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2024

SELECTED PROCEEDINGS

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Preface

There is a growing recognition that food production, especially animal farming, is significantly contributing to climate change. This awareness has fostered further academic studies and a wave of industrial innovations aimed at developing new food products, in particular what we now call alternative protein foods.

In recent years, several events have been organized, in Europe, to discuss the need for a change in the agri-food system. Most of these conferences have focused on novel foods, particularly in the bio-tech sector. One of the reasons is that, over the past decade, the production of meat and dairy alternatives that do not involve animals has moved from research laboratories to spin-off and start-up companies. Several venture capital firms have been attracted by this new sector, prompting many experts and consultant companies to dedicate large part of their work to biotech food innovation.

At the same time, several companies, including major players, introduced plant-based foods into the market. In many cases these are ultra-processed products, where the animal proteins are replaced by extract of legumes, nuts or cereals. Plant-based foods have been a matter of investigations and conference presentations too. However, in both cases the focus was on production technologies, and methods for creating affordable and palatable products, while food safety issues were much less considered. Moreover, the efforts of farmers towards more sustainable livestock and aquaculture production methods have been often ignored.

We recognize that we are on the brink of a radical transformation - if not a revolution - in the agri-food system and in the diets as well. New technologies, such as new genomic techniques that can allow a faster development

of new plant varieties, precision fermentation for producing animal-like proteins in a factory setting, as well as cultivated meat, will certainly change the agri-food business. These new technologies will contribute to reduce the environmental impact of the agrifood sector, but will also present new risks, especially in terms of food safety.

Based on their strong foundation in food safety and food diagnostics, the organizers decided to create a different event, where scientists and industrial leaders could share their achievements in exploring not only the quality of these new products and the efficiency of the new technologies, but to listen to food safety experts, while addressing regulatory issues as well.

In summary, FoodRevolution® was envisioned as a meeting point between the academic world and the industrial sector, encompassing a holistic approach towards a change in the agri-food sector. We all wish not just for a “green” meal, but a nutrient-dense and totally safe one. We want to create a farm-to-fork forum, conscious that meat and dairy products must be produced more sustainably, acknowledging that they will still play a relevant role in human diets even in 2050.

In conclusion, the OneHealth approach is what we need, focusing on biodiversity, soil health, and animal health, as each of these elements are interconnected and have a deep impact on our health.

Maurizio Paleologo

Editor

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In total 73 contributions were included in the scientific programm, 49 oral presentations, 7 short oral communications (pitches), and 17 posters.

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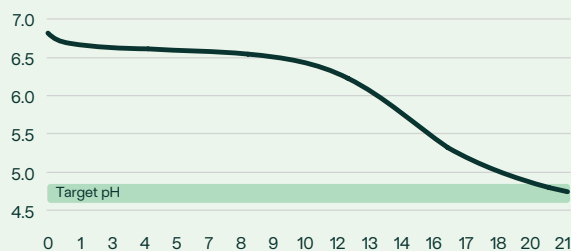
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¹ Novonesis proprietary study conducted by Norstat in November-December 2023. Geography: China, Japan, France, Germany, UK, USA, Brazil, Mexico, Colombia, Argentina. Base: 11044

² FMCG Gurus, Meat & Plant based, top-10 trends for 2023

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Towards a sustainable, safe, and healthy food future

Environmental impacts of food production and nutrition

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Introduction

The global food production is a major driver for environmental impacts. It occupies 38% of the ice- and desert-free land, causes 26% of greenhouse gas (GHG) emissions, 32% of terrestrial acidification, 61% of freshwater withdrawals, and 78% of eutrophication (Poore and Nemecek 2018) (these figures exclude agricultural production for non-food purposes).

The growing world population and changing eating habits, in particular the increasing consumption of meat and other animal-sourced foods, lead to increased burden of food supply on the environment (Godfray et al. 2010).

Large changes in food production and consumption are needed to keep environmental impacts within the planetary boundaries. This requires a solid knowledge of the environmental impacts of food production and consumption. Life Cycle Assessment (LCA) is a methodology of environmental management and offers a high flexibility in assessing environmental impacts of products and production systems (Thoma et al. 2022). It is characterised by a comprehensive assessment of environmental impacts, such as climate change, biodiversity, water scarcity, eutrophication, acidification, resource use, exotoxicity, and human toxicity. Moreover, it covers the environmental impacts along the whole life cycle and is therefore well suited to assess impacts of supply chains. These two characteristics helps to identify and to avoid burden shifts between environmental impact categories and between life cycle stages. Finally,

the environmental impacts are related to a functional unit, which can be 1 kg of food product, but can also consider its nutritional quality in a nutritional LCA (McLaren et al. 2021). This contribution shows the main drivers for environmental impacts as well as some pathways for their mitigation.

Material and methods

Life cycle assessment (LCA) data were derived from 570 studies with a reference year around 2010 in a comprehensive meta-analysis (Poore and Nemecek 2018). The consolidated database covered approximately 38,700 farms in 119 countries. Five indicators were analysed, namely land use (land occupation), freshwater withdrawals (and scarcity-weighted freshwater withdrawals), global warming, terrestrial acidification and eutrophication potentials. The data were standardised by correcting differences in functional units, emission factors, characterisation factors, allocation methods, and system boundaries. Missing life cycle phases were filled by standard data; furthermore emissions and environmental impacts were recalculated, whenever needed. The global totals were validated by comparing with global yield data from FAOSTAT; the deviations were within $\pm 10\%$ for most crops. The LCA data were scaled to the global level using weights. Estimated total arable land, freshwater withdrawals and GHG emissions were consistent with global estimates.

Results and discussion

The results revealed a huge variability in impact between different ways of producing the same food (Poore and Nemecek 2018). The average ratio of the products with 90th percentile impacts to 10th percentile impacts were about a factor of 4 for global warming and acidification, 6 for land use, 11 for eutrophication and higher for freshwater withdrawal and stress-weighted water use. This reveals tremendous differences between producers with high and those with low impacts. This range still covers only 80% of the production, meaning that 20% of producers have even higher or lower impacts. These findings point to a large optimisation potential in food production. Even if part of the variability is determined by natural conditions, which cannot be changed easily, a large mitigation potential exists through improved management practices. The huge range of values for freshwater withdrawals is mainly due to the differences between rainfed and irrigated agriculture and related to climatic conditions. The effects were even stronger for stress-weighted water use, since dry regions tend to have a high need for irrigation and simultaneously a high water stress.

The analysis showed that different pathways to low impacts exist; no universal solutions could be identified. Low impact producers come from different countries, have different production systems and the sources of emissions and impacts differ as well. Nine mitigation strategies were explored using studies evaluating practice changes in the same location and year. Only two strategies, namely diversifying cropping systems and improving degraded pasture showed simultaneous improvements in both, land use and global warming. All other practices caused trade-offs. In general trade-offs between environmental impacts were frequent. To define a mitigation strategy a detailed analysis of each production system in its context is therefore needed.

A further observation was that the distributions of environmental impacts were highly skewed. Between 40 and 50% of the impacts were caused by the 25% of the producers with highest impacts for land use, global warming, terrestrial acidification and eutrophication. This was even more pronounced for water use, where the production of 5% of the food calories causes ~40% of

scarcity-weighted water use. Improving the production of these producers or abandoning production methods and locations with the highest impacts is therefore a very effective mitigation strategy.

We have analysed the contributions of different phases of the supply chain to the climate change impacts of different food groups. In general, agricultural production (land use, crop and animal production) dominates the impacts. Land use and land use change (deforestation, cultivation of peat soils) is highly relevant for some crops like soybean, palm oil or sugar cane. Transport is important mainly for fruit and vegetables and air transport. Storage has a high contribution mainly in case of cold storage of fruits and vegetables. Packaging can be very dominant for beverages. Finally, food loss and waste increased the impact in most food categories.

The challenge to reduce the environmental impacts of the food system is too big to be met by food producers alone, furthermore, there are natural limits in the production systems. Therefore, we need also to consider food consumption. As shown above, an effective strategy is to avoid products with high environmental impacts. The prerequisite is that the environmental impacts of individual food products are known, which is currently not the case.

The comparison between food groups shows that animal-based food products have higher environmental impacts compared to plant-based alternatives, considering the main nutritional role, namely the delivery of proteins. Even producers of meat, dairy products, eggs and seafood with low impacts (10th percentile) have higher impacts than plant-based alternatives, such as legumes or nuts. The potential mitigation effect of changing diets was assessed in two scenarios.

In the first scenario, animal-based foods were completely replaced by plant-derived alternatives. This resulted in halved impacts for global warming, acidification and eutrophication from food, a ~75% reduction in land use and a ~25% reduction in food's water use (Poore and Nemecek 2018). Higher mitigation effects could be achieved in countries with high meat consumption, like the US. In the second scenario, 50% of animal-based food products were replaced by plant-based alternatives by avoiding the producers with the highest impacts.

This synergistic effect allowed to achieve about two-thirds of the mitigation potential of the first scenario.

The various effects of such changes need further investigation, but it is clear that the mitigation potential in food consumption is large.

Since animal-sourced foods have high environmental impacts, their replacement by adequate substitutes is a promising strategy. A comprehensive literature review has evaluated the environmental impacts, nutritional values, social, economic, ethical and legal aspects of substitutes for meat and milk (Mehner et al. 2024) and compared them to meat and dairy products.

Meat substitutes had clearly lower environmental impacts relative to meat (chicken, pork or beef). At the same time, their nutritional profile is of a similar quality as meat.

Milk alternatives also showed lower environmental impacts in general. However, some raw materials for plant-based drinks were linked to risks of deforestation and water scarcity. Furthermore, their nutritional profiles were of lower quality, so that they cannot be considered as equivalent substitutes from a diet perspective.

Soy-based meat and milk substitutes turned out to be the most promising alternatives (Herrmann et al. 2024). If deforestation is avoided, they have low environmental impacts and comparatively high nutritional quality. We showed that considering the protein quality (amino acid profiles) can significantly change the results (Herrmann et al. 2024). These and other studies showed that the environmental impacts of foods should be considered in the light of their nutritional profiles (Green et al. 2023; Reguant-Closa et al. 2024).

In a study for the Swiss food system, we showed that the overall environmental impacts could be reduced by more than 50% (von Ow et al. 2020). This can be achieved by changing the diet, avoiding food waste and optimising the whole food system.

The optimised diet would contain less meat, alcohol, and vegetable oils, more cereals, potatoes, fruits, vegetables, and legumes.

The consumption of dairy products would remain fairly constant, which is due to the constraint in the model scenario that the whole agricultural area of Switzerland

- consisting of 70% grassland - should be used.

Dairy production is the most efficient use of grassland for food production. It is remarkable that this strong mitigation of environmental impacts can be achieved without completely banning animal-sourced food from the diet. The optimised diet would be more compliant with the dietary recommendations than the current diet.

Conclusions

The meta-analysis of food LCA studies (Poore and Nemecek 2018) showed that a large variability exists between producers of the same product indicating substantial mitigation opportunities. Different producers require different approaches to reduce their impacts; no universal solutions could be identified. Furthermore, trade-offs between different environmental impacts have to be taken into account. The impact distributions are highly skewed, with 25% of the producers causing about half of the environmental impacts. Following dietary recommendations is a first important step to the mitigation of environmental impacts.

By reducing the consumption of animal-based food and by avoiding products with high environmental impacts, environmental burdens can be significantly reduced, with synergies between these two strategies. To achieve these improvements, better information on the environmental impacts must be made available and communicated along the supply chain. Furthermore, avoiding food loss and waste offers a substantial potential to mitigate environmental impacts.

Consumers should prefer seasonally produced fruits and vegetables, avoid vegetables from heated greenhouses and food transported by air freight as well as avoid or reduce shopping trips by car.

A study of the Swiss food system showed a potential to reduce environmental impacts by more than half by optimising dietary patterns, notably reducing the meat consumption, avoiding food waste and optimising the whole food system. The resulting dietary patterns were close to the recommended diets and still included certain amounts of meat and dairy.

Plant-based alternatives to meat and dairy products offer a potential to significantly reduce the environmental

impacts of nutrition. However, the nutritional value of these alternatives should be carefully considered, in order to avoid deficiencies, as some nutrients are present in lower amounts or are less available for human nutrition.

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Towards a sustainable, safe, and healthy food future

New genomic technologies for the sustainability of the agrifood system

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The genome editing technology

In 2021, the Nobel Prize in Chemistry was awarded for the first time to two women, Emmanuelle Charpentier and Jennifer Doudna, for their pioneering work in 2012 that led to the development of the genome editing technique using the CRISPR/Cas9 system. Although the Nobel Committee's motivations focused primarily on potential biomedical applications, it is actually in the agri-food sector that we might see the broadest range of applications for this extraordinary technique.

Extraordinary because it turns what was once a geneticist's dream into reality: the ability to take a specific base among the hundreds of millions or billions present in the genomes of living organisms and modify it at will, just as one would edit a specific letter in a text-replacing it, removing it, or adding it. But while editing a text is child's play for me, imagining doing the same in a DNA molecule, within a cell, at that specific base and nowhere else, was a Herculean task before the work of these two laureates.

The broader range of applications in agriculture is due to the fact that while in humans we can use this technique "only" to correct genetic defects, meaning harmful mutations such as those that cause genetic diseases or cancer (and "only" is in quotes because these are applications with an enormous impact on health), in plants we can also use it to improve all those traits that have always been the focus of positive artificial selection

in genetic improvement. Until now, we could only rely on spontaneous mutations - if suitable ones existed to achieve our desired result - or on mutations induced by mutagenic treatments, which, due to their random effects, might produce the desired mutation but certainly also many unnecessary ones.

The mutations we can now generate with genome editing are identical and indistinguishable from those that occur spontaneously or are induced by mutagenic treatments, but we can achieve them much faster (compared to spontaneous mutation) and with greater precision (compared to mutagenesis effects). For this reason, a few years ago, as the Italian Society of Agricultural Genetics, we decided to call them Assisted Evolution Techniques (TEA), as they help us evolve plants and animals of agricultural interest in a way similar to traditional genetic improvement but with much greater precision and speed.

CRISPR/Cas9 is a two-component system. The first component, Cas9, is a protein called a nuclease, whose natural function is to cut the DNA molecule on both strands, creating a double-strand break that disrupts the continuity of the chromosome at the target site. The second component, CRISPR, is the so-called guide RNA, an RNA molecule consisting of two parts: one that binds to Cas9 and another that directs the complex to the specific DNA location where the cut should be made.

