NUTRITION UNIT

SCIENTIFIC PANEL ON NUTRITION, NOVEL FOODS AND FOOD ALLERGENS

MINUTES OF THE 93rd PLENARY MEETING

Held on 02-04 July 2019, Parma (Italy)
(Agreed on 22 July 2019)

Meeting open to observers on 03 July 2019, 9:00-15:30

Participants

- Panel Members:

  Jacqueline Castenmiller, Stefaan de Henauw, Karen Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J. McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri, Dominique Turck (Chair) and Marco Vinceti.

- Hearing Experts:

  Not Applicable

- European Commission and/or Member States representatives:

  DG SANTE: Stephanie Bodenbach (items 8.1, 8.2 and 8.3)

- EFSA:

  NUTRI Unit: Valeriu Curtui, Reinhard Ackerl, Mathias Amundsen, Ester Artau Cortacans, Domenico Azzollini, Janusz Ciok, Paolo Colombo, Agnès de Sesmaisons-Lecarré, Aikaterini Doulgeridou, Céline Dumas, Lucien Ferreira, Wolfgang Gelbmann, Andrea Germini, Tilemachos Goumperis, Leng Heng, Eirini Kouloura, Leonard Matijevic, Federico Morreale, Charlotte Salgaard Nielsen, Ruth Roldan Torres, Annamaria Rossi, Qingqing Sun, Ariane Titz, Emanuela Turla, Silvia Valtueña Martinez, Ermolaos Ververis.

  AMU Unit: Laura Martino (items 8.1 and 8.2), Laura Ciccolallo (items 8.1, 8.2 and 8.3).

- Observers:

  See Annex III.

- Others:

  Not Applicable

CLOSED SESSION

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

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

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. 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 92nd Plenary meeting held on 15-16 May 2019, Parma (Italy)

The minutes of the 92nd Plenary meeting held on 15-16 May 2019 were agreed by written procedure on 28 May 2019.

5. Scientific outputs submitted for discussion and/or possible adoption

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

The draft opinion was presented. The Panel discussed and reviewed the sections related to the characterisation of the food/constituent that is the subject of the claim, and in particular the characterisation of the claimed effect, the proposed outcome variable(s) and the methods of measurement that were used to assess the claimed effect in human studies. The opinion was adopted by the Panel on 3 July subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: http://www.efsa.europa.eu/en/efsajournal/pub/5776

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

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

The draft opinion was presented. In particular, the Panel discussed the sections related to product characterisation, proposed uses and use levels, toxicology information, and animal and human studies. The opinion was adopted by the Panel on 4 July subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link: http://www.efsa.europa.eu/en/efsajournal/pub/5775

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

The draft opinion was presented. In particular, the Panel discussed the sections related to product characterisation, production process, proposed uses and use levels, anticipated daily intake, toxicology, human studies and allergenicity. The opinion was adopted by the Panel on 2 July subject to the incorporation of editorial changes. The full text will be published in the EFSA Journal in the coming weeks via this link:

http://www.efsa.europa.eu/en/efsajournal/pub/5777

12. Other scientific topics for information and/or discussion

In relation to the WG on Sugars, the challenges encountered during the appraisal of intervention studies for the project on metabolic diseases and the solutions found for conflict solving were discussed in detail.

13. Any other business

13.1. Novel Foods Lesser mealworm – Applicant: Proti-Farm Holding NV (EFSA-Q-2018-00282)

Postponed.

14. Next meeting

The next meeting will be held on 17-19 September 2019 in Parma.

OPEN SESSION ON 3 JULY

6. Welcome and apologies for absence

The Chair welcomed the participants and the observers who participated on-site were invited to introduce themselves.

7. Presentation of Guidelines for Observers

Valeriu Curtui, Head of the Nutrition Unit, presented the code of conduct to be followed by the observers attending the open plenary meeting.

Observers were given the possibility to raise questions in relation to EFSA's work when submitting their registration. It was indicated that questions would be answered in the dedicated time during the open session.

It was also indicated that, time permitting, the Chair might grant observers (present in the room and participating via web-streaming) an opportunity to ask additional questions either after they had observed a discussion on a given item or at the end of the open plenary meeting in the dedicated session.

8. Scientific outputs submitted for discussion and possible adoption

8.1. Dietary reference values for sodium - draft technical report on the outcome of the public consultation (EFSA-Q-2019-00184) and draft opinion (EFSA-Q-2011-01224)

The draft opinion on DRVs for sodium was released for public consultation from 3 April 2019 to 22 May 2019. Comments were received from eight interested parties and three individuals in their personal capacity.

The background, the process and methodological steps used for deriving DRVs for sodium were introduced, with focus on the criteria and the data on which to base DRVs. An overview on the Expert Knowledge Elicitation (EKE) process, which was used to weigh/integrate the available evidence and consider the associated uncertainties to inform final conclusions, was given.

Evidence from balance studies on sodium and on the relationship between sodium intake and health outcomes, in particular cardiovascular disease (CVD)-related endpoints and bone health, were not sufficient to enable an Average Requirement (AR) or Population Reference Intake to be derived. However, by integrating the available evidence and associated uncertainties, the Panel considers that a sodium intake of 2.0 g/day represents a level of sodium for which there is sufficient confidence in a reduced risk of CVD in the general adult population. In addition, a sodium intake of 2.0 g/day is likely to allow most of the general adult population to maintain sodium balance. Therefore, the Panel considers that 2.0 g sodium per day is a safe and adequate intake for the general EU population of adults. The same value applies to pregnant and lactating women. Sodium intakes that are considered safe and adequate for children are extrapolated from the value for adults, adjusting for their respective energy requirement and including a growth factor. For infants aged 7–11 months, an Adequate Intake (AI) of 0.2 g/day is proposed based on upwards extrapolation of the estimated sodium intake of exclusively breast-fed infants aged 0–6 months.

