An EU regulatory framework that enables Food Innovation

Estonian Chamber of Agriculture and Commerce online Seminar

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Euroopa Maaelu Arengu Põllumajandusfond: Euroopa investeeringud maapiirkondadesse

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The views expressed are purely those of the speaker and may not in any circumstances be regarded as stating an official position of the European Commission

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Food innovation

- **Key driver to political priorities under the European Union Green Deal and Farm to Fork Strategy**
- **Food safety, security and 'sustainability' key elements**
- **Dietary shifts, healthy diets**
- **Environmental, social, ethical elements**

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Trends in Food Innovation 1

- Alternative proteins from plants, algae, fungi
- Insects
- Algae
- Products of fermentation (‘precision fermentation’)
- Cell based foods

Health and Food Safety

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Trends in Food Innovation 2

- Alternative proteins from plants, algae, fungi
  - New sources (plant, fungi, species)
  - Novel production techniques (mycelial fermentation of plant extracts)
- Insects
  - Staple foods in other parts of the world
  - Whole or used as ingredients
  - High protein content
- Algae
  - New species
  - High protein, vitamin, mineral content

Trends in Food Innovation 3 - Foods produced by 'Precision fermentation'

- No regulatory definition of precision fermentation (PF)
- Term is used to include a range of techniques which, depending on their nature/conditions, may fall under different regulatory regimes
- Experience to date is with 'mainstream' fermentation techniques : production of foods via fermentation using genetically modified microorganisms (GMM))
- Presence or absence of GMM and recombinant DNA a key criterion for the regulatory path of a food produced by PF
- A number of authorised novel foods are produced by 'precision fermentation'

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Trends in Food Innovation 4 - Cell-based Foods

- Part of a portfolio of what promise to be safe and sustainable, innovative foods for the 21st century

- Intended to replace traditional meat, poultry or seafood products

- Elements linked to sustainability (energy, raw materials, ecological footprint, emissions, life cycle analysis) are considered key advantages of cell based foods but concrete technical and scientific supporting evidence is pending

- In the market in Singapore (chicken nuggets) and about to be marketed in the US (pending FDA and DA approvals)

- Anecdotal evidence indicates a number of EU companies working on cell based food (meat) in the EU but no detailed information available

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Regulation (EU) 2015/2283 on novel foods

"The purpose of novel food Regulation is to ensure the effective functioning of **the internal market** while providing a **high level of protection of human health and consumers' interests**."

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Regulation (EU) 2015/2283

- Conceived with a forward looking, anticipatory mode on upcoming food innovation
- Categories of novel foods: balance between the specific and the general to account for future developments
- Insects, alternative proteins, newly synthesised, innovative foods, and food supplements
- Fermentation products (‘precision fermentation’), laboratory grown meat (‘cultured meat’) are/will be covered as long as they do not fall under the GMO Regulation (1829/2003)

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Definition of a novel food in the EU

"Food not used for human consumption to a significant degree before 15 May 1997 and that falls under at least one of the 10 listed categories"

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Regulation (EU) 2015/2283 (Novel Food) requirements (Article 7)

- **Novel foods must:**
  - **Be safe**
  - **Must not mislead the consumer especially when the food is intended to replace another food**
  - **Where it is intended to replace another food, must not be nutritionally disadvantageous**

Novel Food categories

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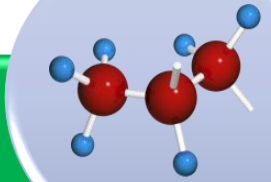
New production process