The portion of the guide RNA that determines the cutting specificity is 21 bases long, and these bases are designed and synthesized in the lab to allow precise cutting at the desired location to induce a mutation. To genetically modify plants, the process always begins with tissue or cell cultures. Genetic manipulation is performed on these cultures - whether or not they go through the formation of a callus, which is a mass of undifferentiated cells - by introducing the CRISPR/Cas9 complex to induce the desired DNA modification. Once the modification occurs, differentiation is induced again to produce what are called somatic embryos, which are then regenerated into plants. Whether the editing was successful is determined only at the end, after the plant has been regenerated, by checking in which individuals the modification has taken place (and if it has occurred at all). In those where it has occurred, further analysis determines whether the modification is present in all cells or only in some.

New genomic technologies and agriculture

Genome editing represents a crucial technology for the future of agriculture, as modern agriculture faces a dual challenge: producing more while consuming less. Sustainable intensification is necessary to address, on one hand, the increasing global food demand driven by population growth and the transition to diets richer in animal products, and on the other hand, the urgent need to reduce the environmental costs of food production - costs that, for now, are entirely borne by our planet with no real accountability.

Scientific and technological advancements could enable us to develop crops that use environmental resources such as water and fertilizers more efficiently and defend themselves better against pathogens - if we are willing to embrace the technologies available to us. In other words, a more environmentally compatible agriculture, or as some prefer to call it, a "more organic" agriculture, cannot ignore genetic progress and the technologies that facilitate its application from laboratories to the fields.

Of course, such a scenario requires trust in the possibilities offered by scientific and technological

progress. It is important to remember that this progress is the foundation of economic and social development worldwide and is responsible for the growing well-being of an increasing share of the global population.

However, for scientific advancements to translate into innovations - that is, for inventions and discoveries to become new processes and products with real-world applications - high-quality research and an effective innovation system facilitating the transition from research to industry are not enough. A regulatory framework is also necessary, one that allows innovations to reach the market promptly without unnecessary restrictions. Most importantly, consumer acceptance of the innovations introduced by the production system is crucial.

Today, genetic innovation in agriculture - particularly in Europe but not exclusively - struggles to reach the market due to both regulatory constraints and, more significantly, consumer reluctance. This reluctance is largely shaped by two simplistic equations, both based on flawed assumptions: first, "old equals good, new equals bad," and second, "natural equals good, artificial equals bad." These misconceptions stem from a distorted perception of what is natural and what is not - a perception shaped by the very development of agriculture itself.

As Western civilization advanced, it increasingly equated highly artificial agricultural landscapes - entirely shaped by human intervention, domestication, and genetic modification - with natural environments formed by evolutionary processes. At the same time, people became increasingly detached from true nature, which they are less exposed to and now often perceive as hostile rather than nurturing. The paradox of modern Western society is that it frequently shows greater concern for preserving its own artificially created "pseudo-nature" than for protecting the actual natural world, which truly requires our care.

Reducing the environmental impact of agriculture

Reducing the environmental impact of agricultural production requires avoiding simplistic solutions, such as lowering yields per hectare. The focus should be on reducing environmental impact per unit of product, not per unit of land.

A common misconception is that intensive farming and cultivation systems have a greater environmental impact than extensive systems. However, FAO data (FAOSTAT Analytical Brief 50, 2022) presents the opposite reality: the greenhouse gas emissions per kilogram of product - whether beef or milk - are highest in Africa, where extensive farming is predominant, and lowest in Europe, where agriculture is largely intensive.

Agricultural policies that simultaneously reduce environmental impact and yields per hectare may achieve local improvements, but they do not provide a global solution if the shortfall in production must be compensated elsewhere, often with a higher environmental cost per unit of product.

Today's approaches to transforming agricultural production systems vary widely, but many share a common flaw: a disregard for scientific evidence. Some advocate for a return to the past, romanticizing outdated methods. Others believe waste reduction alone will solve the problem. Still others argue for rigidly separating different types of agriculture, whether organic, biodynamic, conservation, regenerative, or otherwise.

Yet agriculture is one and the same, with a single objective: to produce more and better while consuming fewer natural resources. A pragmatic, ideology-free approach is more essential than ever, one that avoids segmenting agriculture into incompatible categories and instead seeks the best solutions for each specific context, making full use of all available scientific and technological advancements.

Numbers confirm that simplistic solutions, such as reducing food waste, while necessary, are insufficient. Among the various climate change mitigation measures for the agri-food sector, reducing food waste - both at the consumer level and within distribution systems - is among the least effective (Ivanovich et al. 2023).

Adopting a healthier diet, such as the one recommended by Harvard Medical School (Willett and Skerret 2017), would not only improve public health but also provide significant environmental benefits by reducing CO₂ emissions, mainly through limiting red meat consumption. However, achieving this goal is challenging due to deeply ingrained dietary habits rooted in cultural

traditions, as well as ethical concerns about imposing dietary changes.

Nevertheless, action is necessary. On the one hand, meat, dairy, and related products account for over 50% of the global warming impact of the agri-food system. On the other hand, projections indicate that by 2050, ruminant meat consumption will increase by 90%, while overall consumption of animal-based products will rise by 70% (Sans and Combris 2015).

Unlike the mitigation measures mentioned above - which, while possible, are either ineffective (waste reduction) or challenging to implement (dietary changes) - improvements in agricultural production processes have the greatest potential to reduce emissions and environmental impact without significant drawbacks or unwanted side effects.

A circular, sustainable, and integrated approach to agricultural production that includes soil, water, livestock, crops, nutrients, and even energy production, as seen in some regenerative agriculture models (Schulte et al. 2022), can help reduce greenhouse gas emissions over the long term.

Technological innovations can also play a decisive role in accelerating the transition to zero-emission agriculture or even negative emissions (Northrup et al. 2021). For example, plant genetic improvement using advanced genomic technologies, such as CRISPR/Cas gene editing, could enhance photosynthetic efficiency, fertilizer utilization (particularly nitrogen), reduce the need for synthetic chemical plant protection products, increase drought tolerance, and ensure greater production stability, even under changing climatic conditions.

The path to sustainable agriculture through plant breeding

The path to sustainable agriculture - one that meets the challenges of a changing environment and an agriculture that must improve its environmental footprint - also involves using the most advanced technologies available. Genome editing through CRISPR/Cas9 will undoubtedly play a central role in renewing the genetic pool to better address these challenges.

However, for genome editing innovation to deliver benefits to consumers' tables, changes are needed in the

current regulatory framework within the European Union. On July 24, 2018, the European Court of Justice ruled that organisms created through site-directed mutagenesis (via genome editing) should be treated as genetically modified organisms (GMOs), rather than as products of traditional mutagenesis.

This decision subjects genome-edited organisms to stringent regulations regarding field release and food consumption, with costs ranging from 30 to 50 million euros for each new modification event. In doing so, the Court disregarded the opinions of numerous academic and scientific societies, which unanimously argued that there is no risk difference between traditional mutagenesis products and those from new-generation mutagenesis. The Court's ruling equates substituting one DNA base for another – just like spontaneous or induced mutations – to introducing a foreign gene, which is not scientifically supported.

In response to the ruling, the European Commission, urged by many member states, undertook a process to revise the 2001/18/EC directive that defines and regulates GMOs. This directive, outdated after 17 years, no longer fits the current landscape of scientific and technological progress, which has made sophisticated, precise, and effective technologies available that cannot simply be categorized under the binary “GMOs yes or no” logic.

On July 5, 2023, the Commission published a proposal for a new directive, which introduces two new categories of edited products. The first, called NGT-1, is considered equivalent to traditional genetic improvement and is essentially deregulated. The second, NGT-2, is considered equivalent to GMOs but will be subject to a simplified regulation compared to the 2001/18/EC directive.

The European Parliament approved this proposal on February 7, 2024, with only minor modifications, and it is now awaiting approval from the Council of the European Union. Hopefully, soon, the European Union will be able to embrace genetic innovations for the plants we eat using the most modern, precise, and sensitive technologies available to science.

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Towards a sustainable, safe, and healthy food future

Microbiome-based solution and soil improvers as green biofertilizer for agri-food system sustainability and healthy soil

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Increasing crop yields and productivity without the massive use of chemical inputs such as pesticides and mineral fertilisers is a major challenge of the 21st century. The rising global food demand has led to the intensification of farming practices and exhaustive use of chemical pesticides and fertilisers with high environmental impacts in terms of emissions, soil erosion and loss of plant genetic and soil microbial diversity, and resulting in damage to the balance of soil, water and the ecosystem services. It is more urgent than ever to promote a change in the way we produce and consume food. There is a general consensus on the need to define and adopt more sustainable and environmentally friendly agricultural alternatives (Chen et al. 2018). To guarantee the production of healthy and high-quality food, it is crucial to maintain healthy soil, which serves as the foundational bedrock for robust and sustainable agricultural and food production systems (Suman et al. 2022).

The role of soil microorganisms for sustainable agriculture and healthy soil

In the last decades, a key role in supporting soil ecosystem functions and the broader agri-food chain is exerted by soil and root/plant microorganisms. Microorganisms occur everywhere throughout the entire food system, providing benefits for the planet as a whole and

everything that lives on it. They colonize the roots, leaves and fruits of all cultivated plants, increasing the nutrient absorption of cultivated plants and are key players in food production, essential for the health of plants, animals, humans and the environment. The soil microbiome plays a crucial role in enabling soil functions in agricultural production, being involved in carbon dynamics (decomposition and synthesis of organic matter), nutrient cycling (decomposition, transformation, nitrogen fixation and plant nutrient uptake), soil structure and maintenance (particle aggregation and transport) and biological population regulation (pest and disease control).

To guarantee the production of healthy and high-quality food, it is crucial to maintain healthy soil, which serves as the foundational bedrock for robust and sustainable agricultural and food production systems. In the framework of European Joint Programme SOIL (EJP SOIL), “Soil Health” has been defined as the current capacity of a soil to function as a vital living system, within natural or managed ecosystem boundaries and land-use boundaries, to sustain plant and animal productivity and health, maintain or enhance water and air quality, and to further provide ecosystem services in the long-term without (increased) trade-offs between ecosystem services (van del Elsen 2022). And a key role is exerted by soil microbiome, which is the link between above- and

belowground diversity (Yan et al. 2022). A microbial loop circularly links human health, and food safety and security to the soil microbiomes; in particular, chemicals, microbes, and resources exchanged between soil and humans via plants and animals (Yan et al. 2022).

Bridging scientific knowledge on soil microorganisms with practical agricultural applications, and assessing how microbial data can inform and improve agricultural policies and practices represent a valid strategy to ensure sustainable farming and food safety. In a preliminary study we identified key research trends, gaps, and emerging themes within the scientific community, providing insights into the integration of microbial research into agricultural policy development, underscoring the strategic importance of scientifically validated microbiological indicators in soil management and their key role in the entire food chain, supporting a solid and sustainable 'farm to fork' framework (Bevivino 2024a).

Microbiome-based solution for healthier and more sustainable food systems: A focus on SIMBA project

Healthy soils, less use of fertilisers and pesticides, and new solutions based on microbiomes are key elements to promote sustainable agriculture, the basis for the production of quality food and other resources for a circular bio-economy (Bevivino et al. 2023). Utilising microorganisms to improve the sustainability of agricultural production permits to achieve the objectives of One Health manipulating soil and plant microbiomes and increasing soil microbial diversity. Harnessing the microbiome-based solutions capitalizing the microbial traits beneficial to the host or the environment or both represents a promising avenue for developing more sustainable next-generation agriculture. Complex microbial ecosystems along with their theatre of activity, collectively referred to as microbiome (Berg et al. 2020), play a central position in the concept of One Health. Soil microbiomes as well as plant microbiomes directly impact food composition and quality on one side, and on the other side, they directly and indirectly impact the human microbiome. The employment of microbiome-based solutions and soil improvers from circular food

production will be presented, offering an environmentally friendly alternative to the use of inorganic fertilizers.

The use of efficient microbial inoculants is considered an important strategy for increasing crop productivity and reducing chemical inputs in agriculture (Hayat et al. 2010; Clagnan et al. 2024). The use of Plant Growth-Promoting Microorganisms (PGPM) can improve soil fertility, resistance to plant pathogens and environmental stresses, and hence increase crop productivity and nutritional quality (Berg 2009). To counteract the problem of uncertain or limited field efficacy, a potential strategy is offered by the adoption of multifunctional microbial consortia, taking advantage of stable synergistic effects and increased flexibility of responses under different environmental conditions (Bashan 1998; Tabacchioni et al. 2021).

When considering inoculation with PGPM, the first objective is to find the best bacteria available and to identify the best delivery method, which determines the potential success of the inoculant. Microbial consortia have a higher potential to increase plant growth-promoting (PGP) effects compared to single inoculants, providing more balanced nutrition and improves absorption of nitrogen, phosphorus, and other nutrients (Calvo et al. 2014; Woo and Pepe 2018).

Within the frame of the Horizon 2020 SIMBA project (Sustainable Innovation of Microbiome Applications in Food System), which provided a holistic and innovative approach to the development of microbial solutions to increase crop production and food quality, innovative microbiome-based solutions were developed and highlighted as excellent innovations by the European Commission's Innovation Radar team (<https://simbaproject.eu/simba-partner-recognised-as-key-innovator/>).

Starting from microorganisms with proven ability to exert PGP effects on the target crops, some of them belonging to the ENEA microbial culture collection (<https://www.collezionebica.enea.it/it/>), different SynComs (Synthetic Microbial Communities) or multifunctional microbial consortia were developed (Tabacchioni et al. 2021; Magarelli et al. 2021).

The efficacy and reproducibility of their application were evaluated in greenhouse under different abiotic stresses (Hett et al. 2022; Graziano et al. 2022) and under field conditions on various farms in Germany and Italy, under both organic and conventional cultivation conditions (Hett et al. 2023; Caldara et al. 2024).

A four-species bacterial consortium composed by different bacterial species isolated from the same environmental sample proved capable of producing more biofilm in comparison to the sum of what was obtained by the four strains when grown singularly, improving plant performance and survival under drought, and leading to drought stress protection in a plant host (Yang et al. 2021). To scale up the production process of microbial bio-fertilizers, each bacterial strain was grown in submerged cultures in a 21-L stirred-tank bioreactor (B. Braun Biotech International, Germany).

