

Current trends in Novel Foods and their safety assessment

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Trusted science for safe food

Webinar „De la Piramida alimentară la Nutriția de precizie”

Outline of the presentation

Introduction

**Novel Foods
in the EU**

**Novel Food
Trends**

Conclusions

Introduction

European Food Safety Authority (EFSA)

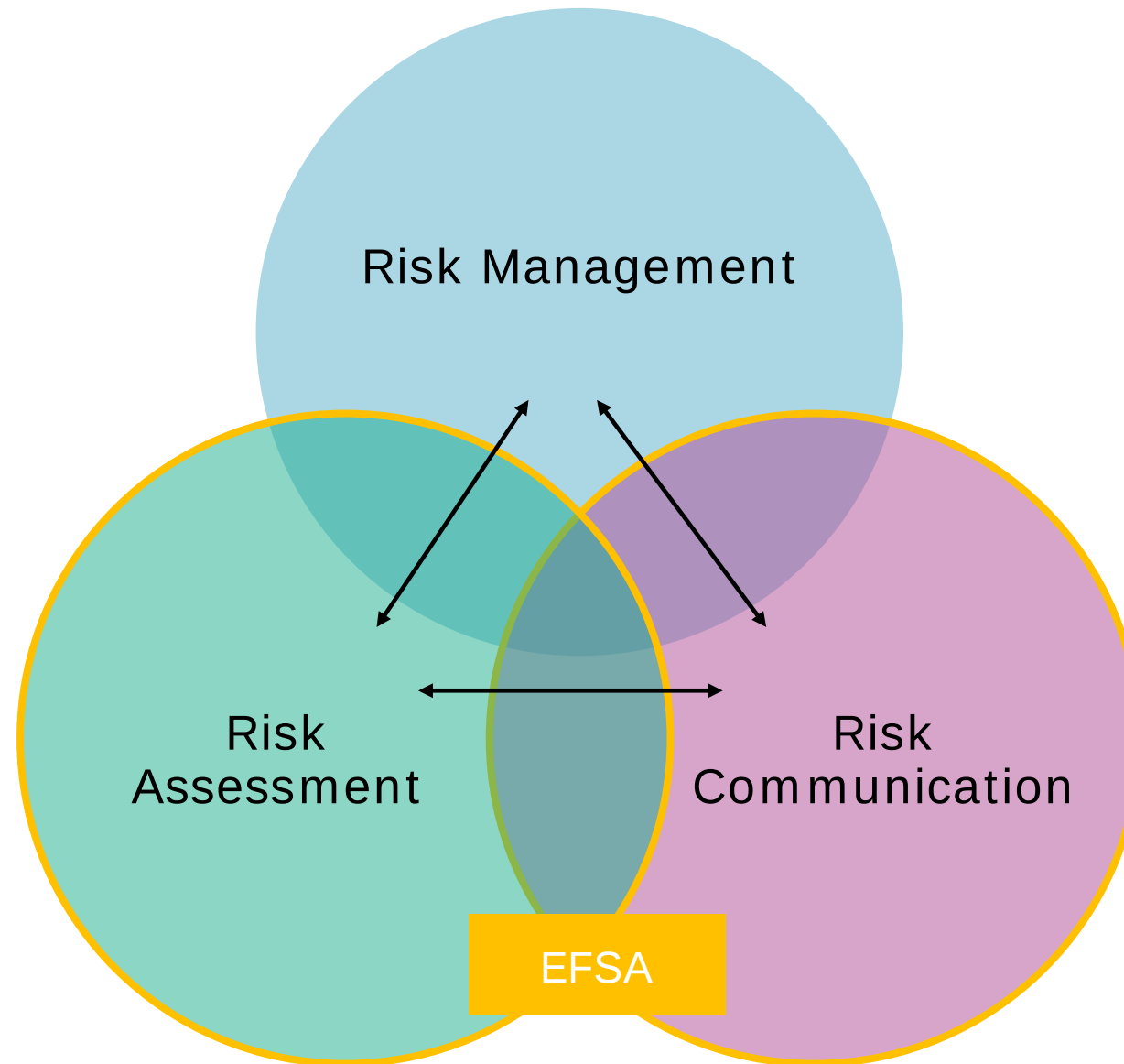


The reference body for risk assessment of food and feed in the European Union. Its work covers **the entire food chain – from field to fork**

