the 120<sup>th</sup> Working Group meeting were agreed by written procedure on 15 March 2021.

## 5. Feedback from the European Commission

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

## 6. 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.

## 7. Scientific topic(s) for discussion

### 7.1. Draft opinion on cetylated fatty acids as a novel food (NF 2020/1828). *Applicant: Pharmanutra S.p.A. (EFSA-Q-2020-00422)*

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

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





**7.2. Draft opinion on dried fruits of *Synsepalum dulcificum* as a novel food (NF 2018/0709). Applicant: Baia 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, toxicology, human studies and allergenicity. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27-29 April 2021 for further discussion and possible adoption.

**7.3. Draft opinion on Rhamnogalacturonan-I enriched carrot fibre as a novel food (NF 2019/1172). Applicant: Nutrileads B.V. (EFSA-Q-2020-00186)**

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 the 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.

**7.4. Draft opinion on Galacto-oligosaccharide (NF 2019/1154). Applicant: Dairy Crest Ltd (EFSA-Q-2020-00466)**

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 the next WG NF meeting for further discussion.

**7.5. Draft opinion on Nicotinamide Riboside chloride as a novel food (NF 2020/1613). Applicant: ChromaDex, Inc. (EFSA-Q-2020-00289)**

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

**7.6. Draft opinion on *Schizochytrium sp.* oil as a novel food (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, composition, 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.

**7.7. 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 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 UV-treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food (NF 2020/1778). Applicant: Lallemand Bio-Ingredients Division (EFSA-Q-2020-00393)**





The WG discussed the draft scientific opinion, and in particular assessed anticipated daily intake. After amendments, the draft opinion will be presented at the next NDA plenary meeting on 27-29 April 2021 for further discussion and possible adoption.

**7.9. Draft opinion on *Rhizomucor pusillus* fungus biomass (NF 2020/1795). Applicant: The Protein Brewery B.V. (EFSA-Q-2020-00476)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding identity, productions process, product characterization, specifications, proposed uses and use levels, nutritional information, toxicology, and genotoxicity. 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 3'-Sialyllactose (3'-SL) (NF 2020/1794). Applicant: Chr. Hansen A/S (EFSA-Q-2020-00625)**

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.

**7.11. Draft opinion on 6'-Sialyllactose (6'-SL) as a novel food (NF 2020/1801). Applicant: Chr. Hansen A/S (EFSA-Q-2020-00623)**

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.

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

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

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

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

**7.14. Draft opinion on an Aqueous ethanolic extract of *Labisia pumila* as a novel food (NF 2019/1337). Applicant: Medika Natura SDN.BHD. (EFSA-Q-2019-00694)**





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

### 8.1. Update on Calcidol as a novel food (NF 2018/0402). *Applicant: DSM Nutritional Products Ltd. (EFSA-Q-2018-00514)*

The working group was informed about the status of the application, which is awaiting additional information from the applicant. After clarification receipt and amendments, the draft opinion will be finalised and presented at the NDA plenary meeting for further discussion and possible adoption.

## 9. Next meeting

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





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 120<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 03-05 March 2021

(Agreed on 15 March 2021)

### Participants

#### Working Group Members:

Francesco Cubadda<sup>1</sup>, 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<sup>2</sup>, Henk Van Loveren<sup>1</sup>.

#### Hearing Experts<sup>3</sup>:

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, Paolo Colombo, Agnès De Sesmaisons Lecarré, Céline Dumas, Antonio Fernández Dumont, Wolfgang Gelbmann, Andrea Germini, Eirini Kouloura, Leonard Matijevic, Estefanía Noriega Fernández, Ruth Roldán Torres, Annamaria Rossi, Roman Svejstil, Emanuela Turla.

<sup>1</sup> Participated on day 2 and 3

<sup>2</sup> Participated on day 1 and 2

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>5</sup> 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 one 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.

## 4. Agreement of the minutes of the 119<sup>th</sup> Working Group meeting held on 03-05 February 2021, via web-conference.

The minutes of the 119<sup>th</sup> Working Group meeting were agreed by written procedure on 12 February 2021.

## 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.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## 8. Scientific topics for discussion

**8.1. Draft opinion on UV treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food (NF 2020/1778). Applicant: *Lallemand Bio-Ingredients Devision* (EFSA-Q-2020-00393)**

The WG discussed the draft scientific opinion, and in particular assessed, 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.

**8.2. Draft opinion on Iron milk proteinate (IMP) as a novel food (NF 2020/1866). Applicant: *Société des Produits Nestlé S.A.* (EFSA-Q-2020-00492)**

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.

**8.3. Draft opinion on Beta-lactoglobulin as a novel food (NF 2020/1707). Applicant: *Arla Foods Ingredients* (EFSA-Q-2020-00538)**

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 *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 toxicology 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 Turmeric extract rich in curcuminoids as a novel food (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, ADME, 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 Bacterial cellulose aqueous suspension as a novel food (NF 2018/0307). Applicant: Satisfibre S.A. (EFSA-Q-2018-00294)**

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

**8.7. Draft opinions on *Yarrowia lipolytica* as a novel food (NF 2020/1908, NF 2020/1950). Applicant: Skotan S.A. (EFSA-Q-2020-00491, EFSA-Q-2020-00655)**

The WG discussed both requests for extensions of use, in particular the 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 these mandates. Therefore, a request for additional information will be sent to the applicant.

**8.8. Draft opinion on citicoline (extension of use) as a novel food (NF 2020/2110). Applicant: Kyowa Hakko Bio Co., Ltd. (EFSA-Q-2020-00775)**

The WG discussed the draft scientific opinion, and in particular assessed 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 Calcium Fructoborate as a novel food (NF 2019/0998). Applicant: VDF FutureCeuticals, Inc. (EFSA-Q-2019-00240)**

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

**9.2. Update 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.

**9.3. Discussion on novel food dossiers on synthetic cannabidiol  
NF 2019/0935, Applicant: Cibdol AG and Labocan BV (EFSA-Q-2020-00084)**

**NF 2019/1371, Applicant: CBDepot, s.r.o. (EFSA-Q-2019-00750)**

**NF 2020/1670, Applicant: Channelel McCoy CBD LTD (EFSA-Q-2020-00257)**

The working group discussed the genotoxicity studies submitted in the context of the novel food dossiers for synthetic cannabidiol.