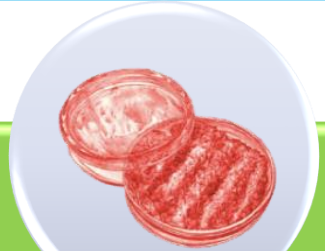
New or modified molecular structure

Micro-organisms, fungi, algae

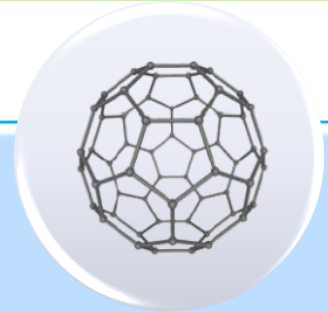
From plants or their parts

Of mineral origin

From animals or their parts



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



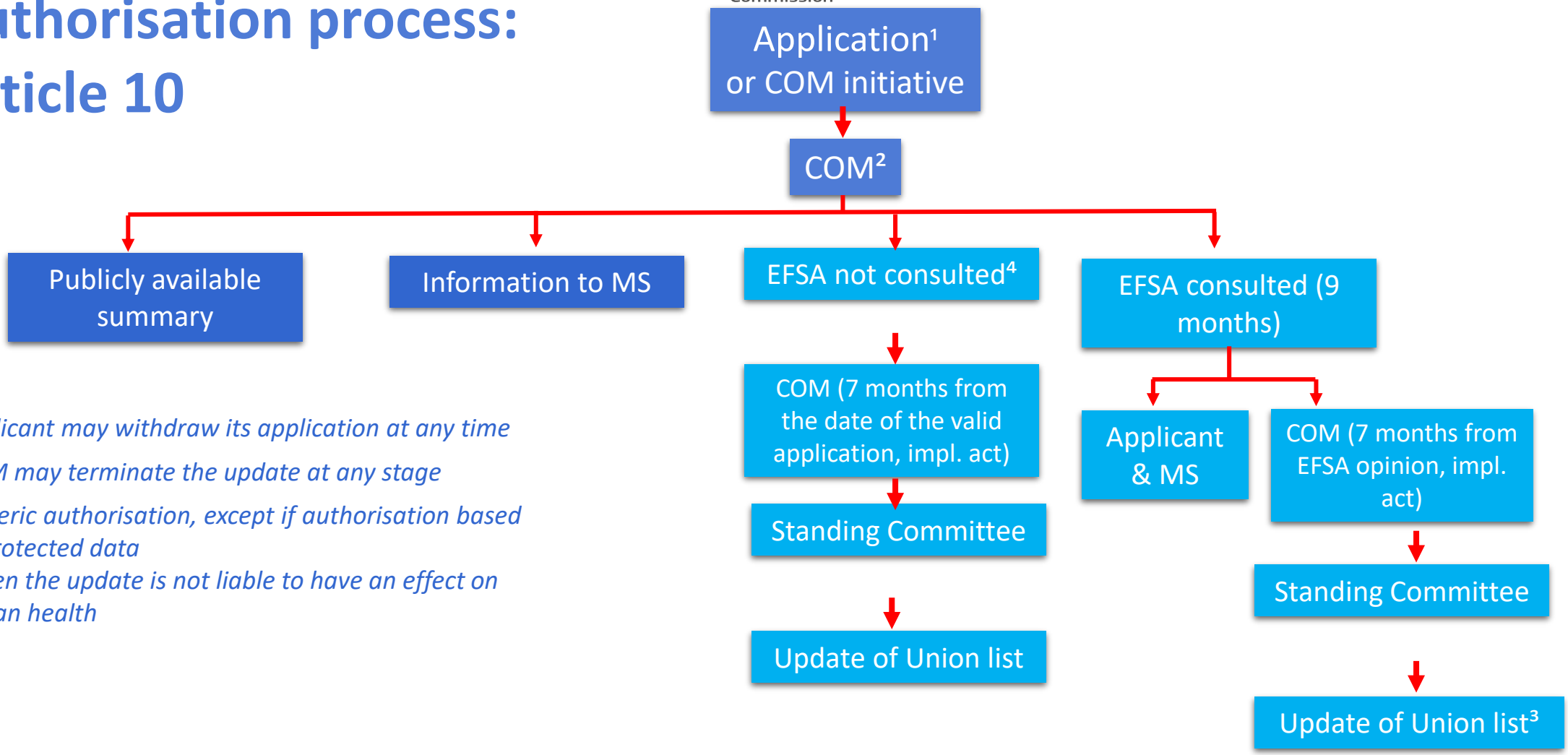
Engineered nanomaterials

EFSA source

Process for an authorisation (Article 10)