The outcome of public consultation was presented, summarising the comments received and how the comments were addressed and were considered in updating the opinion on DRVs for sodium.

The draft technical report and the draft opinion were respectively endorsed and adopted by the Panel on 3 July, subject to the incorporation of editorial changes. The full text of both outputs will be available in the coming weeks in the EFSA Journal via the following links:

Opinion: http://www.efsa.europa.eu/en/efsajournal/pub/5778

Technical report: http://www.efsa.europa.eu/en/supporting/pub/en-1679

8.2. Dietary reference values (DRVs) for chloride - draft technical report on the outcome of the public consultation (EFSA-Q-2015-00671) and draft opinion (EFSA-Q-2011-01207)

The draft opinion on DRVs for chloride was released for public consultation from 3 April 2019 to 22 May 2019 and no comments were received. Thus, the outcome of this public consultation is addressed in one single draft technical report together with the outcome of public consultation on DRVs for sodium (see also item 8.1).

No changes were introduced to the opinion. The Panel notes the close relationship between sodium and chloride balances in the body, the fact that sodium chloride is the main source of both electrolytes in European diets and that similar urinary excretion levels of sodium and chloride (on a molar basis) are typically observed in Western populations. Hence, the Panel considers that reference values for chloride can be set at values equimolar to the reference values for sodium for all population groups. Consistent with the reference values for sodium, these levels of chloride intake are considered to be safe and adequate for the general EU population, under the consideration that the main dietary source of chloride intake is sodium chloride.

The draft technical report and the draft opinion were respectively endorsed and adopted by the Panel on 3 July. The full text of both outputs will be available in the coming weeks in the EFSA Journal via the following links:

Opinion: http://www.efsa.europa.eu/en/efsajournal/pub/5779

Technical report: http://www.efsa.europa.eu/en/supporting/pub/en-1679

8.3. The appropriate age of introduction of complementary feeding into an infant's diet - draft technical report on the outcome of the public consultation (EFSA-Q-2019-00185) and draft opinion (EFSA-Q-2016-00482)

Harry J. McArdle chaired this Agenda item because Dominique Turck presented the draft opinion.

The draft opinion was released for public consultation from 17 April to 29 May 2019. Comments were received from 68 interested parties and three individuals in their personal capacity. The scope of the opinion, the process used, the evidence base for the scientific assessment and methodological steps applied to answer to the Terms of Reference were outlined. The outcome of the public consultation was presented, summarising the comments received and how the comments were addressed and considered in updating the opinion.

Following a request from the European Commission, the Panel revised its Opinion of 2009 on the appropriate age for introduction of complementary feeding of infants.

In the context of this opinion, complementary feeding is defined as the period when complementary foods (CFs) are given together with either human milk or formula or both. CFs in this opinion comprise foods other than human milk and formula, water and vitamins which are given to infants, and can be beverages, spoon-fed pureed foods, spoon-fed lumpy foods or finger-foods, either prepared at home or produced commercially.

The Panel considers that exclusive breast-feeding is nutritionally adequate up to 6 months of age for the majority of healthy infants born at term from healthy well-nourished mothers.

To answer to the terms of reference (ToR), the Panel assesses in its opinion the scientific evidence in relation to whether there are:

1) any developmental factors relevant for the introduction of complementary foods (CFs),
2) any adverse health effects associated with the introduction of CFs before 6 months of age, and
3) any benefits associated with the introduction of CFs before 6 months of age.

In the interpretation of the ToR, the choice has been made by the Panel to limit the assessment to health effects associated with the timing of introduction of CFs or specific foods before the age of 6 months. This led to the exclusion of studies that had been considered by other bodies in their assessments done in different contexts than this opinion. This is, for example, the case for some studies that investigated the introduction of some allergenic foods, such as fish, egg and peanuts, or of gluten after 6 months of age.

The ToR exclude considerations about:

- public health recommendations for the introduction of CFs; this task is outside the remit of EFSA but it is the role of public health authorities in Member States;
- the effects of the duration of exclusive breast-feeding on the selected health outcomes, as the assessment was performed irrespective of whether infants were initially exclusively breast-fed or formula-fed;
- the health benefits of breast-feeding itself (for the infant and the mother);
- the effects on health outcomes of introduction of CFs solely after 6 months of age, since there is a nutritional requirement for CFs for the majority of exclusively breast-fed infants from around 6 months onwards;
- the effects of the amount, order of introduction, variety, composition and texture of CFs;
- the role of aspects, such as social interactions and the cultural context, on the appropriate age of introduction of CFs;
- risks related to e.g. chemical or microbiological contaminants or pesticides.

The Panel undertook a systematic literature search of intervention and observational studies for the assessment of the association between the timing of introduction of CFs and health outcomes, while an extensive literature search was carried out specifically for developmental determinants of the introduction of CFs. The Panel also appraised the risk of bias (RoB) of the studies included from the systematic search, thus classifying them as low, intermediate or high RoB (Tiers 1, 2 or 3).