**9.4. WG feedback on outsourcing scheme**





The working group discussed the current outsourcing scheme for the summary reports of toxicological studies.

## 10. Next meeting

The next meeting will be held on 12-14 April 2021, 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: in 2016 he contributed to the safety assessment performed by the Danish competent authority for UV treated baker's yeast (*Saccharomyces cerevisiae*) as novel food (agenda item 8.1). In accordance with EFSA's Policy on Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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.

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<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 119<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held as web-conference, 03-05 February 2021

(Agreed on dd February 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<sup>1</sup>, Miguel Prieto Maradona, Josef Rudolf Schlatter<sup>2</sup>, Henk Van Loveren.

#### Hearing Experts<sup>3</sup>:

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, Océane Albert, Fabio Alfieri, Paolo Colombo, Agnès De Sesmaisons Lecarré, Céline Dumas, Wolfgang Gelbmann, Andrea Germini, Leng Heng, Eirini Kouloura, Estefanía Noriega Fernández, Ruth Roldán Torres, Roman Svejstil, Emanuela Turla, Ermolaos Ververis.

<sup>1</sup> Participated partially 05/02/21

<sup>2</sup> Participated 03/02/21 from 16:00 and on 05/02/21

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 118<sup>th</sup> Working Group meeting held on 07-08 January 2021 or via web-conference.

The **minutes** of the 118<sup>th</sup> Working Group meeting were agreed by written procedure on 15 January 2021.

## 5. Feedback from the NDA Panel plenary meeting

The working group was informed that no 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 novel food applications received, including a short introduction to recently validated applications.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## 8. Scientific topic(s) for discussion

### 8.1. Draft opinion on Nicotinamide Riboside chloride as a novel food (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.

### 8.2. 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, 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 Zinc L-carnosine as a novel food (NF 2019/1090). Applicant: Hamari Chemicals, JP (EFSA-Q-2020-00263)

The WG discussed the replies submitted to the first request for information regarding product characterization, composition, specifications, production process, proposed use and use levels, ADME 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 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 newly submitted information and data regarding product characterization, specifications, 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 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 the data provided by the applicant in the areas of product characterisation and toxicology.

### 8.6. Draft opinion on coffee husk (cascara) as a novel food (NF 2018/0192). Applicant: Panama Varietals GmbH (EFSA-Q-2020-00229)

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, 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 Calceidiol as a novel food (NF 2018/0402). Applicant: DSM Nutritional Products Ltd. (EFSA-Q-2018-00514)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, composition, specifications, 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 *Lemna minor* (and *Lemna gibba*) whole plant material as a novel food (NF 2020/1757). Applicant: Wageningen Plant Research (EFSA-Q-2020-00512)**

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.

**8.9. Draft opinion on 2'-Fucosyllactose (2'-FL) as a novel food (NF 2020/1825). Applicant: Advanced Protein Technologies Corp (EFSA-Q-2020-00500)**

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.

**8.10. 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 and production process. After amendments, the draft opinion will be presented at the next WG NF meeting for further discussion.

**8.11. Draft opinion on cetylated fatty acids as a novel food (NF 2020/1828). Applicant: Pharmanutra S.p.A. (EFSA-Q-2020-00422)**

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

**8.12. Draft opinion on melatonin as a novel food (NF 2020/1705). Applicant: Pen & Tec Consulting SLU (EFSA-Q-2020-00379)**

The WG discussed the draft scientific opinion, and in particular assessed data regarding product characterization, production process, proposed uses and use levels, toxicology (including absorption, distribution, metabolism and excretion), 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. Next meeting

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





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 118<sup>TH</sup> 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 Experts<sup>1</sup>:

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

<sup>1</sup> 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 117<sup>th</sup> Working Group meeting held on 02-04 December 2020, via web-conference.

The minutes of the 117<sup>th</sup> 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.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 117<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held by web-conference, 02-04 December 2020

(Agreed on 10 December 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, Miguel Prieto Maradona, Josef Rudolf Schlatter, Henk Van Loveren<sup>1</sup>.

#### **n** Hearing Experts<sup>2</sup>:

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: 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.

<sup>1</sup> Only on 2<sup>nd</sup> day

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 116<sup>th</sup> Working Group meeting held on 10-12 November 2020, via web-conference.

The minutes of the 116<sup>th</sup> 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

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 116<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held via web-conference, 10-12 November 2020

(Agreed on 19 November 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<sup>1</sup>, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter<sup>2</sup>, Henk Van Loveren.

#### n Hearing Experts<sup>3</sup>:

Frank Thies<sup>4</sup>

#### n European Commission and/or Member States representatives:

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

#### n 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.

<sup>1</sup> Did not participate on day 2 pm

<sup>2</sup> Participated only on day 1

<sup>3</sup> 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>

<sup>4</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>6</sup> 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 115<sup>th</sup> Working Group meeting held on 07-08 October 2020 via web-conference.

The **minutes** of the 115<sup>th</sup> 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.

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

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<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>8</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





NUTRITION UNIT

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

### MINUTES OF THE 115<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held via web-conference on 07-08 October 2020

(Agreed on 15 October 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<sup>1</sup>, Miguel Prieto Maradona<sup>2</sup>, Josef Rudolf Schlatter, Henk Van Loveren.

**n** Hearing Experts<sup>3</sup>:

Stefaan de Henauw and Frank Thies<sup>4</sup>

**n** European Commission and/or Member States representatives:

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

**n** 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.

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<sup>1</sup> Participated on day 2

<sup>2</sup> Participated on day 1 pm and day 2

<sup>3</sup> 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>

<sup>4</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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 114<sup>th</sup> Working Group meeting held on 08-10 September 2020, via web-conference.