Since 2002, one of the bodies responsible for **food safety** in Europe



Keeping Foods Safe in the European Union



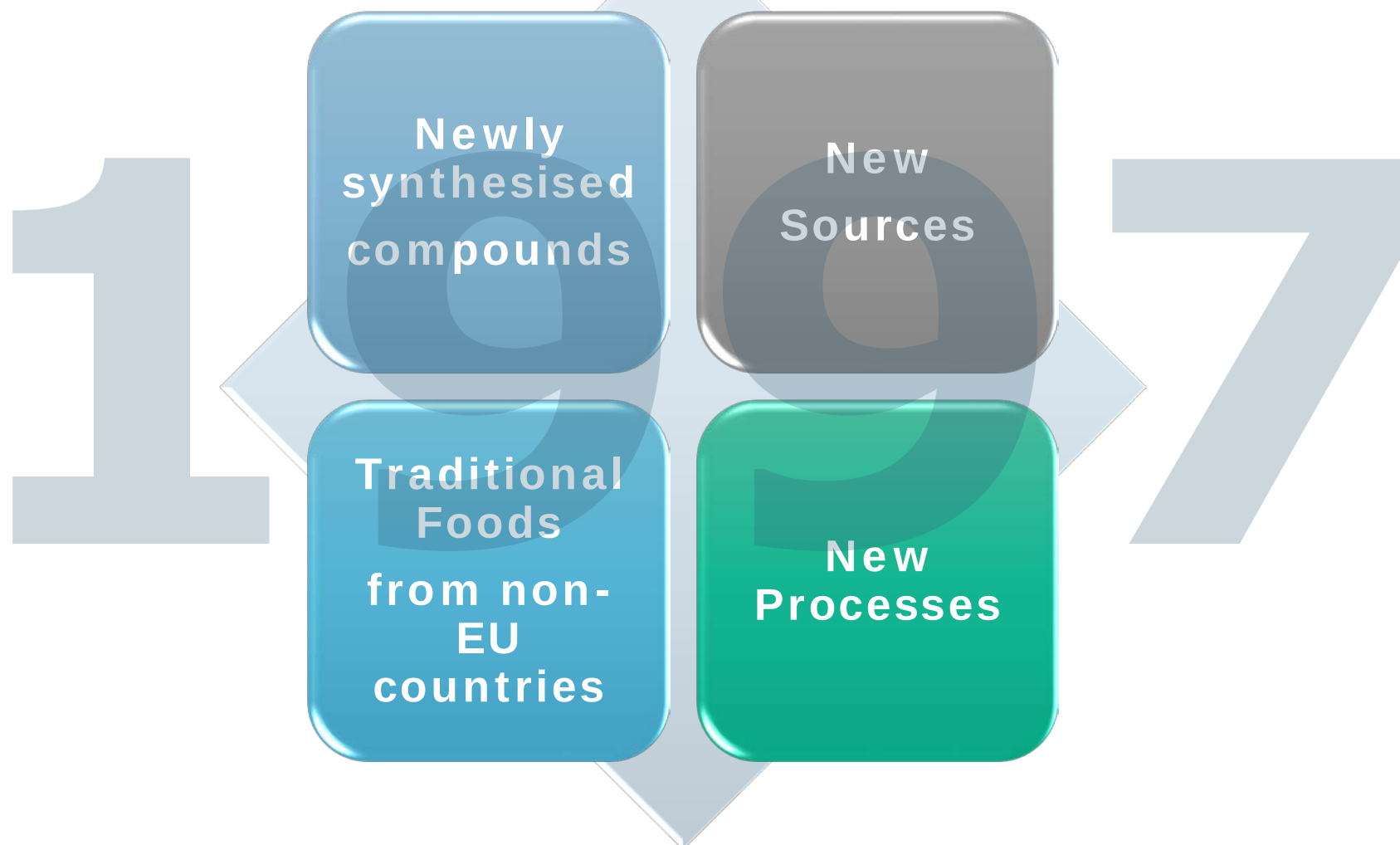
Novel Foods in the European Union

Novel Foods: Current Interest



What is a Novel Food?

