ALTERNATIVE PROTEINS AND NOVEL FOODS IN THE EU (AND BREXIT UPDATE)

28 FEBRUARY 2023
KH Webinar Series on Alternative Proteins
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Important Note

The content of this presentation is not intended as, and does not constitute, legal advice for particularized facts. Regulatory counsel should be consulted in advance for advice on any specific compliance issues.
Alternative Proteins:
Things to Consider

♦ Scope of alternative proteins: cultivated/fermented meat, seafood, dairy, and eggs
  ♦ What is the applicable regulatory pathway?
  ♦ What is the appropriate name?
  ♦ Any unique safety data requirements?
  ♦ How are authorities perceiving this type of new food category?
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- Alternative proteins
- The EU regulatory framework
- Product qualification
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  - Definition
  - Assessment
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Alternative Proteins

**ALTERNATIVE PROTEINS** (i.e., alternatives to traditional animal proteins):

- Plant-based
- Cultured / cell-based
- Obtained through fermentation processes
- Derived from insects
The EU Regulatory Framework

♦ **THE GENERAL FOOD LAW:** Reg. No. 178/2002

♦ **Novel foods:** Reg. No. 2015/2283 (NF Regulation)

♦ **Food additives:** Reg. (EC) No. 1333/2008 (FA Regulation)

♦ **Genetically modified foods and feeds:** Reg. (EC) No. 1829/2003 (GMFF Regulation)
Product Qualification (1)

Food additive or food ingredient?

FOOD ADDITIVES

♦ FA Regulation, Article 3(2)(a) → 3 requirements:
  ◦ 1. Not normally consumed as a food or a characteristic ingredient of food
  ◦ 2. Intentionally added to a food
  ◦ 3. Technological function (e.g., coloring, anti-caking, etc.)
Product Qualification (2)

**FOOD ADDITIVES**

- **General Food Law** and **Food Additives Regulation**
- Only permitted food additives may be utilized
- If genetically modified (**GMO**), it must be:
  - 1) approved as a genetically modified food (GMFF Regulation) and
  - 2) authorized as a food additive (Regulation No. 1331/2008)
Product Qualification (3)

FOOD ADDITIVES

Example: soy leghemoglobin produced from genetically modified *Pichia pastoris*:

- GMO petition to the EC/EFSA ([EFSA-GMO-NL-2019-162](#))
- Food additive petition to the EC/EFSA ([EFSA-Q-2022-00031](#))
Product Qualification (4)

FOODS/FOOD INGREDIENTS

♦ They provide a **flavor**, **taste**, or **nutritional properties**

♦ They may have an (ancillary) technological

♦ → **General Food Law**, but:

  ◯ **If it consists of, contains, or is derived from GMO***: GMFF Regulation

  ◯ **If novel food**: NF Regulation

GENETICALLY MODIFIED FOOD OR NOT?

- Food produced FROM and WITH GMO:
  - Produced WITH GMO: the GMO is removed/filtered → it is not a GMFF
  - Produced FROM GMO: GMO traces are present → it is a GMFF

- **EFSA**: the operator should investigate
  - 1) Production strain DNA < 10 ng per g/ml of product (10 ppb) and
  - 2) Absence of viable cells
GENETICALLY MODIFIED FOOD OR NOT?

◊ **EFSA**: 4 product categories of products
  
  ◇ 1: Simple compounds with no GMMs/new genes → **NOT GMFF**
  
  ◇ 2: Complex products (e.g., proteins) with no GMMs/new genes → **NOT GMFF**
  
  ◇ 3: Products with no recombinant DNA/RNA but with new genes → **GMFF**
  
  ◇ 4: Products with recombinant DNA/RNA and/or new genes → **GMFF**
GENETICALLY MODIFIED FOOD OR NOT?