The minutes of the 114<sup>th</sup> 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 114<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held via web-conference, 08-10 September 2020

(Agreed on 17 September 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<sup>1</sup>, Miguel Prieto Maradona, Josef Rudolf Schlatter<sup>2</sup>, Henk Van Loveren.<sup>3</sup>

**n** NDA Panel members:

Frank Thies<sup>4</sup> and Stefaan de Henauw<sup>4</sup>

**n** European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore

**n** 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.

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<sup>1</sup> On days 1 and 2

<sup>2</sup> On days 2 and 3

<sup>3</sup> On days 2 (pm) and 3

<sup>4</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup> 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 113<sup>th</sup> 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

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 113<sup>TH</sup> 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 Experts<sup>1</sup>:**

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.

<sup>1</sup> 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 114<sup>TH</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held via web-conference, 08-10 September 2020

(Agreed on 17 September 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<sup>1</sup>, Miguel Prieto Maradona, Josef Rudolf Schlatter<sup>2</sup>, Henk Van Loveren.<sup>3</sup>

**n** NDA Panel members:

Frank Thies<sup>4</sup> and Stefaan de Henauw<sup>4</sup>

**n** European Commission and/or Member States representatives:

EC: Ivona Babic, Stella D'Amore

**n** 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.

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<sup>1</sup> On days 1 and 2

<sup>2</sup> On days 2 and 3

<sup>3</sup> On days 2 (pm) and 3

<sup>4</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup> 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 113<sup>th</sup> 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

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 consultation<sup>4</sup> 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.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)

<sup>4</sup> <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 112<sup>TH</sup> 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 Cubadda<sup>1</sup>, 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 Experts<sup>2</sup>:

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.

<sup>1</sup> Participated on day 1 and day 2 pm

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 111<sup>th</sup> Working Group meeting held on 18-19 June 2020, via web-conference.

The minutes of the 111<sup>th</sup> 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

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 111<sup>TH</sup> 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 Loveren<sup>1</sup>.

**n** Hearing Experts<sup>2</sup>:

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.

<sup>1</sup> Participated only first day in the morning

<sup>2</sup> 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 110<sup>th</sup> Working Group meeting held on 27-28 May 2020, via web-conference.

The minutes of the 110<sup>th</sup> 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 30<sup>th</sup> 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 30<sup>th</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





## NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 110<sup>TH</sup> 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 Cubadda<sup>1</sup>, 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 Experts<sup>2</sup>:

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.

<sup>1</sup> Did not participate on 27 May am

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>4</sup> 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 109<sup>th</sup> Working Group meeting held on 22 April 2020 via web-conference

The **minutes** of the 109<sup>th</sup> 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.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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.

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





NUTRITION UNIT

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

### MINUTES OF THE 109<sup>TH</sup> 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 Experts<sup>1</sup>:

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.

<sup>1</sup> 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 108<sup>th</sup> Working Group meeting held on 02-03 April 2020, via web-conference.

The minutes of the 108<sup>th</sup> 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.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 108<sup>TH</sup> 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 Loveren<sup>1</sup>.

#### Hearing Experts<sup>2</sup>:

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.

<sup>1</sup> Participated on day 2 and 3

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 107<sup>th</sup> 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.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 107<sup>th</sup> MEETING OF THE WORKING GROUP ON NOVEL FOODS

Held on 3-5 March 2020, via web conference<sup>1</sup>

(Agreed on 10 March 2020)

### Participants

#### Working Group Members:

Francesco Cubadda, Thomas Frenzel<sup>2</sup>, Marina Heinonen<sup>3</sup>, 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 Experts<sup>4</sup>:

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.

<sup>1</sup> 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.

<sup>2</sup> Participated on day 1 pm and on day 2 and 3

<sup>3</sup> Participated on day 1 and 2

<sup>4</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>6</sup> 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 106<sup>th</sup> 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

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

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- [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)  
- [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





NUTRITION UNIT

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

### MINUTES OF THE 106<sup>th</sup> 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 Experts<sup>1</sup>:

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.

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<sup>1</sup> 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 105<sup>th</sup> Working Group meeting held on 08-09 January 2020

The **minutes of the 105<sup>th</sup> 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 105<sup>th</sup> 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 Heinonen<sup>1</sup>, 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 Experts<sup>2</sup>:

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.

<sup>1</sup> Participated on day 2 via web conference

<sup>2</sup> 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 104<sup>th</sup> Working Group meeting held on 10-11 December 2019

The **minutes of the 104<sup>th</sup> 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  $\beta$ -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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 104<sup>th</sup> 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 Cubadda<sup>1</sup>, Thomas Frenzel, Marina Heinonen<sup>2</sup>, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle<sup>3</sup>, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren<sup>3</sup>.

#### Hearing Experts<sup>4</sup>:

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.

<sup>1</sup> Participated on day 1 and day 2 until 13:00

<sup>2</sup> Participated on day 1

<sup>3</sup> Participated on day 2

<sup>4</sup> 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 103<sup>rd</sup> Working Group meeting held on 06-08 November 2019

The **minutes of the 103<sup>rd</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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.

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- [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)  
- [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)





NUTRITION UNIT

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

### MINUTES OF THE 103<sup>rd</sup> 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 Heinonen<sup>1</sup>, Karen-Ildico Hirsch-Ernst, Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle (chair), Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen<sup>1</sup>, Josef Rudolf Schlatter, Henk Van Loveren.

**n** Hearing Experts<sup>2</sup>:

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.

<sup>1</sup> Participated on day 2 and 3

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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 102<sup>nd</sup> Working Group meeting held on 15-16 and 24 October 2019.

The **minutes of the 102<sup>nd</sup> 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.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)  
[http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 102<sup>ND</sup> 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 Engel<sup>1</sup>, Thomas Frenzel<sup>2</sup>, Marina Heinonen, Karen-Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle<sup>1</sup>, Monika Neuhäuser-Berthold<sup>3</sup>, Carmen Pelaez, Morten Poulsen, Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren<sup>4</sup>.

