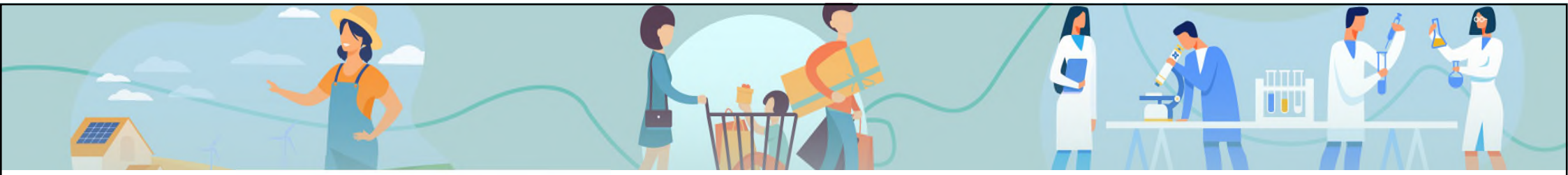

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28 – 30 SEPTEMBER 2021, Parma

Food Safety Aspects of Integrated Food Systems

Trends in Novel Foods

Andrea Germini
Team leader Novel Foods
EFSA

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Outline

EFSA Novel foods risk assessment context

Alternative proteins and their sources

Novel carbohydrates

Other Trends in Novel Foods

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EFSA Novel foods risk assessment context

Novel foods framework

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WHY

Regulation (EU) 2015/2283 introduces a **centralised assessment** and authorisation procedure for novel foods as of January 2018

WHAT

Novel foods (NF) are "foods or ingredients that have not been used for human consumption to a significant degree in the EU **before 15 May 1997**"

WHEN

EFSA has a **legal deadline** to adopt its scientific opinion within **9 months** from the date of receipt of a valid application from the EC

HOW

Data requirements for NF applications are outlined in "**EFSA Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283**"

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What is a Novel food in the EU?

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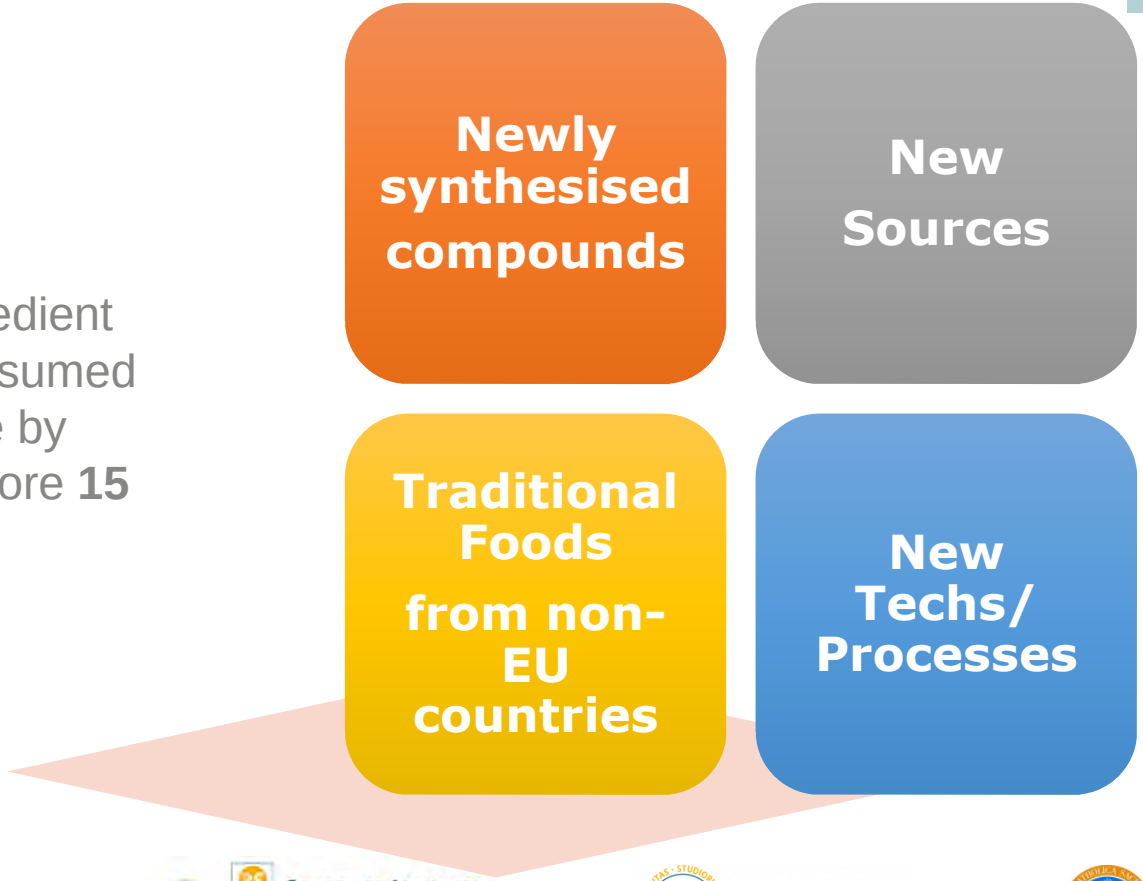
Novel Food
defines a food or ingredient that has not been consumed to a significant degree by humans in the EU before **15 May 1997**



