RISK ASSESSMENT OF NOVEL FOODS

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EUROPEAN FOOD SAFETY AUTHORITY

PRESENTATION OUTLINE

EFSA NOVEL FOODS FRAMEWORK

- What is a novel food?
- How are novel foods regulated?
- How are novel foods assessed?

NOVEL FOODS IN THE EU

- What are the different categories of novel foods?
- What are the trends in novel foods at the moment?
- Recent examples

EFSA NOVEL FOODS FRAMEWORK

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WHAT IS A NOVEL FOOD?

Foods or ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997

- Phenylcapsaicin
- Non-sticky base for chewing gum
- Ice-structuring protein

New synthetised or isolated compounds


- Krill oil
- Lycopene from *Blakeslea trispora*
- Yellow mealworms (*Tenebrio molitor*)

New sources

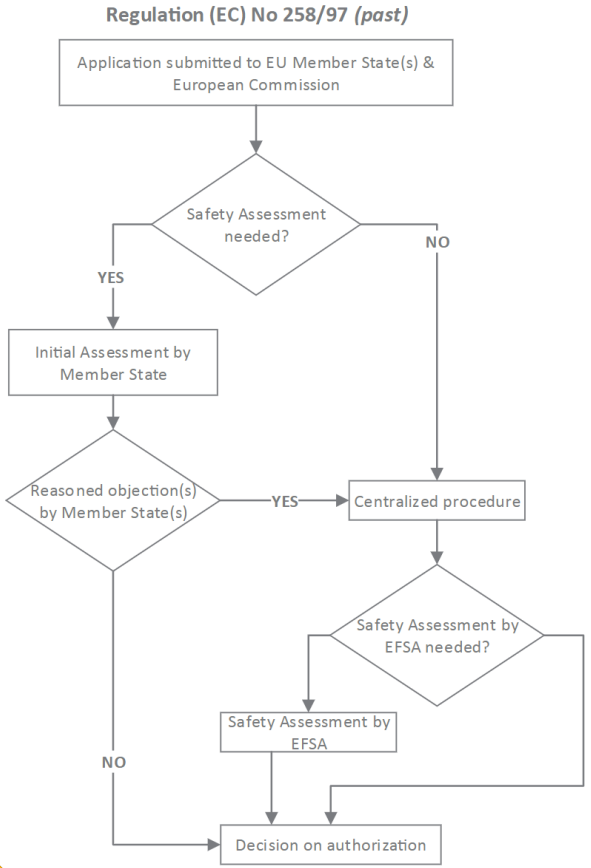

- UV-treated yeast or mushrooms
- Milk products fermented with *B. xylanisolvens*

New processes & technologies


- Haskap berries
- Cacao pulp
- Coffee leaves

Traditional foods (non-EU countries)


NOVEL FOODS REGULATION IN THE EU



European Commission

efsa European Food Safety Authority

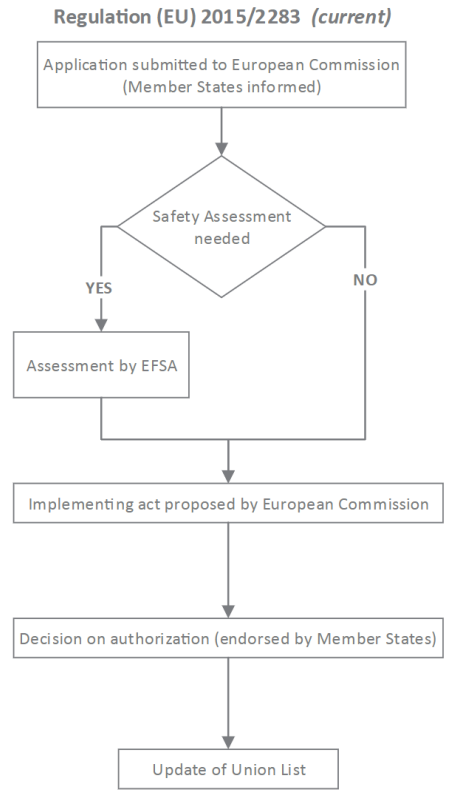
Risk assessment by Member States, European Commission and EFSA (*ad hoc*)

Regulation (EC) No 258/97

Regulation (EU) 2015/2283

From January 2018, centralised risk assessment by EFSA

efsa EUROPEAN FOOD SAFETY AUTHORITY



Ververis et al. Food Research International, 2020

NOVEL FOOD AUTHORISATION PROCEDURE

European Commission

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European Commission

NF: 9 months
TF: 4 months

Submit a dossier according to the Novel Food (NF) or Traditional Food (TF) Guidance

