



# EFSA Colloquium: cell-culture derived foods and food ingredients

## Brussels, 11 May 2023

A regulatory framework that enables Food Innovation in the EU

Bruno Gautrais  
European Commission,  
DG Health and Food Safety (SANTE)  
Unit E2 'Food processing technologies and novel foods'

*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*

## Cell culture-derived food/food products: a test case

- Not seen as natural
- New sophisticated techniques and processes
- Questioning the traditional food production system
- Naming the products

# What are the expectations?

- for the Civil society
- for Businesses
- for Regulators

# Regulatory framework

Regulation (EU) 2015/2283 on novel foods.  
**Cell culture-derived food** is a novel food unless the technique used to culture it falls under the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed.

# Food/Food ingredients 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 (GM, NF, others)
- Experience to date is with 'mainstream' fermentation techniques : production of food/ingredients via fermentation using genetically modified microorganisms (GMM)
- A number of authorised novel foods are produced by 'precision fermentation'



European  
Commission

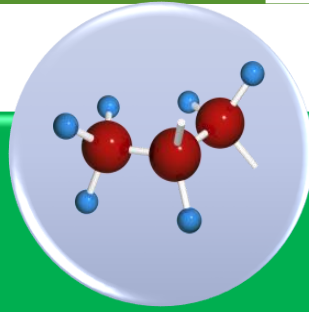
# Definition of a novel food in the EU

*"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"*

# Novel Food categories



**New production process**



**New or modified molecular structure**



**Micro-organisms, fungi, algae**



**From plants or their parts**



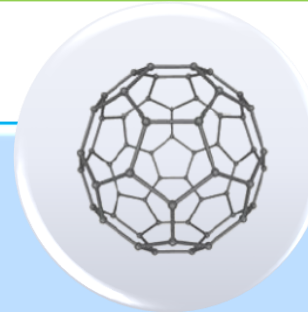
**Of mineral origin**



**From animals or their parts**



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



**Engineered nanomaterials**



European  
Commission

# Cell-based food as a novel food...

...would fall under the category:

*(vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;*

..



# Regulation (EU) 2015/2283 on novel foods (art.1)

"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.**"

# Regulation (EU) 2015/2283 (art.7)

Novel foods must:

- Be safe
- Not mislead the consumer, especially when the novel food is intended to replace another food
- Not be nutritionally disadvantageous where it is intended to replace another food