##### Hearing Experts<sup>5</sup>:

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.

<sup>1</sup> Participated the third day

<sup>2</sup> Participated the second and third day

<sup>3</sup> Participated the first and third day

<sup>4</sup> Participated the first and second day

<sup>5</sup> 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 Independence<sup>6</sup> and the Decision of the Executive Director on Competing Interest Management<sup>7</sup>, 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 101<sup>st</sup> Working Group meeting held on 03-05 September 2019.

The minutes of the 101<sup>st</sup> 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

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 Calcidol (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 Pötting**

**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.





NUTRITION UNIT

# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 101<sup>ST</sup> 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 Frenzel<sup>1</sup>, Marina Heinonen<sup>2</sup>, Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Rosangela Marchelli, Harry J McArdle<sup>3</sup>, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen<sup>4</sup>, Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren<sup>5</sup>.

#### Hearing Experts<sup>6</sup>:

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.

<sup>1</sup> Participated via web conference

<sup>2</sup> Participated physically on the first and second day and via web conference on the third day

<sup>3</sup> Participated via web conference only the second and third day

<sup>4</sup> Participated only the second and third day

<sup>5</sup> Participated via web conference for agenda item 7.1

<sup>6</sup> 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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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 100<sup>th</sup> 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.

<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>8</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 100<sup>TH</sup> 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 Cubadda<sup>1</sup>, Karl-Heinz Engel, Thomas Frenzel, Marina Heinonen<sup>2</sup>, Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen<sup>2</sup>, Yolanda Sanz, Josef Rudolf Schlatter, Henk Van Loveren.

#### Hearing Experts<sup>3</sup>:

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.

<sup>1</sup> Participated via web conference

<sup>2</sup> Participated via web conference only the first day

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 99<sup>TH</sup> 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 Cubadda<sup>1</sup>, Karl-Heinz Engel<sup>2</sup>, Thomas Frenzel, Marina<sup>3</sup> Heinonen, Karen Ildico Hirsch-Ernst, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen<sup>4</sup>, Annette Pöting<sup>5</sup>, Josef Rudolf Schlatter<sup>6</sup>, Henk Van Loveren<sup>7</sup>

#### 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

<sup>1</sup> Second day only am, last day only pm

<sup>2</sup> First day only am

<sup>3</sup> Apologies the last day

<sup>4</sup> First day only am; last day only am

<sup>5</sup> Participated partially only the second day

<sup>6</sup> Not present on the last day

<sup>7</sup> 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 Independence<sup>8</sup> and the Decision of the Executive Director on Competing Interest Management<sup>9</sup>, 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.

<sup>8</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>9</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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  $\beta$ -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 98<sup>TH</sup> 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 Frenzel<sup>1</sup>, Marina Heinonen, Helle Katrine Knutsen (chair), Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle<sup>2</sup>, Monika Neuhäuser-Berthold<sup>3</sup>, Carmen Pelaez, Morten Poulsen, Annette Pöting<sup>4</sup>, Yolanda Sanz<sup>2</sup>, Josef Rudolf Schlatter, Henk Van Loveren<sup>5</sup>

#### Hearing Experts<sup>6</sup>:

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

<sup>1</sup> Participated on day 1 and 2

<sup>2</sup> Participated via web conference on day 1 and 2

<sup>3</sup> Participated via web conference on day 1 and physically on day 2 and 3

<sup>4</sup> Participated on day 2 and 3

<sup>5</sup> Participated via web conference on day 1 and physically on day 2

<sup>6</sup> 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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

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<sup>7</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>8</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 97<sup>TH</sup> 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 Experts<sup>1</sup>:**

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.

<sup>1</sup> 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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.

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 96<sup>TH</sup> 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 Engel<sup>1</sup>, 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 Schlatter<sup>2</sup>, Henk Van Loveren

**n Hearing Experts<sup>3</sup>:**

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

<sup>1</sup> Partially attended on 10<sup>th</sup> April

<sup>2</sup> Attended on 10<sup>th</sup> April

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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)

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 30<sup>th</sup> April via web-conference.



# SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

## MINUTES OF THE 95<sup>TH</sup> 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 Marchelli<sup>1</sup>, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen, Josef Rudolf Schlatter, Henk Van Loveren<sup>2</sup>

Annette Pöting, Helle Katrine Knutsen<sup>2</sup>, and Harry McArdle<sup>1</sup> 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

<sup>1</sup> Attended on 6<sup>th</sup> March

<sup>2</sup> Attended on 5<sup>th</sup> March pm and 6<sup>th</sup> March





## 1. Welcome and apologies for absence

EFSA<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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 94<sup>th</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 94<sup>TH</sup> 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 Experts<sup>1</sup>:**

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.

<sup>1</sup> 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 93<sup>rd</sup> 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)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



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## Scientific Panel on Nutrition, Novel Foods and Food Allergens

### Minutes of the 93<sup>rd</sup> 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 Cubadda<sup>1</sup>, Karl-Heinz Engel, Thomas Frenzel, Marina Heinonen, Helle Katrine Knutsen (Chair), Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Carmen Pelaez<sup>1</sup>, Morten Poulsen<sup>2</sup>, Annette Pöting, Yolanda Sanz<sup>1</sup>, Josef Rudolf Schlatter, Henk Van Loveren

##### Hearing expert<sup>3</sup>

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.

<sup>1</sup> Participated on 09/01/2019

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

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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**

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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.

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## Scientific Panel on Nutrition, Novel Foods and Food Allergens

### Minutes of the 92<sup>nd</sup> 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 Pöting<sup>1</sup>, Josef Rudolf Schlatter, Henk Van Loveren<sup>2</sup>

##### Hearing expert<sup>3</sup>

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.