Studies considered pertinent for this assessment were those in infants and children, generally healthy at the time of introduction of CFs, either born at term or pre-term. The study groups had to be alike in terms of the type of milk-feeding (breast-milk or formula or mixed, with no additional behavioural interventions), i.e. the study groups had to differ only in the timing of the introduction of CFs. The selected papers were studies in which at least one group was introduced to CFs before 6 months of age. Studies on a specific CF item or food group were also considered for certain health outcomes (e.g. gluten in relation to the risk of coeliac disease).

In the systematic review, the Panel has assessed 283 studies that reported on the relationship between the timing of introduction of CFs (or specific foods for some outcomes) in relation to (1) body weight and growth, including body mass index (BMI), risk of developing overweight and obesity, as well as body composition, (2) risk of developing atopic diseases or symptoms of atopic diseases, such as asthma-like symptoms, eczema, allergic rhinitis and symptomatic food allergy, (3) risk of developing coeliac disease and type 1 diabetes mellitus, (4) blood pressure, (5) infections, (6) sleep, (7) infant and child development, (8) nutrient status (i.e. iron) and (9) food preferences and eating behaviours later in life. For these outcomes, whenever enough data were available, forest plots were created, and pooled estimates were calculated from the individual studies, with associated 95% confidence and prediction intervals, using random effects meta-analyses. Evidence was discussed separately for infants born at term and those born pre-term.

Overall conclusions of the Panel

The appropriate age range of introduction of CFs has been evaluated taking into account effects on health outcomes, nutritional considerations and infant development.

The available data do not allow the determination of a single age for the introduction of CFs for infants living in Europe. The appropriate age range depends on the individual's characteristics and development, even more so if the infant was born pre-term.

As long as the foods are given in an age-appropriate texture, are nutritionally appropriate and prepared according to good hygiene practices, there is no convincing evidence that the introduction of CFs is associated with either adverse or beneficial health effects (except for infants at risk of iron depletion) at any age investigated in the included studies (<1 months to <6 months for earlier introduction).

For nutritional reasons, the majority of infants need CFs from around 6 months of age. For pre-term infants, this refers to post-term age.

Infants at risk of iron depletion (exclusively breast-fed infants born to mothers with low iron status, or with early umbilical cord clamping (<1 minute after birth), or born pre-term, or born small-for-gestational age or with high growth velocity) may benefit from introduction of CFs that are a source of iron before 6 months of age.

The earliest developmental skills relevant for the consumption of spoon-fed pureed CFs can be observed between 3 and 4 months of age. Skills necessary for consuming self-fed finger foods can be observed in some infants at 4 months, but more commonly between 5 and 7 months of age. For pre-term infants, this refers to post-term age.

The fact that an infant may be ready from a neurodevelopmental point of view to progress from a liquid to a more diversified diet before 6 months of age does not imply that there is a need to introduce CFs.

The draft technical report and the draft opinion were respectively endorsed and adopted by the Panel on 3 July, subject to the incorporation of editorial changes.

NOTES: The EFSA Journal should be checked for confirmation of the final version of the documents. Please note that only the final, published version should be considered as the reference document. The full text of both outputs will be available in September in the EFSA Journal via the following links:

Opinion: http://www.efsa.europa.eu/en/efsajournal/pub/5780

Technical report: http://www.efsa.europa.eu/en/supporting/pub/en-1686

9. New mandates

The Nutrition Unit updated the Panel members on new mandates received since the last Plenary meeting, as follows:

- Two requests from EC to EFSA for scientific advice on the safety & suitability of infant and/or follow-on formulae manufactured from protein hydrolysates. To address these mandates, the Panel agreed to set a working group on protein hydrolysate-based formula, with Dominique Turck as the chair.
- A request from EC to EFSA for scientific advice on an application for the exemption from labelling of food ingredients or substances with known allergenic potential listed in Annex II of Regulation (EU) No 1169/2011 or products thereof. To address this mandate, the Panel agreed to set a working group on food allergy, with Stefaan de Henauw as the chair.
- EFSA will be initiating an internal mandate requesting the Panel to review the scientific basis to derive the uncertainty factor (UF) to establish a health-based guidance value (HBGV) for copper. The Panel accepted this mandate and agreed to set a working group on the UF for the HBGV for copper, with Harry J. McArdle as the chair.
- Five new applications on health claims (four Art. 13.5 and one Art. 14) have also been received and are under completeness check.

Information about the mandates received and their status are available on EFSA Register of Questions.

10. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

In relation to the Scientific Committee (SC) activities, the SC will be initiating a self-task mandate to advise on derivation of Health Based Guidance Values (HBGV) for food additives and other regulated products that are also nutrients, in particular the terminologies and the method/approach to apply. In this context, a working group of the SC will be established.