“a food that was *not consumed to a significant degree by humans in the EU prior to 15 May 1997.*”



Regulation (EU) 2015/2283 on Novel Foods

NO

- Legislation
- Regulatory decisions
 - Classifications
 - Authorisations
 - Conditions of authorisations
 - Labelling, post-monitoring
- Law enforcement
 - Food inspections
 - Sanctions

YES

- Scientific advice
- Guidelines
- Safety assessment
- Collaboration
- Communication
 - risk managers
 - stakeholders



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**”)



WHY

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



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**”

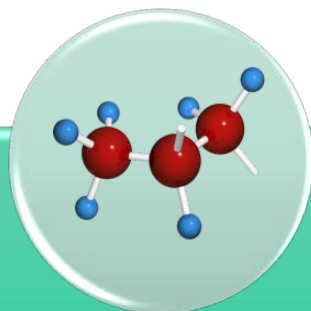


*EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA)

Novel Foods Categories



**New production
process**



**New or modified
molecular
structure**



**Micro-
organisms,
fungi, algae**



**From plants or
their parts**



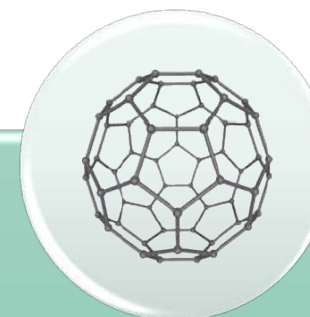
Of mineral origin



**From animals or
their parts**



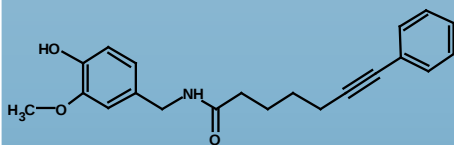
**cell or tissue cultures
derived from
animals/ plants/
fungi/ algae**



**Engineered
nanomaterials**

Examples of Novel Foods

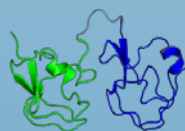
Newly synthesised / isolated compounds



Phenylcapsaicin



Non-sticky
chewing gum base

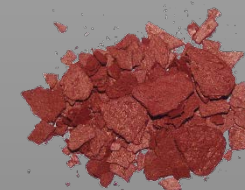


Ice-structuring
protein

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

- Administrative data
- Introduction
- 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