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Novel foods categories

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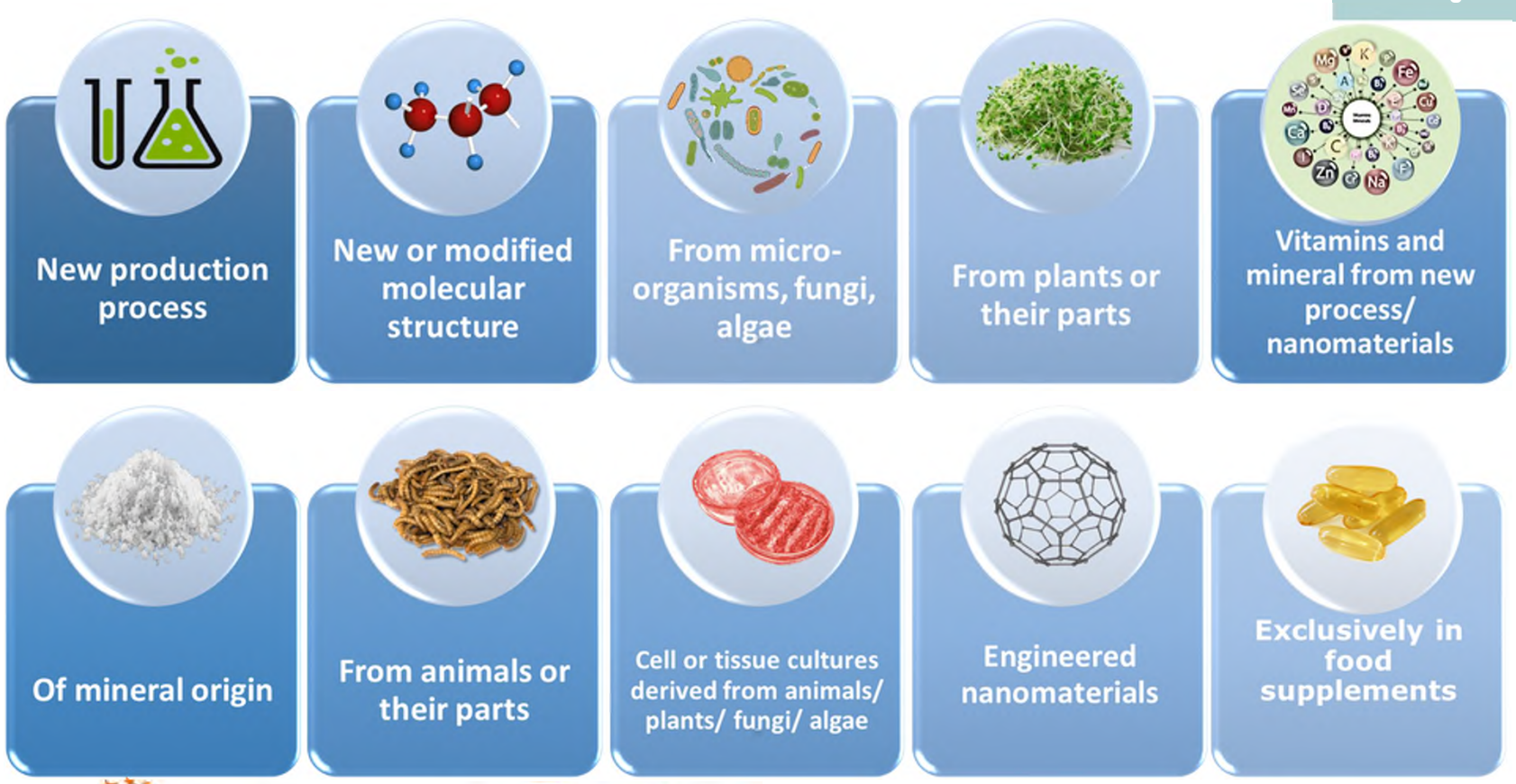