The Chairs of respective Working Groups (WG) reported back to the Panel:

- **WG on Claims** - The WG discussed and elaborated an Art. 13.5 claim opinion related to "A combination of beta-sitosterol and beta-sitosterol glucoside and contributes to the normal function of the immune system by restoring balance between TH1- and TH2- mediated immunity", which was submitted to the Panel for discussion/possible adoption (see item 5.1).
- **WG on Novel Foods (NF**) – The WG discussed and elaborated several draft opinions, two of which were submitted to this plenary for possible adoption (see items 5.2, and 5.3).
- **WG on Sugars** – The WG Chair briefed the Panel on the work done so far in relation to this mandate and on the next steps. The food composition database on total sugars has been developed and preliminary intake data is available now for data checks. The food composition databases on added and free sugars will be developed in the next months in collaboration with the mandate requestor. Regarding the systematic literature reviews, title, abstract and full-

text screening has been completed for both projects (metabolic diseases and dental caries). Data extraction and appraisal of intervention studies are finalised, data analysis is ongoing. Data extraction for observational studies is piloted. Authors of the papers on dental caries have been contacted to obtain individual data. Whereas the project is running according to the charter, a new deadline is under negotiation with the mandate requestor owing to the heavy workload to address this mandate.

11. Questions from and answers to Observers (in application of the guidelines for Observers)

Observers present in the room and participating via web-streaming were given the possibility to ask questions. Please refer to Annex **IV**.

Annex III

List of on-site observers

Observer	Company	Country
FLORES-VIDAL Rosalía	Pen & Tec Consulting SLU	ES
GEISER Stefanie	EAS Strategies	BE
GHILOUFI Rana#	Institute of Nutrition and Food Technology	TN
RUNDALL Patty	Baby Milk Action - IBFAN UK	UK
SOCZEWINSKA Joanna	Walmark Sp. z o.o.	PL
SOLAK Kamila	Inbiose	BE
STURM Lisa	Austrian Agency for Health and Food Safety (AGES)	AT

 # Registered but did not attend

Observers who attended the open plenary via web-streaming		
Observer	Company	Country
ABITANTE Lucia	Private capacity	IT
ASUKAS Tiia#	Tiia Asukas	FI
BELTOFT Vibe#	Vibe Beltoft	DK
BROCK Steen	Steen Brock	DK
BÜTTNER Rebecca	Hipp-Werk Georg Hipp OHG	DE
CATTANEO Adriano	Retired	IT
CHARLES Ruth#	Nutrikids	IE
COGALNICEANU Elena	EAS Strategies	BE
DE HAUTECLOCQUE Laure	Specialised Nutrition Europe	BE
DI MARIO Simona	Regional Health Authority of Emilia-Romagna	IT
DUGUINE Maria#	Private capacity	ES
DURAZZO Alessandra	CREA Research centre for food and nutrition	IT
ELSOM Rachel	Public Health England	UK
ERAN'OGWA Bronson#	The sours plus	KE
FEAKDU LASHTEW Habtamu#	Save the Children US	USA
FINCK Alex	Alex Finck/n.a.	DE
FRANNETTA SOPACUA Tirzania	Chr. Hansen A/S	DK
FRIEDRICH Katharina	HiPP Werk Georg Hipp OHG	DE
GARCIA Javier#	Campofrio	ES
GENTILUCCI Micaela#	Asst-rhodense	IT
GIORDANO Vincenzo Gioacchino#	Private capacity	IT
HEARNE Aoife#	Nutrition solutions	IE
KARUNARATHNE Krishanthi#	Government Analyst Department	LK

KING Caroline#	Imperial college NHS trust	UK
KRUMA Zanda#	Latvia University of Life Sciences and Technologies	LV
LAMONACA Sara	FoodDrinkEurope	BE
LEIBOVITCH MAJSTER Emilie	CEFS	BE
LENGYEL Jennifer#	Family Food LLC	USA
LINDSTRØM NIELSEN Kirstine#	Danish food and veterinary administration	DK
LUCARINI Massimo	CREA Research gentre for food and nutrition	IT
MacGOWAN Carol	Centers for Disease Control and Prevention	USA
MALDONADO Claudio#	Nestlé	CH
MANACHINI Barbara#	Barbara Manachini	IT
MARTUFI Antonella#	Antonella Martufi	IT
MATHEW Joash	International Platform of Insects for Food and Feed	BE
NOUGUEZ Etienne#	Centre National de la Recherche Scientifique (CNRS)	FR
ONO Kaori	AJINOMOTO	FR
O'SULLIVAN Elizabeth#	Technological University Dublin	IE
PAGEREY Marie-France	Société des Produits Nestlé S.A.	CH
PODOLSKA-CHARLERY Agnieszka	Agnieszka Podolska-Charlery	DK
POHER Aliénor	EUsalt	BE
RIMAC BRNČIĆ Suzana#	University of Zagreb	HR
ROUW Elien	Self-employed physician	DE
SAAM Sam#	Abuyaam	KW
SERVER GOMEZ Antonio#	Consultora Hospitales y Compañías Aseguradoras de salud	ES
SIBSON Victoria	First Steps Nutrition Trust	UK
SOBAJIC Sladjana#	Faculty of Pharmacy	RS
SPAINI Guillermo#	Cedyat	ES

STRAUMITE Evita#	Latvia University of Life Sciences and Technologies	LV
VANKANN Astrid	Hipp-Werk Georg Hipp OHG	DE
VENTURA Gabrielle	Synadiet	FR
VOGIATZOGLOU Konstantinos	Private capacity	GR
VON GARTZEN Aleyd	German Midwives Association	DE
WASIOLEK Virginie	Microphyt	FR
WEINER Danielle	Public Health England	UK
ZEHNER Elizabeth#	Helen Keller International	USA

 # Registered but did not connect

Annex IV

Answers to questions from observers

A dedicated session was organised to provide observers with answers to the questions submitted prior to the Plenary meeting, or that had arisen during the course of the Plenary meeting.