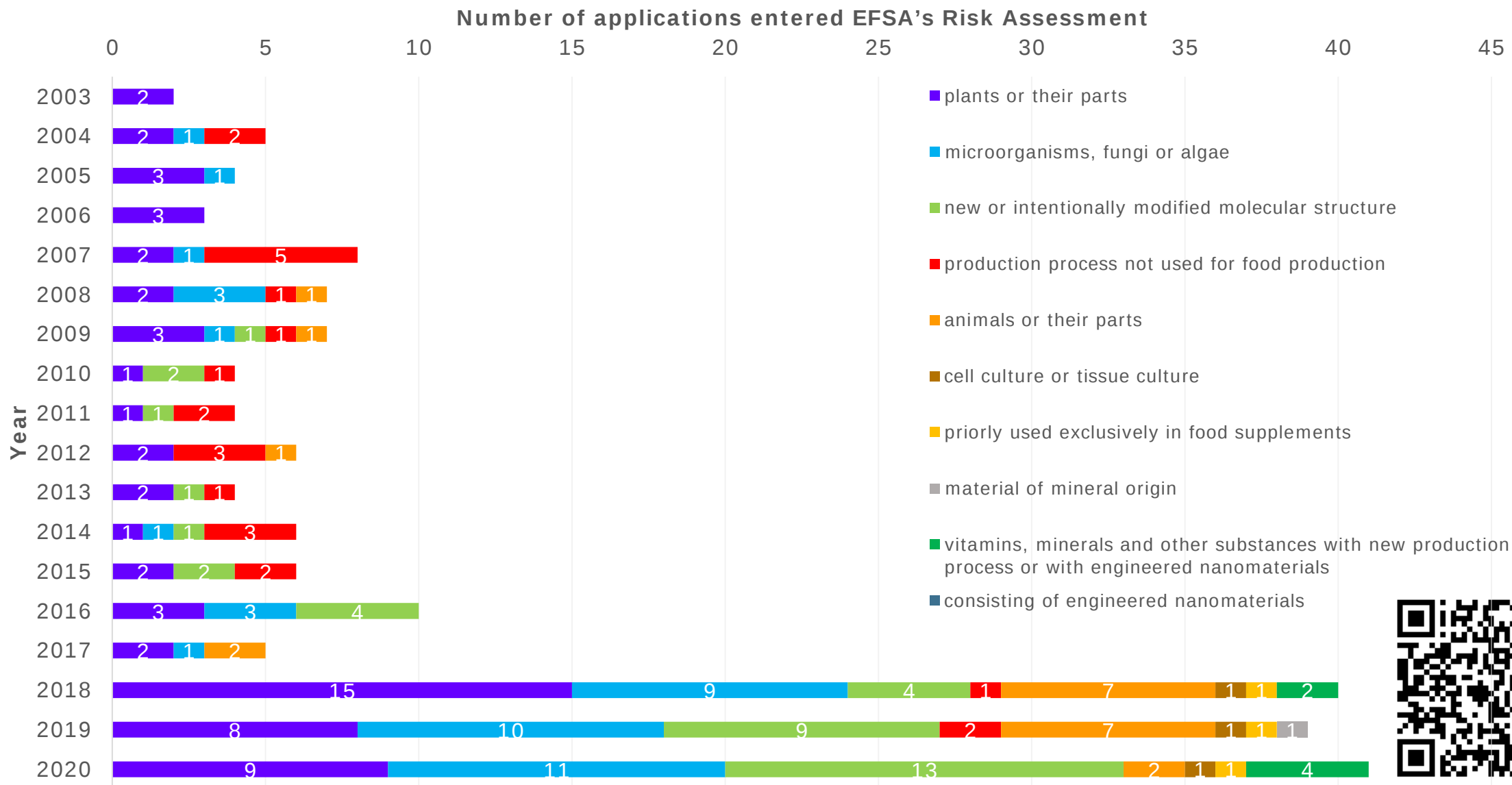
- Toxicological information
- Allergenicity
- Concluding remarks
- Annexes, references

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**

Novel Food Trends

Novel Food Applications by Category



Trends in the Novel Food area



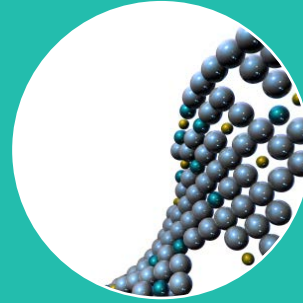
Alternative
proteins and
their sources



Novel
carbohydrates



Plant Extracts



Nanomaterials



Process-
related



Safety assessment of proteins and their sources as NFs



Safety assessment of Alternative proteins



Insects



**Plant-based
products**



Algae



***in vitro* meat**

Insects & Products thereof as Novel Foods

(NF dossiers received by EFSA) November 2021



Adults



Acheta domesticus



Locusta migratoria



Gryllodes sigillatus

Larvae



Tenebrio molitor



Alphitobius diaperinus



Hermetia illucens



Apis mellifera



Production process & Characterisation

- Impact of **feed** (bioaccumulation/cross-contamination)
- Harvest & **microbiological profile** (e.g. fasting step)
- **Processing contaminants**
- Whole insects: complex foods
- Qualitative and quantitative characterisation of the **main constituents** & proximate analysis
- Inherent substances of possible **concern** to human health
- **Nutritionally** relevant constituents (e.g. vitamins, minerals)
- **Stability** (microbiological & oxidative stability of fats)
- Quantification of **protein** and **interference of chitin**
- Analytical **accreditations** are **matrix-related**





Examples of NF applications

- Rapeseed protein
- Mung bean protein
- Water lentils
- Beet leaf protein
- Alfalfa protein



Examples and chemical profiles

Alfalfa protein concentrate



- 45 - 60 % protein
- L-canavanine
- Phytoestrogens (coumestrol and isoflavones)
- Saponins, phytate

