

Novel or not novel? A guidance through EU legislation

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Fermented tempeh alternatives: Novel or not novel?

- Traditional product based on soybean using *Rhizopus* sp.



Lupin



Hemp



Mungbean



- Traditional product using *Rhizopus* sp.



Rhizopus sp. *Propionibacterium freudenreichii*



Guidance tree to establish novelty developed in the B-Twelve Insight project

- The tree serves to familiarize stakeholders with the EU regulation – guidance documents of EFSA and EC on novel food application are leading*
- Six questions to be addressed to help determine if a fermented food product may be subject to novel food regulation

1 Question 1: What is your fermented product? (Give description)

2 Question 2: Has the product as such been consumed in the EU before 15 May 1997? YES / NO (Then your fermented food may be subject to Novel Food Regulation) / Proceed to Question 3

3 Question 3: Is your fermented food eaten in a third country for the past 25 years? YES / NO (Then your fermented food may be subject to Novel Food Regulation) / Proceed to Question 4

4 Question 4: Does the culture have history of use in food before 15 May 1997 in the EU? (use IDF culture list OR EFCA culture list as starting point) YES / NO (Then your food may be subject to novel food regulation due to a novel culture) / Proceed to Question 5

5 Question 5: Does the substrate have a history of significant consumption in food before 15 May 1997 within the EU? YES / NO (Then your food may be subject to novel food regulation due to a novel substrate) / Proceed to Question 6

6 Question 6: Does your fermented food have any significant changes in the composition or structure to a comparable food/product affecting its nutritional value, metabolism or level of undesirable substances? YES / NO (Then your food may be subject to novel food regulation) / Then your fermented food may not be subject to novel food regulation

NFR Guidance tree team



Dr. Addie van der Sluis

Scientist Food & Health Research

Focus area: Food legislation, nutrition and health claims, novel food regulation



Dr. Jerome Diaz

Food Scientist

Focus area: Clean labelling, sustainability, reformulation



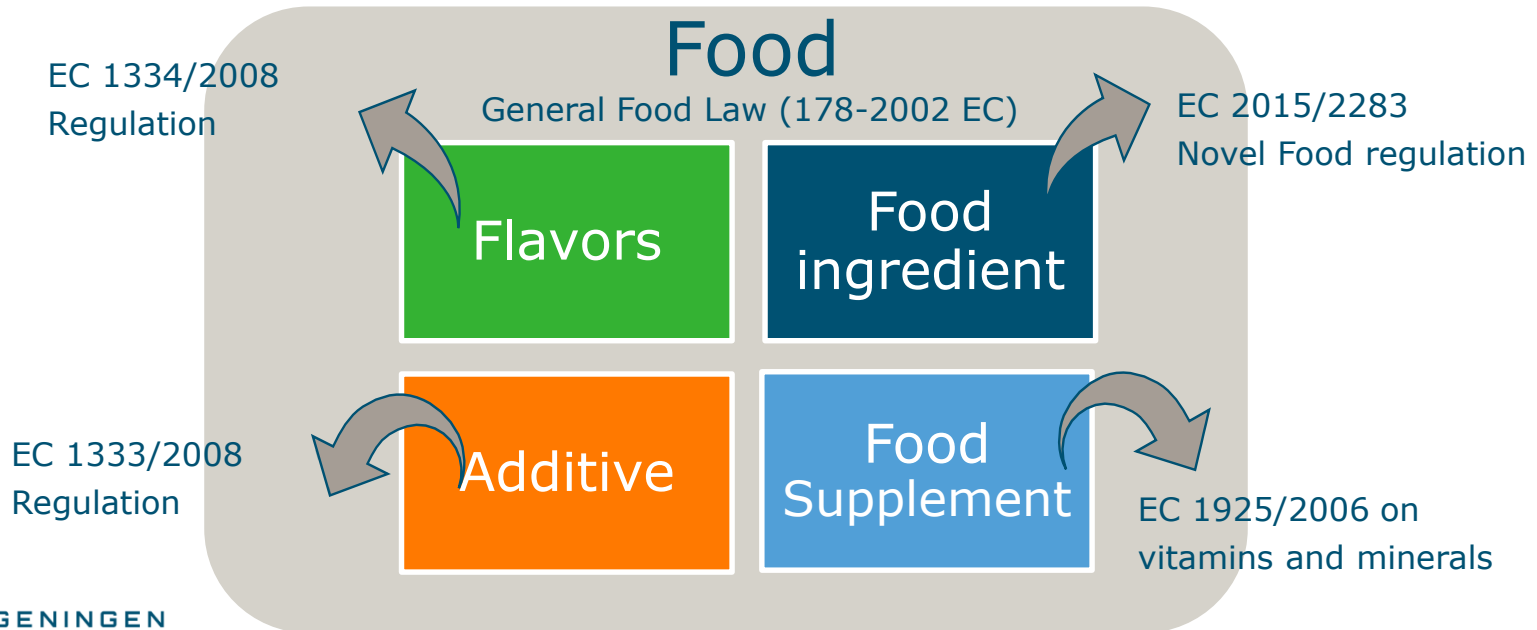
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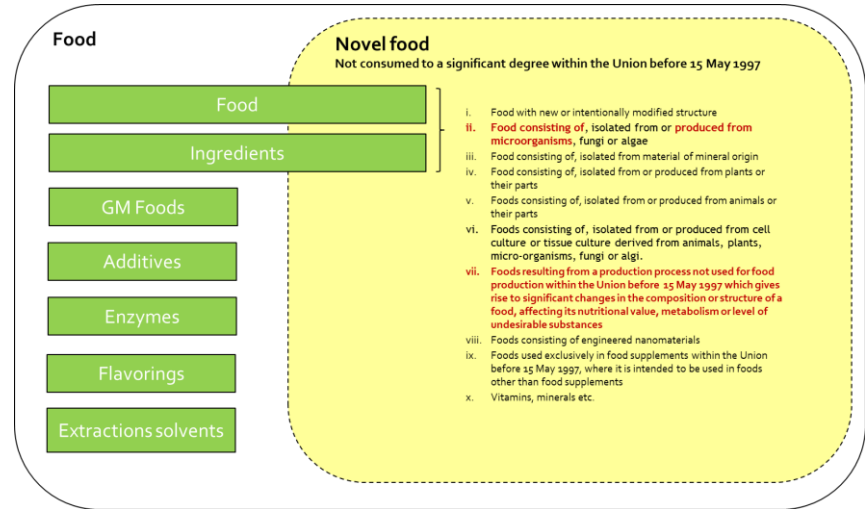
Regulatory landscape (EU)