Name	Questions (PRE-submitted and received via web-streaming)	EFSA / Panel reply
Questions related to item 8.3.: The appropriate age of introduction of complementary feeding into an infant's diet		
Patti Rundall Baby Milk Action	How can this report be finalised so quickly when so many serious concerns have been raised about its flaws and omissions, including: its lack of attention to the impact on breastfeeding, its poor conflicts of interest declarations, its failure to consider the impact it could have on public health in third countries and the importance of global policy coherence.	These questions have been addressed in the presentation given related to the Agenda item 8.3. The scope of the opinion, the process used, the evidence base for the scientific assessment and methodological steps applied to answer to the Terms of Reference (ToR) have been explained. Clarifications were given regarding EFSA rules on Competing Interest Management for Experts and EFSA statuary staffs. The ToR are clear: EFSA Panel is asked to revise its 2009 Opinion on the appropriate age for introduction of complementary feeding of infants. **The ToR to EFSA exclude considerations about**: ▪ public health recommendations for the introduction of CFs - this task is outside EFSA remit but it is the role of public health authorities in Member States; ▪ the effects of the duration of exclusive breast-feeding; the health benefits of breast-feeding itself (for the infant and the mother);

Name	Questions (PRE-submitted and received via web-streaming)	EFSA / Panel reply
		▪ the effects of introduction of CFs solely after 6 months of age; the effects of the amount, order of introduction, variety, composition and texture of CFs; ▪ the role of aspects, such as social interactions and the cultural context, on the appropriate age of introduction of CFs; ▪ risks related to e.g. chemical or microbiological contaminants or pesticides Further considerations such as, introduction of CFs and economic/environmental impacts, impact on breastfeeding, impact on public health in third countries - **These are beyond the remit of EFSA (an EU Risk Assessor) but are the role of EU Risk Managers / Public health authorities in Member States/ Policy makers**.
Victoria Sibson First Steps Nutrition Trust	Will all the consultation responses be published, with details of how they have been addressed by the expert panel?	For transparency, comments received from interested parties will be published in a technical report on "Outcome of a public consultation on the Scientific Opinion". The report includes a brief summary of the comments received and how the comments were addressed. Subsequently the Panel prepares an updated version of the Opinion taking into consideration the comments received. The organisations who submitted comments will be disclosed. As announced on public consultation page, the name of individuals is not disclosed Owing to protection of personal data.

Name	Questions (PRE-submitted and received via web-streaming)	EFSA / Panel reply
Simona Di Mario Regional Health Authority of Emilia-Romagna	1) Why breast-feeding is not considered in the outcomes? 2) It seems that the problem is the ToR but if all the feedbacks are merely used not to amend the text but to tailor definition of ToR and scope of the opinion what is the point? 3) Decision on [comment] nb 90 appropriate age is between 3-4 and 6 months: what is the new phrasing? 4) [comment] nb24 it is not true that the majority of EBF [exclusive breast-fed] infants need CF before 6 months of age? Where is the evidence? See Perezx Escamilla and many more evidence 5) But is it possible to know who provided comments nb59? 6) [comment] nb46 not considering the paper from Natsume you bias the available evidence. 7) [comment] nb53 but in the letter by Lawson they say that interaction for age and peanuts introduction is not significant, so even in their answer there is not a better protection at earlier ages.	***Ad1:*** The ToR received from the European Commission (EC) relates to the appropriate age for introduction of complementary feeding into an infant's diet. The introduction of CFs does indeed influence the duration of (exclusive) breast-feeding, but an assessment of the effect of breast-feeding on the selected (health) outcomes is outside the scope of this Opinion. The commenter is invited to refer to the technical report and the final Opinion once published for further details. ***Ad2:*** EFSA replies to requests from the EC as they are received. ToR cannot be changed by EFSA. ***Ad3:*** It is noted that the conclusion is now phrased as follows: '*For nutritional reasons, the majority of infants need CFs from around 6 months of age […]'* and '*The earliest developmental skills indicative of developmental readiness for spoon-feeding of pureed CFs can be observed between 3 and 4 months of age […]'.* The commenter is invited to refer to the final Opinion once published. ***Ad4:*** It is not stated that the majority of infants need CFs before the age of 6 months. On the contrary, it is indicated that before 6 months of age the majority of exclusively breast-fed infants do not need CFs from a nutritional point of view. ***Ad5:*** The organisations who submitted comments will be disclosed in the technical report once published together with the final Opinion. Owing to protection of personal data, the name of individuals will not be disclosed. ***Ad6:*** In the study by Natsume et al. (2017) the infants were introduced to egg at 6 or 12 months of age. Hence, the study