Validate the dossier
Mandate EFSA to carry out the risk assessment (NF only)

Carry out the risk assessment (NF)
May request additional information to the applicant (NF) or raise duly reasoned safety objections (TF)

Decide on market authorisation
Integration to the Union List of authorized novel foods

RISK ASSESSMENT PROCESS

EFSA Scientific Officers
Nutrition & Food Innovation Unit

Working Group on Novel Foods
14 experts

Panel on Nutrition, Novel Foods and Food Allergens
16 experts

NOVEL FOOD GUIDANCE (2016 & 2021)

- Administrative data
- Introduction
- Identity of the novel food
- Production process
- Compositional data
- Specifications
- History of use of the novel food and its source
- Proposed uses and use levels, anticipated intake
- Absorption, distribution, metabolism, excretion (ADME)
- Nutritional information
- Toxicological information
- Allergenicity
- Conclusions

SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 21 September 2016

doi: 10.2903/j.efsa.2016.4594

Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

EFSA Panel on Dietetic Products, Nutrition and Allergie
Dominique Turck, Jean-Louis Bresson, Barbara Burlingame
Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Erns
Harry McArdle, Androniki Naska, Monika Neuhäuser-Berthold,
Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Marti
Marco Vinceti, Peter Willatts, Karl-Heinz Engel, Rosangela Marche
Morten Poulsen, Seppo Salminen, Josef Schlatter, Davide Arcella,
Agnès de Sesmaisons-Lecarré, Hans Verhagen and Hendrik

Abstract

Following the adoption of Regulation (EU) 2015/2283 of the European Parl
on novel foods, the European Commission requested EFSA to update a
technical guidance for the preparation and presentation of applications
foods. This guidance presents a common format for the organisation
presented in order to assist the applicant in preparing a well-structured appl
safety of the novel food. The application should be comprehensive and
outlined the data needed for the safety assessments of novel foods. Requ
covered in all applications relate to the description of the novel f
compositional data, specification, proposed uses and use levels, and antic
food. Further sections on the history of use of the novel food and/
distribution, metabolism, excretion, nutritional information, toxicological int
should be considered by the applicant by default. If not covered in the
justified. The applicant should integrate the data presented in the differen
overall considerations on how the information supports the safety of t
proposed conditions of use. Where potential health hazards have been
discussed in relation to the anticipated intakes of the novel food and the pr
On the basis of the information provided, EFSA will assess the safety of
proposed conditions of use.

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GUIDANCE

EFSA Journal

doi:10.2903/j.efsa.2021.6555

Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283[1] (Revision 1)[2]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA),[3]
Dominique Turck, Jean-Louis Bresson, Barbara Burlingame, Tara Dean,
Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf,
Harry J McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grazyna Nowicka,
Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé,
Marco Vinceti, Peter Willatts, Karl-Heinz Engel, Rosangela Marchelli, Annette Pöting,
Morten Poulsen, Seppo Salminen, Josef Schlatter, Davide Arcella, Wolfgang Gelbmann,
Agnès de Sesmaisons-Lecarré, Hans Verhagen and Hendrik van Loveren

Endorsement date	**21 January 2021**
Implementation date	**27 March 2021**

Abstract

Following the adoption of Regulation (EU) 2015/2283 on novel foods, the European Commission requested EFSA develop scientific and technical guidance for the preparation and submission of applications for authorisation of novel foods. This guidance presents a common format for the organisation of the information to be presented by the applicant when preparing a well-structured application to demonstrate the safety of the novel food. It outlines the data needed for the safety assessments of novel foods. Requirements relate to the description of the novel food, production process, compositional data, specification, proposed uses and use levels, and anticipated intake of the novel food. Further sections on the history of use of the novel food and/or its source, absorption, distribution, metabolism, excretion, nutritional information, toxicological information and allergenicity should be considered by the applicant by default. If not covered in the application, this should be justified. The applicant should integrate the data presented in the different sections to provide their overall considerations on how the information supports the safety of the novel food under the proposed conditions of use. Where potential health hazards have been identified, they should be discussed in relation to the anticipated intakes of the novel food and the proposed target populations. On the basis of the information provided, EFSA will assess the safety of the novel food under the proposed conditions of use.
This guidance was originally adopted in 2016. It has been revised to inform applicants of the new provisions introduced by Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain. This revised guidance

[1] The guidance was adopted on 21 September 2016 by the former Panel on Dietetic products, Nutrition and Allergies. This revision only aims to inform applicants of the new provisions introduced by the General Food Law (Regulation (EC) No 178/2002, as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain), and to guide to EFSA's practical arrangements implementing these new provisions. For this purpose, the revision concerns only the administrative part. The scientific content remains unchanged. The present guidance (revision 1) was endorsed on 21 January 2020 by the Panel on Nutrition, Novel Foods and Food Allergens (NDA): Dominique Turck, 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 and Marco Vinceti.