- *Applicant submits an application*
- *Information to public – Summaries + Transparency Provisions*
- *Evaluation by the European Food Safety Authority (EFSA)*
- *COM and EFSA do not charge fees for managing applications*
- *Authorisation by the Commission (and MS) – Union list of Novel Foods*
- *Time limits for each step*
- *Experience has shown the process to take around 18 months (versus 3.5 years with the previous Novel Food Regulation). Depends on the degree of novelty and complexity of the file*

Authorisation process: Article 10



[1]Applicant may withdraw its application at any time

[2]COM may terminate the update at any stage

[3]Generic authorisation, except if authorisation based on protected data

[4]When the update is not liable to have an effect on human health

EFSA Novel Food Guidance (2016)

Content of the Application file

- 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 composition of the food and the conditions of its use **do not pose a safety risk** to human health in the Union
- ✓ whether the normal consumption of the NF would be **nutritionally disadvantageous** for the consumer

https://www.efsa.europa.eu/en/efsajournal/pub/6555

Union list of Novel Foods

The Union list consists of 2 tables:

- **Table 1**
  - ✓Conditions under which the NF may be used (specified food category and Maximum levels)
  - ✓Additional specific labelling requirements
  - ✓Other requirements
  - ✓Data protection, where necessary
- **Table 2**
  - ✓Specifications

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Example of entry in Table 1 of the Union list

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

'Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
	Specified food category	Maximum levels			
Calcium fructoborate	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding food supplements for pregnant and lactating women	220 mg/day	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'calcium fructoborate'. 2. The labelling of food supplements containing calcium fructoborate shall bear a statement that those food supplements should not be consumed by population under 18 years of age and by pregnant and lactating women.		Authorised on 23 December 2021. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: VDF FutureCeuticals, Inc., 300 West 6th Street Momence, Illinois 60954, the United States. During the period of data protection, the novel food calcium fructoborate is authorised for placing on the market within the Union only by VDF FutureCeuticals, Inc., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of VDF FutureCeuticals, Inc. End date of the date protection: 23 December 2026'

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Example of entry in Table 2 of the Union list

(2) in Table 2 (Specifications), the following entry is inserted:

'Authorised Novel Food	Specifications
Calcium fructoborate	*Description/Definition* The novel food is calcium fructoborate, a calcium salt tetrahydrate of a bis(fructose) ester of boric acid in the form of a powder, represented by Ca[(C6H10O6)2B]2•4H2O, with a molecular mass of 846 Da. The novel food is produced by chemical synthesis whereby fructose is combined with boric acid in water to produce a bis(fructose) ester of boric acid through various heating and mixing processes. Calcium carbonate is then added to produce a solution containing the calcium salt of fructoborate (tetrahydrate). The solution is freeze-dried, ground to produce the final powdered product, and then packaged and stored under representative storage conditions (22 ± 1°C RH 55-60 %). *Characteristics/composition* Free moisture: < 5,0 % Calcium: 4,5-5 % Boron: 2,5-2,9 % Fructose: 80-85 % Ash: 15-16 % *Heavy metals* Arsenic: ≤ 1 mg/kg *Microbiological criteria* Total plate count: ≤ 1 000 CFU/g [a] Yeast and mould: < 100 CFU/g Coliforms: ≤ 10 CFU/g *Escherichia coli*: < 10 CFU/g *Salmonella* spp.: Absence in 25 g Coagulase-positive staphylococci: Absence in 1 g

(a) CFU: colony forming units'