Rapeseed powder & protein isolate



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

Mung bean protein



- >84 % protein
- Lectins
- Phytic acid
- Tannins
- Cyanogenic glycosides





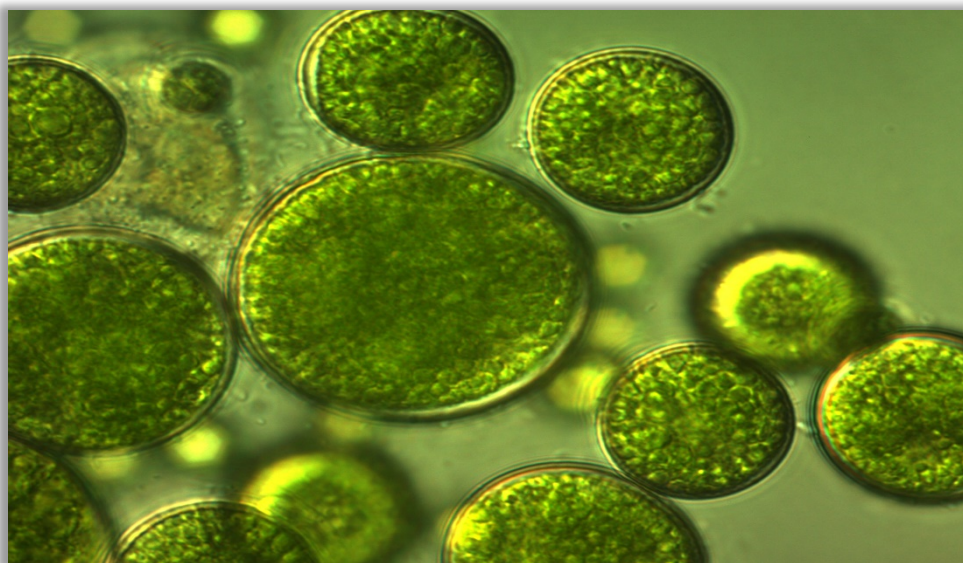
Examples of NF applications

Macroalgae

- *Laminaria digitata*

Microalgae

- *Galdieria sulphuraria*
- *Tetraselmis chuii*



Production process & Characterisation

- Qualified Presumption of Safety (QPS) status
- Fermentation/cultivation conditions (e.g. open vs. close systems, culture medium)
- Absence/ presence of **viable cells** of the production strain in the NF
- **Algal toxins** and other **toxic substances** (e.g. accumulation of heavy metals)
- **Particle size** in case of dried biomass (powder)
- Stability tests in relation to their composition and the indented uses
- Nutritional composition (e.g. iodine)



Nutritional Information

- Protein quantification, non-protein nitrogen, nitrogen-to-protein conversion factor
- Protein quality (e.g. amino acids, digestibility)
- Antinutritional factors (e.g. inhibiting absorption or modifying bioavailability)