- The regulatory status is based on the primary use /intended function
- Novel foods and ingredients are subject to pre-market approval



Novel Food Regulation (EC 2015/2283)

- Definition under **Novel Food Regulation**:
'a food that does not have a significant history of consumption within the EU before 15 May 1997'
- 'Novel Food' can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside of the EU.



Novel or not novel status of food

- Consult **Novel Food Catalogue** (list of products of animal and plant origin and other substances subject to the NFR):
https://ec.europa.eu/food/safety/novel_food/catalogue_en
- Consult **list of authorisations** (already authorised foods or food ingredients)
https://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations_en
- **Union list** of novel foods (most recent version 23-02-2021)
Commission Implementing Regulation (EU) 2017/2470
- Consultation of **CA** (competent authorities)
Commission Implementing Regulation (EU) 2018/456

Tempeh variants: Novel or not novel

- Traditional tempeh fermentation using soybeans has a long history of use (before 15 May 1997)



Lupin



Hemp



Mungbean



- Recital 17 (NFR):** 'Food produced exclusively from food ingredients that do not fall within the scope of this Regulation, **in particular by changing the ingredients of the food or their amount, should not be considered a novel food.** However, modifications to a food ingredient that has not yet been used for human consumption to a significant degree within the Union, should fall within the scope of this Regulation'

Tempeh using lupin beans

■ Lupin bean https://ec.europa.eu/food/safety/novel_food/catalogue_en

The edible parts of *Lupinus albus* are the seeds (originated from the pod). Before 1997 high-alkaloid-containing *L. albus* seeds have been used in the Mediterranean area. The seeds need preparation cooking, and soaking until bitterness disappear. Otherwise acute poisoning may occur. Additionally a low-alkaloid-containing *L. albus* strain has been marketed (and accepted) at least in France. Seeds from this strain does not need preparation before use but can be used in flour. *Lupinus albus* is an annual upright plant (Leguminosae Family, subfam. Papilionoideae) with coarse stems and medium-sized fingerlike leaves. Require cool weather for full development and grow best in sandy soils. Exist in bitter (toxic alkaloid) and sweet varieties. The sweet varieties (alkaloid-free) can be distinguished by taste and smaller growth.

Novel Food Status



What does it mean?



Long history of use
before 15 May 1997



equivalent



Based on recital 17
not subject to NFR

This product was on the market as a food or food ingredient and consumed to a significant degree before 15 May 1997. Thus its access to the market is not subject to the Novel Food Regulation (EU) 2015/2283. However, other specific legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.