The production of microbial bio-fertilisers on a pilot scale using *O. ficus-indica* juice from pruning wastes as a cheap medium permits to reducing both economic and environmental impacts associated with the generation of wastes and increasing the viability of microorganisms after drying processes (Magarelli et al. 2021). The application of microbial consortia in combination with biochar increased grain yield and improved food quality by affecting low-molecular-weight gliadins and glutenin subunits, that impart the viscoelastic properties of the dough without altering the biodiversity of the resident microbiome (Caldara et al. 2024; Bevivino et al. 2024). To guarantee the efficacy of plant biostimulants in agronomic field experiments, a set of requirements should be considered when testing PGPM efficacy in field trials (Neuhoff et al. 2024). Overall, our results suggest that multifunctional microbiome-based solutions may be effectively exploited as biofertilizer in sustainable crop cultivation without altering the biodiversity or the resident microbiota, thus avoiding risks of long-term impacts on natural biodiversity. The genome sequencing of strains composing the inoculum confirmed the plant-growth-promoting (PGP) activity of selected strains and the exclusion of any traits related to virulence and

multidrug resistance genes, suggesting the safe application of selected strains as “plant probiotics” for sustainable agriculture and food production (Cangioli et al. 2024).

The role of soil improvers: A focus on DELISOIL project

Maintaining healthy soil is essential for sustaining ecosystems and to ensure the production of healthy and high-quality food. Soils are healthy when they are in good chemical, biological and physical condition, and thus able to continuously provide their important ecosystem services (Lehmann et al. 2020). Use of recycled fertiliser products would contribute to independence from mineral fertilisers and improve soil health. Organic matter and nutrients in food industry waste products could be reused but are instead released to the nearby environment, such as waterways where they can cause eutrophication. Applying circular bioeconomy methods to the food industry value chain, and improving use of residue streams and regional production of soil improvers will enhance food system sustainability, reducing waste. The main aim of the DELISOIL (Delivering safe, sustainable, tailored & societally accepted soil improvers from circular food production processes for boosting soil health) project is to contribute to the European Union’s Mission “A Soil Deal for Europe”, by improving the sustainability of food systems and enhancing soil health (Bevivino et al. 2024). By developing improved recycling and processing solutions for food industry residues, safe, sustainable, tailored and societally accepted soil improvers (defined as a material obtained from a food processing residue stream, whose main function when added to soil is to maintain or improve its physical and/or chemical and/or biological properties) will be produced and their ability to enhance and restore soil health and fertility will be evaluated in selected cropping systems. Processing of food industry residue streams into tailored soil improvers and organic fertilisers will reduce the use of other nutrient sources, lower energy consumption and increase national self-sufficiency. A data mining approach was

performed to analyse large data sets and scientific literature related to European projects to evaluate how soil improvers can improve soil health, and to understand the challenges and opportunities in sustainable agriculture related to the application of soil improvers (Bevivino 2024). The application of tools like word clouds, heatmaps, and VOSviewer allowed us to grasp not only individual elements but also the complex interactions among them, thus providing a solid foundation for the development of strategies and policies aimed at promoting sustainable agriculture.

Key terms such as fertilizer use, crop yield improvement, soil health, and the environmental impact of agricultural practices reflected the priorities and trends within soil health research. The application of biochar, compost, and digestate and other soil improvers has demonstrated significant improvements in soil health metrics, crop yields, and environmental sustainability (Bevivino 2024b).

A multi-actor approach, involving research organisations and companies with partners along regional food industry value chains in five regional Living Labs and Lighthouses, will permit to combine food processing and production industries, technologies for food residue treatments, companies generating soil improvers and organic fertiliser products, and landowners to test the tailored soil improvers (Delisoil n.d.).

Conclusion

In conclusion, the combined use in agricultural fields of microbiome-based solutions and safe, sustainable, and tailored soil improvers, represents an eco-friendly approach to promote agricultural productivity and boost soil health and sustainability.

The growing need for sufficient food resources to meet population growth, to increase food security, to counter the increasing loss and erosion of soil and biodiversity, to make available sustainable models of development and consumption, are driving the world of research and production to find alternative solutions. The principles of the Circular Bio-Economy make it possible to respond

effectively to the global challenges we face also through innovative ways such as microbial culture collections and recycled soil improvers that can bring safe, regulated, sustainable fertiliser products to market and promote their use.

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New food products – Focus on production technologies

Microbial fermentation for alternative proteins: Challenges and opportunities

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The global food system faces unique challenges: whilst demand for protein rises, recent global shocks have underscored the urgency of strengthening the resilience of agri-food supply chains and enhancing food security whilst simultaneously meeting climate targets.

In this context, new applications of age-old fermentation have emerged as a promising technology that could transform how proteins are produced and consumed. We explore how microbial fermentation can play a role in producing alternative proteins, the opportunities it presents, and the challenges that must be overcome for it to reach its full potential.

The growing demand for sustainable proteins

Global demand for meat is projected to increase by at least 52% by 2050 (FAO 2018), with Europe already feeding 45% of its crops to animals and using half of its farmland for animal agriculture (EC 2023).

This growing demand, paired with the environmental and health concerns associated with conventional animal farming, has driven calls for a more diversified, sustainable protein supply. Current research, including studies from Oxford University (Clark et al. 2020), indicates that meeting global climate targets will be impossible without reducing reliance on conventional animal agriculture. The European meat consumption rate has stabilised at nearly double the global average per capita (EC 2023), further highlighting the need for

change in the region's food systems.

Diversifying Europe's protein supply is also essential if governments are to address global public health challenges such as diet-related ill health, the public health effects of climate change, antimicrobial resistance and pandemic risk. Alternative proteins can be produced through various innovative methods, including microbial fermentation, which offers substantial opportunities for a healthier, more sustainable food system (Mazac et al. 2023). Yet, despite this promise, Europe remains heavily reliant on animal agriculture, and the development of alternative proteins has not seen the same level of investment as other climate technologies (Climate Works Foundation & UK Foreign, Commonwealth, and Development Office 2021).

Microbial fermentation: An overview

Microbial fermentation is a biotechnological process that uses microorganisms to convert raw materials (such as sugars) into value-added products. Three primary forms of microbial fermentation are used for alternative protein production: traditional fermentation, biomass fermentation, and precision fermentation.

1. Traditional fermentation: This method has been used for centuries to produce food products like cheese, yoghurt, and beer. In the context of alternative proteins, traditional fermentation can be utilised to improve the texture, nutrition, and flavour of plant ingredients to

produce plant-based meat alternatives.

2. Biomass fermentation: In biomass fermentation, microorganisms are grown on organic substrates (such as sugars derived from plant-based materials), and the microbial biomass is harvested as a protein source.

This biomass can be used as an ingredient in various food products, including meat substitutes, providing a high-protein, low-cost alternative.

3. Precision fermentation: Precision fermentation generally involves using genetically modified or gene edited microorganisms to produce specific proteins or other compounds. This method has been used to produce ingredients like rennet and citric acid and is increasingly used to create food enzymes, functional ingredients, or animal-free versions of proteins like whey or heme.

Fermentation processes are well-established and scalable and have been used for decades to produce a range of industrial chemicals, feed ingredients, and food products.

Alternative proteins made through fermentation hold the potential to play a central role in meeting Europe's growing food security challenges while contributing to its climate goals.

Opportunities in microbial fermentation for alternative proteins

Microbial fermentation presents various opportunities for the food industry, from scalability to cost-effectiveness. Several factors make fermentation an attractive option for producing alternative proteins.

First, fermentation technology is mature and has already been scaled to large production volumes in industries such as biofuels, pharmaceuticals, and chemicals. Microbial fermentation can occur at scales up to 600,000 litres, making it well-suited for the large-scale production of alternative proteins.

This scalability is crucial as the demand for protein alternatives grows. Fermentation is also a low-cost process, particularly when compared to conventional animal agriculture, which requires significant land, water, and energy resources (Humpeöder et al. 2022). Moreover, the food industry is already familiar with many of the microbial species used in fermentation, as many

strains are already approved by regulators around the world for food production.

Another key advantage is the speed at which microbial fermentation can be developed and scaled. R&D cycles for fermentation technologies are significantly faster than those for plant-based or animal-based products. In some cases, microbial biomass can be harvested every few hours, providing a rapid turnaround for product development and production.

Finally, fermentation-derived products can also play a role in reducing the environmental impact of food production.

For example, meat alternatives made through fermentation uses a fraction of the land compared to traditional animal agriculture (Humpeöder et al. 2022).

By reducing the need for vast amounts of farmland dedicated to livestock, fermentation could enable up to 21% of European domestic farmland to be repurposed for other food production needs (Green Alliance 2024), contributing to greater food security across the continent.

Challenges and bottlenecks

While microbial fermentation for alternative proteins holds great promise, several challenges must be addressed to unlock its full potential.

- Investment gaps and regulatory hurdles

Although fermentation is poised for rapid growth, alternative proteins remain significantly underinvested compared to other climate solutions (Good Food Institute 2024). To reach public and private net-zero commitments, much more investment is needed in alternative protein technologies, particularly in R&D.

The regulatory landscape is another challenge. In the European Union, fermentation-made products are generally regulated under the novel foods regulation, and those produced with genetic modification are subject to additional scrutiny under the European regulation on genetically modified food and feed. This approval process remains a lengthy and complex barrier for many companies.

- Feedstock optimisation for sustainability

Fermentation bioprocesses typically rely on glucose

derived from starch crops like corn or sugar from sugarcane (Piercy et al. 2023). While this feedstock is currently available at scale and has many advantages, it raises future concerns regarding resource use, cost, and sustainability.

Ongoing R&D efforts aim to diversify and optimise feedstock sources - such as the use of agricultural sidestreams - which could reduce costs, minimise waste, and improve the overall sustainability of fermentation-based protein production.

- The need for increased scaling capacity

The fermentation ecosystem for alternative proteins is expanding rapidly, from R&D to commercial-scale manufacturing.

As of 2023, there are at least 16 million litres of food-grade fermentation capacity worldwide, with the majority of this in Europe and North America (Good Food Institute 2023). However, further expansion is necessary, particularly in multipurpose pilot and demonstration-scale fermentation facilities. The need for more facilities capable of adapting to different fermentation processes and products is evident.

- Sensory and consumer acceptance

While fermentation holds great potential, the acceptance of alternative proteins by consumers remains a critical barrier (Smartprotein 2023).

Currently, fermentation-made products do not yet match conventional meat in taste, price, or convenience. To achieve the climate and public health targets set by European governments, more investment is required to make animal-free meat alternatives as delicious and affordable as traditional options.

The path forward: Expanding the fermentation ecosystem

Microbial fermentation holds significant promise for diversifying Europe's protein supply, supporting food sovereignty, and contributing to climate goals. To unlock the full potential of this technology, however, substantial investment in R&D, infrastructure, and regulatory reform is necessary. As governments and private stakeholders ramp up efforts to support the growth of fermentation technologies, the food industry should continue to

innovate to meet consumer demand for sustainable, affordable, and delicious alternative proteins.

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New food products – Focus on production technologies

The next food revolution is landing: Advances to make it happen

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Abstract

Demand for food proteins is growing. In fact, the United Nations warns that we need to double food production by 2050 to feed our growing and ageing population. Conventional agriculture and animal farming are not sustainable. And have serious climate consequences.

On the other hand, plant-based diets have limited environmental footprints, but fail to provide the adequate supply of essential amino acids for human health. Precision Fermentation (PF) is poised to revolutionize traditional protein-rich products like milk and eggs, offering a sustainable solution to meet the needs of a growing global population.

Certain milk and egg proteins along with specific meat substitutes produced by PF are already in -or entering- the market.

However, the high cost-efficiency requirements demand a high production titer at very large scale, making strain engineering, process optimization, and scale-up critical and challenging success factors.

Titer alone has a tremendous influence on achieving cost-parity and determining the ultimate cost of goods. A new PF beta-lactoglobulin (BLG) has been developed

by 21st.BIO using advanced *Aspergillus oryzae* expression technology and has obtained a GRAS status in less than two years. BLG titers are approaching cost parity at pilot scale. Some details of this work are presented here.

Technology (strains, fermentation, scaling) is approaching a stage that can support this food revolution.

However, there are significant challenges to establish PF as a core technology for protein supply.

Large fermentation capacity needs to be built that requires sizeable investments. Additionally, regulatory approvals in Europe remain an important roadblock, currently driving innovation and production to e.g., USA. We need to make this food revolution happen.

Introduction

Why precision fermentation – something old, some-thing new?

The future of food supply is a critical issue, especially with the global population projected to reach around 9.7 billion by 2050, driving up food demand by 59% to 98% (Abideen et al. 2021). Precision fermentation (PF) is not new: in fact, it has been used for more than 1,000 years

for food production. Bread and beer are produced by a yeast fermentation process. Rational thinking clearly establishes that traditional agriculture (e.g. meat production) is not sustainable nor scalable to provide food for a growing population. There is simply not land enough to sustain food production.

And that we need to find a different path for protein supply and sustainability. As an example, replacing just 20% of the world's beef with PF meat could halve global deforestation (Humpenöder et al. 2022). Lowering carbon footprint, increasing vegan adoption, increasing investments, livestock disruption, and minimizing dependence on animal-based food are all driving the global PF market. In addition, the increasing adoption of a healthy lifestyle is estimated to generate excellent opportunities in the PF market.

Visionary voices claim that "We are on the cusp of the deepest, fastest, most consequential disruption in food and agricultural production since the first domestication of plants and animals 10,000 years ago" (Tubb and Seba 2019). PF can be a major solution as it has "all the advantages" e.g., lower environmental burden, lower land and water use, higher protein titer per land unit, etc. Like other disrupting technologies, the current stage of development and the path to establish PF as a main protein supply is still very challenging.

Production and process technology needs to provide significant titer improvements to enable PF of bulk food proteins. It is envisaged that the cost of PF proteins will be five times cheaper by 2030 and 10 times cheaper by 2035 than existing animal proteins, before ultimately approaching the cost of sugar (Tubb and Seba 2019). These expectations put a firm pressure to find new approaches to optimize protein titers to very high levels, as protein titers have a great influence in total cost of production.

As mentioned above, PF is not new. All of the above arguments are rational and embraced by the public opinion. But there is more. Not only shortage of protein supply is an urgent issue. There is also a need for nutritional protein supply, that provides a balanced intake of essential amino acids that are not present in vegan diets. Food is simply "packages of nutrients", such

as proteins, fats, carbohydrates, vitamins, and minerals. Of these, proteins – needed by all cells – are the most important, the building blocks of life. In traditional food production, macro-organisms produce these packages, but to access the individual nutrients within them requires further processing, which adds additional cost (and diminishes nutritional quality). Single molecules within these packages are, therefore, the hardest and most expensive to extract. And are amenable to PF.

Will PF succeed?