Name	Questions (PRE-submitted and received via web-streaming)	EFSA / Panel reply
	8) [comment] nb60 there is plenty of evidence about duration of EBF [exclusive breast-feeding] and risk of infection. 9) [comment] nb61 but you do not clarify how can you use Perkin paper as a source of data for infections (it is merely a self reporting of adverse events). 10) [comment] nb74 clearly it depends from the point of view that you choose: timing of cord clamping has noting to do with physiology if it anticipates when cord stops to pulse. 11) Not a single criticism has been accepted. 12) All of us feel sad for the procedure. 13) I totally agree with what the observer in the room is saying. 14) If you are doing science why did you choose to assess developmental skills for spoon feeding and not self-feeding? This is a choice and has nothing to do with science.	did not meet the inclusion criteria (section 2.1.1.1.) of the Opinion and its omission could not bias the results. ***Ad7:*** The data presented in the Opinion is in line with this comment. ***Ad8:*** The statement in this comment is considered correct. However, such an assessment is outside the scope of this Opinion as requested by the ToR (i.e. relates to the appropriate age for introduction of complementary feeding into an infant's diet). ***Ad9:*** The data provided in the study by Perkin et al. (2016) is of relevance for the assessment as the most likely cause of 'diarrhoea' in this study was considered to be infectious disease. The way in which the outcome was assessed is taken into account in the risk of bias (RoB) assessment and therefore reflected in the RoB Tier to which the study was assigned for the outcome. ***Ad10:*** The commenter is invited to refer to a response that had already been given when the technical report was discussed in which it was explained how delayed clamping of the umbilical cord (i.e. >2 minutes after birth) increases iron stores of the infant. ***Ad11:*** The commenter is invited to refer to the technical report once published with the Opinion, in which it is outlined how comments were considered and how the Opinion was amended as appropriate. ***Ad12:*** The commenter was reminded that TWO public consultations, one on the draft protocol and one on the draft Opinion were carried out to get inputs from stakeholders. The

Name	Questions (PRE-submitted and received via web-streaming)	EFSA / Panel reply
		outcomes of both public consultations were discussed in TWO OPEN Plenary meetings to observers (on 28-29 June 2018, and 3rd July 2019). All comments received were considered and addressed in published technical reports. ***Ad13:*** No comments. ***Ad14:*** The commenter is invited to read section 3.3.1 and 3.3.2 in the final Opinion in which gross and fine motor skills relevant for both spoon-feeding and self-feeding are addressed.
Adriano Cattaneo	1) Interesting: breastfeeding not considered as an outcome. 2) I can't believe that risk managers will not be influenced by this assessment 3) The EFSA opinion on timing of introduction of complementary foods of 2009 is often cited by my paediatrician colleagues as a recommendation, not like an opinion. How do we avoid this?	***Ad1:*** An assessment of breast-feeding is not in the ToR received from the EC; hence it is outside the scope of this Opinion. The commenter is invited to refer to the technical report and the final Opinion once published where this is further addressed. ***Ad2:*** EFSA, an EU Risk Assessor, provides scientific advice (assessed the scientific evidence on the timing of introduction of CF before the age of 6 months) upon the request from the EC. The Outcome of EFSA scientific assessment serves as basis to support the decision-making process or setting legislation by the EU Risk Managers (i.e. the EC, the European Parliament and the Member States). In addition to the EFSA opinion, EU risk managers may take into consideration other legitimate factors, such as public health aspects, to make well founded decisions. ***Ad3:*** In most EU Member States, public health recommendations for the introduction of CFs are available upon which recommendations for paediatricians can be based. In EFSA's Opinion it is clearly stated that the opinion is not a public health recommendation.

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Victoria Sibson First Steps Nutrition Trust	1) It seems inappropriate to revise the inclusion and exclusion criteria for the review following your consideration of the results of the public consultation e.g. in relation to nutritional status of the study population and the hygiene conditions 2) Nb 30 the published paper by Perkin et al 2016 does not reference in the text any 'supplementary appendix' reporting weight outcomes 3) [comment] Nb. 43 Rito et al 2019 examines breastfeeding, including exclusive breastfeeding as an exposure, so how can it be irrelevant to the question of the effect of the timing of CF? How can this process be judged as a full and appropriate risk assessment without considering the effect of the timing of CF on BF? Please can the panel provide a clearer explanation for how exclusive breastfeeding can be ignored when it is the timing of the introduction of foods or fluids other than BM which impacts on the duration of EBF 4) Is there a precedent with past EFSA opinions whereby there has been a public consultation, then on the basis of the feedback EFSA has suggested a widespread misunderstanding of the	***Ad1:*** The inclusion and exclusion criteria were not revised following the public consultation. However, it was clear from the comments received that some aspects were misunderstood, or insufficient information was provided. Therefore, clarifications on certain concepts were given - the commenter is invited to refer to the technical report and the final Opinion once published. ***Ad2:*** Supplementary material in the study by Perkin et al. (2016) does report on weight outcomes. As outlined in the technical report, the supplementary material is accessible online alongside the published article. ***Ad3:*** An assessment of breast-feeding is not in the ToR received from the EC to EFSA, hence it is outside the scope of this Opinion. The commenter is invited to refer to the technical report and the final Opinion once published where this is further addressed. ***Ad4:*** ToR are provided by the mandate requestor and cannot be changed by EFSA. In one particular case, after the public consultation on the draft protocol (that outlines the scientific approach to be followed), the comments received were discussed with the mandate requestor and had led to a revision of the ToR in agreement with the requestor. For this Opinion no comments related to the ToR were received during the public consultation.