<sup>1</sup> Participated via web conference

<sup>2</sup> Attended the meeting on 06/12

<sup>3</sup> 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 Independence<sup>4</sup> and the Decision of the Executive Director on Competing Interest Management<sup>5</sup>, 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.

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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.

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## Scientific Panel on Nutrition, Novel Foods and Food Allergens

### Minutes of the 91<sup>st</sup> 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 Cubadda<sup>1</sup>, Karl-Heinz Engel<sup>2</sup>, Thomas Frenzel<sup>3</sup>, Marina Heinonen, Helle Katrine Knutsen (Chair), Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Carmen Pelaez, Morten Poulsen<sup>1</sup>, Annette Pöting, Yolanda Sanz<sup>1</sup>, Josef Rudolf Schlatter, Henk Van Loveren

##### Hearing expert<sup>4</sup>:

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.~~

<sup>1</sup> Participated via web conference

Attended the meeting on 7/11 (am) and 8/11 (pm)

<sup>2</sup> Attended the meeting on 6/11 and 7/11

<sup>3</sup> 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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~~

<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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.

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**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.

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## 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 Independence<sup>7</sup> and the Decision of the Executive Director on Competing Interest Management<sup>8</sup>, 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.

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[http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>8</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



# Scientific Panel on Nutrition, Novel Foods and Food Allergens

## Minutes of the 90<sup>th</sup> 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 Pötting<sup>1</sup>, Morten Poulsen, Josef Rudolf Schlatter and Hendrik van Loveren (Chair)

#### Hearing expert<sup>2</sup>:

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

<sup>1</sup> joined via web conference

<sup>2</sup> 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](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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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.

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## **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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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.

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<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)  
<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## Scientific Panel on Nutrition, Novel Foods and Food Allergens

### Minutes of the 89<sup>th</sup> 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 Poulsen<sup>1</sup>, Josef Rudolf Schlatter and Hendrik van Loveren (Chair)

##### Hearing expert<sup>2</sup>:

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.

<sup>1</sup> Via web-conference

<sup>2</sup> 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 Independence<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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.

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## 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 Independence<sup>5</sup> and the Decision of the Executive Director on Competing Interest Management<sup>6</sup>, 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.

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<sup>5</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)  
<sup>6</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## Scientific Panel on Nutrition, Novel Foods and Food Allergens

### Minutes of the 88<sup>th</sup> 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 Heinonen<sup>1</sup> 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the

<sup>1</sup> On 18<sup>th</sup> July 2018, via web-conference

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup>

[http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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.

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## Scientific Panel on Nutrition, Novel Foods and Food Allergens

### Minutes of the 87<sup>th</sup> 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 Pöting<sup>1</sup>, Morten Poulsen, Hendrik van Loveren (Chair)

##### Hearing expert<sup>2</sup>:

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

<sup>1</sup> Via web-conference

<sup>2</sup> 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<sup>3</sup> and the Decision of the Executive Director on Competing Interest Management<sup>4</sup>, 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

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>4</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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.

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## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 86<sup>th</sup> 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 Heinonen<sup>1</sup>, Inge Mangelsdorf, Rosangela Marchelli, Harry J McArdle, Monika Neuhäuser-Berthold, Annette Pötting, Morten Poulsen, Hendrik van Loveren (Chair)

##### Hearing expert<sup>2</sup>:

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.

<sup>1</sup> Attended via web-conference on 11 June 2018

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 Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, 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.

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

<sup>4</sup> <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.

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## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 85<sup>th</sup> 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 expert<sup>1</sup>:

Not applicable

##### European Commission representative:

Ivona Babic<sup>2</sup>

##### 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.

<sup>1</sup> 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>.

<sup>2</sup> ~~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 Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, 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

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

<sup>4</sup> <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.

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## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 84<sup>th</sup> 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 McArdle<sup>1</sup>, Monika Neuhäuser-Berthold, Rosangela Marchelli, Annette Pötting<sup>1</sup>, Morten Poulsen<sup>2</sup>, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

##### Hearing expert<sup>3</sup>:

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.

<sup>1</sup> Participated via web-conference on 22 and 23 March

<sup>2</sup> Participated via web-conference on 22 March

<sup>3</sup> 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 Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, 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.

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## 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

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<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>5</sup> <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.

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## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 83<sup>rd</sup> 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 Mangelsdorf<sup>1</sup>, Harry J McArdle, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

##### Hearing expert<sup>2</sup>:

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.

<sup>1</sup> Participated via web-conference

<sup>2</sup> 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 Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, 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)**

<sup>3</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>4</sup> <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.**

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## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 82<sup>nd</sup> 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 expert<sup>1</sup>:

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.

<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

<sup>3</sup> <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](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.

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## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 81<sup>st</sup> 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 Heinonen<sup>1</sup>, Inge Mangelsdorf, Monika Neuhäuser-Berthold, Rosangela Marchelli, Morten Poulsen, Annette Pöting<sup>2</sup>, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

##### Hearing expert<sup>3</sup>:

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.

<sup>1</sup> Participated on 22-23 November

<sup>2</sup> Participated via web-conference

<sup>3</sup> 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 Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, 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

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



countries. Minutes of the NF Network will be available on the EFSA web-site.

### **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 80<sup>th</sup> 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 expert<sup>1</sup>:

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.

<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

<sup>3</sup> <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.

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## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 79<sup>th</sup> 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 expert<sup>1</sup>:

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.

<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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.

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

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



## Scientific Panel on Dietetic Products, Nutrition and Allergies

### Minutes of the 78<sup>th</sup> 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 Sanz<sup>1</sup>, Josef Rudolf Schlatter, Hendrik van Loveren (Chair)

##### Hearing expert<sup>2</sup>:

Not applicable

##### European Commission representative:

Takis Daskaleros (DG Sante)

##### EFSA:

Nutrition Unit: Reinhard Ackerl, Wolfgang Gelbmann, Andrea Germini, Emanuela Turla

GMO Unit: Antonio Fernandez Dumont<sup>3</sup>

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Karl-Heinz Engel, Harry J McArdle and Tara Dean.