For PF to succeed, the main challenges to be addressed include:

- **Cost of goods:** Optimizing the expression level and the growth conditions for microorganisms to ensure consistent and high protein yields in a process that is scalable (Arnau et al. 2020).
- **Functionality in the food product:** Ensuring that the PF proteins produced have the same functional and sensory properties as their animal-derived counterparts can be difficult. This includes replicating the diverse range of proteins found in traditional milk and eggs (Nielsen et al. 2024).
- **Infrastructure and capacity:** There is a need for investment in large-scale fermentation and downstream processing facilities. Many start-ups lack the infrastructure to operate at the necessary scale (CSIRO 2022)
- **Regulatory hurdles:** Navigating the regulatory landscape for novel foods can be complex. Comprehensive guidelines and updates are needed to address safety, efficacy, and ethical concerns (Knychala et al. 2024). Despite these challenges, and adding consumer acceptance, PF holds great promise for creating sustainable and ethical protein sources.

Results and discussion

1. A nutritious PF beta-lactoglobulin (BLG) in - or entering - the market.

The cost of producing a single molecule by PF has fallen from \$1m/kg in 2000 to about \$100/kg today.

And it is expected to fall below \$10/kg by 2025 (Tubb and Seba 2019). This is especially challenging for small size proteins like most milk proteins. It is of paramount importance to choose a production organism that has demonstrated high titers for many different proteins and

that has been intensively optimized and upscaled consistently. Companies choosing available, laboratory strains encounter a “valley of death” trying to increase titers from mg/L or few g/L to economically feasible levels at manufacturing scale.

21st.BIO was established based on an exclusive license to Novozymes (now Novonesis) expression technology with the vision to aid in bringing innovation (food proteins, biomaterials, etc.) to the market. Access to this proprietary, advanced technology that has a long history of safe use in food represents a unique opportunity to make PF feasible. Before this access was made possible, these microbial strains, genetic tools and fermentation processes were used to manufacture more than 100 products. One of the main species used by 21st.BIO for food proteins is the filamentous fungus *Aspergillus oryzae*. *A. oryzae* has been used for food production for more than a thousand years e.g., as the organism present in fermented soy or rice. We decided to use *A. oryzae* to investigate the potential for production of BLG.

1.1. BLG is more than just BLG B.

BLG is one of the main whey proteins in cow milk and is not present in human milk. BLG is one of the most nutritious proteins with a high level of essential amino acids. In consumer milk, BLG is composed of different sequence variants with BLG A, BLG B and BLG C as frequently present and are very similar in amino acid sequence. Currently approved or under regulatory evaluation PF BLG products use exclusively the BLG B variant (FDA 2020; FDA 2023; FDA 2024). At 21st.BIO, we decided to combine the most nutritional BLG sequences from the main variants present in consumer milk in a single molecule, providing additional essential amino acids, as this would better mimic milk consumption (Lehmbeck and Arnau 2024).

1.2. Fast track from strain construction to process optimization, upscale and regulatory approval

Using a limited design space (one promoter, one signal peptide, few codon optimization sequences, a suitable recipient strain, etc.), a primary screening was performed in *A. oryzae* multicopy strains with the designed BLG.

As shown, one of the combinations tested resulted in a remarkable high titer at microtiter scale (Fig. 1).

This strain (strain B) showed a strong band corresponding to BLG and the presence of BLG dimers in SDS-PAGE suggesting a much higher titer compared to all other strains tested (Fig. 1).

1.3. Fermentation and process optimization

Strain B was selected for fermentation testing and optimization.

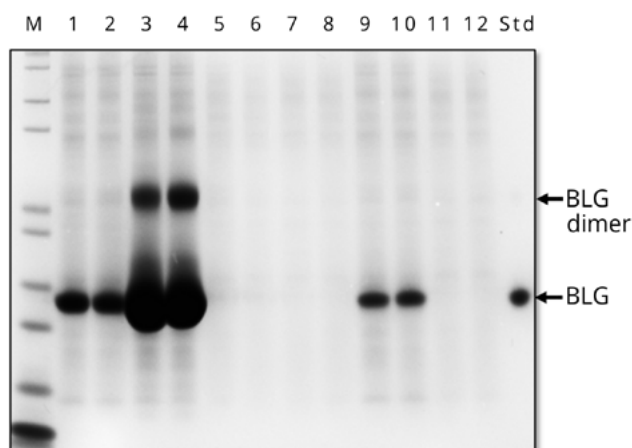


Fig. 1. Screening of different *A. oryzae* strains producing BLG at micro-plate scale. Four-day incubation in inducing medium at 30°C was performed (in duplicates). Supernatant samples were diluted before running in SDS-PAGE and staining. Lane M: Molecular Weight Marker (Mark 12); lanes 1 and 2: strain A; lanes 3 and 4: strain B; lanes 5 and 6: strain C; lanes 7 and 8: strain D; lanes 9 and 10: strain E; lanes 11 and 12: strain F; lane Std: BLG B (Sigma). The position of BLG is indicated with an arrow (18.3 kDa), as it is the position of the BLG dimer.

Strain B yielded more than 30 g/L BLG that is secreted into the supernatant in the initial lab scale fermentation tests. Combining process optimization and a second round of strain development, commercially feasible titers of secreted BLG were readily obtained at pilot scale (Fig. 2).

This productivity level unlocks an economically feasible large-scale production of BLG, depending on scale, media costs, etc.

Batches of BLG produced at pilot scale were used for regulatory approval. A GRAS self-affirmation was obtained in July 2024, enabling 21st.BIO customers to commercialize BLG in the US. Efforts are now focused on upscaling to manufacturing. 21st.BIO continues to

optimize BLG titers using a variety of approaches (Arnau et al. 2020) with the goal of further reducing production costs. The robustness of the strain and the scalability demonstrated not only for strain B but for so many existing products manufactured in this *A. oryzae* strain lineage provide a clear path to PF produced nutritious BLG.

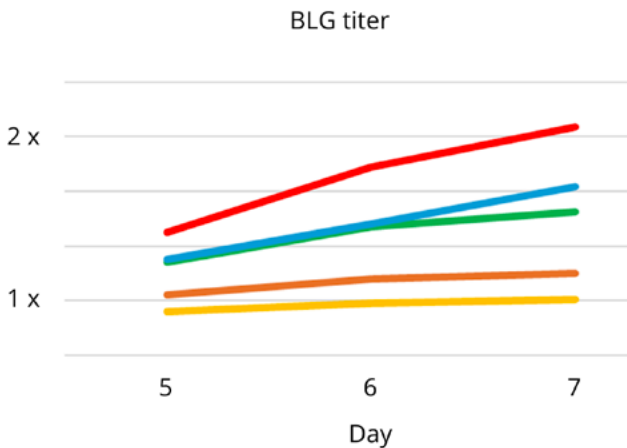


Fig. 2. BLG titer optimization at pilot scale. Data from different fermentation runs using different conditions and strains. “1x” is the titer of the benchmark strain. BLG titer was determined by size-exclusion chromatography HPLC. Samples (supernatant) were analysed at day 5, 6 and 7 (end) of fermentation.

2. Other nutritious proteins from milk are under development

Milk proteins (BLG, alpha-lactalbumin, caseins) have a small molecule size (around 20 kDa). This is another significant challenge to obtain high titers using PF. The smaller the protein, the higher the number of protein molecules that need to be synthesized by the production organism per time unit to achieve the same titer in e.g., g/L. At 21st.BIO, we are currently developing other milk proteins with focus on nutritional values and applications. One example of this is caseins. We have developed strains of *A. oryzae* producing a significant titer of either individual or combinations of caseins. Some of these are expected to be submitted for regulatory approval in 2025. The outlook? Technology alone will not make a food revolution.

Technology and high titers, even when paired with the significant environmental upside associated to PF, are not enough to enable the transition from traditional food production. A case example is the progress on BLG produced by precision fermentation described above. Investments in large fermentation capacity are needed to enable PF to become the technology for sustainable food supply. There is a growing need to expand infrastructure and capabilities to meet increasing consumer demand and support the scaling of this technology. Larger capacities with bigger bioreactors will be crucial in enabling companies to manufacture sufficient quantities needed to reach cost parity with animal-derived products (Blue Horizon and Synonym 2022).

Regulatory approvals in the US are predictable.

The situation is quite different in the EU. Significant contributions from the EU and EFSA are key to make this sustainable alternative for food production a reality in Europe for products already available in the market in other geographies.

Finding a way for fast and “predictable” approvals will enable innovation, sustainable protein supply and nutrition in the EU instead of the current situation (“America innovates, China replicates, Europe regulates”). Regulatory requirements should always be proportional to the risk. Especially for milk proteins produced in systems like the 21st.BIO *A. oryzae* strain lineage, there is no safety risk for either the protein or the microbe.

This should guarantee fast approval in the EU. But this is far from the reality today.

Lastly, consumer acceptance is central to the transition from current food products made by traditional agriculture (e.g. milk) to PF-based food products.

The substantially improved environmental footprint and sustainability of precision fermentation may not be the only factors at play.

Supporting the transition from current food production to PF can help create a more sustainable, efficient, and ethical food system. And it involves many different stakeholders. Ultimately, we must balance our planet’s resources to produce nutritious food sustainably, benefiting humans and animals.

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New food products – Regulatory issues

Regulatory challenges for novel ingredients in the EU

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Overview of the EU novel food framework

The EU novel food framework, governed by Regulation (EU) 2015/2283, defines “novel” as foods or processes not consumed or used within the EU before 15th May 1997. The scope explicitly excludes food additives, enzymes, flavourings, and GM foods but includes food products derived from microorganisms, plants, cell cultures, and other innovative processes.

Key regulatory bodies involved are the European Commission (EC), European Food Safety Authority (EFSA), and EU member states.

The authorization process for novel foods

The novel food authorization process is comprised of three main steps: submission and validation, risk assessment and risk management.

Once an applicant has prepared their novel food dossier, it is submitted to the EC via the e-submission food chain platform. The EC performs a suitability check without delay and send a mandate to EFSA. EFSA also performs a suitability check to ensure that the dossier is complete. Once the suitability checks have been completed and the dossier is validated, EFSA starts their scientific risk assessment. The risk assessment should take nine months, but this timeline can be extended, and the clock can be stopped for EFSA to ask the applicant for more information or additional studies.

Once the risk assessment has been completed, EFSA publish their scientific opinion, which is then reviewed by the EC and Member States during the risk management phase. During risk management, the EC prepares a draft implementing regulation and presents it to the Member

States to vote on. To get a novel food approved is by qualified majority voting (QMV) whereby 55% of EU Member States representing 65% of the EU population must vote in favour. The risk management phase should take seven months.

Timelines for novel food approval

The legal timelines for novel food approval as written in the novel food regulation add up to 1.5 years. However, the timelines are often extended beyond 2.5 years, with some novel foods taking more than five years to get approved.

While it is understood that the quality and completeness of the data and dossier significantly influence the duration of the validation and risk assessment, the current timelines far exceed those outlined in the regulation. The additional information requests (clock-stops) from applicants during the evaluation, also contributes to these delays.

This discrepancy between regulated and actual timelines underscores a critical need for understanding why this is happening. Streamlining the evaluation process and exploring measures to align actual timelines will not only enhance efficiency but also support innovation and development within the food sector.

Issues causing delays in approval

One of the main reasons for these delays include companies failing to notify their studies correctly to EFSA before the study start date, which is a requirement under the EU Transparency regulation. Failure to notify

studies correctly will lead to the applicant being issued with a six-month penalty meaning that their dossier non-valid, and the applicant must resubmit. Once the dossier is resubmitted, it is subjected to the six-month penalty and after the six months has elapsed, EFSA will start the validation again. A recent example includes the novel food application from Remilk for their recombinant betalactoglobulin, which was received by EFSA on 12th June 2023, it was deemed not valid on 21st October 2023, resubmitted on 13th November 2023 (from which timepoint the 6-month penalty applied), and was finally validated on 13th August 2024.

In total, it took 14 months from submission to the start of the risk assessment!

Another issue leading to delays is the lack of pre-submission advice (PSA). Receiving PSA can ensure that companies avoid common pitfalls that may lead to delays or rejection of their application and may reduce the time taken during the risk assessment phase. One of the biggest advantages of PSA is the ability to identify potential concerns early in the process. If there are safety issues or data gaps, PSA can highlight them before the formal submission, giving companies time to address these issues. Seeking advice early can also help establish a relationship with the authorities and engaging with them in an open and transparent manner can foster trust and ensure familiarity with the product when it is submitted. EFSA offers general pre-submission advice (GPSA) which can be requested via the EFSA.Connect platform. EFSA has and recently launched an initiative for SMEs to help applicants understand the updated novel food guidance (which was published in September 2024 and will apply from 1st February 2025).

Whilst this initiative is very welcome, the scope of the GPSA is limited and EFSA is not able to discuss specific study requirements or provide feedback on a proposed regulatory strategy. EFSA will prepare a non-confidential summary of the PSA, which will be published on OpenEFSA along with the non-confidential version of the dossier. The scope of PSA is defined in Article 32a of Regulation (EC) No 178/2002, so legislative change would be required if we want more expansive PSA in the EU! The presence of host strain DNA from genetically

modified microorganisms (GMMs) that are used as processing aids is another issue. Based on the current legislation, fermentation ingredients obtained through the use of GMMs under contained use do not fall in scope of the GM food/feed regulation unless they contain live GMMs. Hence, there is a lot of confusion about what falls in the scope of the GM food/feed regulation, causing anxiety within the industry, especially for precision fermentation-derived ingredients.

Impossible Foods recombinant soy leghaemoglobin was classified as a GM food because of the presence of GMM DNA. They submitted their dossier in 2019 and EFSA published their opinion in November 2024, highlighting the extensive length of time it took to perform the risk assessment. However, this is only half of the story and now, the product is under risk management and requires a QMV from Member States in order to be approved.

It is worth noting that the risk management process for GM Food is more complex compared to novel foods and Member States. If the Member States fail to reach a decision, the draft decision moves to the Appeal Committee.

If no consensus is reached again, the EC has the authority to adopt or reject the application independently. If the EC moves to approve the GM Food, EU Member States have the right to reject the marketing of the GMO in their territory.

Regulatory uncertainty and the path forward

These challenges in the current regulatory landscape in the EU, lead to regulatory uncertainty and prolonged timelines, hindering innovation. However, applicants must ensure that they follow the relevant EFSA guidance documents and prepare and submit good quality, compliant novel food dossiers to help reduce timelines.

New food products – Food safety issues

Navigating challenges in microbiological hazards for sustainable food systems

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Introduction

Transformation of food production and distribution systems is on-going to deliver co-benefits for environmental sustainability, healthy diet, food poverty reduction and empowerment of communities, and thriving businesses. Transition in food systems challenges us on how to think or deal with food safety management. There are a number of factors that can contribute to emergence or re-emergence of foodborne pathogens (Smith and Fratafico 2018; Welch 2024). Pathogens can emerge due to factors like changing consumer preferences, such as the trend towards more sustainable plant-based foods including the introduction of alternative protein sources and associated changes in microbial ecology. But also introduction of alternative food production systems, such as increased attention for a circular food economy seeking to reduce waste and supplant traditional linear supply chains. Higher interest in unprocessed foods or low or unregulated production and distribution routes in the food supply chain leads to new microbial challenges. Globalization and climate change are also identified as factors that increase the risk of pathogen contamination in food systems. Moreover, the decrease in food literacy may impact safe eating habits. Or the raise in immunocompromised groups and thus susceptible population for foodborne illness within our population may result in re-emergence of foodborne pathogens.