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	scope of work/terms of reference, EFSA has then redefined the scope of work/terms of reference, made some amendments and then revised and approved without further consultation?	
Aleyd von Gartzen German Midwives Association	1) Please give me the evidence for your opinion to on [comment] Nb 46 to introduce egg at 3-4 months into the diet of an infant. In the cited references I can only find 4 - 6 months: • from age 4 - 6 months, Perkin: median age 19,6 weeks. • Bellach 4 - 6 months • Palmer: 4 -6 months • Tan: from the time of solid introduction • Tham: only a few infants before 6 months • so, where is the evidence for your opinion 3 to 4 months? 2) To complete my comments on egg: Perkin et al state that the "the primary outcome ie any allergy {…} whilst egg remains borderline significant" when studying the references the panel has cited I quite often observed the fact, that these studies examined the outcome of starting CFs at the age of 4 months and not at the age of 3 - 4 months. But still they were cited to support the introduction at 3 - 4 months.	***Ad1:*** The requestor is invited to refer to section 8.7.3 in the final Opinion once published. The conclusions that introduction of egg between 3 and 4 months of age compared with 6 months of age may reduce the risk of developing egg allergy was derived from the timing of introduction of egg in the RCT by Perkin et al. (2016). For this study, the per protocol analysis was considered, i.e. only infants who followed the protocol and were introduced between 3-4 months of age to egg and were compared with those introduced at 6 months of age. The conclusion section was again explained in detail to the observers. ***Ad2:*** In the conclusion section, it was also explained that the per protocol analysis in relation to egg of the study by Perkin et al. (2016) showed a statistically significantly lower risk for egg allergy in infants introduced to egg between 3-4 months of age as compared to those introduced at 6 months of age. With respect to the reporting of ages at introduction of CFs, it has been clarified in the Opinion that the ages that are reported in relation to RCTs are the ages at which infants were randomised in these studies to consume CFs. However, variability is to be expected as to when infants were introduced to CFs or were able to consume the assigned CFs after randomisation. This may well span over some weeks.

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		Reported ages for RCTs should not be interpreted as a single time point, but rather as a time span of one month. For example, introduction of CFs at 4 months should be read as introduction during the 5th month of life and an introduction of CFs at 3-4 months of life as an introduction during the 4th and 5th months of life. Therefore, the Panel considered it valid to summarise the timing of introduction of CFs in individual studies, in particular RCTs, into an overarching age range of introduction of CFs in these studies (e.g. an introduction of CFs at 3-4 months and one at 4 months is summarised into an age of 3-4 months).
Questions related to upcoming EFSA Opinion on the Tolerable Upper Intake Level of dietary sugars		
Emilie Leibovitch Majster CEFS, the European association of sugar manufacturers	1) Since a linear dose-response most likely results in an elevated risk that starts above zero consumption and since biological systems are characterized by thresholds, what is the starting point of the dose-response relationship? 2) What are the criteria that EFSA accepts as sufficient evidence? Can an upper limit be based solely on cohort studies or should also evidence from clinical trials be available? 3) How will EFSA use info on frequency of, for instance, daily SSB (sugar-sweetened beverages) servings? Is an upper limit formulated in daily/weekly/monthly frequency of a serving (size) acceptable for EFSA to quantify the intake of sugars? Based on 91st NDA Panel meeting minutes and p.16 of EFSA protocol, CEFS is not clear about what EFSA will do with observational	***Ad1:*** The starting point is often given by data availability, e.g. the lowest dose tested in intervention studies or the lowest dose consumed in observational studies. Non-linear dose-response models would also be explored when possible. ***Ad2:*** Whether a UL can be set or not would depend on data availability (evidence for a dose-response relationship with a threshold for adverse events). Evidence integration (e.g. from intervention and observational studies, where available) can be an important step for setting ULs. ***Ad3:*** Observational studies reporting on frequency of consumption only have been excluded by protocol. If the paper reports on frequency of servings per unit of time and the serving size is known, a quantitative sugars intake could be calculated depending on the source. This work is ongoing, no details can be given at present. ***Ad4:*** For intervention studies, data analysis will consider whether the study was done, by design, in eucaloric

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	studies that provide only information on frequency of consumption 4) Regarding the confounding and effects modification in the context of EFSA' systematic review, when adjusting is done for energy intake, will it be done by partitioning the energy intake coming from sugars and that coming from other sources?	conditions, in hypercaloric conditions, or *ad libitum*. For observational studies, for which aggregated (and not individual) data will be available, how energy intake has been taken into account in statistical models will depend on the authors' choice and will be reported accordingly.
Questions related to DRVs on Sodium		
CREA AN working group	1) Congratulations on your work. We wonder why stroke has been inserted among selected health outcomes to inform the setting of DRV for sodium, since it does not meet 2 out of 3 panel criteria (that are: 1 Type of evidence, 2 Biological relevance for the general healthy population, 3 Biological plausibility (annex A section 2.4)). In fact, the evidence linking a reduction of sodium intake with an increase of stroke is very weak and inconclusive, moreover, the mechanism by which sodium could be inversely associated with the risk of stroke remains absolutely unclear (no biological plausibility) 2) A question arises from table 10. The rationale associated with the choice 2.5-3.5 g / day as AI for sodium is not clear (for me). The other choices in table 10 are well referenced but this choice does not seem well referenced. This point inserted in the curve of figure 3 strongly influences the final value of AI.	***Ad1:*** These criteria were defined at the protocol stage to select the health outcomes that would be included in the assessment. This was to focus the work on the outcomes that would most likely provide evidence that could be used to inform the setting of DRVs. On the basis of these criteria several health outcomes were excluded 'a priori' (eg. stomach cancer, kidney function) and two categories of endpoints were retained: CVD related outcomes (blood pressure, risk of hypertension and cardiovascular diseases, including stroke) and bone health. These criteria were NOT meant to select the health outcomes that would be retained for drawing conclusions. The strength of the evidence and the lack of biological mechanisms about an inverse association between sodium intake and risk of stroke in the lower end of the sodium intake distribution is acknowledged and was considered when integrating the evidence. However, there was no scientific ground (e.g. methodological limitations, risk of bias) to dismiss this evidence fully.