<sup>1</sup> Attended on 5 September.

<sup>2</sup> 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>.

<sup>3</sup> 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 Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, 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.

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>5</sup> <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).

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## Scientific Panel on Dietetic products, Nutrition and Allergies

### Minutes of the 77<sup>th</sup> 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 Engel<sup>1</sup>, Harry J McArdle<sup>2</sup>, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Hendrik van Loveren (chair)

##### Hearing expert<sup>3</sup>:

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.

<sup>1</sup> Participation on 15 (pm) and 16 June

<sup>2</sup> ~~Participation via tele-conference on 15 June~~

<sup>3</sup> 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 Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, 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)

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>5</sup> <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.

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## Scientific Panel on Dietetic products, Nutrition and Allergies

### Minutes of the 76<sup>th</sup> 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 Pöting<sup>1</sup>, Morten Poulsen, Yolanda Sanz, Josef Rudolf Schlatter, Hendrik van Loveren (chair)

##### Hearing expert<sup>2</sup>:

Not applicable

##### European Commission representative:

Rafael Perez-Berbejal (DG Sante)

##### EFSA:

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui<sup>3</sup>, Wolfgang Gelbmann, Andrea Germini<sup>4</sup>, Emanuela Turla

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tara Dean.

<sup>1</sup> Participated via tele-conference

<sup>2</sup> 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>.

<sup>3</sup> Attended on 18 May

<sup>4</sup> 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 Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, 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

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

<sup>6</sup> <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.

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## Scientific Panel on Dietetic products, Nutrition and Allergies

### Minutes of the 75<sup>th</sup> 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 Mangelsdorf<sup>1</sup>, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter<sup>2</sup>, Hendrik van Loveren (chair)

##### Hearing expert<sup>3</sup>:

Not applicable

##### European Commission representative:

Rafael Perez-Berbejal (DG Sante)

##### EFSA:

Nutrition Unit: Reinhard Ackerl, Agnès De Sesmaisons-Lecarré<sup>4</sup>, 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.

<sup>1</sup> Participated via teleconference

<sup>2</sup> Attended on 7 March (all day) and 8 March (afternoon)

<sup>3</sup> 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>.

<sup>4</sup> 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 Processes<sup>5</sup> and the Decision of the Executive Director on Declarations of Interest<sup>6</sup>, 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-100<sup>TM</sup>. 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.

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

<sup>6</sup> <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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, 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

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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.

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## Scientific Panel on Dietetic products, Nutrition and Allergies

### Minutes of the 73<sup>rd</sup> 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 Engel<sup>1</sup>, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Henk van Loveren (chair)

##### Hearing expert<sup>2</sup>:

Not applicable

##### European Commission representative:

Ivona Babic (DG Sante)

##### EFSA:

Nutrition Unit: Reinhard Ackerl, Valeriu Curtui, Agnès de Sesmaisons-Lecarré<sup>1</sup>, 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.

<sup>1</sup> ~~Attended on 16 January~~

<sup>2</sup> 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 Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, 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

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

<sup>4</sup> <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.

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## Scientific Panel on Dietetic products, Nutrition and Allergies

### Minutes of the 72<sup>nd</sup> 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 Engel<sup>1</sup>, Marina Heinonen, Harry McArdle, Inge Mangelsdorf, Rosangela Marchelli, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

##### Hearing expert<sup>2</sup>:

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.

<sup>1</sup> ~~Attended on 29 November~~

<sup>2</sup> 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 Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, 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.

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

<sup>4</sup> <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.

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## Scientific Panel on Dietetic products, Nutrition and Allergies

### Minutes of the 71<sup>st</sup> 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 expert<sup>1</sup>:**

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-

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<sup>1</sup> 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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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<sup>®</sup>. 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.

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

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



## Scientific Panel on Dietetic products, Nutrition and Allergies

### Minutes of the 70<sup>th</sup> 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 Pötting<sup>1</sup>, Morten Poulsen, Yolanda Sanz<sup>2</sup>, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert<sup>3</sup>:**

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

<sup>1</sup> Participated via teleconference on 11–12 October

<sup>2</sup> Participated via teleconference on 11 October

<sup>3</sup> 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 Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, 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.

<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>5</sup> <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.

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## Scientific Panel on Dietetic products, Nutrition and Allergies

### Minutes of the 69<sup>th</sup> 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 Heinonen<sup>1</sup>, Harry McArdle, Inge Mangelsdorf, Rosangela Marchelli<sup>2</sup>, Monika Neuhäuser-Berthold<sup>3</sup>, Annette Pöting<sup>4</sup>, Morten Poulsen, Yolanda Sanz<sup>1</sup>, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert<sup>5</sup>:**

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.

<sup>1</sup> Attended on 7–8 September

<sup>2</sup> Attended on 8–9 September

<sup>3</sup> Attended on 7 September

<sup>4</sup> Attended on 7 and 9 September

<sup>5</sup> 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 Processes<sup>6</sup> and the Decision of the Executive Director on Declarations of Interest<sup>7</sup>, 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-100™). 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.

<sup>6</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>7</sup> <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.

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## 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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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 meeting<sup>3</sup> for further discussion and possible adoption.

**5. Any other business**

The next WG meeting will be held on 7–9 September 2016.

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<sup>3</sup> 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 Engel<sup>1</sup>, Marina Heinonen, Inge Mangelsdorf, Rosangela Marchelli, Harry McArdle, Monika Neuhäuser-Berthold, Annette Pötting<sup>2</sup>, Morten Poulsen<sup>1</sup>, Yolanda Sanz<sup>1</sup>, Josef Schlatter, Hendrik van Loveren (chair)~~

- ~~Hearing expert<sup>3</sup>:~~

~~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.

<sup>1</sup> Attended on 25–26 May

<sup>2</sup> Attended by teleconference on 25–27 May

<sup>3</sup> 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 Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, 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 Committees 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.