Three examples on when striving towards sustainable food and food production systems we need to navigate new challenges in microbial hazards are discussed.

1. Concerns on microbial biocontrol agents in plant production as food safety hazard when plant becomes food

The Farm to Fork Strategy of the European Green Deal, lays out a roadmap towards limiting chemical pesticides, promoting healthy foods and preserving biodiversity. The sustainable use of pesticides along with the promotion of organic farming seeks to reduce or replace chemical pesticides in crop protection by microbial biocontrol agents.

Closely related to the established foodborne pathogen *B. cereus* is *B. thuringiensis*, some strains of the latter being authorized as commercial biopesticides. Both are spore-forming bacteria that are widely distributed in the environment. *B. cereus* is a human pathogen that can cause 2 syndromes: a diarrheal form (toxico-infection) and an emetic form (food intoxication). *B. thuringiensis* is an entomopathogenic bacterium to various insect pests, such as Lepidoptera, Coleoptera, and Diptera by producing insecticidal parasporal crystal proteins or δ -endotoxins. However, it has been reported that many *B. thuringiensis* isolates also carry the diarrheal toxin

genes and have the ability to produce these enterotoxins that can cause human illness. Besides, the difficulty of differentiation between *B. cereus* and *B. thuringiensis* encountered in food or clinical diagnostic labs due to the high similarity in morphology and genome has contributed to this uncertainty about *B. thuringiensis* to be recognized as emerging food borne pathogen (De Bock 2021).

Concerns on this food safety issue of biopesticides are raised, in particular because during application pre-harvest deliberately quite high numbers of *B. thuringiensis* are deposited on the (edible) crop without the mandatory respect of a set pre-harvest interval (waiting time before harvest). This might result in contamination with elevated levels of this bacterium situated at or above the current food safety action limit (105 CFU/g) established for *B. cereus* post-harvest when the plant becomes food. However, *B. thuringiensis* is also naturally associated with soil and plants.

Moreover, no track record of association of fresh produce to foodborne outbreaks of *B. thuringiensis* due to its use as a biopesticide in agricultural edible crop production was available until a report of an alleged foodborne outbreak in one Member State in the EU discussed by EFSA BIOHAZ (2016). There are few studies investigating the prevalence of *B. thuringiensis* in fresh produce (lettuce, tomatoes, bell peppers, etc.) sampled at retail. But the occurrence of *B. thuringiensis* in fresh produce higher than 105 CFU/g seemed to be rare (Zhao 2022; Zhao 2023). This is most probably because on fresh (raw) vegetables usually Gram-negative bacteria (in particular *Pseudomonas* spp.) dominate and act as competing microbiota leaving less opportunities for *B. thuringiensis* to multiply.

This case study is an example of the need for debate in society on the benefits and safety of sustainable agricultural production seeking to avoid the use of chemical pesticides and promoting biocontrol agents such as *B. thuringiensis* biopesticides - but also other *Bacillus* spp. or other microorganisms as biocontrol agents or biostimulants (Etesami 2023) - while minimizing the risk of such plant beneficial micro-organisms to become emerging food borne pathogens causing foodborne

disease to susceptible human hosts when plant becomes food.

Overall, this type of microbial hazard identification and hazard characterization is in need of a multi-method approach including genomic, functional and epidemiological data.

2. Food safety of alternative food production systems

The Horizon Europe FoodSaferR project aims to establish a joined-up approach to the identification, assessment and management of emerging food safety hazards and associated risks. The focus with regard to microbiological risks relates to alternative food production or short distribution networks that are innovative and often still lack knowledge on hazard identification or are a grey zone in food safety regulations. Several case studies were identified including natural unpasteurized fermented vegetables, ethnic and plant-based protein foods, artisanal cheeses, ready-to-eat multi-ingredient bowl salads with last-mile delivery to consumers and urban aquaponics to produce herbs. These case studies were selected as they are subject of increasing interest by the consumers due to their sustainability perception as either being local, healthy, or environment-friendly. Changing production systems, ingredients, distribution systems or new actors being introduced in the food supply chain driven by sustainability objectives are in need for new, revised or repeated provision of evidence-based and targeted food safety information.

Case study: unpasteurized spontaneously fermented vegetables

Fermentation of vegetables is often done on small scale to prevent food waste (Van Beeck 2020). However, the reliance on indigenous microbiota can affect safety and predictability of the fermentation process because the microbial load and activity of naturally present lactic acid bacteria that reside on the (shredded/cut) vegetables can be variable.

A market survey was conducted in Belgium (by UGent) and Austria (by AIT). Selected products were sampled and analysed for several microbiological parameters either linked to the fermentation process (lactic acid

bacteria) or to process hygiene (*E. coli*, Enterobacteriaceae) and relevant foodborne pathogens (*Listeria monocytogenes*, *Salmonella* spp.).

Challenge tests were performed to assess the growth potential of *L. monocytogenes* during vegetable fermentation, considering different food handling scenarios. It showed that spontaneous fermentation is highly variable. A rapid pH drop to a level below 4.2 is the major microbiological safety determinant for vegetable fermentations. Most (but not all) market samples have shown to comply with a pH level lower than 4.2. On a few occasions, persisting Enterobacteriaceae indicated either a too slow pH-decrease with related favorable initial growth conditions or a too short fermentation time. Pathogens were not detected in the survey samples but laboratory challenge tests strengthened the importance of the fermentation time (minimum 14 days) for pathogens to be no longer detected (Vermeersch 2024). Fermented vegetables meet many societal expectations. The microbiological and biochemical changes that occur during fermentation are increasingly known. In many areas however, further investigations are necessary to better document the potential sanitary issues and the ways of controlling them as well as the potential health benefits of these “microbial foods”, to better exploit the potential of innovation in this area without compromising food safety (Thierry 2023).

Case study: food safety of aquaponics

Aquaponics is a controlled environment agriculture technique which combines soil-less plant cultivation (hydroponics) with recirculating aquaculture. A decoupled urban aquaponic system, producing aromatic herbs and salmon trout, was identified in the EU FoodSafeR project. Sampling was focused on the safety and quality of the herbs as they are ready-to-eat products. The plants (from seeds to fully growing plants), soil-less substrate and all water streams (well water, rain water, aquaculture wastewater, etc.) composing the irrigation water were analysed for general microbiological parameters, relevant foodborne pathogens and generic *E. coli* as hygiene indicator. Similar as was also reported by Topalcengiz (2024) it was noted in the EU FoodSafeR

research that introduction of foodborne pathogenic bacteria remains possible and the initial quality of introduced water streams, seeds, and soilless substrate play a major role in food safety governance. Moreover, avoiding contact of irrigation water with edible parts of the herbs and the effect of UV treatment for disinfection of the water are also a critical points to be verified.

In conclusions, alternative food production systems contribute to prevention of food waste and the development of (urban) sustainable food systems, achieving a combination of environmental and social goals. But when running these alternative food production systems, it is fundamental to also be aware of microbial hazards that might be introduced and thus the need to implement appropriate and effective food safety control measures.

3. Validation of food safety control measures in the (minimal) processing of plant-based foods

There is a growing variety of ready-to-eat plant-based dairy and meat substitutes placed on the market. Understanding the effects of processing and safety of alternative proteins is paramount to ensuring food safety and understanding the risks to consumers. However, the data here is limited (Banach 2023). The plant-based formulations of dairy and meat substitutes can include a wide array of different ingredients with variations in chemical, nutritional, and microbiological composition. This includes pulses (e.g. soy, pea, faba bean, chickpea, mung bean), cereals (e.g. rice, oat, wheat, quinoa), nuts (e.g. almond, cashew, coconut), and oilseeds (e.g. canola and sunflower). However, the reformulation of traditional products with new plant ingredients or alterations of processing conditions for the known ingredients requires careful consideration with respect to the microbiological safety and stability of the developed recipes (Kyrlyenko 2023).

The processing of some plant-based substitutes can be different from the traditional heat-treatment based processes used to produce the animal-based products which they are replacing (e.g. cooked deli meats, pasteurised dairy liquid milk and cheese). This could lead to microbiological hazards being present in these food

types that are not removed by a specific control step, such as a heat treatment during its manufacture. For example, some non-heat treated plant-based cheeses are based on raw nuts as a base ingredient which could be contaminated with microbiological hazards such as *Salmonella* spp. An outbreak of *Salmonella enterica* serovar Weltevreden linked to consumption of fermented cashew cheese in a restaurant occurred in a Victoria, British Columbia, Canada (Schmitt 2018). Ready-to-eat plant-based dairy or meat substitutes are vulnerable to cross-contamination with *Listeria monocytogenes* from the food business operators environment and/or from contaminated raw materials. An outbreak of listeriosis associated with consumption of vegan cheese occurred in January 2023 in EU (Leclercq 2024). Spore-forming bacteria such as *Bacillus* spp. and *Clostridium* spp. might be a potential risk for certain plant-based products. Moreover, traditional heat treatment to remove spores (as commonly used in dairy products), may not be suitable for plant-based dairy alternatives. This is due to the differences in chemical and physical properties of plant-based ingredients compared to milk (for instance, differences in protein solubility/precipitation or substrate availability). As such there is a need for enhanced understanding of food pathogen behavior and research to validate critical control points in the production process of plant-based foods.

Furthermore, to balance nutrition security with food safety, but also in an attempt to save energy and other costs, and to comply to consumer demands on clean label and fresh(like) convenience foods one seeks for minimal processing of foods. For example dried fruits, vegetables, herbs, and spices are produced in and sourced from many countries worldwide, but they have been increasingly reported to be involved in outbreaks and alerts due to the presence of foodborne pathogens such as *Salmonella*. From a technological point of view the general trend is to optimize and standardize the drying process to ensure high-quality products to be offered (Bourdoux 2016). Minimal processing comprises other (new) processing technologies that are regarded as milder alternatives to the conventional food preservation processes based on heat treatment (pasteurization and

sterilization), such as (gentle) drying, high-pressure processing, etc. However, the process lethality of any given technology needs to be validated at an industrial level where the introduction of pathogenic strains is not allowed due to biological hazard concerns (Zhou 2020). Hence, the use of surrogate strains, which utilizes non-pathogenic proxies that respond to a treatment in an equivalent or more resistant manner than the pathogen of concern, is of increasing interest (Busta 2003; Hu and Gurtler 2017). However, the proper selection of surrogate strains depends highly on the type of process, product and targeted pathogens.

Evaluation of surrogate strains and paired comparison between surrogate and relevant pathogenic strains during the alternative or modified (thermal or non-thermal) mild processing or decontamination step needs to be established.

This is a prerequisite to effectively validate results in an actual food matrix or food business' production context and evaluate the real-life performance of (thermal or non-thermal) inactivation or other control treatments to ensure food safety of minimal-processed foods.

Conclusion

Food safety is an important component of a holistic approach to sustainable, healthy, and nutritious food. Ensuring food safety helps to prevent foodborne illnesses, supports public health, and maintains consumer trust. Food safety practices need to be integrated in a sustainable agri-food system. Traditional approaches to improving sustainable food production, food safety or nutrition, tend to have a narrowly defined focus that leads to technical fixes, which are subjected to the scope of one discipline or (scientific) committee, ministry or public agency. A food systems approach is a way of thinking and doing that considers the food system in its totality. It considers the entire food system, from farm to table, to address potential hazards at every stage but also reflects on interactions that go beyond single sectors or disciplines taking into account all the elements, their relationships and related effects. This approach encourages a broader perspective, fostering collaboration among scientists, practitioners, and policymakers to tackle future challenges together.

While there will clearly be trade-offs to be made (i.e. between key priorities of the food systems: increased agricultural productivity, improved nutrition, enhanced environmental sustainability and ensuring food safety), there will also be opportunities to simultaneously accomplish multiple objectives. A food systems approach can help identify such synergies, as well as facilitate the coordination needed to achieve them (Nguyen 2018).

Acknowledgement

I appreciate the continuous on-going interactions and discussions with colleagues and PhD students at the research group of Food Microbiology and Food Preservation at Ghent University that led to the challenges and reflections described in this proceeding text.

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New food products – Food safety issues

Is it still necessary to use an ISO standardized method to ensure the best performance for microbiological controls, particularly with new foods?

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In 2005, the European Community Commission published a first text to regulate microbiological criteria for foodstuffs (Commission Regulation (EC) No 2073/2005). The objective was a high level of protection for public health. For public health criteria, mainly pathogens, process acceptability criteria, and enumeration of quality control bacteria, all microbiology analytical methods must be validated. The ISO standards must be validated according to ISO 17468:2023 and the proprietary methods according to ISO 16140-2:2016 (Tab. 1) There is a transition period until December 31st of 2027 for the validation and verification of these methods.

In recent years, the regulations surrounding food microbiological testing have evolved, allowing the use of validated methods for regulatory analyses alongside traditional ISO-standardized methods, as stipulated in Regulation 2073/2005, reflecting the growing acceptance of alternative methodologies.

Since the introduction of ISO 16140 more than two decades ago, significant advancements in microbiological testing have led to the development of rapid methods that offer distinct advantages over traditional ISO standards. These alternative qualitative or quantitative methods have demonstrated superior performance in some instances (see NF Validation and Microval websites), raising questions about the continued relevance of the “gold standard” approach of ISO methods.

As an example, the validation of Neogen One Broth One Plate for *Listeria monocytogenes* obtained a sensitivity of 84.2% during the ISO 16140-2 validation whereas ISO 11290 obtained a sensitivity of 76.5% testing the same samples for *Listeria monocytogenes* detection (Mesnard 2024). The significantly improved sensitivity was achieved with 50% less media.

The sensitivity is calculated during the sensitivity study. A value below 100% is explained by discrepancies due to low level of inoculation, stressed cells or naturally

ISO 16140-2 : 2016 or ISO 17468 : 2023		
Method Comparison Study	Inclusivity & Exclusivity Testing	Pure cultures Harmonized with AOAC
	Relative detection levels	1 matrix/strain pair per tested category, 20 replicates providing fractional recovery, 5 negative & 5 positive controls = AOAC Design RLOD calculations & AL*
	Sensitivity study	60 individual samples per tested category AL*
Inter-Laboratory Study		1 matrix, 3 contamination levels, 1 fractional level 8 replicates/level, 10 laboratories AL*

AL*: acceptability limits

Tab. 1. Summary of the validation steps for a qualitative method (pathogen detection) - AL*: acceptability limits

contaminated samples. In Fig. 2, a pairwise study shows that the same enrichment from the same sample increases the initial inoculum to reach the detection limits of both the alternative and reference methods, resulting in few discrepancies.