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Examples of Novel foods

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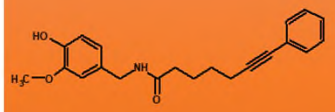
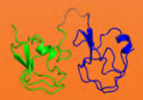
Newly synthesised/ isolated compounds



Phenylcapsaicin

Non-sticky chewing gum base



Ice-structuring protein

New Sources

Krill oil

Lycopene from *B. trispora*

Yellow mealworms *(Tenebrio molitor)*

Traditional Foods from non-EU countries

Haskap berries

Cocoa pulp

Coffee leaves

New Technologies/ Processes

UV treated yeast

UV treated mushrooms

Milk products fermented with *B. xylanisolvens*

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Novel foods applications by category

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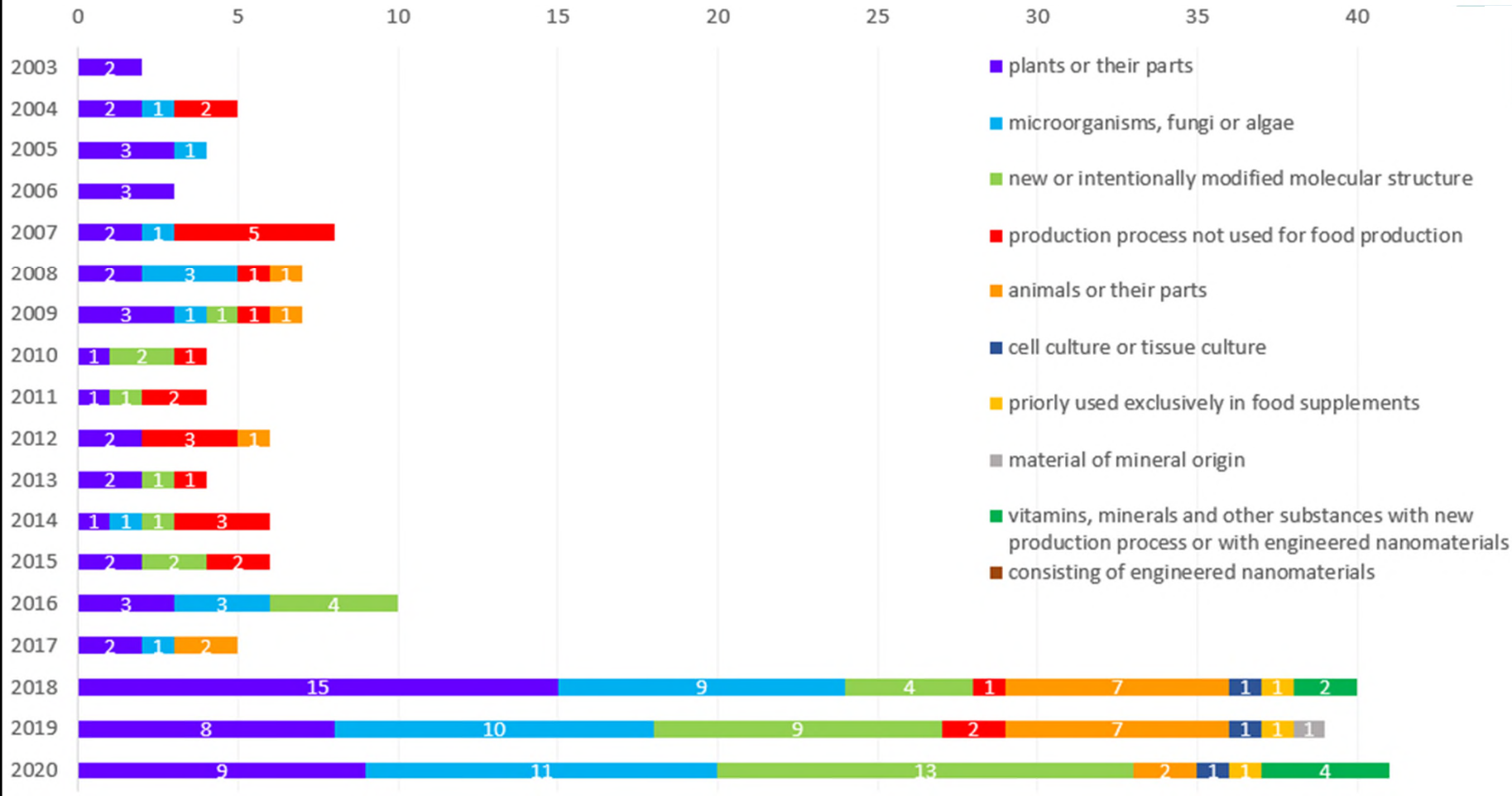

Updated from Ververis et al. Food Research International, 2020.

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Risk assessment of Novel foods

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

EFSA shall consider the following:

- ✓ whether the NF is **safe** under the proposed conditions of use
- ✓ whether the normal consumption of the NF would be **nutritionally disadvantageous**