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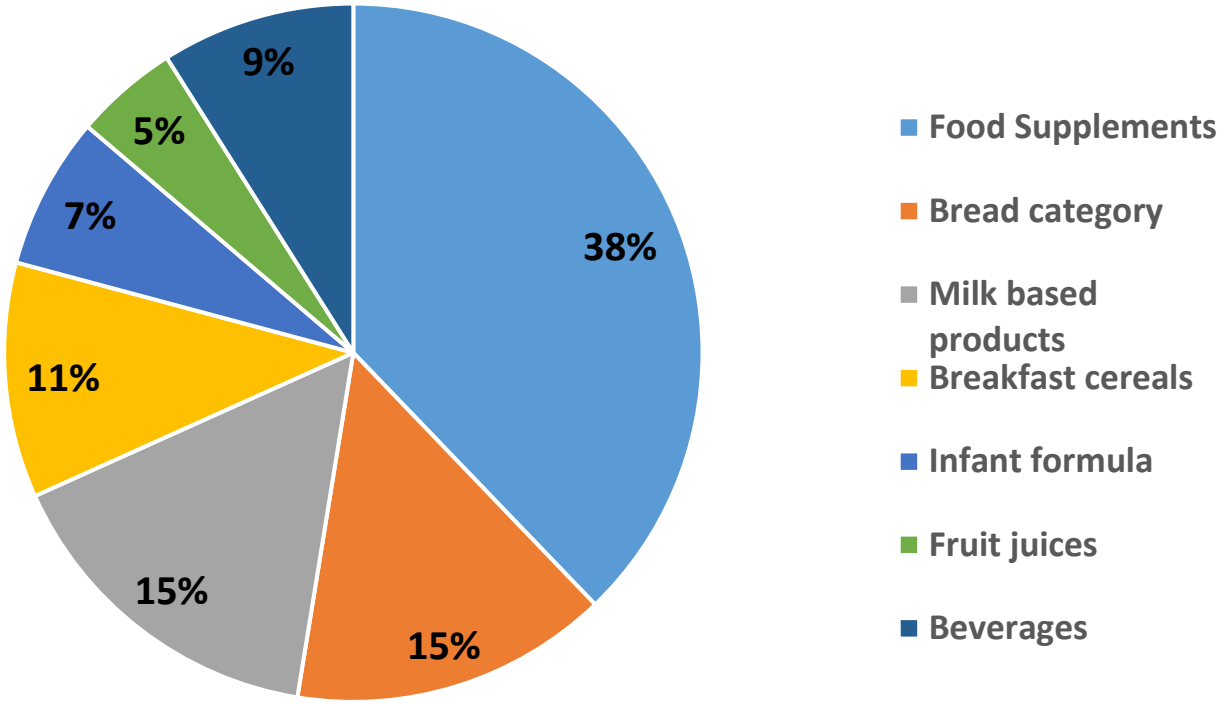
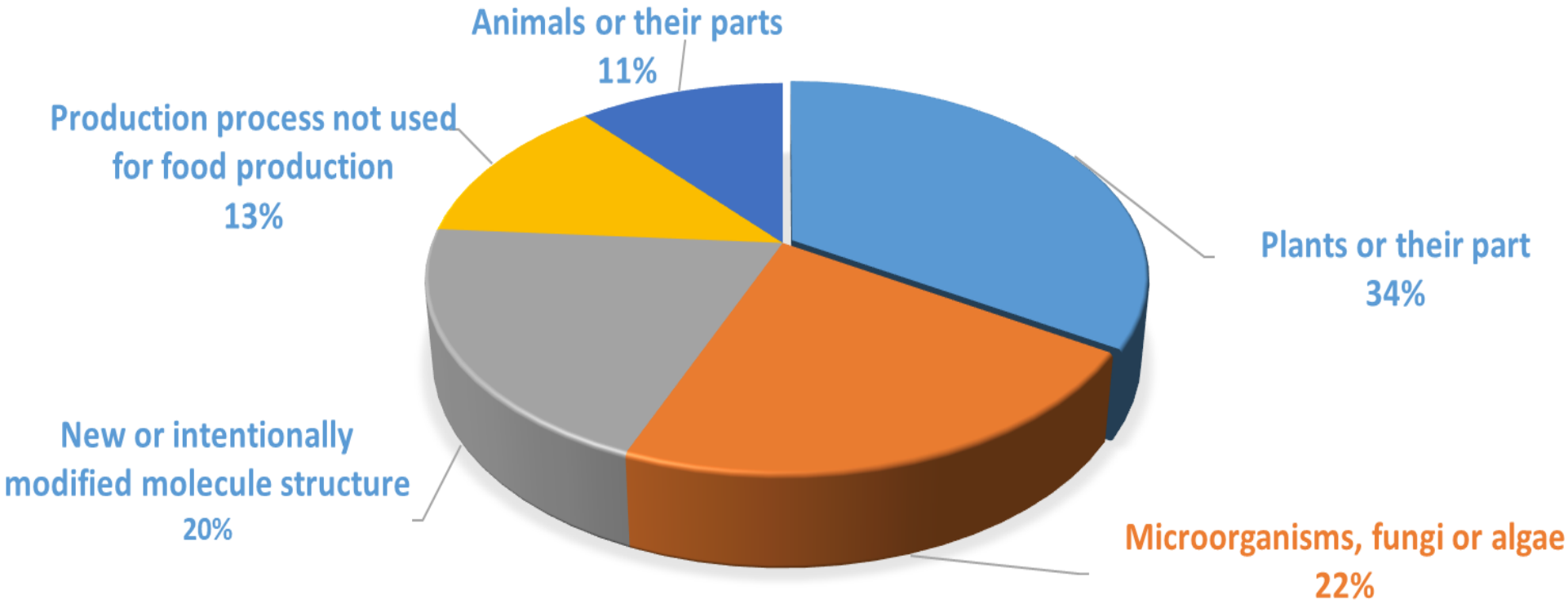
Food categories Novel foods are used




