Precision Fermentation: practices, challenges and suggestions for the novel food framework

FOOD FERMENTATION EUROPE

EFSA ad-hoc stakeholder meeting, Parma
18.10.23

EXECUTIVE SUMMARY

Today, there are protracted delays in the processing of novel food applications that cause great uncertainty, and are therefore causing FFE members to be discouraged to consider the EU market for their innovative alternative proteins.

We wish to introduce the PF sector to EFSA, share challenges we identified in the current process, as well as our recommendations. More specifically, as detailed in the coming slides, we wish for:

1. New, consolidated, and clearer guidelines for novel foods combined with;

2. The possibility for much broader prescriptive pre-submission advice in order to offer a clear, predictable, and efficient pathway to novel food approval.

Agenda

1. Presentation of Food Fermentation Europe

2. Novel foods regulation: overview of challenges

3. Suggestions for EFSA's implementation of the novel food authorisation process

4. Q&A

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1. Presentation

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WHO WE ARE

Better Dairy, Bon Vivant, Formo, Imagindairy, Onego Bio, Standing Ovation, Those Vegan Cowboys and **Vivici** form **Food Fermentation Europe**, the European alliance that represents **fermentation-enabled food and food ingredients.**

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OUR MISSION

We have been developing Food Fermentation Europe over the past year and we aim to:

- Act as the **unified voice representing the transformative fermentation food and food ingredient sector.**
- Pursue an **expeditious development and rollout of innovative fermentation technology and products** to enable more sustainable food systems in Europe.

We launched in March 2023!

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OVERVIEW OF PRACTICES

Definition

Fermentation for alternative proteins can be broken down into three categories: **traditional fermentation, biomass fermentation, and precision fermentation.**

1. **Traditional fermentation:** used in food production for millennia, it uses microbial cultures to preserve foods, create alcoholic beverages, and improve the nutritional value and bioavailability of foods ranging from yogurt to tempeh.

2. Biomass fermentation: uses the high-protein content and rapid growth of microorganisms to efficiently make large amounts of protein-rich food. For example, Quorn grows filamentous fungi via fermentation to use as the primary ingredient in their products.

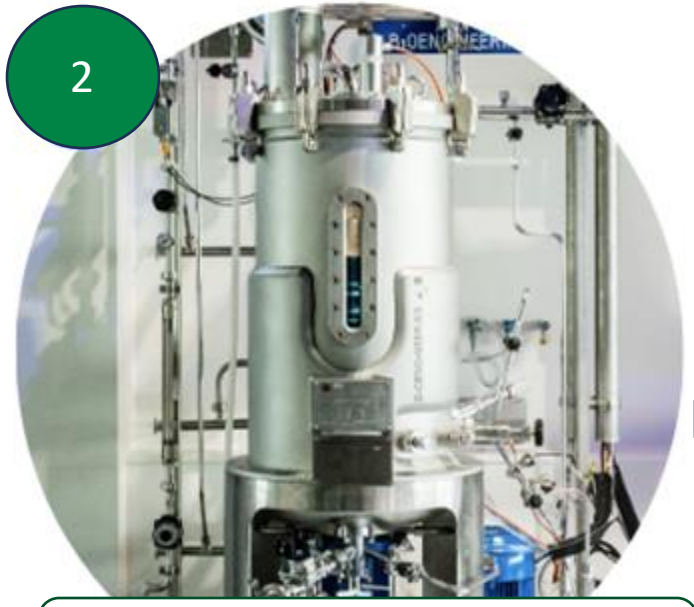
3. Precision fermentation: the Good Food Institute describes it as an application that uses microorganisms such as bacteria, yeast, or fungi to produce specific functional ingredients.

State of play

- Precision fermentation is a powerful, flexible process for using microorganisms to produce **alternative proteins.**
- FFE is currently working on a global definition of precision fermentation with its US counterpart (US Precision Fermentation Alliance).

STEP-BY-STEP FROM FERMENTER TO TABLE

MOLECULAR BIOLOGY



BIOPROCESS ENGINEERING

FOOD SCIENCE

STRAIN DEVELOPMENT

PROCESS DEVELOPMENT

PRODUCT DEVELOPMENT

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STEP-BY-STEP FROM FERMENTER TO TABLE

PRECISION FERMENTATION PROCESS

Upstream

Target selection

E.g., protein, lipid, pigment, vitamin

Host selection & strain development

Host is selected for target expression and strain functionality is optimized

Feedstock selection

E.g., sugar or industry side streams depending on host strain and target

Fermentation

Fermentor design

Submerged, solid-state, or membrane cell-recycle bioreactor

Process optimization

pH, temperature, oxygen (or no oxygen), concentration of salt

Downstream

Pre-treatment

Separation

Concentration

Purification

Product formulation

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2. Novel Foods regulation: overview of challenges

OVERVIEW OF CHALLENGES

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State of play

- FFE members have not submitted novel foods applications to date, but first applications could be filed in Q1 2024.
- FFE has nonetheless retrieved insights from other applicants in the fermentation space which it would like to raise to facilitate future applications from the sector.