♦ **GMFF Regulation**: pre-market authorization by the EC based on EFSA’s risk assessment

♦ Time for the approval (up to 5 years)

♦ The authorization lasts 10 years (but it is renewable)

♦ Other important requirements: traceability and **labelling**
Novel Foods: Definition (1)

**Regulation (EU) No. 2015/2283 - Novel Foods Regulation**

1) Not used for **human consumption to a significant degree** within the Union **before 15 May 1997**, and

2) Fall under **at least one of 10 categories** [Article 3(2)(a), e.g., **cat. (vi): food consisting of, isolated from or produced from cell culture or tissue culture**]
Novel Foods: Definition (2)

Do not fall under the Novel Foods Regulations [Art. 2(2)]:

- **GMFF** [Regulation (EC) No. 1829/2003]
- Food **enzymes** [Regulation (EC) No. 1332/2008]
- Food **additives** [Regulation (EC) No. 1333/2008]
- Food **flavourings** [Regulation (EC) No. 1334/2008]
- Extraction **solvents** used for foods [Directive 2009/32/EC]
Novel Food Assessment (1)

Determination of novel food status (Art. 4)

♦ It is Responsibility of the Food business operators

♦ Union List of Novel foods
♦ Novel food online catalogue
♦ Open EFSA portal
♦ Consultation with the Member State where the food will be marketed for the first time
1) NOVEL FOOD LIST

Commission Implementing Regulation (EU) No. 2017/2470 establishing the Union list of novel foods

<table>
<thead>
<tr>
<th>Authorised Novel Food</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ice Structuring Protein type III HPLC 12</td>
<td>Description/Definition: The Ice Structuring Protein (ISP) preparation is a light-brown liquid produced by submerged fermentation of a genetically-modified strain of food-grade baker’s yeast (<em>Saccharomyces cerevisiae</em>) in which a synthetic gene for the ISP has been inserted into the yeast’s genome. The protein is expressed and secreted into the growth medium where it is separated from the yeast cells by micro-filtration and concentrated by ultra-filtration. As a result, the yeast cells are not transferred into the ISP preparation as such or under an altered form. The ISP preparation consists of native ISP, glycosylated ISP and proteins and peptides from the yeast and sugars as well as acids and salts commonly found in food. The concentrate is stabilised with 10 mM citric acid buffer. Assay: ≥ 5 g/l active ISP pH: 2,5-3,5 Ash: ≤ 2,0 % DNA: Not detectable</td>
</tr>
</tbody>
</table>
Novel Food Assessment (3)

2) NOVEL FOOD CATALOGUE

The catalogue is a practical tool regularly updated that shows a non-exhaustive list of products for which the assessment has already been done.
Novel Food Assessment (4)

Cannabidiol

**Description**
Please consult the entry “cannabinoids”

**Novel Food Status**

- What does it mean?

- 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 (EC) No. 258/97. 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.

- According to information available to Member States competent authorities this product was used only as or in food supplements before 15 May 1997. Any other food uses of this product have to be authorised pursuant to the Novel Food Regulation.

- There was a request whether this product requires authorisation under the Novel Food Regulation. According to the information available to Member States’ competent authorities, this product was not used as a food or food ingredient before 15 May 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient a safety assessment under the Novel Food Regulation is required.

- There was a request whether this product requires authorisation under the Novel Food Regulation. Further information is required.
Novel Food Assessment (5)

3) OPEN EFSA PENDING QUESTIONS [link]
## Novel Food Assessment (6)

### 4) MEMBER STATE CONSULTATION (Commission Implementing Regulation (EU) No. 2018/456 - link)

<table>
<thead>
<tr>
<th>Name and description of the food concerned</th>
<th>Date of publication</th>
<th>Statement on the food concerned</th>
<th>Reasons justifying the statement</th>
<th>Where the food is novel, the most appropriate food category under which it falls in accordance with Article 3(2) of Regulation (EU) 2015/2283</th>
</tr>
</thead>
<tbody>
<tr>
<td>A plant protein concentrate that is fermented with the mycelium of shiitake (Lentinus edades).</td>
<td>25 February 2019</td>
<td>Novel when used as or in foods.</td>
<td><a href="#">View document</a></td>
<td>Category 3(2) (a)(ii)</td>
</tr>
<tr>
<td>Agaricus blazei dehydrated mycelium powder</td>
<td>29 October 2019</td>
<td>Novel when used as or in foods.</td>
<td><a href="#">View document</a></td>
<td>Category 3(2) (a)(ii)</td>
</tr>
<tr>
<td>Albizia julibrissin Durazz. - flowers</td>
<td>8 August 2019</td>
<td>Novel when used as or in foods.</td>
<td><a href="#">View document</a></td>
<td>Category 3(2) (a)(iv)</td>
</tr>
</tbody>
</table>
Novel Food: Authorization (1)

