



# SAFETY ASSESSMENT OF NOVEL FOODS BY EFSA

## LESSONS LEARNT

Andrea Germini  
Nutrition & Food Innovation Unit

# WHAT IS A NOVEL FOOD IN THE EU?



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 synthesised  
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)



# EC REGULATION AND EFSA NOVEL FOOD GUIDANCE DOCUMENTS

2015

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods

2017

- Implementing Regulation 2017/2469 on administrative and scientific requirements for **novel foods applications**
- Implementing Regulation (EU) 2020/1824 amending Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning **traditional foods from third countries**
- Implementing Regulation 2017/2470 on establishing the **Union list of novel foods**

2016

EFSA **scientific guidance on novel food** in the context of Regulation EU 2015/2283 (updated in **2021** with requirements for transparency regulation)

2016

EFSA **scientific guidance on traditional foods** in the context of Regulation EU 2015/2283 (updated in **2021** with requirements for transparency regulation)

2018

EFSA **Administrative guidance on novel food** pursuant to Article 10 of Regulation EU 2015/2283 (updated in **2022** with requirements for transparency regulation)



# 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



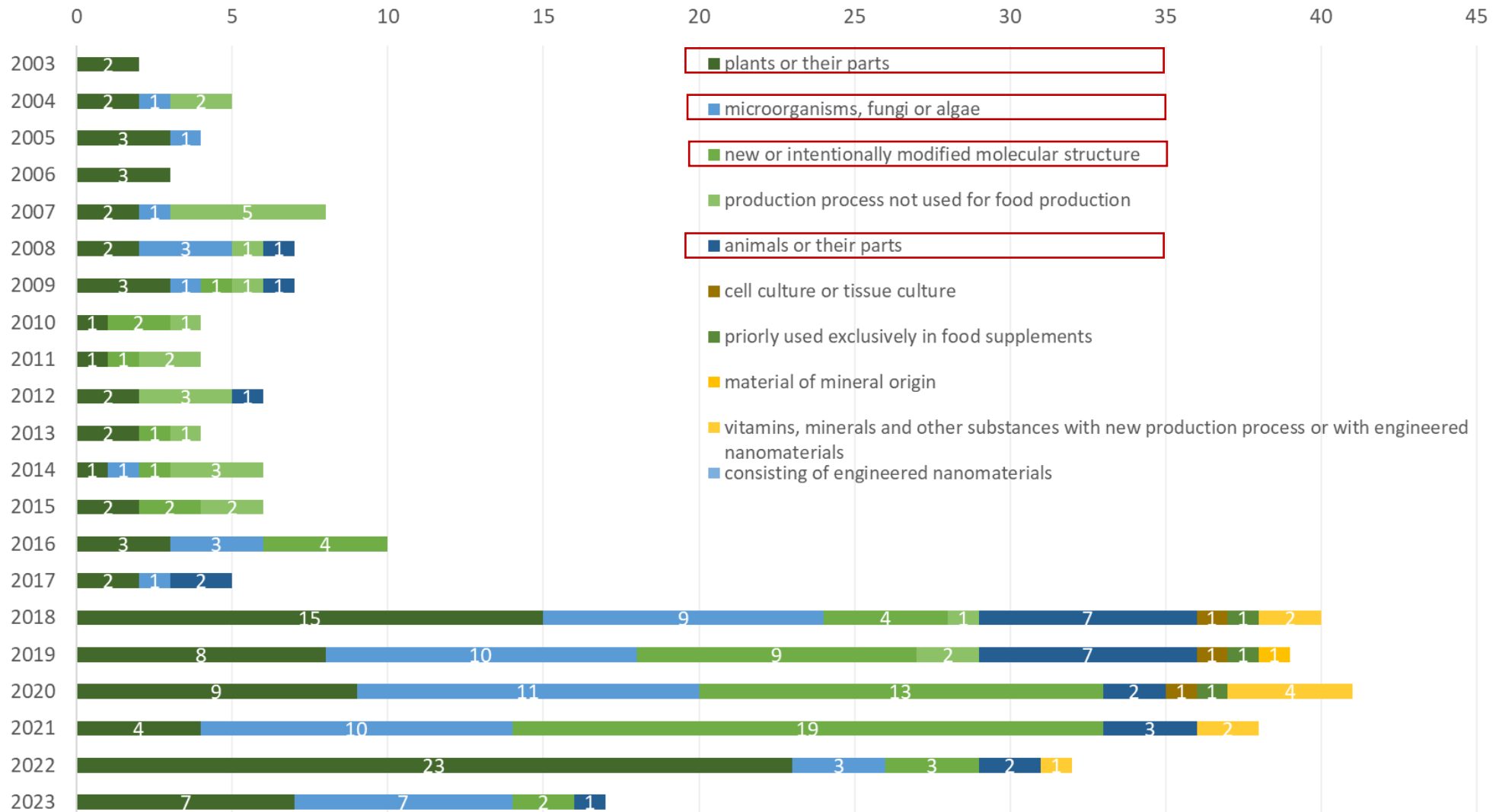
Engineered nanomaterials



Exclusive use in food supplements prior to May 1997



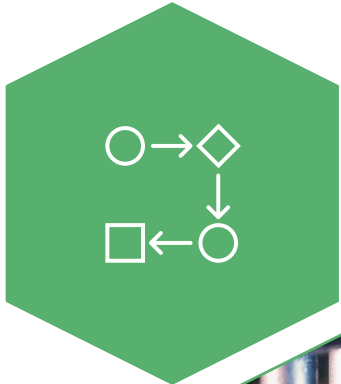
# NOVEL FOOD APPLICATIONS ENTERED EFSA'S RISK ASSESSMENT



Categories according to Regulation (EU) 2015/2283



# TRENDS IN THE NOVEL FOODS AREA



Novel carbohydrates

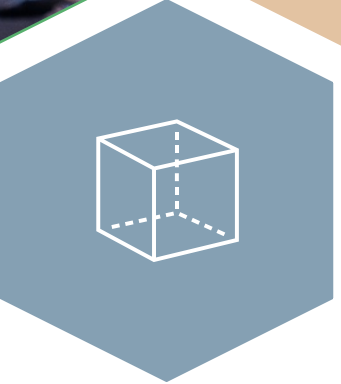


Novel proteins and their sources

New processes



Nanomaterials



Plant extracts





Plant-based



Insects



Algae



Microorganisms  