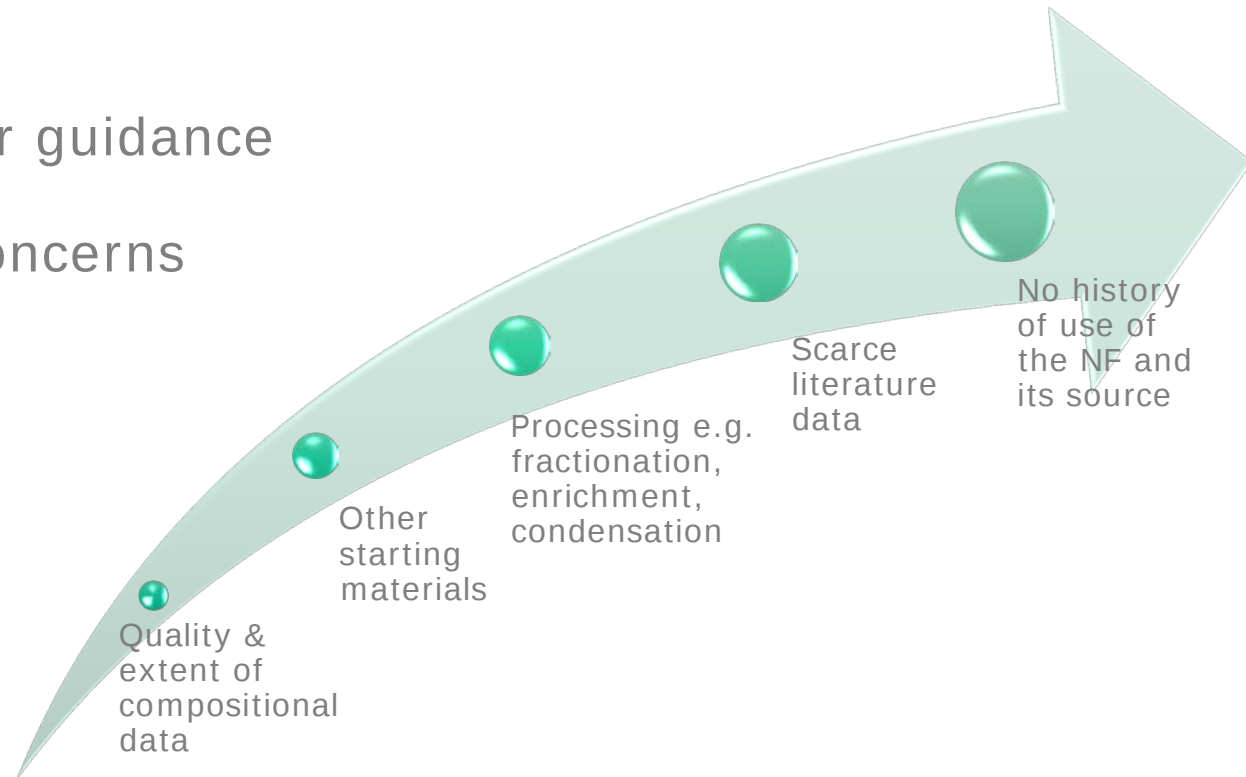
Allergenicity

- Scarce evidence in the existing literature
- *de novo* sensitization
- Cross- reactivity
- Allergens from the feed (e.g. gluten) in insects
- Characterisation of novel proteins (e.g. proteomic analysis, in silico approaches)



Toxicological Information

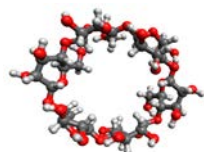
- Toxicity of **inherent substances** (e.g secondary metabolites) and **contaminants** (e.g heavy metals, toxins)
- **Limited toxicological studies** (Tier I) as per guidance
- **Genotoxicity studies** to rule-out specific concerns (fractions of NF to be considered)
- **Sub-chronic studies** (e.g. 90-day) challenging for complex mixtures/ whole foods



Novel carbohydrates as NFs



Alpha-cyclodextrin



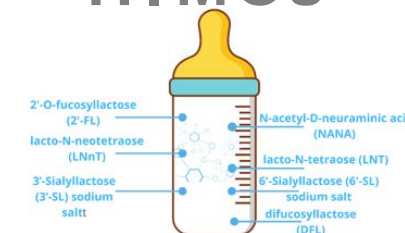
- Starting material: starch
- Converted enzymatically into a circular structure
- cannot be hydrolysed by human amylases

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

HIMOs*



- substances identical to HMOs*
- use in infant and follow-on formulae, foods and food supplements