2 routes:

♦ **Standard procedure** and

♦ **Notification of a traditional food from a third country** (‘fast-track’)

♦ **Important!** Reg. (EU) No. 2019/1381 (‘Transparency Regulation’)

♦ **Guidance** by the EC and EFSA: see [here](#), in particular [EFSA administrative guidance](#)
Novel Food: Authorization (2)

- European Food Safety Authority (EFSA): scientific risk assessor
- The EU Commission decides after a vote by the Standing Committee on Plants, Animals, Food and Feed – SCoPAFF (where Member States representative votes, ‘double majority’ rule).
Novel Food: Authorization (3)

- The applicant must **prove** that the NF:
  - is **not unsafe**
  - does **not mislead** consumers
  - is **not nutritionally disadvantageous** compared to a conventional food that it is replacing
Novel Food: Authorization (4)

STANDARD PROCEDURE

♦ General pre-submission advice [optional]
♦ Pre-submission phase (notification of the studies)
♦ Submission phase, validity and suitability check
♦ Risk assessment phase (EFSA)
♦ Post-adoption phase (EC)
Pre-application ID creation on EFSA portal + Pre-notification of studies and possible request for general pre-submission advice (‘GPSA’)

Submission of the application via e-submission system available on the DG SANTE website

EC validity check + possible suitability check by EFSA (30 days).

The EC seeks EFSA opinion

Application to EFSA (1 month from check)

EFSA discloses the non-confidential dossier

EFSA decides on confidentiality request of certain parts of the dossier (10 weeks from request)

EFSA publishes the FINAL non-confidential dossier and launches public consultation (that lasts for 3 weeks)

Draft EC regulation submitted to SCoPAFF (7 months from EFSA’s opinion or validity check)

The EC makes a summary of the application publicly available

EFSA issues its opinion (9 months from the receipt). Possible "clockstop" for new data

EFSA publishes the FINAL non-confidential dossier and launches public consultation (that lasts for 3 weeks)

The EC adopts the Commission Regulation that authorizes the novel food
Novel Food: Authorization (5)

- All studies in support of the application commissioned or carried out after March 27, 2021 need to be pre-notified to the EFSA's.
- The same obligation applies to the laboratories and other testing facilities located in the EU.
- The application will be declared invalid if it does not include all and only the pre-notified studies (the applicant can re-start the process and EFSA will carry out its risk assessment after 6 months).
Novel Food: Authorization (6)

- The authorization is **general and not individual**
- **Timeline:** ≈ **2 years** from the submission
- If the scientific data provided in the dossier are (i) proprietary, (ii) exclusive, and (iii) crucial to the safety assessment → "**data protection**" for **5 years** (the authorization is individual for 5 years)
CONTENT OF THE NOTIFICATION

♦ Administrative data
♦ Summary data
♦ Technical dossier
  ◊ See EFSA scientific guidance;
  ◊ Other specific EFSA guidance, such as: safety evaluation of sources of nutrients and their bioavailability; genotoxicity assessment, etc.).
Novel Foods: A Possible Issue

- Only approved novel foods can be placed on the market.
- Placing on the market: holding of food or feed for the purpose of sale and any other form of transfer, whether free of charge or not [Reg. (EC) No. 178/2002].
- Is a sensory evaluation/tasting panel prior to approval legal?
  - UK FSA statement
  - Singapore SFA guidance
Edible Insects