SCIENTIFIC OPINION

ADOPTED: 21 September 2016

doi: 10.2903/j.efsa.2016.4588

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

Abstract

Following the adoption of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, the European Commission requested EFSA to update and develop scientific and technical guidance for the preparation and presentation of applications for authorisation of novel foods. This guidance presents a common format for the organisation of the information to be presented in order to assist the applicant in preparing a well-structured application to demonstrate the safety of the novel food. The application should be comprehensive and complete. This guidance outlined the data needed for the safety assessments of novel foods. Requirements which should be covered in all applications 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.

Keywords: guidance, novel foods, traditional foods, authorisation, safety, toxicity

Requestor: European Commission

Question number: EFSA-Q-2014-00216

Correspondence: nda@efsa.europa.eu

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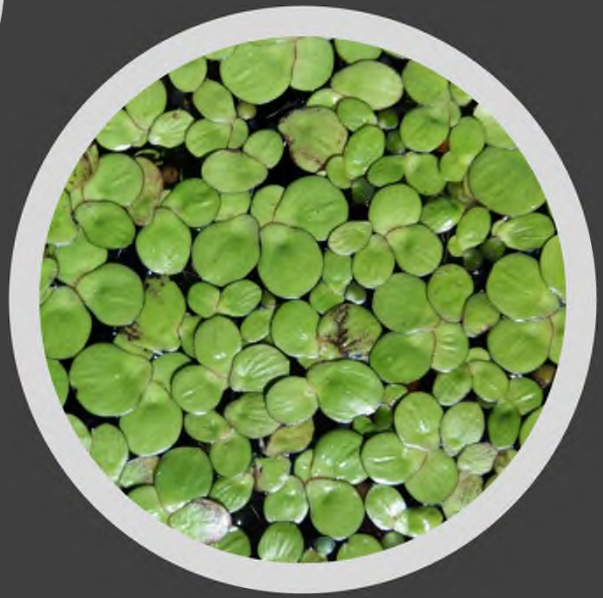

