Debate summary and recommendations towards policies Innovation in microbial protein for agrifood

OCCASION

The Flemish Government is stimulating discussions around microbial protein.

Stakeholders came together the Open Food Conference in Leuven, March 11th 2024.

The thematic discussion was coordinated by The ProteInn Club, a Flemish-based ecoof 4 leading knowledge centers and 30 industrial partners spanning the whole value chain of microbial protein.

Many Club members contributed to the discussion, all of whom state their support for the recommendations outlined below.



Today, a number of pioneering companies are already implementing microbial fermentation for the production of proteins for food, feed and fine chemicals on a lab, demo or industrial scale.

Microbial proteins have significant potential not only for the further development of the bio-economy with a broad variety of interesting fermentation products, but also for contributing to the implementation of the Green Deal and supporting the transition towards more sustainable agricultural production. The production of proteins and all kinds of fermentation products in a more sustainable way with a lower environmental impact also contributes to mitigating climate change.

However, the widely extended and multifaceted potential of this technique encounters many regulatory and investment hurdles.

Obstacles arise when building value chains based on technological innovations for microbial proteins, related to the use of sustainable bioresources, the necessary investments to build production facilities, and the regulatory hurdles to bring products to market.

To develop this sector, several requirements were stated: a stimulating environment and regulatory framework, funding, and faster acceptance procedures with the aim of contributing to a more sustainable agriculture, the development of a green bio-economy and climate mitigation.

SUMMARY



INTRODUCTION

Microbial protein is a sustainable solution in the protein transition.

Production of microbial proteins is a form of biomanufacturing that uses bacteria, yeasts or fungi brewed in a bioreactor. Either the entire biomass or a welldefined protein can be harvested. Today, this type of fermentation is already commonly used to produce enzymes, additives other functional compounds.

However, the great potential to meet the growing global demand for proteins is still largely unexplored. The main driver for this innovation is sustainability.

Microbial protein can be produced in a particularly **sustainable** manner. Low-value and globally abundant raw materials (side streams from either agrifood or industrial emissions) can be converted into high-value components in a highly efficient way with minimal use of land and water. In addition, this represents an opportunity to reduce emissions of greenhouse gases, nitrogen and phosphorus.

As a result, microbial protein production can contribute to the Green Deal in the form of a circular bioeconomy and climate mitigation.





RECOMMENDATIONS

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Systemic approach in R&D

> Novel food authorization

Innovation in an international context

Sustainable resources and regulation

Need for investment

Embed the anticipation to legislative requirements and inclusion of a scaling process in the project approach

Shorten the procedure, foresee more interaction with EFSA, and create a worldwide level playing field

Avoid innovations to move away from Europe when it comes to implementation. Create a supportive policy for industrialisation with regard to legislation and funding.

Promote the development and use of underutilized resources. Make sure that regulations do not make it unfavourable to implement these novel techniques

Investments in pilot, demo and flagship equipment have already proven effective. More of these are needed

QUOTES FROM THE DEBATE

1. Systemic approach

From the very beginning of the R&D process, it is crucial to maintain a broad perspective on the challenges ahead.

Geert Maesmans, head of R&D at Cargill, shared his insights on this:

"Besides the technology readiness level (TRL), other factors need to be considered, such as the readiness of regulatory environment, market, consumer acceptance, availability of product and infrastructure. These factors need to be **aligned**. Additionally, when product streams are moved across the system, the overall balance must always be respected. In other words, the overall sum always needs to be 100%, just as when plant material is fermented. This requires a multiplayer type of **collaboration**. Scaling up also needs an integrated system of actors. A combination of collaboration, resilience, and competitiveness will help to conquer the 'valley of death'."

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2. Novel food authorization

Legislation is sometimes seen as a hurdle, such as laws regarding food safety. This should not be seen as an obstacle but rather as **part of the innovation process**. Every member of the discussion agreed on the importance of food safety. In Europe, food safety is established through the General Food Law. Additionally, a Novel Food law regulates a premarket authorization. This involves many aspects: in the case of proteins, is the nutritional quality equivalent to the traditional proteins? Is the labelling not misleading? What about the allergenicity of the new protein?

In Belgium, the Federal Public Service of Health, Food safety and Environment, assists companies with legal advice about the Novel Food procedure. As an expert in this service, Isabelle Laquiere elaborated on the significant potential benefits of preparing a Novel Food dossier:

"Preparing such as dossier demands considerable effort, but the company definitely gets high value in return." Besides getting the pre-market authorization, a company can request 5 years data protection, which allow you to get exclusivity to market the novel food in 27 member states. Moreover, the approval success rate is very high, after a positive EFSA opinion. The 'PAFF' (Plants, Animals, Food and Feed) Standing Committee then finalizes the authorization by specifying the details such as the maximum use levels of the novel food in the proposed food categories, the denomination, labelling requirements, proprietary data protection and specifications, to guarantee the safe and appropriate use of the novel food."