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<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

<sup>5</sup> <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 McArdle<sup>1</sup>, Monika Neuhäuser-Berthold, Annette Pöting, Morten Poulsen, Yolanda Sanz, Josef Schlatter, Hendrik van Loveren (chair)

- **Hearing expert<sup>2</sup>:**

Not applicable

- **European Commission representative:**

Siret Surva<sup>3</sup> (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.

<sup>1</sup> By teleconference on 5 April

<sup>2</sup> 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>.

<sup>3</sup> 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 Processes<sup>4</sup> and the Decision of the Executive Director on Declarations of Interest<sup>5</sup>, 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.

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<sup>4</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>5</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



NUTRITION UNIT

**Scientific Panel on Dietetic products, Nutrition and Allergies**  
**Minutes of the 65<sup>th</sup> 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 Engel<sup>1</sup>, Marina Heinonen<sup>2</sup>, 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 Processes<sup>3</sup> and the Decision of the Executive Director on Declarations of Interest<sup>4</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the

<sup>1</sup> Present only on 11<sup>th</sup> February

<sup>2</sup> Present via teleconference on 10<sup>th</sup> February

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

<sup>4</sup> <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 (18<sup>th</sup> 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 11<sup>th</sup> 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 - 5<sup>th</sup> April and 25 - 27<sup>th</sup> May 2016.

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## NUTRITION UNIT

**Scientific Panel on Dietetic products, Nutrition and Allergies**  
**Minutes of the 64<sup>th</sup> 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 15<sup>th</sup> 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 14<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, 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

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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.

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NUTRITION UNIT

**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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, 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

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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.

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NUTRITION UNIT

**Scientific Panel on Dietetic products, Nutrition and Allergies**

**Minutes of the 62<sup>nd</sup> 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 Pötting (by webconference on 11<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, 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

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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.

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NUTRITION UNIT

**Scientific Panel on Dietetic products, Nutrition and Allergies**  
**Minutes of the 61<sup>st</sup> 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 5<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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.

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## NUTRITION UNIT

### Scientific Panel on Dietetic products, Nutrition and Allergies

#### Minutes of the 60<sup>th</sup> 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 2<sup>nd</sup> Sept 3-5 pm); Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen, Rosangela Marchelli, Morten Poulsen, Annette Pötting, 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 applicant's 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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, EFSA screened the Annual Declaration of Interest and the Specific Declaration of Interest filled in by the working group members invited for the

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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.

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NUTRITION UNIT

**Scientific Panel on Dietetic products, Nutrition and Allergies**

**Minutes of the 59<sup>th</sup> 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 4<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>



Interest<sup>2</sup>, 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.

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



NUTRITION UNIT

**Scientific Panel on Dietetic products, Nutrition and Allergies**  
**Minutes of the 58<sup>th</sup> 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. Apologies 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 Processes<sup>1</sup> and the Decision of the Executive Director on Declarations of Interest<sup>2</sup>, 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.

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>



## NUTRITION UNIT

**Scientific Panel on Dietetic products, Nutrition and Allergies**  
**Minutes of the 57<sup>th</sup> 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 Brantom<sup>1</sup>, 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 12<sup>th</sup> 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.

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<sup>1</sup> [Joining in the morning of 11 March on item EFSA-Q-2014-00232 by tele-conference](#)



## **2. Adoption of agenda**

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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 Processes<sup>2</sup> and the Decision of the Executive Director on Declarations of Interest<sup>3</sup>, 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.

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

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



**Nutrition Unit**

**Scientific Panel on dietetic products, nutrition and allergies**

**Minutes of the 56<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, 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.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



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.

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**Nutrition Unit**

**Scientific Panel on dietetic products, nutrition and allergies**

**Minutes of the 55<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, 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.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



#### 4. Agreement of the minutes of the 54<sup>th</sup> Working Group meeting held on 3-4 September 2014 in Parma.

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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.

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Nutrition Unit

## Scientific Panel on dietetic products, nutrition and allergies

### Minutes of the 54<sup>th</sup> 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 4<sup>th</sup> Sept; joining by teleconference on the 3<sup>rd</sup>) Karl-Heinz Engel, Marina Heinonen, Hannu Korhonen and Morten Poulsen (for 3<sup>rd</sup> Sept; joining by teleconference on the 4<sup>th</sup>).

#### 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, 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.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



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#### **4. Agreement of the minutes of the 53<sup>rd</sup> 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.

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#### **6. Any Other Business**

None. –

#### **7. Next meeting**

The next meeting will take place on 6-7 November 2014 in Parma.

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**Nutrition Unit**

**Scientific Panel on dietetic products, nutrition and allergies**

**Minutes of the 53<sup>rd</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, 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.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



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](#)).

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## 6. Any Other Business

None. —

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## 7. Next meeting

The next meeting will take place on 3-4 September 2014 in Parma.

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Nutrition Unit

**Scientific Panel on dietetic products, nutrition and allergies**

**Minutes of the 52<sup>nd</sup> Meeting of the Working Group (WG) on Novel Foods**

**Held on 20 March 2014, Parma**

**(Agreed on 21 May 2014)**

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**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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding

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<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>



Declarations of Interests<sup>2</sup>, 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 51<sup>th</sup> 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.

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



## Nutrition Unit

### Scientific Panel on dietetic products, nutrition and allergies

#### Minutes of the 51<sup>st</sup> 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 10<sup>th</sup> 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 10<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>



Declarations of Interests,<sup>2</sup> 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 50<sup>th</sup> 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](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.

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<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



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**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.

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**Nutrition Unit**

**Scientific Panel on dietetic products, nutrition and allergies**

**Minutes of the 50<sup>th</sup> 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 8<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests,<sup>2</sup> EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest filled in by the experts invited for the present meeting.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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 49<sup>th</sup> 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.

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**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.

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Nutrition Unit

**Scientific Panel on dietetic products, nutrition and allergies**  
**Minutes of the 49<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests,<sup>2</sup> EFSA screened the Annual Declaration of Interest and the Specific Declaration of interest filled in by the experts invited for the present meeting. No

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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 48<sup>th</sup> 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.