An unpaired study, with two different test portions of the same sample, enriched in two different broths, can produce discordant results, even more so when the initial inoculum is low.

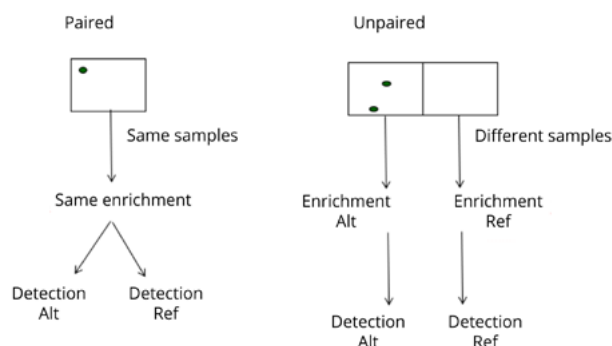


Fig. 2. Comparison of paired and unpaired studies.

The results of the ISO 16140-2 study are shown in Tab. 3. These results were all confirmed; therefore, the positive deviations are true positives detected with the alternative method and not with the standardized method. Negative deviations are the opposite. The acceptability criteria of ISO 16140-2 are set with a maximum of negative deviations in relation to positive deviations. Tab. 3 clearly shows that the alternative One Broth One Plate for *Listeria monocytogenes* method, as an example, has a greater number of positive deviations than negative deviations. When, as in this study, 6 categories are tested, the difference becomes significant when it exceeds 6, and in the case of the example, it is 17.

This clearly demonstrates the superiority of the rapid method over the reference standard NF EN ISO 11290-1:2017 Microbiology of the food chain - Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of *Listeria* spp. - Part 1: Detection method.

	ISO+	ISO-
OBOP <i>Listeria monocytogenes</i> +	PA=142	PD=55
OBOP <i>Listeria monocytogenes</i> -	ND=38	NA=308
		$\Delta = -17$

Tab. 3. Results of ISO 16140-2 Study for One Broth One Plate (OBOP) *Listeria mon.* Over the years, the validation standard has become stricter, with more difficult samples and lower levels of inoculation. The latest changes are harmonization with AOAC® International (American standard) (Latimer 2023), the possibility of validating semi-quantitative methods and for sterility controls.

Only a few microbiological analysis methods have been able to obtain sensitivity results significantly higher than the standard method. These results indicate that these methods are particularly suitable for testing difficult food matrices. As the food industry continues to innovate, particularly with the introduction of new foods responding to emerging trends in healthier eating, such as reduced salt, fewer preservatives, the incorporation of probiotics, or dietary supplements with health impacts such as vitamins, herbs, minerals, and other substances intended to be consumed in food supplements, the microbiological safety of these products has become a critical concern. These novel formulations may impact the growth dynamics of pathogens, necessitating a reevaluation of traditional analytical methods. While the ISO standards have historically been regarded as the benchmark for food microbiology, the changing landscape of food production calls into question whether these methods are still the best tool for ensuring food safety, particularly in the context of new food categories. The introduction of new foods is also a key topic within the international standard organization working group working on validation of food microbiology analytical methods (ISO TC34/SC9/WG3), where ongoing discussions focus on the validation of methods for challenging food categories.

These debates highlight the need for updated categories and definitions that reflect the unique characteristics of modern food products, especially those intended for medical purposes. Given the complexity of new food products and their potential impact on pathogen behavior, it is essential that these foods be incorporated

into the validation and verification process for microbiological analysis methods.

In conclusion, while ISO-standardized methods have played a foundational role in food microbiology, the evolving landscape of food innovation and microbiological testing underscores the importance of validating and incorporating alternative methods into regulatory frameworks. This approach will ensure the continued effectiveness of food safety controls in an era of rapidly changing food products such as novel foods.

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NF EN ISO 17468:2023 Microbiology of the food chain - Technical requirements and guidance on the establishment or revision of a standardized reference method

New food products – Food safety issues

Towards a greener plate: Serving quality in quality control

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Abstract

This proceeding presents an overview of Merck KGaA, Darmstadt, Germany's contributions to the Food & Beverage (F&B) sector, particularly in the context of alternative protein testing. It discusses the challenges associated with regulatory compliance and the need for standardized testing methods, highlighting Merck's solutions and commitment to sustainability. With over 355 years of experience in regulated industries, Merck's innovations in analytical testing and quality control are integral to supporting the evolving landscape of the F&B industry.

Introduction

Merck KGaA, Darmstadt, Germany operates in 66 countries with a workforce of approximately 63,000 employees. The company is divided into three main sectors: healthcare, electronics, and life sciences.

As part of the life sciences division, our mission is to support innovation and quality across diverse industries, including food and beverage. This proceeding aims to address key challenges in alternative protein testing and outline our solutions to support the industry while emphasizing our commitment to sustainability.

Historical context and milestones

Merck has a rich history of innovation, particularly in the F&B sector. In 1885, we claimed our first patent for dehydrated media at a time when the structure of DNA was still unknown. Over the next century, we expanded our analytical and microbiological capabilities, releasing products ranging from microbiology membranes to

chromatography columns.

Significant milestones include:

2010: Merck acquired Millipore, enhancing our filtration and cell culture portfolio.

2015: The acquisition of Sigma expanded our analytical testing capabilities, particularly in reagents and reference materials.

2017: The acquisition of Biocontrol strengthened our offerings for food and beverage testing.

2020: Merck approved cultured meat as a focus area for innovation, marking a significant step forward in our engagement with the alternative protein industry.

These milestones represent our commitment to providing a comprehensive workflow designed to meet the diverse needs of the F&B sector.

Our products and services in food & beverage testing

Merck's product offerings encompass various stages of food testing, including:

- **Sample Preparation:** We provide advanced filtration techniques, extraction methods, and purification tools to ensure high-quality sample preparation.
- **Chemical Analysis:** Our capabilities include both organic and inorganic workflows, with products tailored for chromatography, ICP analysis, spectroscopy, and photometry.
- **Microbiology Analysis:** Our robust product line for micro analysis includes high-quality media, pathogen detection kits, and hygiene monitoring solutions crucial for ensuring food safety and compliance with health regulations.

Navigating the complex regulatory landscape can be challenging for our clients.

Therefore, we offer comprehensive Q&A support, detailed documentation, and tailored regulatory assistance to help them meet compliance requirements and enhance operational efficiency.

Merck offers an extensive portfolio of reference materials for F&B testing, continuously expanding our offerings to meet the evolving challenges in the industry. Recent partnerships with metrology institutes have enabled us to provide food matrix products addressing new challenges, such as: trace elements, vitamins, and isoflavones in soy flour, mycotoxins in oat flakes, whey protein matrices and many more. Our traditional portfolio remains relevant to novel food testing needs, covering physical properties, PFAS, MOSH/MOA, and ready-to-use microbiology reference standards for quality control.

Challenges in alternative protein testing

The rise of alternative proteins presents several challenges, particularly in regulatory compliance.

The current landscape is dynamic, with a lack of validated and standardized methods for testing these novel foods. To address safety concerns, a multi-disciplinary collaborative approach is essential, involving regulatory bodies, industry players, suppliers, and the scientific community.

New and novel foods often undergo new manufacturing processes and possess complex compositions that differ from traditional food products. For instance, plant-based products may require specific allergen testing distinct from traditional animal-based products, while cultured meats necessitate tests to ensure the absence of contaminants introduced during cultivation.

Insects, as an emerging food source, require species identification testing, particularly since the European Commission permits consumption of only a limited number of species.

Beyond composition and nutritional profiles, companies focus on specific control metrics to guarantee the quality and safety of their end products. For example, physical parameters like viscosity and density are critical for

plant-based drinks, while moisture analysis is vital for plant-based “meat analogues.”

The role of Merck in supporting the industry

As a leader in the life sciences sector, Merck plays a crucial role in supporting the F&B industry through the development and implementation of new testing methods tailored to plant-based and cultured meat products. Our cultured meat webpage serves as a resource for multiple alternative protein industries, providing a comprehensive workflow of products tailored to research and development (R&D) and scale-up phases, along with our analytical testing offerings.

We have released a cultured meat white study addressing regulations in this industry, general food safety, and quality control. Additionally, we have developed specific analytical methods, such as pesticide testing in soy milk, and launched a flyer detailing our full offering for plant-based product testing.

Sustainability initiatives

Merck is dedicated to sustainability, and our investments extend to media preparation tools that support industry needs while aligning with our sustainability goals.

The ReadyStream® system exemplifies this commitment by rehydrating irradiated DCM filled in bags with sterile filtered water to generate 10x concentrated media stock. This system requires only 20 minutes for setup and can dispense up to 100 L of media, which can be stored for up to five days.

The ReadyStream® system reduces energy and water consumption by eliminating the need for intensive autoclaving and general cleaning. Its packaging also promotes waste reduction, as one ReadyStream bag delivers the same media volume as ten classic ready-to-use media bags.

In addition, we have applied this packaging reduction ideology to various products. Our titration buffers can now be purchased in box format, allowing for direct connection to instruments with reduced waste production. Furthermore, we have launched a line of Stericup-E filtration devices that eliminate the need for a plastic filter funnel, enabling direct use on commercially

available media bottles. Our research on bio-renewable greener solvents also contributes to sustainable practices in research and development.

Conclusion

In conclusion, Merck KGaA, Darmstadt, Germany is committed to supporting the Food & Beverage sector through innovative testing solutions and a robust sustainability agenda. Our historical milestones, comprehensive product offerings, and dedication to addressing the challenges of alternative protein testing position us as a leader in the industry.

New food products – Further tech solutions

Opportunities with plant and cellular agriculture foods

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Abstract

Hybrid foods, combining plant-based, microbial, and cellular agriculture ingredients, offer a scalable solution for sustainable protein diversification. While plant-based proteins face sensory and nutritional limitations, and cellular agriculture struggles with cost and scalability, hybrid formulations enhance taste, nutrition, and consumer acceptance. Advances in fermentation yielding sustainable and bioidentical animal proteins and more healthy fats can result in improvements in texture and mouthfeel, making hybrid foods a practical bridge between traditional and alternative proteins. Consumer acceptance depends more on taste than sustainability claims, highlighting the need for familiar sensory attributes. Overcoming regulatory and scale-up challenges through innovation and policy support will be key to mainstream adoption and the future of sustainable food systems catalyzed by fermentation.

Introduction

Protein is an essential nutrient, and diversifying protein sources is critical for transitioning to a more sustainable food system. Currently, a significant portion of global protein consumption comes from meat and dairy, with two-thirds of the EU's protein derived from these sources. Shifting towards plant-based and other alternative proteins could enhance human health and significantly lower greenhouse gas emissions. According to a report by MarketsandMarkets™, the global protein ingredients market is projected to expand from \$61 billion to \$85.6 billion by 2028, registering a Compound Annual Growth Rate of 7%. This growth is primarily attributed to rising health awareness, a surge in fitness-focused lifestyles,

and increased consumer interest in protein-rich diets and plant-based options (MarketsandMarkets Research 2024). Besides plant-based solutions, emerging cellular agriculture technologies can offer transformative potential, reducing environmental impacts such as land use and emissions while unlocking new opportunities for sustainable protein production (Tuomisto 2022).

Cellular agriculture (cellag) is a novel food production approach that utilizes single-cell organisms and bioreactors instead of traditional farming methods (Fig. 1).

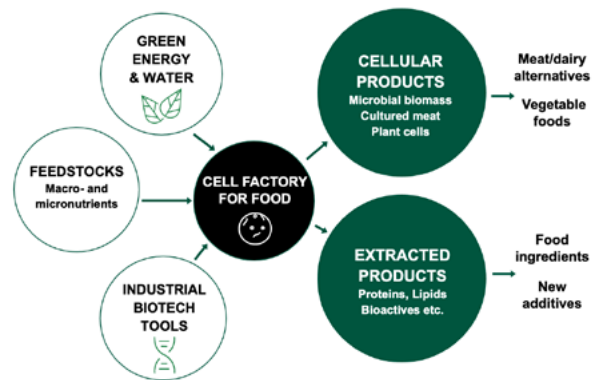


Fig. 1. New wave of biotechnology in food production.

As a complementary technology to conventional agriculture, it offers an efficient and scalable alternative for producing sustainable food ingredients. This approach relies on microbial cells as production factories, which require feedstocks, green energy, and water resources for growth. Biotechnology toolboxes play a crucial role in optimizing efficiency and functionality, enabling precise control over production processes. Through cellag technologies, a wide range of cellular

products, including microbial biomass, cultured meat, and plant cells can be produced which serve as key components in meat and dairy alternatives or other

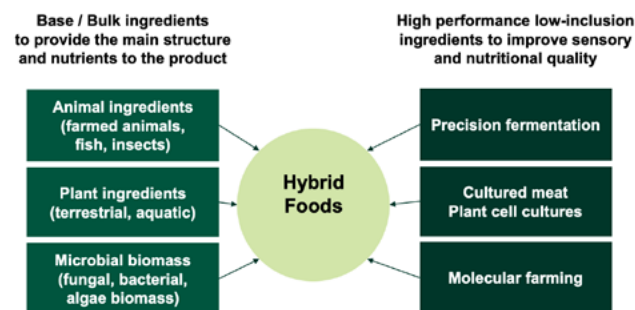


Fig. 2. Hybrid foods as a concept.

forms of plant-based foods. Additionally, it enables the production of extracted compounds, such as proteins, lipids, and bioactive ingredients, which contribute to the development of novel functional ingredients and food additives.

Current plant-based and cellag technologies are not advancing quickly enough to support the necessary shift toward reduced animal product consumption.

While plant-based foods are scalable and often meet price parity, their sensory and nutritional limitations hinder widespread adoption. In contrast, cellag offers the potential for nutritious and flavorful alternatives, it can also enable development of new value chains but at the same time faces significant challenges in scalability, cost and societal adaptations. Neither approach alone can drive the full transition of the food system. Hybrid foods, combining plant-based and cellag ingredients, present a transformative opportunity to diversify protein sources, reduce environmental impact, and meet consumer expectations for taste and nutrition (Zhang et al. 2019).

As a bridge between conventional and alternative proteins, hybrid foods allow for stepwise dietary shifts, making it easier for consumers to transition toward more sustainable diets without compromising on sensory attributes.