& Fungi

---

# NOVEL PROTEINS AND THEIR SOURCES



## Sugars replacers

Isomaltulose

Allulose

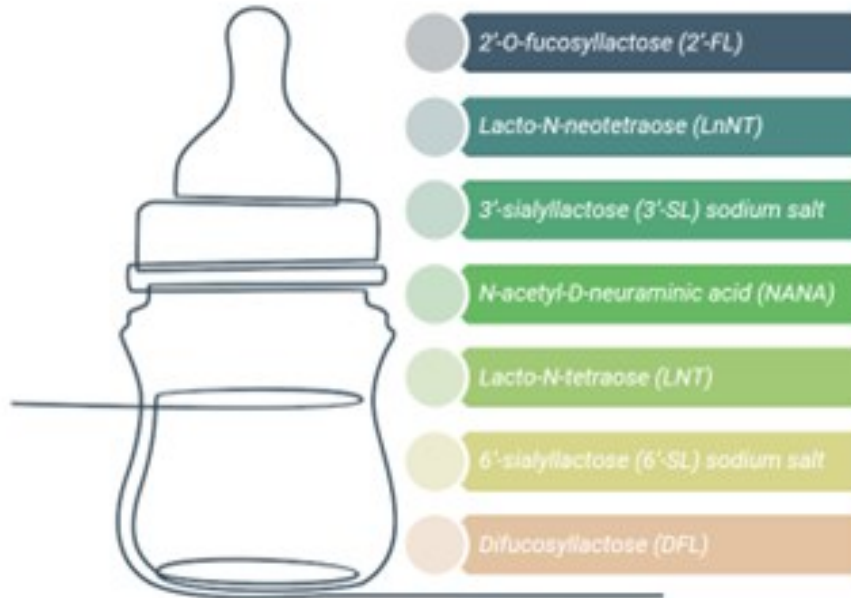
Isomalto-oligosaccharide

Cellobiose

Galacto-oligosaccharides

D-tagatose

## Human identical Milk Oligosaccharides (HiMOs)

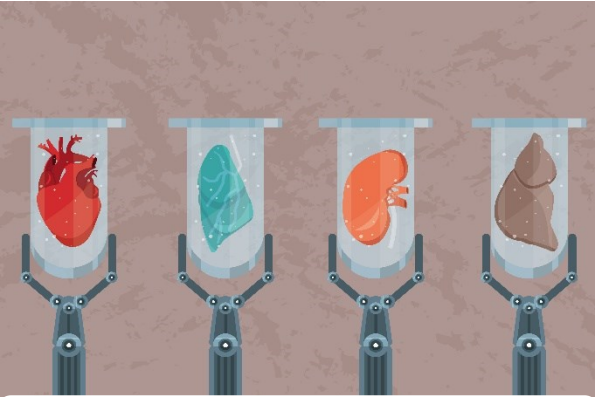


# NOVEL CARBOHYDRATES





# CELL CULTURE-DERIVED FOODS OF ANIMAL/PLANT ORIGIN

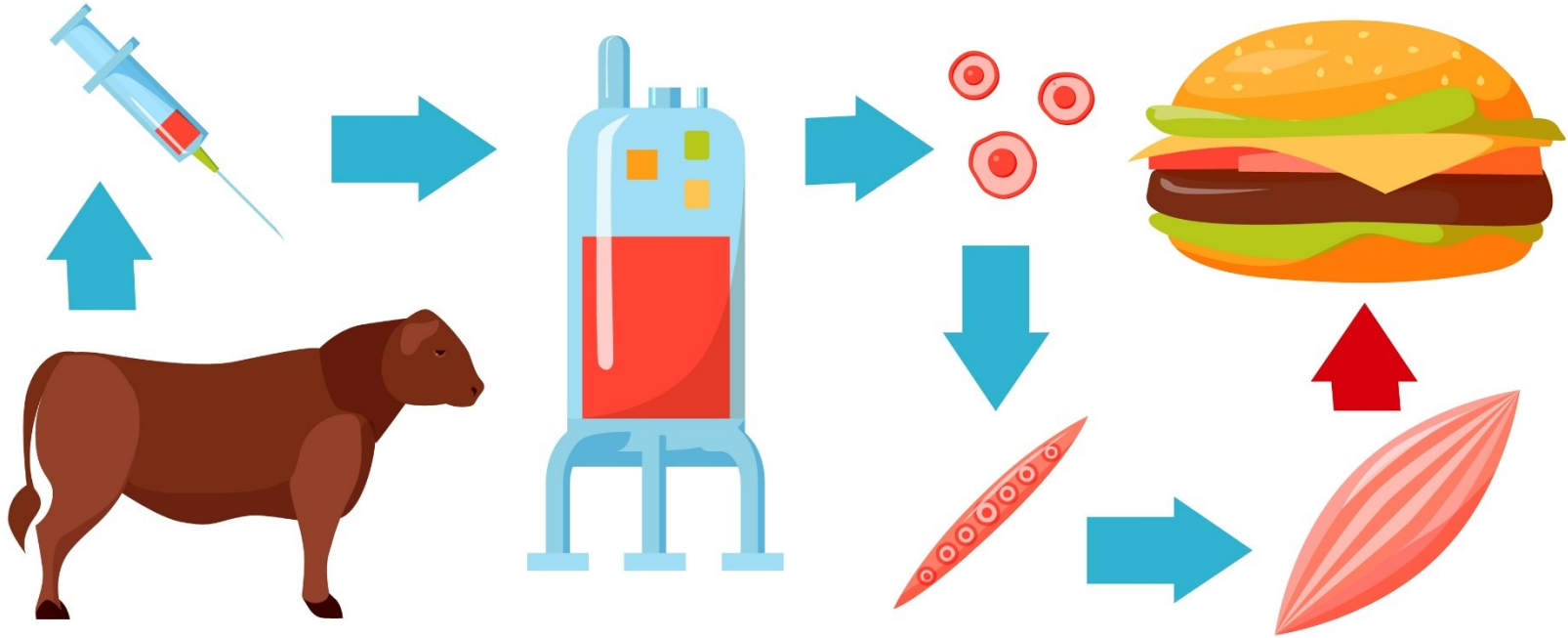


Tissue engineering

+



Cell culture

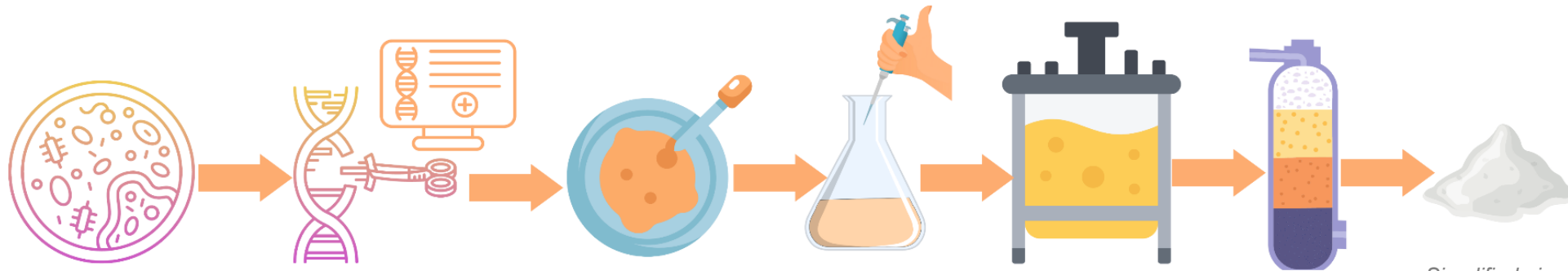


Simplified view of the production process

Source: shutterstock.com



# PRECISION FERMENTATION



*Simplified view of the production process*

**Absence of a regulatory definition**

**Engineered microbial cell factories** in the production of food ingredients

Pre-market authorisation under **different regulatory frameworks** (e.g., novel foods, food additives and flavourings, GMOs, etc.)