**All novel foods**: category (v) → food consisting of, isolated from, or produced from animals or their parts

- **Authorized insects in the EU** (source: IPIFF, https://ipiff.org)
  - Dried yellow mealworm (*Tenebrio molitor*)
  - Dried and frozen migratory locust (*Locusta migratoria*)
  - Frozen, dried, and powder yellow mealworm (*Tenebrio molitor*)
  - Dried, ground, and frozen house cricket (*Acheta domesticus*)
  - Partially defatted house cricket powder (*Acheta domesticus*)
  - Frozen, paste, dried and powder forms of lesser mealworm (*Alphitobius diaperinus* larva)
Cultured Meat (1)

Case-by-case analysis

- Cells are taken from an animal (e.g., feather), then are fed with nutrients such as amino acids, carbohydrates, etc., and grown in a bioreactor.
- If the product is:
  - 1) GM Product (Cat. 3 or 4) → GMFF applies,
  - 2) Otherwise → NF Regulation applies [category (vi) → food consisting of, isolated from, or produced from animal cell culture or tissue culture]
- As of February 2023, still no authorization and petition in the EFSA portal
- Possible reason: lack of specific EFSA guidance, uncertainty among operators
Possible issue with cultured meat


- If a product falls under this definition, it can be labelled as ‘meat’

- If it is ‘meat’, it is subject to hygiene requirements set out in this Regulation, that are stricter than those applicable to other products

- A legal name will be provided with the first authorization
Fermentation-Derived Proteins (1)

1. **Traditional fermentation**: microorganisms modify the properties of foods, e.g., textures or flavors, e.g., yogurt

2. **Biomass fermentation**: microbial cells multiply quickly forming the edible biomass, e.g., mycoproteins

3. **Precision fermentation**: microorganisms are engineered to produce specific proteins, such as chymosin or heme
Fermentation-Derived Proteins (2)

Case-by-case analysis for precision fermentation-derived proteins

- 1) They may fall under the GMFF Regulation
- 2) They may be food additives
- 3) They may be NF [category (ii) → food consisting of, isolated from, or produced from microorganisms, fungi or algae]. The safety of the GMM must be demonstrated
- Currently, none approved in the EU
Plant-Based Proteins (1)

Case-by-case analysis for plant-based proteins

♦ Conventional foods or

♦ Novel foods [category (iv) → food consisting of, isolated from, or produced from plants or their parts]

♦ Selective extracts, in particular those selective-enriched, are not novel if:
  ◊ the matrix has a history of safe use
  ◊ the manufacturing process and the solvent have a history of safe use
  ◊ the final product has a history of safe consumption
Plant-Based Proteins (2)

♦ **Example** of novel food plant-based proteins:
  ◊ **Mung bean** (*Vigna radiata*) **protein** *(EFSA-Q-2020-00284)*: it is a dry, white powder and the major constituents are protein (88–91%)

♦ **Example** of non-novel food plant-based proteins:
  ◊ **Pea and soy protein hydrolysate**
# Plant-Based Proteins (3)

<table>
<thead>
<tr>
<th>Authorised novel food</th>
<th>Conditions under which the novel food may be used</th>
<th>Additional specific labelling requirements</th>
<th>Other requirements</th>
<th>Data protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>'Mung bean (Vigna radiata) protein</td>
<td>Specified food category</td>
<td>Maximum levels</td>
<td>The designation of the novel food on the labelling of the foodstuffs containing it shall be &quot;mung bean protein from Vigna radiata&quot;.</td>
<td>Authorised on 15 May 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Eat Just, Inc., 2000 Folsom Street San Francisco, CA 94110 USA. During the period of data protection, the novel mung bean protein is authorised for placing on the market within the Union only by Eat Just, 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 Eat Just, Inc. End date of the data protection: 15 May 2027.</td>
</tr>
<tr>
<td>Protein products</td>
<td>20 g/100 g</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Authorised Novel Food

<table>
<thead>
<tr>
<th>'Mung bean (Vigna radiata) protein</th>
</tr>
</thead>
</table>

**Description/Definition:**
The novel food is mung bean protein powder extracted from seeds of the plant *Vigna radiata* by several processing steps followed by pasteurization and spray drying.