Animals or their parts
11%
Production process not used for food production
13%
Plants or their part
34%
New or intentionally modified molecule structure
20%
Microorganisms, fungi or algae
22%

Food innovation - Challenges and expectations - 1

- **Food innovation can be seen as both**
  - Creative : shift to more sustainable, 'green' food production and consumption systems
  - Disruptive : may challenge some well embedded traditional, cultural and for some ethical codes
- **Carry high expectations and challenges for and from civil society, food businesses, and regulators**

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Food innovation - Challenges and expectations - 2

- For **civil society**
  - Offer new taste experience, alternative foods
  - Address environmental/ecological/climate needs, ethical/moral/religious requirements, animal welfare, address specific dietary needs
  - May be seen as not natural, could be perceived as 'Frankenstein food'
  - Questioning the current paradigms of food production systems, established culture around food production
  - Must be proven to be safe, nutritious, wholesome and tasty (acceptance element)
  - Price versus 'established' foods
  - Taste and texture of 'established foods'

- For **food businesses**
  - A solid regulatory framework – As quick as possible entry to market
  - Technical and scientific challenges of scaling up and production
  - Data supporting safety and sustainability

Food innovation - Challenges and expectations - 3

- For **regulators**
  - The legal framework will deal with safety, which is a first essential step is there
  - Need very solid data on safety
  - Depending on the novelty and innovative nature of the products, close scrutiny on each and every element concerning safety and nutrition is to be expected
  - Address civil society and food business expectations so that innovative foods find their way to the EU market under win-win conditions for all

European Commission, DG Health and Food Safety website
https://ec.europa.eu/food/food/novel-food_en

Functional mailbox: SANTE-NOVELFOODS@ec.europa.eu