[2] As of 1 July 2018, it has been renamed 'Panel on Nutrition, Novel Foods and Food Allergens (NDA)'

FUNDAMENTAL PRINCIPLES

The novel food shall be safe under the proposed conditions of use

The novel food cannot be nutritionally disadvantageous

The efficacy of the novel food is not assessed

NOVEL FOODS IN THE EUROPEAN UNION

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NOVEL FOOD CATEGORIES | REGULATION (EU) 2015/2283

- New production process
- New or modified molecular structure
- From microorganisms, fungi or algae
- From plants or their parts
- Vitamins and minerals from new process / nanomaterials
- Of mineral origin
- From animals or their parts
- Cell or tissue cultures derived from the living
- Engineered nanomaterials
- Exclusive use in food supplements prior to May 1997

NOVEL FOOD APPLICATIONS UNDER RISK ASSESSMENT

TRENDS IN THE NOVEL FOODS AREA

NOVEL PROTEINS AND THEIR SOURCES

NOVEL PROTEINS AND THEIR SOURCES

Traditional sources & novel processing*

Novel sources

Insects

Plant-based

Algae

In vitro meat

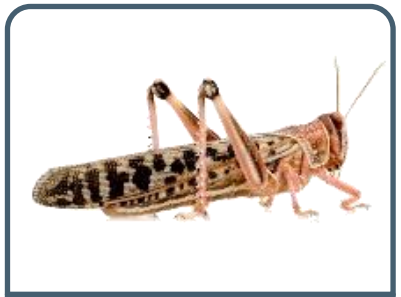
Fungi

By-products

*Food processes not used within the EU before 15/05/1997, with a potential significant impact on the product

INSECTS & PRODUCTS THEREOF

Acheta domesticus adults (house cricket)



Locusta migratoria adults (grasshoppers)

Tenebrio molitor larvae (yellow mealworm)

Alphitobius diaperinus larvae (lesser mealworm)

Hermetia illucens larvae

Apis mellifera (honey bee drone)

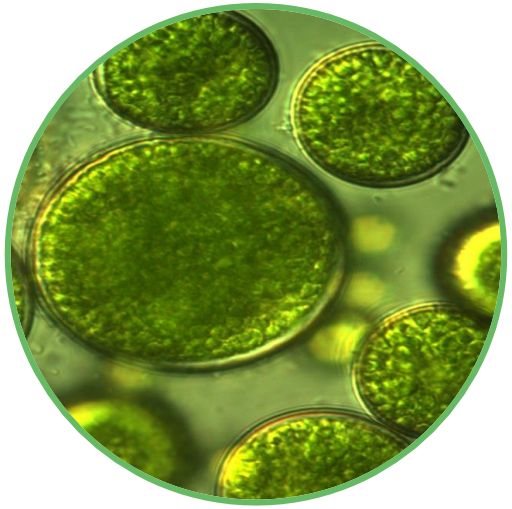
Gryllodes sigillatus adults (banded cricket)*

- 17 novel food applications
- Alternative source of proteins and fat
- Frozen, dried, powder

PLANTS & PRODUCTS THEREOF: PROTEIN CONTENT

				
Rapeseed powder & protein isolate	**Mung bean protein powder**	**Alfalfa protein concentrate**	**Chia seeds**	**Water lentil powder**
Powder: 33-43 % Isolate: ≥ 90 %	85 %	45 - 60 %	Seeds 15-26 % Powder ≥ 40 %	35-55 %