**Characteristics/composition:**
- Moisture: ≤ 6%
- Protein (w/w)*: ≥ 84%
- Ash (w/w): ≤ 6.0%
- Fat (w/w): ≤ 5.5%
- Carbohydrate (w/w): ≤ 5.0 by calculation

**Microbiological criteria:**
- Aerobic plate count: < 5 000 CFU/g
- Yeasts and moulds: < 100 CFU/g
- Coliforms: < 100 CFU/g
- *Escherichia coli*: < 10 CFU/g
- *Listeria monocytogenes*: Not detected in 25 g
- *Salmonella* spp.: Not detected in 25 g

* w/w: weight per weight.
* CFU: colony forming units.
Plant-Based Proteins (4)

Issues with legal names of the products

♦ Milk/dairy product names cannot be used on plant-based products (e.g., ‘veggie milk’) as per Regulation (EU) No. 1308/2013

♦ See also the EU Court of Justice Case C-422/16 (‘TofuTown’)

♦ The use of dairy descriptors is allowed if not misleading: ‘milk alternative’, ‘yoghurt-style’, ‘creamy’, ‘buttery’, ‘does not contain milk,’ since the Amendment No. 171 to Reg. (EU) No. 1302/2013, that aimed to prohibit “imitation or evocation” of dairy products, was withdrawn
Plant-Based Proteins (5)

Issues with legal names of the products

♦ **Meat product names** (e.g., ‘steak’, ‘sausage’, ‘burger’, and ‘poultry’) are not legally protected by Reg. (EU) No. 1308/2013

♦ **Amendment No. 165** proposed to reserve such names only to animal meat products but was ultimately rejected by the European Parliament

♦ **Member State legislation and enforcement practices must be assessed**
Plant-Based Proteins (6)

♦ GERMANY. Rule 1.4 of the Deutsche Lebensmittelbuch-Kommission (German Food Book Commission): the vegan or vegetarian character be clearly and legibly indicated, as well as the ingredient that is the primary substitute, e.g., ‘with pea protein’

♦ FRANCE. Decree No. 947 of 29 June 2022 prohibits names recalling meat on processed ‘meat-like’ plant-based products, with few exceptions. On July 27, 2022, the Conseil d'État (Council of State) issued an interim urgent order to suspend the entry into force of the Decree (originally set for October 2022)
UK Updates (1)

- Authorities: **Food Standards Agency** (FSA) for England and Wales and **Food Standards Scotland** (FSS) for Scotland
- The legislation still reflects EU Regulations (‘retained EU law’)
- **Retained EU Law (Revocation and Reform) Bill** (still not approved): retained EU law will either be repealed or assimilated into UK domestic law by **December 31, 2023**
- **Northern Ireland**: EU regulations still apply ([Northern Ireland Protocol](#)), EC authorizations cover also NI
UK Updates (2)

- The **GB novel food list**: Annex to **retained EU regulation 2017/2470**
- **Online register** of authorized novel foods in Great Britain (GB)
- New portal **GB Regulated Products Application Service** (FSA-FSS)
- The UK government has already stated that it wants to make its food legislation **more efficient** to support innovation
UK Updates (3)

♦ Novel foods/food additives permits issued by the EC as of 1.1.21 are valid

♦ Petitions pending as of 1.1.21 must be (re)submitted to FSA/FSS

♦ Regulation 20 of The Food and Feed (Miscellaneous Amendments) Regulations 2022: transitional measures for edible insects → Insects legally marketed in the EU/UK as of 1.1.2018 and petitioned to the EC before 1.1.2019 may remain on the UK market, if such applications are resubmitted to the FSA-FSS by 31.12.23, until a decision is made
The seven insect varieties covered by the Transition Arrangement:

- Lesser mealworm (Alphitobius diaperinus larvae)
- House cricket (Acheta domesticus)
- Yellow mealworm (Tenebrio molitor)
- Banded or decorated cricket (Gyllodes sigallatus)
- Bird grasshopper / desert locust (Schistocerca gregaria)
- Migratory locust (Locusta migratoria)
- Black soldier fly (Hermetia illucens larvae)
Thank You

Any questions?

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