Alternative proteins and their sources

Plants & products thereof

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Alfalfa protein concentrate

- **45 - 60 % protein**
- L-canavanine
- Phytoestrogens
- Saponins
- Phytate

Rapeseed powder & protein isolate

- **Powder 33–43 % protein, isolate ≥ 90 % protein**
- Glucosinolates
- Phytate
- Erucic acid

Chia seeds

- **seeds 15-26 % proteins, powder ≥ 40 % protein**
- Phenolic acid derivatives and flavonoids
- Process contaminants

Insects & products thereof

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Acheta domesticus (crickets)


Locusta migratoria (grasshoppers)


Gryllodes sigillatus (house cricket)


Tenebrio molitor


Alphitobius diaperinus


Hermetia illucens

Apis mellifera (honey bee drone)

EFSA has been assessing so far 17 novel foods applications covering 7 insect species.

To date EFSA adopted 4 opinions covering products derived from 3 species

Tenebrio molitor larvae
Acheta domesticus
Locusta migratoria

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(Micro)Algae & products thereof

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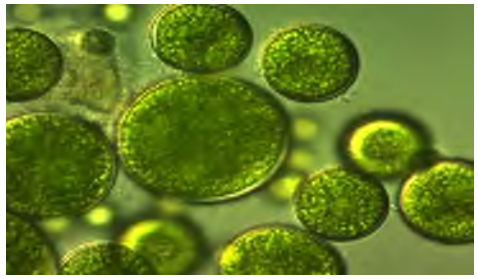

Macroalgae

- *Laminaria digitata*

Microalgae

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

- Nutrients
- Fibre
- Biomass
- Fatty acids
- Pigments
- …

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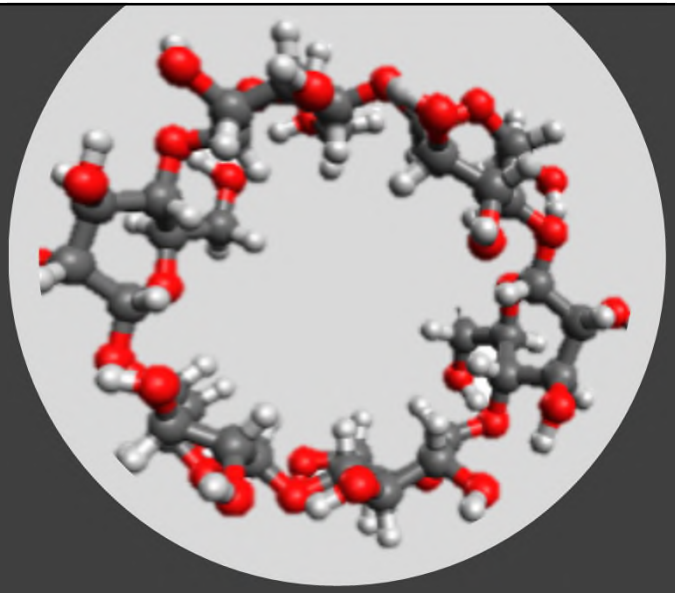

Novel carbohydrates

Sources and production processes

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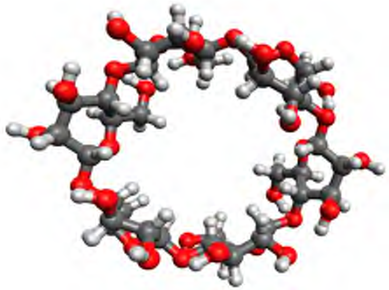
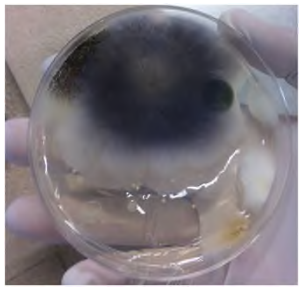
Alpha-cyclodextrin