Insights

To complement Cellular Agriculture and EuropaBio's overview of challenges experienced by novel foods applicants, below are the issues that applicants in the fermentation space have identified:

- Complex set of EFSA guidelines
- Lack of pre-submission advice on content of applications
- Long and unpredictable authorisation process for novel foods

CHALLENGES 1/4

Complex set of EFSA guidelines

- Lack of a single guidance document for novel foods applications.
- A multitude of documents covering many topics must be cross-referenced to obtain EFSA's latest recommendations applicable for a novel food dossier (example: for precision fermentation novel foods, latest applicable recommendations on particular aspects may be found in guidance for GMOs, feed, or food enzymes).

CHALLENGES 2/4

Lack of pre-submission advice on content of applications

- The current interpretation of the Transparency Regulation by EFSA limits pre-submission advice to general advice on applicable requirement without allowing any discussion on the content of applications or specific applicant strategies to establish the safety of its novel food, postponing potential key discussions to the risk assessment phase.

CHALLENGES 3/4

Long and unpredictable authorisation process for novel foods

- The default timeline for authorisation of novel foods as established by the novel food regulation, from dossier submission to update of the Union List, is under 18 months
- Yet average approval time is closer to twice that time, and sometimes longer
- This lengthy, costly and unpredictable approval time compared to other markets leads to great business uncertainty when making necessary preparations and investments in Europe for market launch of new products
- This is particularly burdensome for precision fermentation start-ups, key players in promising alternative protein innovation, as they are SMEs with limited financial capabilities conditioned to predictable market access
- **We also lack** clear criteria for the need of an amendment for an existing authorisation to reflect product innovation

CHALLENGES 4/4

Long and unpredictable authorisation process for novel foods - diagnostic

- Recent applicants have reported being in the intake phase (validity check) for up to 1,5 years, as opposed to the 30 working days deadline established in the novel food Implementing Regulation (Article 6.2 of Regulation 2017/2469)

- "Clock-stops" following EFSA requests for additional information seem to be the main cause for delays in overall evaluation time, as early as during the intake phase.

- Our understanding and interpretation is that:

  - "Clock-stops" are supposed to be the exception rather than the default rule, only in "*duly justified cases*" (Article 11.4 of Regulation 2015/2283)

  - "Clock-stops" are only envisioned in the risk assessment phase, not during the suitability check / intake phase which should be limited to a quick check of completeness of an application.

  - Especially since the novel food regulatory framework allows for flexibility in the content of a dossier: "*an application may be considered valid even if it does not contain all the elements required [...], provided that the applicant has submitted appropriate justification for each missing element*" (Article 6.4 of Regulation 2017/2469)

3. Suggestions for EFSA's implementation of the novel food authorisation process

OUR SUGGESTIONS

The upcoming revision of EFSA's novel foods guidelines are a key opportunity to address issues faced by novel foods applicants and provide clarity for future applicants.

- **Suggestion #1:** **Consolidate guidelines** to reduce the number of potentially applicable guidelines, clarify the scope of each document, and include clear criteria to determine when changes in microorganisms or manufacturing process trigger the need for a new application.

- **Suggestion #2:** **Allow proper time for EFSA stakeholders to comment**, and for EFSA to consider said comments, before finalizing the new guidelines to optimize their clarity and usefulness to stakeholders.

- **Suggestion #3:** Allow for **broader scope of pre-submission advice**, including outline of data planned to establish the safety of a novel food, so that applicants can anticipate EFSA requests for additional information. This would allow for the submission of more complete dossiers satisfying EFSA's expectations, and lead to shorter suitability check and risk assessment phases.

- **Suggestion #4:** Appoint a single point of contact between applicants and EFSA handling pre-submission advice and potential EFSA requests on dossiers.

4. Q&A

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QUESTIONS ON EVALUATION PROCESS

1. How can we as industry build better dossiers and facilitate EFSA's timely evaluation process?

2. How can we avoid "clock stops" in the suitability phase?

3. How can we avoid "clock stops" in the risk assessment phase?

QUESTIONS ON FUTURE OF NOVEL FOOD GUIDELINES

1. Is EFSA considering only an update of its 2016 Guidance on novel foods or other guidelines as well?

2. Will there be an opportunity for stakeholders to provide input on considered revisions before finalizing of the new document(s)?

THANK YOU.

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