ALGAE & PRODUCTS THEREOF

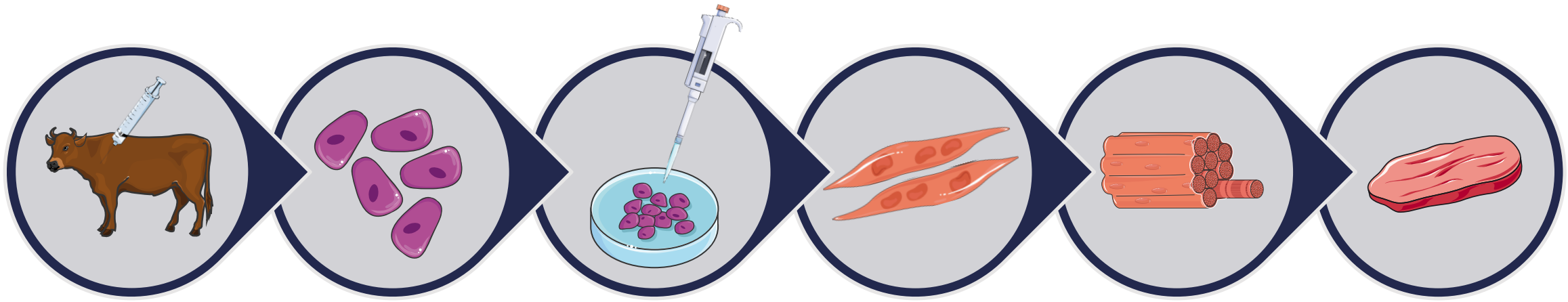
Macroalgae

- *Laminaria digitata*

Microalgae

- *Galdieria sulphuraria*
- *Tetraselmis chuii*
- *Phaeodactylum tricornutum*
- *Schizochytrium* sp.

CELL-CULTURED DERIVED FOODS

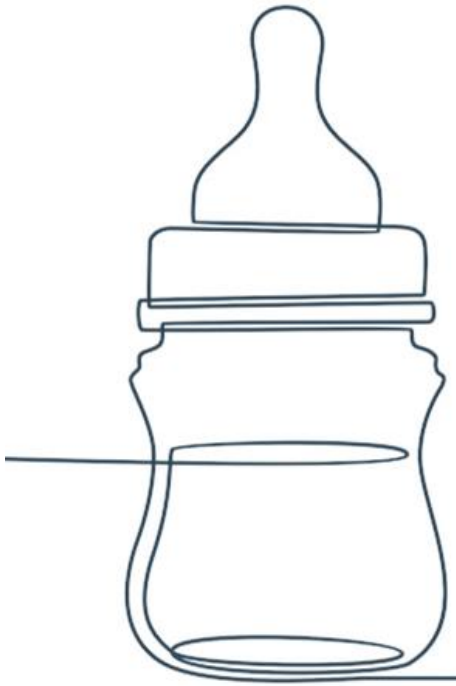


Simplified view of the production process

NOVEL CARBOHYDRATES

HUMAN IDENTICAL MILK OLIGOSACCHARIDES (HiMOs)

- HiMOs are substances that are identical to HMOs (oligosaccharide fraction of milk)
- Produced through chemical synthesis and/or microbial fermentation
- Use in food products (*e.g.*, infant and follow-on formula) and food supplements



- *2'-O-fucosyllactose (2'-FL)*
- *Lacto-N-neotetraose (LnNT)*
- *3'-sialyllactose (3'-SL) sodium salt*
- *N-acetyl-D-neuraminic acid (NANA)*
- *Lacto-N-tetraose (LNT)*
- *6'-sialyllactose (6'-SL) sodium salt*
- *Difucosyllactose (DFL)*