This proceedings article as presented at the first FoodRevolution international conference series held in Parma, Italy (Oct 21st-23rd, 2024) explores the tech-

nological advancements, market trends, and challenges in hybrid food development, highlighting its role in shaping the future of sustainable nutrition.

Defining hybrid foods

Hybrid foods integrate ingredients from multiple sources to optimize taste, texture, nutrition, and environmental impact (Fig. 2).

They typically fall into three main categories:

1. Plant-animal hybrids: Combining plant-based ingredients with traditional meat, dairy, or egg proteins to reduce animal-based content while maintaining familiar sensory experiences. Examples include pea protein-minced beef meat analogues (Pöri et al. 2023), pea protein-fish blended burgers with mushrooms or milk-based yogurts fortified with plant proteins (Olivas et al. 2024).

2. Plant-cellag hybrids: Utilizing cultured meat, precision fermentation-derived dairy proteins, or plant cell cultures to enhance the functionality and nutritional profile of plant-based foods. Examples include plant-based burgers enriched with cultured fat for a meatier texture (Schiell et al. 2025).

3. Microbial biomass-plant hybrids: Incorporating single-cell proteins, algae, or fungi-derived ingredients into plant-based formulations. Innovations such as fungal mycoproteins blended with legume-based proteins enhance structure and digestibility (Guyomarch et al. 2020; Calton et al. 2023).

These technology solution paths not only provide nutritional and functional advantages but also reduce reliance on industrial animal farming, addressing sustainability and food security concerns.

The technological landscape

Precision fermentation enables the production of bioidentical animal proteins without traditional farming (Zhao et al. 2021; Biermann et al. 2025). Companies such as Perfect Day (<https://perfectday.com/>), Those Vegan Cowboys (<https://thosevegancowboys.com/>) and Motif FoodWorks (<https://madewithmotif.com/>) have successfully created dairy proteins (e.g. casein, whey) and functional meat compounds (e.g. heme for color and taste) using microbial fermentation. These components

can be incorporated into plant-based matrices to create more convincing dairy and meat alternatives with enhanced sensory properties. A good commercial example for this is the Impossible Burger (<https://impossiblefoods.com/>) which contains soy leghemoglobin that brings in “meaty features” to its plant-based burger.

Similarly, cellag allows for controlled growth of animal-derived components, such as fermentation made fats, to improve the taste and mouthfeel of hybrid food formulations (Fish et al. 2020). Fat is essential for enhancing the taste and texture of both plant-based and hybrid meat products. By improving the sensory qualities of alternative meats, cultured fat could help reduce reliance on conventional animal farming while advancing sustainable food production. However, expression of optimized adipogenic cell lines, scalable bioprocesses and regulatory issues remains to be major hurdles. Oleaginous microorganisms like certain yeasts and microalgae can accumulate up to 70% of their biomass as triacylglycerol under nutrient-limited conditions much faster than animal cells. Yeast fermentation can be also used to produce highly functional dairy or meat fat-like lipids in an efficient and scalable way (Småros et al. 2025). These lipids can be combined with plant proteins to close the sensory gap between plant and animal-based meats by improving both flavor and juicy texture. Food processing innovations, including high-moisture extrusion and 3D printing, enable better mimicry of whole-muscle meat structures and textural improvements (See et al. 2025; Calton et al. 2023). Texturized plant proteins can be combined with cultured cells, microbial lipids or microbial proteins to enhance the chewiness and juiciness of plant-based alternatives. These methods also allow for the precise layering of different protein sources, optimizing nutrient density and digestibility.

Consumer acceptance & market trends

Despite technological advancements, consumer acceptance remains a critical factor in the success of meat and dairy alternatives either made of plant-based and/or cellag ingredients. Research shows that for example taste, affordability and familiarity drive purchasing decisions (Onwezen and Dagevos 2024). Hybrid foods which combine cellag ingredients with animal and plant-

based ingredients can speed up reaching environmental goals and facilitating market uptake. They offer scalable solutions to improve the mouthfeel and nutritional quality and allow for more efficient use of resources and manufacturing processes. Additionally, these foods have bigger potential to taste similar to traditional animal-based foods, helping consumers get used to them. According to a recent cross-cultural European consumer study, sensory appeal is the key driver of acceptance, outweighing health and sustainability claims (Banovic et al. 2022). To maximize market success, hybrid products should be designed to resemble traditional meat or dairy, with their environmental benefits communicated in a way that complements rather than dominates their sensory appeal.

There are several consumer motivations, both direct and indirect, that dictate market trends in the alternative protein space. For instance, gradually reducing animal-based ingredients through hybrid formulations can boost consumer adoption. However, it is crucial to focus on using clean-label and recognizable ingredients. Advances in food technology enable the development of customized protein blends that cater to specific dietary needs, such as fortification with iron-binding proteins or fat-soluble vitamins. It is important to note that not all consumers are driven by climate and ethical concerns, making hybrid foods a practical option for those reluctant to fully embrace plant-based diets.

Challenges & future directions

Hybrid foods represent a pragmatic and scalable solution to transitioning toward a more sustainable food system. By leveraging plant-based, microbial, and cellular agriculture innovations, these formulations offer nutritional, sensory, and environmental advantages. The large-scale production of cellag ingredients requires significant infrastructure investments, while hybrid food processing methods still need further optimization. Additionally, regulatory frameworks for novel food ingredients vary across regions, making standardized definitions and transparent labeling essential for consumer trust. From a nutritional standpoint, hybrid formulations must ensure protein digestibility, balanced amino acid profiles, and the mitigation of anti-nutrients. Research continues to explore the integration of functional ingredients, such as fermentation made

proteins and lipids to enhance health benefits and improve both macro and micro- nutrient bioavailability. Addressing these challenges will be crucial for the widespread adoption and success of plant-cellulose based hybrid foods in the market. With continued advancements in food technology, consumer engagement, and regulatory frameworks, hybrid foods are set to play a key role in shaping the future of protein diversification and food security.

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The future of livestock and aquaculture

The Blue Frontier: EFSA's ongoing activities on aquaculture

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The role of aquaculture in global seafood demand

Aquaculture plays a crucial role in meeting the growing global demand for seafood while potentially alleviating pressure on wild fish stocks.

In the European Union (EU), aquaculture represents a significant sector which could contribute to food security and economic growth. However, as the industry evolves to meet increasing demands, it faces multifaceted challenges, particularly concerning sustainability and food/feed safety.

Transformative changes and sustainability goals

With the EU's ambitious goals for environmental protection and high food safety standards, the aquaculture industry is undergoing transformative changes. The European Food Safety Authority (EFSA) ongoing activities explore the future trajectory of aquaculture in the EU, focusing on implications and emerging risks to food and feed safety.

The preparedness to these risks requires proactive strategies and future-oriented methodologies, including enhanced monitoring, revised risk assessment frameworks, environmental scanning and foresight, and interdisciplinary stakeholders' collaboration.

In this regard, EFSA has run a foresight project on "Future challenges for the safety of food and feed from the oceans".

Scenarios for marine aquaculture in 2050

A foresight study is a helpful tool to look into the future, anticipate possible scenarios and take appropriate decisions to face emerging risks for food and feed safety. A scoping study was carried out to analyse drivers of change that may impact/promote the future uses of the ocean and its resources. From bibliographic search, different ocean uses were identified: coastal and open-sea mining, marine aquaculture, sea transport and trade, energy production and related infrastructures, fisheries, ocean crops, saline farming, desalination, extraction of bioresources, marine protected areas and conservation of the ocean. Through the information gathered in the scoping study and the input of several experts, three key ocean uses were prioritised to proceed to a participatory foresight exercise: (i) coastal and open-sea mining; (ii) marine aquaculture; and (iii) sea transport and trade.

The foresight exercise produced three possible scenarios for 2050 for each prioritised use of the ocean.

Scenario 1 describes a shift towards sustainable aquaculture.

In Europe, species diversification and holistic environmental considerations drive a slow growth, with offshore cultivation and integrated multi-trophic aquaculture systems gaining prominence.

Wealthy consumers in Europe seek sustainable production and incorporate ethical considerations into their

choices. While there is a decline in consumption of animal products, the demand towards algae and low-trophic species is a new trend. However, scenario 1 presents challenges such as the limited availability of farming areas. The authenticity of new ingredients raises concerns about their impact on the food chain. The traceability and authenticity of new species are essential to ensure the sustainable growth of the green aquaculture industry. Additionally, market forces also imply a compromise between globalisation - with its competitive prices from third countries - and maintaining quality. Government subsidies must take into account safety and quality.

Scenario 2 focus on the intensification of the production of high-performance specialised species, which could override the quality of aquaculture products. The intensification of aquaculture systems could lead to an increase in chemical contamination, and emerging pathogens. This may lead to a change in the risk profile also due to the use of alternative feed ingredients, possibly containing pesticides and mycotoxins. The absence of harmonised labelling standards may pose a risk to food safety (regarding the authenticity of novel feed ingredients). However, while intensive production can raise concerns in terms of animal health and welfare, and environmental impact, it can also stimulate the development of pharmaceutical products from other low trophic marine sources, such as micro- and macroalgae. In scenario 3, the aquaculture industry faces persistent challenges with the unregulated use of antibiotics, particularly in imported products.

This has significant implications for antimicrobial resistance (AMR), which poses a global health threat. Additionally, the industry's reliance on alternatives to fishmeal and unknown raw materials raises concerns about the sustainability of aquaculture practices, with potential unrecognised environmental impacts.

Public governance remains limited, affecting the reliability of labelling and the enforcement of standards. Additionally, the lack of government subsidies delays innovation, resulting in limited technological advancements, and sustainable practices within the sector. Health standards diverge locally, and international

standards have not been universally adopted, leading to discrepancies in food and feed safety. Moreover, the consequences of past incidents involving allergies and digestive disorders have left consumers wary, potentially restricting aquaculture sector growth and public trust in aquaculture products sources.

Emerging issues and risk assessment

On the basis of these scenarios, possible implications and potential emerging issues for the safety of food and feed from the oceans were identified and characterised through bibliographic data.

The probability to drive the emergence of an issue was considered higher in the case of an intensive marine aquaculture production, which is expected in scenario 2. The potential emerging issues identified were related with biological and chemical issues:

- a) increases in AMR due to antimicrobial use in intensive aquaculture, which can also lead to residues of new chemicals in the aquatic environment;
- b) other microbiological threats can include “ghost and zombie” viruses and bacteria from environmental sources like melting or ship-broken ice, and specific diseases like acute hepatopancreatic necrosis disease (AHPND), caused by some *Vibrio* spp., or *Tenacibaculum* species;
- c) the presence of biotoxins enhanced by nutrients and various contaminants (e.g. ammonia, antifouling's like TBT, rare metals, heavy metals) that can disrupt the environmental and health status of aquaculture practices.

Several contaminants and pollutants which are released by other industries, such as mining and sea transport and trade (e.g. lithium extraction), can also have an impact on marine aquaculture;

- d) contaminants (e.g. pesticides and mycotoxins) present in new and old feed ingredients (e.g. due to climate change) were also reported, as well as environmental pollution from technological applications.

Strategic directions for sustainable aquaculture

The analysis of these scenarios gave insights on the strategic direction of aquaculture development and

allowed the identification of potential risks to food and feed safety and challenges for sustainability, driven by factors such as climate change, globalization, technological innovations, geopolitical developments and intensifying uses of the oceans resources. In conclusion, the ultimate EFSA's objective is to provide information usefull to support the design of practices embracing food and feed safety as a pillar of a sustainable aquaculture.

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The future of livestock and aquaculture

Innovations and sustainability in Norwegian aquaculture: Addressing global food system challenges

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Introduction

The global food system faces significant challenges, with current production and consumption patterns responsible for 60% of global biodiversity loss on land, 33% of soil degradation, and 24% of greenhouse gas emissions. Furthermore, food production needs to increase by 60% to feed a projected population of 9 billion people. We must fundamentally reconsider our dietary habits and food production methods to effectively address climate change and contribute to the preservation of our oceans and forests.

Innovations in food systems

To address these pressing issues, significant efforts are being made to innovate within food systems throughout the value chain. It is essential to ensure applied research and foster collaboration between industry and academia to develop better and more sustainable solutions. Implementing improved solutions along the way is crucial, but it is equally important to have long-term strategies to truly secure better production practices in the future. These innovations aim to create sustainable solutions that can meet the growing demand for food while minimizing environmental impact. Research-based solutions are only effective when implemented. A recipe for success involves collaboration between

industry and research in joint projects to generate value. Key areas of focus include:

- Development of alternative protein sources: Exploring plant-based and lab-grown proteins to reduce reliance on traditional livestock farming.
- Advancements in aquaculture technology: Implementing new methods and technologies to improve efficiency, welfare and sustainability in fish farming.
- Ensuring fish health and welfare: Prioritizing high standards, innovative and effective solutions and knowledge sharing to promote sustainable aquaculture practices that ensure fish health and welfare.
- Improved resource management: Utilizing smart farming techniques to optimize resource use and reduce waste.
- Circular economy practices: Promoting the reuse and recycling of materials within the food production process and waste streams to minimize waste and environmental impact.
- Enhanced food safety and quality control: Ensuring that food products meet high standards of safety and quality through rigorous testing and monitoring.

Global seafood trade dynamics

Norway has emerged as the leading seafood net exporter globally, maintaining its position from 2017 to 2022 with

exports reaching USD 15,218 million in 2022. This represents a significant increase from USD 7,549 million in 2012, demonstrating the country's growing dominance in seafood exports. Notably, China's position has shifted dramatically, moving from the top exporter in 2012 to falling off the top 10 list by 2022.

Sustainable aquaculture development – Key challenges and opportunities

The sustainable development of Norwegian salmon aquaculture faces several interconnected challenges that we aim to address through research and industry collaboration to develop solutions for:

Access to areas: The industry is experiencing a geographical transformation with aquaculture operations moving both offshore and on land. This expansion is driven by technological developments that enable:

- Access to new ocean areas
 - Separation of fish from lice and pathogens
 - Diversification of fish species in aquaculture
- Good health and welfare: Two primary bottlenecks currently limit industry growth:
- Salmon lice infestations
 - Impaired skin health conditions

These challenges are being addressed through science-based solutions, technical innovations, and governmental regulations, including specific lice limits per salmon.

Operational welfare management: The industry in collaboration with Nofma and other research institutions has developed comprehensive welfare indicator systems for both Atlantic salmon (*Salmo salar*) and rainbow trout (*Oncorhynchus mykiss*).

These operational welfare indicators (OWI) are specifically designed for different production systems and operations, providing easily measurable parameters to assess and maintain fish welfare.