- Starting material: starch
- Converted enzymatically into a circular structure

→ cannot be hydrolysed by human amylases

Chitin-glucan



- Starting material: cell wall of the mycelium of the fungi *Aspergillus niger*
- Obtained by fermentation
- Contains 90% chitin glucan

Fibre-rich biomass

- Starting material: Yeast cells of *Yarrowia lipolytica*
- Obtained by fermentation
- Dried biomass ~25% fibre (beta-glucan)
- Also enriched with Se or Cr

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Human identical milk oligosaccharides

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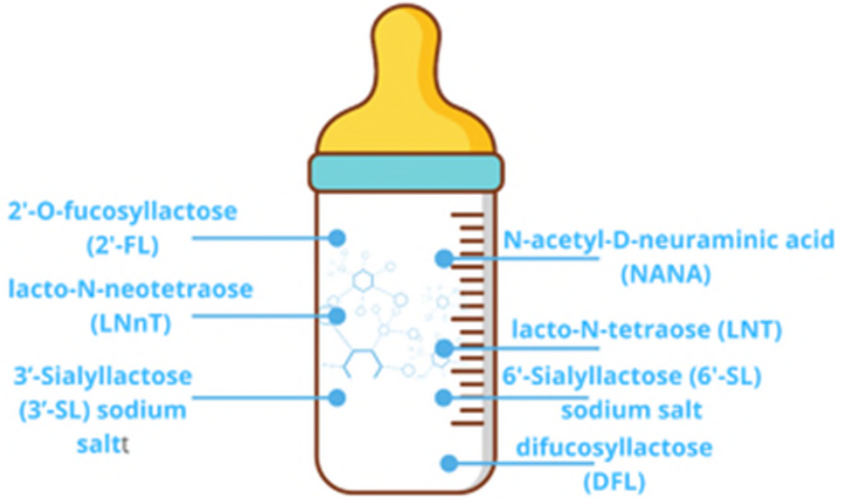
- HMOs: 3rd largest solid component (after lipids and lactose) of the breast milk (> 150 HMOs identified)
- HiMOs are substances that are identical to HMOs, produced through chemical synthesis or microbial fermentation
- Applications for use in infant and follow-on formulae, variety of food and food supplements
- EFSA has been assessing approximately 24 applications for HiMOs and finalized 10 of them