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	3) Please, in relation to a previous question on table 10, we didn't catch how many experts voted for the AI of sodium.	***Ad2***: 5% probability was attributed to the range 2.5 and 3.5 g/day, driven by • limited evidence from the Holbrook balance study in free-living individuals that sodium balance was maintained with observed sodium intake in this range. Importantly this study was observational (measured actual sodium intake and excretion – did not test different sodium levels as in classical balance studies) and thus provide only limited evidence on what is the "lowest" level of sodium intake adequate for the majority of the population • the consideration that the value of interest should be adequate for the vast majority of the population. Having in mind that the main piece of evidence comes from one balance study conducted in healthy young males who could maintain balance with sodium intake of 1.5g/day, there are substantial uncertainties (because the lack of evidence available for other population groups) as to whether this value is adequate for the general population. Thus, experts judged that, on the basis of available evidence, it could not be fully excluded that this 'true' value would be in the range 2.5-3.5 g. Still, the probability that it would actually be the case was judged to be very low (5%). With respect to figure 3, the empirical probability distribution elicited from the experts on the sub-ranges of sodium intake (histogram) were used to compute centiles of the uncertainty empirical distribution and derive the cumulative probability function. Looking at the figure, we see that the 'true value' was judged to be actually BELOW 2.5 g/d with 95 % probability.

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		Ad3: We would like to clarify that experts did not "vote" for any value and that the uncertainty probability distributions do not quantify variation in opinion between experts or the number of experts who expressed a particular judgement (not frequency histograms). They represent the consensus judgement of the experts about the value of the quantity elicited through the EKE.
Javier Garcia Campofrio	What is the method of choice for measuring sodium levels	Regarding the quantification of sodium content in foods, standards are established by the Codex Alimentarius by categories of commodities (Codex Committee on Methods of Analysis and Sampling; e.g. CODEX STAN 234-1999). Advice on analytical methods for measuring sodium is outside of the scope of our work.
Others		
Guillermo Spaini Cedyat	Analisis de riesgo de la informacion al consumidor sobre trazabilidad de sus productos. *[EN: Risk analysis on the consumer information on products traceability]*	Aspects related to consumer information / labelling & product traceability are outside the remit of EFSA, but under the responsibility of national competent authorities.
Alex Finck	The EU has in the past played decisive roles in changing consumer behaviours for example by fostering a phase-out of incandescent light bulbs. Following a Workshop "Autoimmune Diseases – Modern Diseases", held at the European Parliament in Brussels on Monday 25 September 2017, not much seems to have been done to address raised concerns about the interaction diet*autoimmunity. What are	EFSA was not involved in that workshop and no question on that topic was sent to EFSA. EFSA's role is to provide EU risk managers (EC, European Parliament, Member States) with scientific and technical support in order to inform management decisions regarding the adoption and implementation of EU legislation. Risk management decision is outside the remit of EFSA.

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	future measures that may get implemented and have an impact on the general public in this area?	Impact on the general public and implementing measures in the EU are NOT under EFSA Remit but are for Risk Managers/Policy makers.
Antonio Server Gomez Consultora Hospitales y Compañías Aseguradoras de salud	Vemos frecuentemente en los medios de comunicación afirmaciones en cuanto alimentación de la población en general en la que no se cita ninguna referencia científica que lo avale. Esta en su ánimo en algún momento proponer que cualquier medio de comunicación de la comunidad europea, cuando habla de estos asuntos se asesore con ustedes y lo cite en su comunicación para mayor garantía de seguridad de las personas. *[EN: We often see on the media some statements on general population's nutrition without citing any supporting scientific evidence. Are you planning to propose that before EU media can make such statements they get your previous advice and then refer to it to confirm the safety guarantee for the population]*	It's one of EFSA's core tasks to communicate its advice clearly not only to its principal partners and stakeholders but also to the public at large. EFSA work closely with the media as part of this, which includes interviews with EFSA scientific experts, providing background to journalists and seeking rectifications for false statements. However, EFSA cannot impose any measures on media.
Bronson Eran'Ogwa The Source Plus	On pesticide residues in food: Small scale farmers account for 92% of food produced in the world, what is EFSA doing to ensure that the small scale farmers meet this requirement without being suppressed in terms of low yields?	Aspects related to compliance with regulatory requirements set for pesticides residues in food and impact on small scale farmers are outside the remit of EFSA, but under the responsibility of national competent authorities.

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Rosalía Flores-Vidal Pen & Tec Consulting SLU	"If a certain mineral is used in a processing aid for a food supplement, and in the final product there are salts of this mineral, should it be considered that the mineral is present and should be labelled. E.g. nickel without UL or DRV?"	In the case of novel foods: Specifications of the food should specify if traces are left in the NF (e.g. cadmium). For food supplements: Directive 2002/46/EC sets out specific labelling requirements for food supplements. Labelling aspects are under the remit of Member States who monitor the placing on the market in their territory of a food supplement. The requestor is invited to check with national competent authorityies.