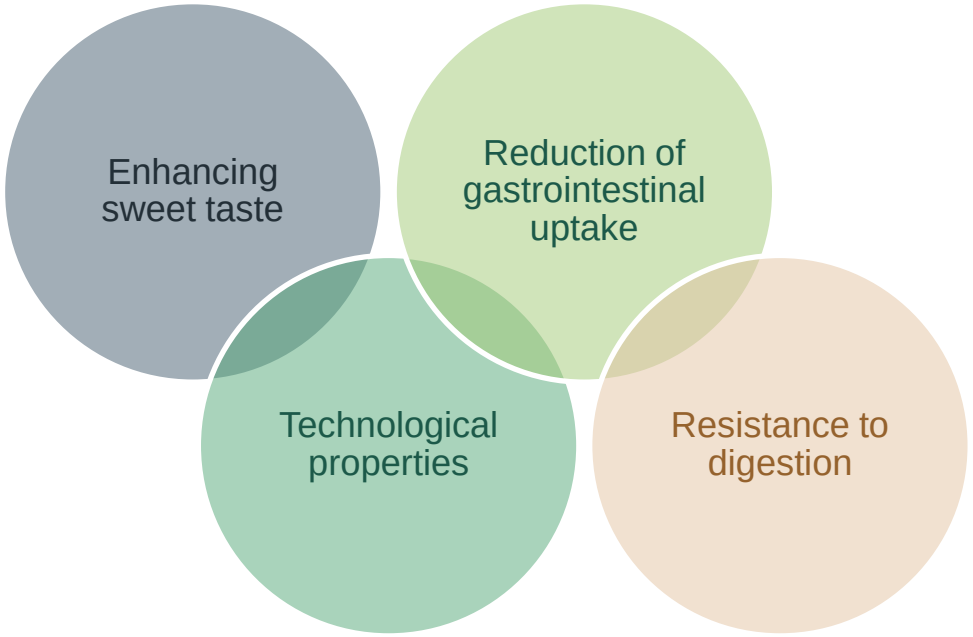
SUGAR REPLACERS

All mono-, di- and oligo-saccharides with new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997

Starch hydrolysates
Other sugars

Enzymatic reactions

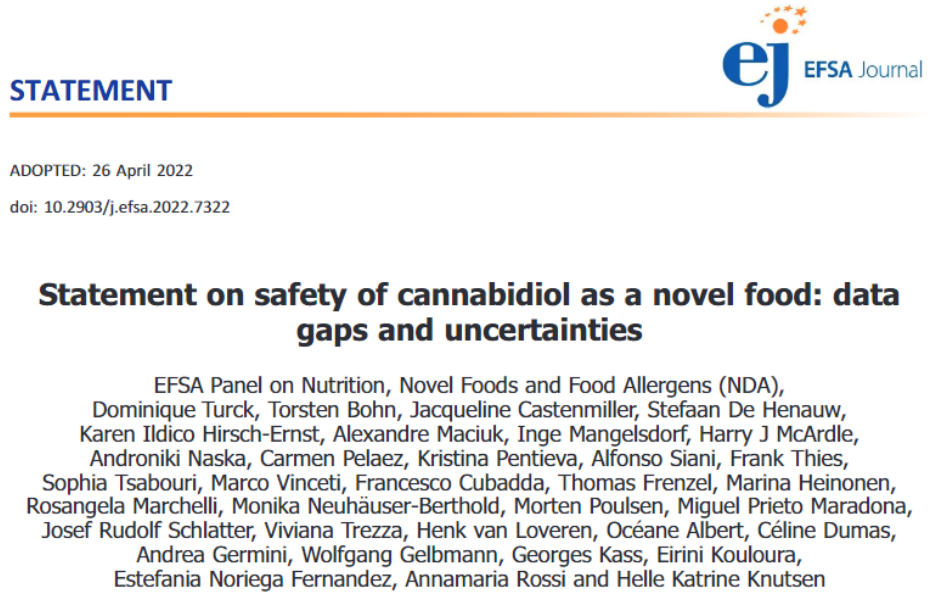
- Isomaltulose
- Isomalto-oligosaccharide
- Galacto-oligosaccharides
- Allulose
- Cellobiose



PLANT EXTRACTS

PLANT EXTRACTS: THE EXAMPLE OF CBD

- Cannabidiol (CBD) extracted from *Cannabis sativa L.* or chemically synthetised
- Authorized in the EU as orphan drug for the treatment of rare epilepsies (Epidyolex®)
- European Court of Justice (Nov. 2020) decided that CBD was not a narcotic and should be considered as novel for uses as food ingredients and supplements
- 20 dossiers under evaluation at EFSA, >150 dossiers at the European Commission level
- All dossiers under assessment at EFSA were requested additional data to fill in the data gaps identified in the Statement



STATEMENT

EFSA Journal

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Statement on safety of cannabidiol as a novel food: data gaps and uncertainties

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA), Dominique Turck, Torsten Bohn, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri, Marco Vinceti, Francesco Cubadda, Thomas Frenzel, Marina Heinonen, Rosangela Marchelli, Monika Neuhäuser-Berthold, Morten Poulsen, Miguel Prieto Maradona, Josef Rudolf Schlatter, Viviana Trezza, Henk van Loveren, Océane Albert, Céline Dumas, Andrea Germini, Wolfgang Gelbmann, Georges Kass, Eirini Kouloura, Estefania Noriega Fernandez, Annamaria Rossi and Helle Katrine Knutsen

QUESTIONS ?

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