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**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.

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Nutrition Unit

**Scientific Panel on dietetic products, nutrition and allergies**

**Minutes of the 48<sup>th</sup> 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 Pötting 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests,<sup>2</sup> 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.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



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## 5.1 Applications

Working Group (WG) discussed and elaborated on draft opinions on the following Novel applications: Gantrez novel chewing gum ingredient ([EFSA-Q-2012-00653](#)) and seed Protein ([EFSA-Q-2013-00231](#)).

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.

an application on UV-treated yeast ([EFSA-Q-2013-00335](#)) was discussed.

### Any Other Business

4.

## Next meeting

next meeting will take place on 5 and 6 September 2013.



Nutrition Unit

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**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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, 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.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <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.

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**Nutrition Unit**

**Scientific Panel on dietetic products, nutrition and allergies**

**Minutes of the 47<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, 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.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



## Agreement of the minutes of February 2013, in Amsterdam

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**Nutrition Unit**

**Scientific Panel on dietetic products, nutrition and allergies**  
**Minutes of the 46<sup>th</sup> 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 Processes<sup>1</sup> and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests<sup>2</sup>, 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.

<sup>1</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencpolicy.pdf>

<sup>2</sup> <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>



#### **4. Agreement of the minutes of the 45<sup>th</sup> 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.

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Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 5 February 2013

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 45<sup>th</sup> 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 44<sup>th</sup> 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<sup>®</sup> - novel chewing gum base ingredient (EFSA-Q-2012-00653) and Taxifolin (EFSA-Q-2012-00961).







Parma, 3<sup>rd</sup> December 2012

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 44<sup>th</sup> 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 43<sup>rd</sup> 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 42<sup>nd</sup> 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**



Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 31 May 2012

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 41<sup>st</sup> 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-



**4. A.O.B. none**



Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 29 March 2012

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 40<sup>th</sup> 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-



The Working Group (WG) had a general discussion on intake assessment methodologies.

**4. A.O.B. none**



Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 16 February 2012

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 39<sup>th</sup> 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-



4. **A.O.B.** none

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**Panel on dietetic products, nutrition and allergies (NDA) Unit**

Parma, 1-2 December 2011

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 38<sup>th</sup> 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**

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Helsinki, 8<sup>th</sup> July 2011

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 37<sup>th</sup> 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, 26<sup>th</sup> May 2011

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 36<sup>th</sup> 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 Pötting, 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  $\beta$ -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.



Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 12<sup>th</sup> January 2011

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 35<sup>th</sup> 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 Pöting, 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  $\beta$ -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" (Revolymex 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



#### **4. A.O.B.**

The WG discussed the WG dates for 2011.



Parma, 25<sup>th</sup> November 2010

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 34<sup>th</sup> 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 16<sup>th</sup> 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  $\beta$ -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, 16<sup>th</sup> Sept 2010

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 33<sup>rd</sup> 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



**Panel on dietetic products, nutrition and allergies (NDA) Unit**

Parma, 16<sup>th</sup> Sept 2010

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 32<sup>nd</sup> 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 Pötting, 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.







Parma, 27<sup>th</sup> May 2010

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 31<sup>st</sup> meeting of the Working Group (WG) on Novel Foods**

**Parma, 18-19 March 2010**

**(Adopted by the WG on 27<sup>th</sup> 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



Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 18<sup>th</sup> March 2010

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 30<sup>th</sup> meeting of the Working Group on Novel Foods**

**Brussels, 7<sup>th</sup> January 2010**

**(Adopted by the WG on 18<sup>th</sup> March 2010)**

**Participants**

WG Experts: Karl-Heinz Engel, Ines Golly, Rosangela Marchelli, Monika Neuhäuser-Berthold, 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 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).



A power point presentation related to the approach of safe maximum levels, prepared by Hans Verhagen was postponed to the following WG meeting.



Parma, 7<sup>th</sup> January 2010

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 29<sup>th</sup> meeting of the Working Group on Novel Foods**

**Amsterdam, 18<sup>th</sup> November 2009**

**(Adopted by the WG on 7<sup>th</sup> 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, 18<sup>th</sup> November 2009

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 28<sup>th</sup> meeting of the Working Group on Novel Foods**

**Brussels, 9<sup>th</sup> October 2009**

**(Adopted by the WG on 18<sup>th</sup> 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, 9<sup>th</sup> October 2009

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 27<sup>th</sup> meeting of the Working Group on Novel Foods**

**Munich, 27<sup>th</sup> August 2009**

**(Adopted by the WG on 9<sup>th</sup> 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, 4<sup>th</sup> May 2009

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 26<sup>th</sup> meeting of the Working Group on Novel Foods**

**Parma, 23<sup>rd</sup> April 2009**

**(Adopted by the WG on 4<sup>th</sup> 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



Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 23<sup>rd</sup> April 2009

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 25<sup>th</sup> meeting of the Working Group on Novel Foods**

**Parma, 11<sup>th</sup> February 2009**

**(Adopted by the WG on 23<sup>rd</sup> 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.







Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 11<sup>th</sup> February 2009

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 24<sup>th</sup> meeting of the Working Group (WG) on Novel Foods**

— **Parma, 7<sup>th</sup> November 2008**

**(Adopted by the WG on 11<sup>th</sup> 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 2<sup>nd</sup> - 4<sup>th</sup> 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.



Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 7<sup>th</sup> November 2008

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 23<sup>rd</sup> meeting of the Working Group on Novel Foods**

**Parma, 18 September 2008**

— **(Adopted by the WG on 7<sup>th</sup> November 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 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 30<sup>th</sup> 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.



Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 18 September 2008

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 22<sup>nd</sup> 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-



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.

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Panel on dietetic products, nutrition and allergies (NDA) Unit

Parma, 05 June 2008

**PANEL ON DIETETIC PRODUCTS, NUTRITION AND ALLERGIES**

**Minutes of the 21<sup>st</sup> 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