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Sugars replacers

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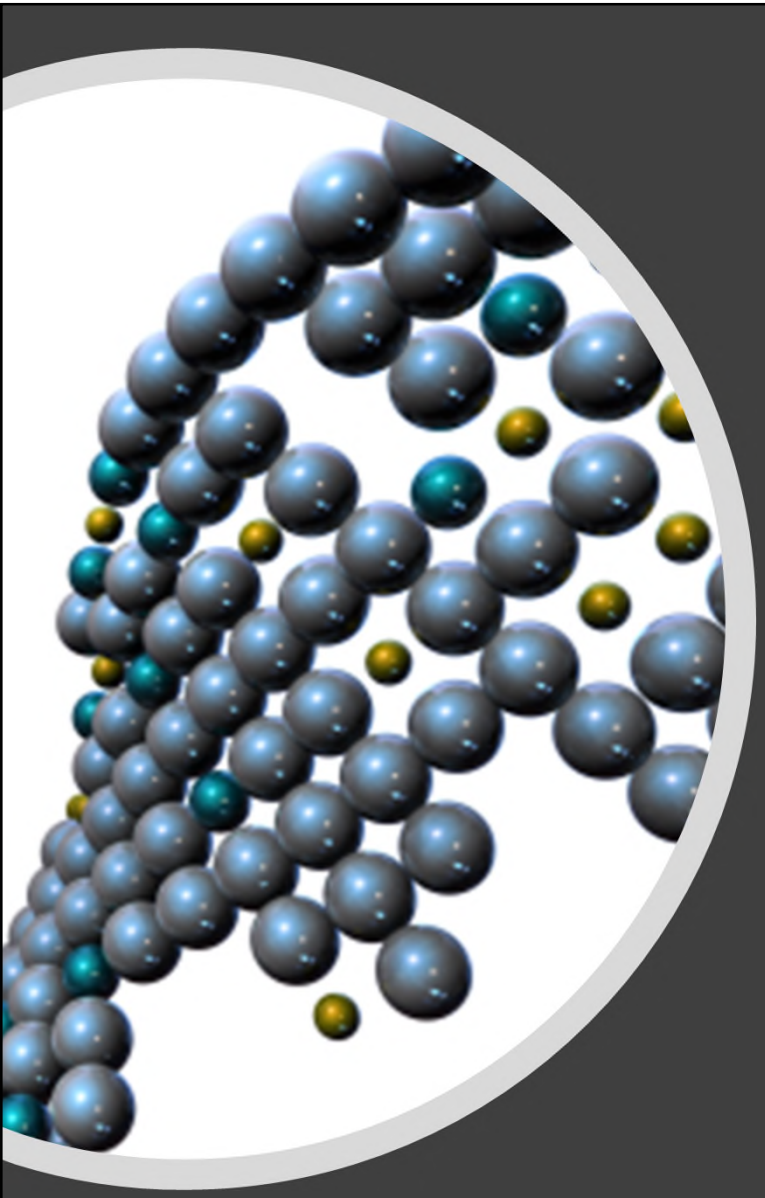
- All mono-, di- and oligo-saccharides with new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997 are considered novel foods
- Often obtained by enzymatic reactions from starch hydrolysate or from other sugars to e.g.
  - Enhance sweet taste
  - Obtain technological properties
  - Reduce substance gastrointestinal uptake
  - Resistant to diestion

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



Other Trends in Novel Foods

Plant extracts

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Cannabidiol (CBD) and hemp extracts

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- Cultivation of *Cannabis sativa L.* is permitted in the EU provided inclusion in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and THC content does not exceed 0.2 % (w/w)
- Extracts of *Cannabis sativa L.* and derived products containing cannabinoids are considered novel foods
- Synthetically obtained cannabinoids are considered as novel foods

Currently with EFSA:

- 5 applications for synthetic CBD
- 15 applications for CBD extracted from hemp

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Nanomaterials as/in novel foods

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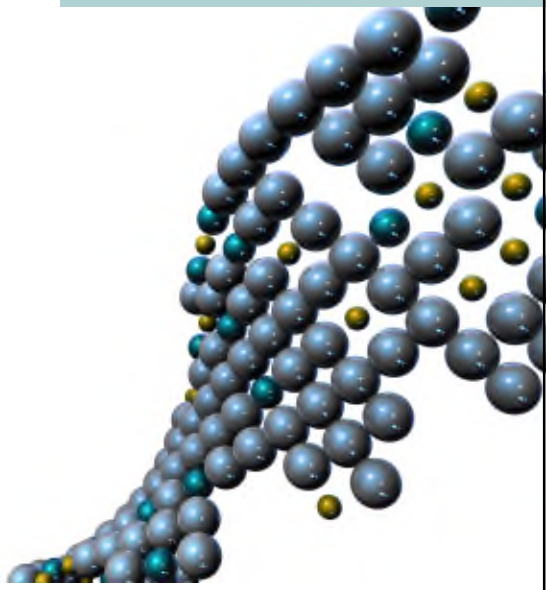

Engineered nanomaterials

EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health (2018)

- 1 ongoing application as source of iron

Nanoparticles

Draft EFSA Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles (2021)

- 8 ongoing applications

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Thank you

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