Hermes Sanctorum, CEO of Paleo, pioneer-company in precision fermentation, agreed that food safety is absolutely crucial and one of Europe's strengths to guarantee the safest food on earth:

"The pile of data that is asked in Europe is strikingly higher than in the US or South-East Asia, and that is good for the consumer. Still, the procedure is quite **lengthy**. We'd also like to see more possibilities for **interaction** with EFSA."

Isabelle Laquiere of the Federal Public Service of Health, Food safety and Environment, gave further recommendations to the companies:

"We advise strict adherence to the instructions from the Commission and the guidelines provided by EFSA. Recently, an EFSA update made the **guidelines** more tailored to the latest developments. The better companies follow these guidelines or toolkits, the smoother the procedure will go. Companies can also interact with EFSA using its portal."

Will van den Tweel, CEO/CTO of Those Vegan Cowboys, adds:

"Authorization procedures are costly, but companies know this up front. They can save money by combining studies and using them in dossiers for different regions. Still, more alignment is needed as data requirements differ between regions. The real issue is: there is **no level playing field**, because requirements are much more strict in Europe than in the US. We'd like to see more alignment in this area."

Finally, the lack of a **legal framework for tasting** sessions of Novel Foods before authorization was identified as an area needing attention. Hermes Sanctorum of Paleo stated that there is currently no legal way to organize tastings for potential investors or other business partners, and there really is a need to. Isabelle Laquiere of the Federal Public Service of Health, Food safety and Environment explained:

"Certain member states do allow such tastings, under strict conditions laid down in a 'code of conduct'. The Netherlands' code of conduct is publicly available and is limited to cultured meat producers based in the Netherlands. There are currently no adapted harmonised rules for such tasting sessions of unauthorised novel foods. However, the same question was also recently asked by another member state. This will certainly be discussed in the Novel Food working group. We're really glad that these issues are being raised so we hopelfully can address them appropriately."

4. Sustainable resources and regulation

Today, only 16% of biowaste potential is being utilized in Europe. In order to make use of this abundance of resources, the collection, development of, and use of underutilized sources needs to be promoted. Dirk Carrez of BIC presented some numbers to the group:

"Besides biowaste, biomanufacturing offers great opportunities for recycling carbon emissions. For example, using microbial fermentation, carbon emissions from the metal industry can be transformed into valuable organic compounds."

However, Eric De Coninck, general manager of ArcelorMittal adds a serious concern.

"Current **regulations** in Europe make it difficult **to actually implement** these techniques in several industries (e.g., biofuel) in Belgium. This issue requires special attention when drafting regulations for food production based on microbial fermentation."

3. Innovation in an international context

Often, companies build knowledge in Europe but **start a factory abroad**, as Anna Handschuh of Future Affairs pointed out.

"As a result, we are absolute champions in research and innovation, but commercialization and value creation often go to other regions. The reason for this can be traced back to the lack of a supportive legislative and regulatory environment for food biomanufactoring especially in the current political climate."

Regional differences create opportunities for both companies and the European market. Hermes Sanctorum of Paleo shared his insights:

"Europe, and specifically Flanders, is very supportive of innovation. For example, we recently received a 2 million euro grant from VLAIO to execute our R&D project. Separately, Paleo established a branch in Singapore, an ideal test region to learn about the business case. After Singapore, other regions will follow, and finally the European market will follow, which is known as a big and stable market. Thus, the exploration of international markets is part of the broader strategy towards commercialization in Europe."

For Those Vegan Cowboys, Will van den Tweel agreed and emphasized that working towards commercialization is a **stepwise process**:

"Our company is preparing regulatory approvals in various countries and regions. We expect the quickest approval in the US. Once we have approval, we initially plan to produce via tolling to incrementally derisk the market, and simultaneously derisk the technology. Subsequently, we will decide where to build a dedicated large-scale factory. Since oour R&D team is based in Europe, the US is not necessarily the best option. So overall, when you look at the bigger picture, the delay in approval of the Novel Food dossier in Europe is likely not negatively influencing our plans to build a plant in Europe, because we are not going to start building a plant right away anyway."

5. Need for investment

Dirk Carrez of BIC explained the sector's request for support, co-funding and derisking via **policy measures**:

"Good examples teach us that investments in knowledge and infrastructure should be made step-bystep, so that innovations lead to successful implementation. We must continue on this course.

More biomanufacturing infrastructure are needed for pilot projects, demonstrations and first commercial productions are needed."