Tempeh using hemp seeds

■ Hemp seeds https://ec.europa.eu/food/safety/novel_food/catalogue_en

Description

In the European Union, the cultivation of *Cannabis sativa* L. varieties is permitted provided they are registered in the EU's 'Common Catalogue of Varieties of Agricultural Plant Species' and the tetrahydrocannabinol (THC) content does not exceed 0.2 % (w/w). Some products derived from the *Cannabis sativa* plant or plant parts such as seeds, seed oil, hemp seed flour, defatted hemp seed have a history of consumption in the EU and therefore, are not novel. Other specific national legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities

Novel Food Status



What does it mean?



Long history of use
before 15 May 1997

equivalent



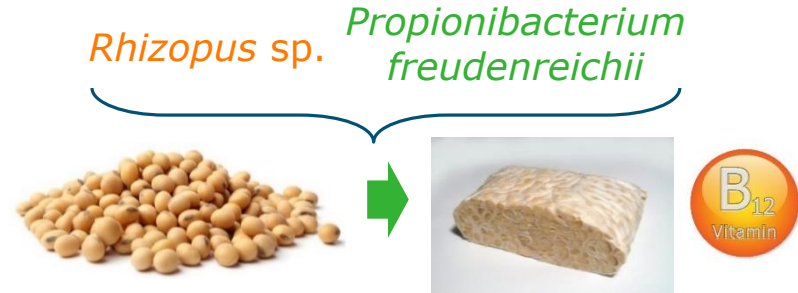
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not subject to NFR

This product was on the market as a food or food ingredient and consumed to a significant degree before 15 May 1997. Thus its access to the market is not subject to the Novel Food Regulation (EU) 2015/2283. However, other specific legislation may restrict the placing on the market of this product as a food or food ingredient in some Member States. Therefore, it is recommended to check with the national competent authorities.

Microbial Food Cultures (MFC)

- General characteristics:
 - Live micro-organisms (bacteria, yeasts, mould) that are selected to ferment food and beverages or to have a beneficial effect/purpose (e.g. preservation, protection, structure/texture, flavour)
- Legal status
 - No EU regulatory definition
 - Definition by European Food and Feed Cultures Association (EFFCA)
 - Generally considered as an ingredient (i.e. not food additive)
 - Long history of use MFC are considered traditional food ingredients (no pre-market authorization required)
 - Long history of use: human consumption to a significant degree

New substrates + MFC: novel or not novel?



- Traditional tempeh fermentation using soybeans has a long history of use (before 15 May 1997)
- *Propionibacterium freudenreichii* has a history of use before 15 May 1997 (IDF/EFFCA)
- New combination of MFC and substrate with both long history of safe use. Is the product subject to novel food regulation???

New substrates + MFC: novel or not novel?

- The answer to this question should be addressed on a case-by-case basis
- *"Foods resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances " - Article 3.2 vii, Novel Food Regulation 2015/2289*
- Therefore, if the production process is NEW but does not give rise to significant changes in the composition or structure of the final food, it is not likely to be considered a novel food
- Therefore, the characteristics of the final fermented food product should be considered

Summary

Food fermentation

Traditional food:
Human consumption to a significant degree in EU pre-1997

Known combination (culture + substrate)

Cultures, as used pre-1997

Substrates, as used pre-1997

New combination (culture + substrate)

Case-by-case analysis:
New combinations of cultures (pre-1997) and substrates (pre-1997)

Novel Food

Cultures with no history of consumption pre-1997

Substrates with no history of use pre-1997



Thank you for your attention

For more information, feel free to contact us:

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tion 1

2 Question 2

Has the product as such been consumed in the EU before 15 May 1997?

3 YES

4 Give supporting document: production volumes, consumption data, etc

5 NO

6 Then your fermented food may be subject to Novel Food Regulation

7 Proceed to Question 3

3 Question 3

Is your fermented food eaten in a third country for the past 25 years?

4 YES

5 Then you can apply for novel food as a traditional food from a third country (See Guidance Document)

6 NO

7 Then your fermented food may be subject to Novel Food Regulation

4 Question 4

Does the culture have history of use in food before 15 May 1997 in the EU? (use IDF culture list OR EFFCA culture list as starting point)

5 YES

6 Proceed to Q5

7 NO

8 Then your food may be subject to novel food regulation due to a novel culture

5 Question 5

Does the substrate have a history of significant consumption in food before 15 May 1997 within the EU?

6 YES

7 Proceed to Q6

8 NO

9 Then your food may be subject to novel food regulation due to a novel substrate

6 Question 6

Does the fermented food have any significant change in the composition or structure to a comparable food/affect nutritional value, metal or level under substance?

7 YES

8 Then the focus of the novel regulation

9 NO

10 Then the focus of the novel regulation