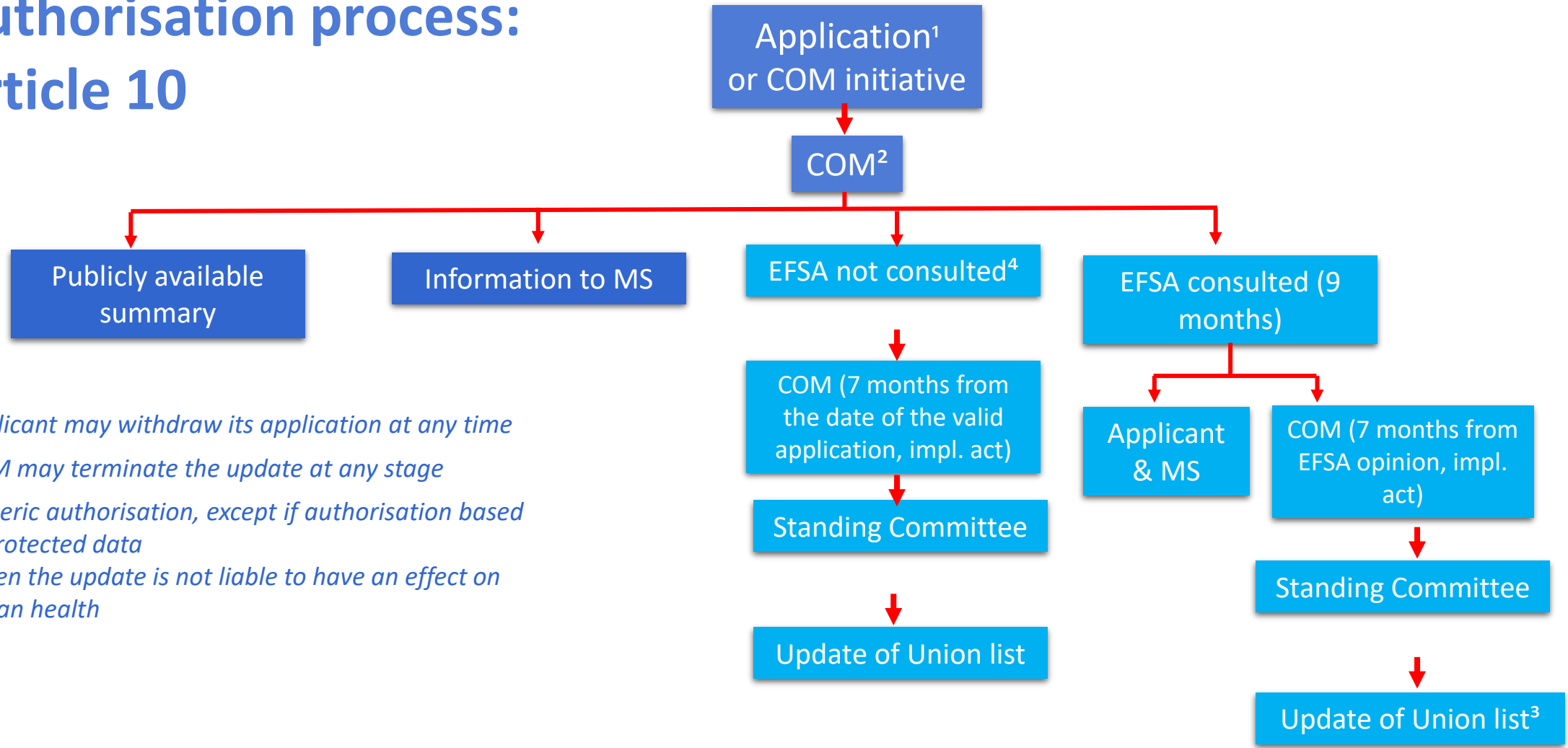
# Process for an authorisation (Article 10)

- 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)
- 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



European Commission

# Authorisation process: Article 10



<sup>1</sup>Applicant may withdraw its application at any time

<sup>2</sup>COM may terminate the update at any stage

<sup>3</sup>Generic authorisation, except if authorisation based on protected data

<sup>4</sup>When the update is not liable to have an effect on human health



- 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/TF would be **nutritionally disadvantageous** for the consumer

# EU research and funding for Cell culture-derived food

- *Green Deal, Farm to Fork, EU Climate ambition*: cultivated food identified as a promising potential alternative source of protein.
- **Funding opportunities** exist and will continue developing
- Horizon Europe: Project on cultured meat and seafood (7 Mio€)
- REACT-EU – recovery plan (e.g. Nutreco and Mosa meat, 2021, NL, 2Mio€)
- H2020- *ongoing*: Meat4all (1,9 Mio€), CCMeat (2,5Mio€)
- H2020- *completed*: Cultured beef (50k€), SUSTAINABLEMEAT (50k€)

# Conclusions

- The legal framework will deal with safety, which is a first essential step. Close scrutiny is expected there.
- Many questions will still have to be answered and evidence provided: *environmental footprint and sustainability (scaling up), consumer acceptance and information, socio-economics*



European Commission, DG Health and Food Safety website  
[https://ec.europa.eu/food/food/novel-food\\_en](https://ec.europa.eu/food/food/novel-food_en)

Functional mailbox: [SANTE-NOVELFOODS@ec.europa.eu](mailto:SANTE-NOVELFOODS@ec.europa.eu)