Chitin-glucan



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

Sugar replacers



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

* Human milk oligosaccharides

NF dossiers received by EFSA



2 EFSA Suitability check



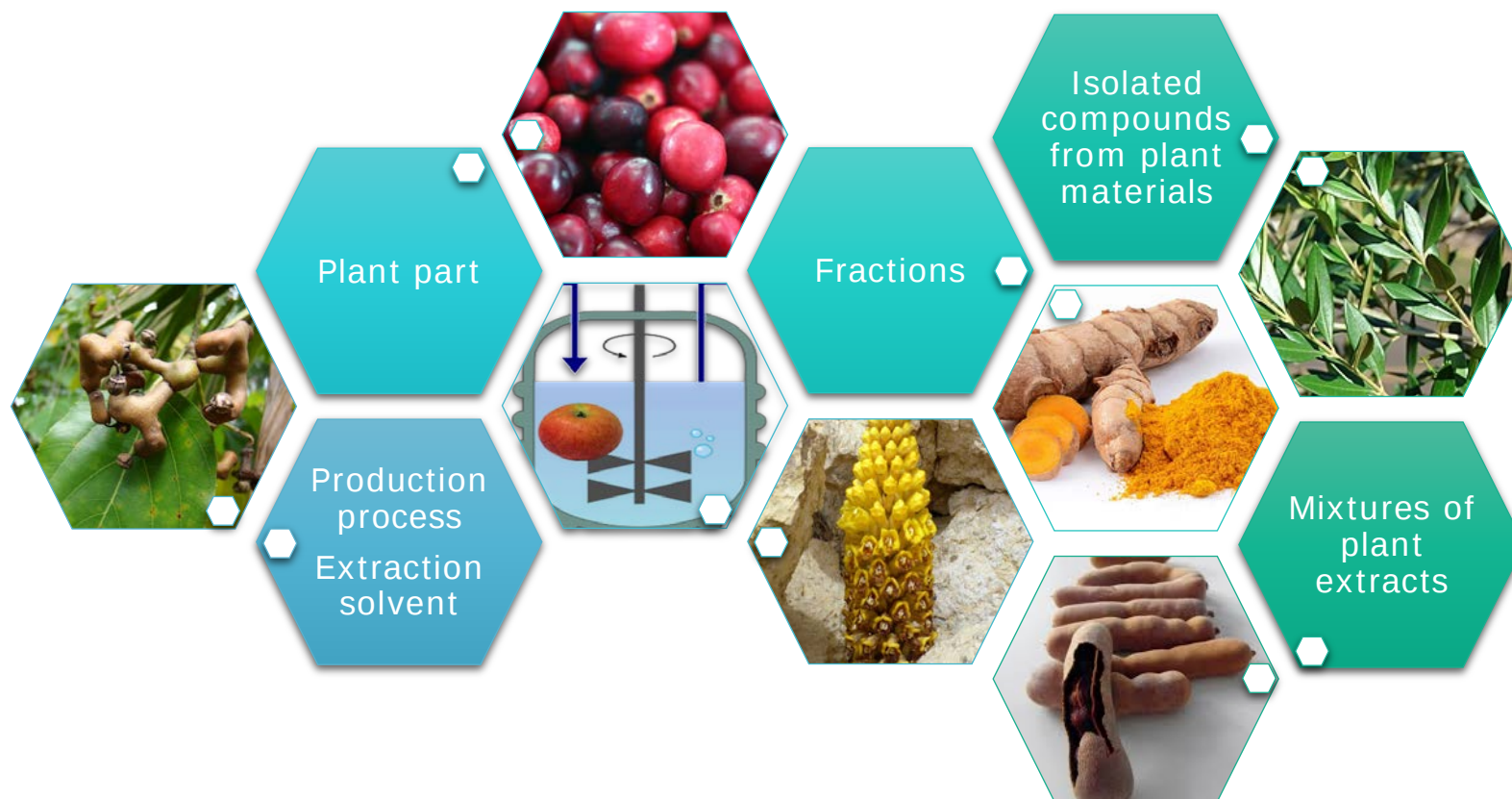
13 EFSA Risk assessment



10 Adopted Opinions

- 3-fucosyllactose (**3-FL**) (2 + **1**)
- 2'-fucosyllactose (**2'-FL**) (3 + **1** + **2**)
- 3'-Sialyllactose (**3'-SL**) sodium salt (1 + **1** + **1**)
- 6'-Sialyllactose (**6'-SL**) sodium salt (1 + **1** + **1**)
- N-acetyl-D-neuraminic acid (**NANA**) (**1**)
- Lacto-N-tetraose (**LNT**) (2 + **1**)
- Lacto-N-neotetraose (**LNnT**) (1 + **3**)
- **2'-FL** / difucosyllactose (**DFL**) (1 + **1**)
- Lacto-N-fucopentaose I (**LNFP-I**) / **2'-FL** (**1**)

Other trends



Cannabidiol (CBD) & hemp extracts



- 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 (under validation check - EC)



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



- EFSA evaluates the safety of novel foods in EU
- Novel food applications have notably **increased** since the beginning of 2018
- Novel Foods **areas with increasing numbers** in terms of application dossiers:
 - **Alternative proteins & their sources**
 - **Novel carbohydrates**
 - **Plant extracts**
 - **Nanomaterials**
 - **Process-Related**
- High heterogeneity among products to be evaluated



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Thank you for your attention!
Questions?

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