Sustainable feed and food safety

The development of sustainable feed and ensuring food safety are critical components of the aquaculture industry. This includes utilizing applicable alternative protein sources and valuable side- and waste streams, securing that nutritional needs to ensure good fish

health and welfare are met, also adhering to food safety standards.

Climate change considerations

The aquaculture industry, particularly salmon farming, demonstrates favorable environmental performance compared to other protein sources.

This positions seafood as a crucial component in reducing CO₂ emissions in food production through increased incorporation of seafood in the diets and explore the opportunities in low trophic level species production.

Production optimization

The industry's sustainability framework encompasses multiple dimensions including production efficiency, genetic improvements, and health and welfare management. It also addresses seasonal adaptation and diet optimization to ensure the best possible outcomes. Additionally, efforts are made to reduce the climate and environmental footprint, assure food safety, and maintain high standards of quality control. Furthermore, the framework aims to generate employment opportunities, contribute to the overall sustainability of the industry and further development of food systems.

Future perspectives

The continued success of the Norwegian aquaculture industry hinges on achieving a balance between growth, welfare and sustainability. This involves focusing on several key areas, such as the development of technology for both offshore and closed containment aquaculture on land and at sea, enhancing biosecurity measures, and creating sustainable feed solutions. Additionally, efforts to reduce environmental impact and improve fish welfare systems are crucial.

To optimize the industry's potential, it is essential to balance the opportunities presented by offshore and land-based aquaculture with the optimization of current sea-based technologies.

The industry's evolution highlights the necessity for technological advancement to align with biological understanding, adhering to the principles of sustainable development.

This is underscored by the notion that “neither technology nor money can fool biology,” emphasizing

the importance of integrating scientific insights in biology with technological progress.

Conclusion

Norwegian salmon aquaculture represents a significant component of the solution to global food system challenges.

Through continuous innovation in production methods, welfare management, and sustainability practices, the industry is positioned to contribute to food security while minimizing environmental impact.

However, this demands an approach where knowledge from research institutions like Nofima and framework from the authorities enable the industry to implement sustainable innovations in the food system.

Innovation in food ingredients and food supplements

The regulation of food supplements and nutritional claims: Challenges and future perspectives

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Introduction

Food supplies nutrients to the human body and is essential for nutrition and human health. As concentrated sources of nutrients, food supplements are also expected to contribute to nutrition and human health. In the past decades, the EU, the US and other countries have developed rules to regulate food and food supplements in reference of potential nutrition and health benefits, and on how they can be communicated. As Artificial Intelligence (AI) revolutionizes our approach to food and communication, such rules - especially the ambitious EU Nutrition and Health Claim Regulation (NHCR) of 2006 (Regulation (EC) No 1924/2006) (EU 2006) - have come of age, and an evaluation is necessary to prepare for future challenges.

Food, food supplements and health benefits

Despite the growing and persistent interest in “food as medicine” (Downer et al. 2020), there is a general understanding – from dictionaries, for example – that food merely is “what humans eat” (Cambridge Dictionary 2024), and considered necessary for survival through nutrition (Merriam-Webster Dictionary 2024).

The definition of food in EU law, as outlined in Regulation (EC) No 178/2002 (EU 2002a), is even more restrictive and encompasses only ingestion (any substance

intended for human consumption through ingestion). No reference is made to nutrition, or benefits to health. Therefore, being beneficial to health is not inherently necessary for a product to be food, and laws see it as an add-on.

On the other hand, food supplements are distinguished by their purpose from food: to supplement the diet with concentrated sources of nutrients or other substances, typically in dose form ((Directive 2002/46/EC) (EU 2002b)). In the US, dietary supplements are similarly defined under Section 201(ff) of the FDCA (Federal Food, Drug, and Cosmetic Act). Food supplements include products containing vitamins, minerals, botanicals, amino acids, and other dietary substances. Unlike conventional foods, supplements are not intended to replace meals but to augment nutritional intake. Both jurisdictions, the US and EU, regard supplements as a subset of food but impose specific labeling and safety requirements.

Such concentrated sources deliver more of the nutrient, and a higher expectation for consumers of nutrition and health benefits. Perhaps surprisingly, neither requires supplements to provide specific health benefits.

The “food as medicine” concept lacks therefore support in the key elements of food law. As for consumers,

understanding consumer expectations is obviously critical to formulating effective regulations. A 2012 German study identified taste and convenience as the primary drivers for food consumption, while health-related factors ranked much lower (Renner et al. 2012). Conversely, and in line with the “food as medicine” concept, a US survey (Bailey et al. 2013) found that consumers use supplements primarily to improve or maintain health, prevent specific conditions, and address nutrient deficiencies.

As a consequence of this situation, where legal definitions do not require a beneficial effect, and consumer expectations in terms of health are specific to food supplements and possibly specific foods, special legislation has been required for those foods and supplements with health benefits, and on how such benefits should be communicated.

Communication of health benefits of foods and food supplements is warranted because scientific research indicates that the efficacy of some foods and supplements in improving health outcomes varies widely. While supplementation is effective for addressing micronutrient deficiencies, the evidence for broader health benefits is less consistent. There is no doubt that a healthy diet is linked to positive health outcome; also, some substances in food and in supplements have clear, science-based benefits (e.g. vitamin D for bone health) but for many other substances evidence is lacking or indicative of little benefit (Coppens 2020).

These differences highlight the complexity of translating scientific findings into regulatory frameworks. Both the EU and US systems aim to protect consumers, although their approaches to evidence and claim approval diverge significantly.

Regulating information on health benefits

In terms of laws on health benefits of food and food supplements, regulations such as the EU NHCR and the US Federal Food, Drug, and Cosmetic Act (FDCA) have

established rules for the substantiation and communication of nutritional and health claims.

The US has specific rules for dietary supplements in terms of structure-function claims (e.g. 21 CFR § 101.93), guidance on claims on conventional foods¹, restrictive rules on health claims (21 CFR § 101.14 and 21 CFR § 101.70), while the EU regulates all information on health benefits under the NHCR, for both supplements and other foods. The EU and US have been chosen for comparison, while recognizing that other jurisdictions have different approaches.

The evolution of health claim submissions to the European Food Safety Authority (EFSA) between 2008 and 2021 is fascinating (Fig. 1).

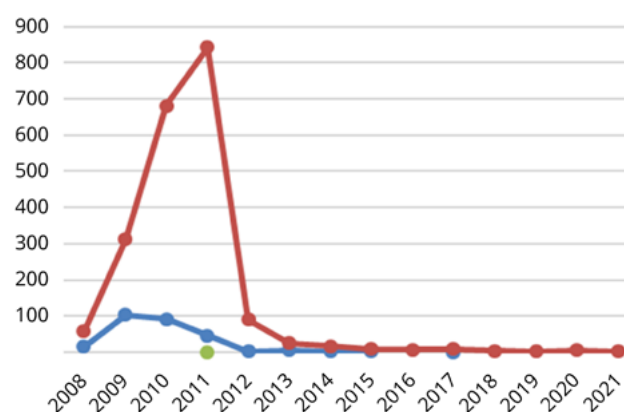


Fig. 1. Evolution of health claim submissions to the European Food Safety Authority (EFSA) between 2008 and 2021, and outcome.

Authorised health claims in blue; submissions ending in a refusal in red; revoked health claims, in green.

A notable surge in submissions occurred in 2011 when claims based on existing science needed to be submitted. However, the subsequent decline suggests that the process of obtaining authorization for health claims is challenging and requires substantial scientific evidence. Declining confidence of industry is shown by the lack of

¹ <https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/structurefunction-claims>

submissions, reflecting the dismal rate of success, and the limited benefits of a new health claim. The objective of fostering research into health benefits of food has not been reached.

In contrast, structure-function claim notifications submitted to the FDA between 2013 and 2023 (Fig. 2) show different trends. The initial surge in notifications, particularly between 2013 and 2015, suggests a period

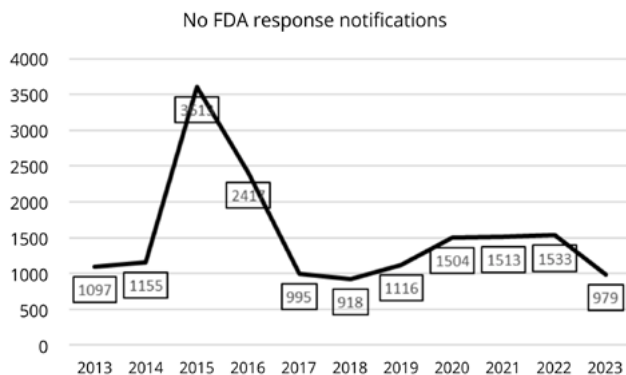


Fig. 2. Structure-function claim notifications submitted to the FDA.

of heightened industry interest in leveraging these claims to market dietary supplements.

However, the subsequent decline in notifications indicates a shift in the regulatory approach. It is noteworthy however that, in contrast to the EU, levels remain high.

US data show that industry's appetite for claims has not abated since 2017: this is likely to be the case in Europe as well. The underlying scientific research is probably similar on both sides of the Atlantic. While structure-function claims notifications are merely an administrative step, they prove a continued interest of industry, and that the EU system is not responding to this demand in a proportionate manner.

EU NHCR: Objectives and challenges

The NHCR was designed to ensure that health claims are

substantiated by scientific evidence, promoting consumer confidence while supporting innovation. However, the framework has struggled to achieve these objectives. On top of the lack of submissions which void the NHCR's objective to foster research noted above, most authorized health claims relate to vitamins and minerals, leaving other substances, such as plant extracts, without approved claims despite growing scientific interest.

The lack of nutrient profiles further complicates the situation, allowing unhealthy products to feature claims based solely on added vitamins or minerals.

Probiotic claims exemplify these challenges. Despite extensive research, EFSA has not approved any health claims for probiotics, leading to regulatory inconsistency across EU Member States which, given growing consumer interest and the need for consumer information, have tolerated some form of communication.

This fragmentation undermines the NHCR's goal of harmonizing consumer protection and market competition. The EU's rejection of probiotic claims - as health claims - contrasts sharply with their acceptance in other jurisdictions.

This inconsistency has hindered market growth and innovation, emphasizing the need for a more balanced approach to evidence evaluation, which has so far failed to materialise.

The US regulatory system, governed by the FDCA, offers greater flexibility for structure/function claims. Manufacturers can make such claims without pre-approval, provided they notify the Food and Drug Administration (FDA) and include a disclaimer that the claim has not been evaluated by the FDA.

This approach encourages innovation but increases the risk of misleading claims, as enforcement is reactive rather than proactive (Borchers et al. 2016).

New challenges

While such challenges remain unresolved in the EU, the

rise of personalized nutrition, driven by AI and big data, seems to require a paradigm shift in food and supplement regulation. Consumers increasingly seek tailored advice on what to eat or supplement based on their health status, lifestyle, and goals.

Apps and algorithms promise to deliver this information, but their scientific validity and regulatory oversight remain questionable. Regulatory frameworks like the NHCR were designed for traditional foods and supplements, focusing on individual nutrients rather than complex dietary patterns.

This static approach is ill-suited to the dynamic nature of personalized nutrition. Furthermore, regulating algorithms presents unique challenges, as it requires oversight of both input data and decision-making processes. Finally, the amount of information available to consumers, generated by humans or AI and available on social media, requires an enforcement approach that is only slowly starting to emerge, and lacks proper resources and legal basis. Indeed, social media may have escaped enforcement of the NHCR almost completely.

In summary, the experience with the EU NHCR underscores the importance of aligning regulations with scientific progress and consumer expectations.

While the EU framework has succeeded in establishing high standards for evidence, its rigidity has stifled innovation. In contrast, the US system's flexibility encourages market growth but seems to expose consumers to greater risks of being misled.

Overall, the EU NHCR, which remains exemplary in terms of aims and approach, has failed to fully deliver on its promises of fostering innovation and protecting consumers. Meanwhile, the rapid growth of personalized nutrition and AI threatens to outpace existing regulatory frameworks.

A comprehensive review of current regulations is urgently needed to address these gaps, including nutrient profiles, a more flexible approach to evidence evaluation, and the development of guidelines for

algorithm-driven nutrition and product advice.

Without such reforms, regulatory systems risk becoming obsolete, leaving consumers unprotected and stifling innovation in the food and supplement industries.

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Innovation in food ingredients and food supplements

Enhancing medicinal botanicals through fermentation: Bioavailability, bioactivity, and microbiota benefits

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Fermentation Uncovered: Hidden treasures for digestive health

Consider your last meal-have you ever wondered how its nutrients nourish your body? This process begins with digestion, where the microbiome plays an essential role. The beneficial bacteria in your gut facilitate food breakdown through fermentation, releasing vital nutrients for absorption, which fuels your cells and organs.

Thus, fermentation is not only crucial for extracting food's benefits but also for unlocking the medicinal properties of botanicals, enhancing overall well-being. Recent research identifies fermentation as a significant approach for enhancing digestive health (Leeuwendaal et al. 2022).

Digestive disorders are increasingly prevalent, driving demand for targeted gut health supplements (Wang et al. 2023).

Scientific evidence supports the benefits of fermented foods and ingredients on microbiome diversity and gastrointestinal function, boosting consumer interest. Integrating fermented ingredients opens avenues for innovative gut health products.

This article explores the health benefits of fermented foods and ingredients, underscoring their essential role in supporting gut and overall health.

Digestive health: Beyond the surface

According to the World Health Organization (WHO), digestive health encompasses a state of well-being free from gastrointestinal complaints (Bischoff 2011). True gut health, however, transcends the absence of symptoms, requiring proactive care of the microbiome, digestion, nutrient absorption, and immune defense.

In recent years, gut-related disorders, such as irritable bowel syndrome (IBS), leaky gut, and inflammatory bowel disease (IBD), have risen globally. It is now recognized that gut health influences the brain, heart, skin, and other organs. This surge in issues correlates with reduced microbiome diversity, attributed to modern diets, antibiotics, sedentary lifestyles, and chronic stress (Shaikh et al. 2023). Low microbiome diversity impairs nutrient absorption and is linked to immune dysfunction, metabolic disorders, and cardiovascular disease (Hou et al. 2022).

The science behind fermentation

Fermentation is an ancient process where microorganisms like bacteria and yeasts convert sugars into acids, gases, or alcohol, enhancing food preservation and flavor (Siddiqui et al. 2023).

This process breaks down complex plant matrices, transforming sugars into beneficial metabolites, such as

organic and short-chain fatty acids (Nkhata et al. 2018). Fermentation also reduces antinutrients (e.g. phytates, lectins), thereby enhancing nutrient availability (Knez et al. 2023).

Not only does fermentation preserve food, but it also enriches its nutritional profile. Foods such as yogurt, kimchi, and kombucha have been cherished for their flavors and health-promoting qualities (Gondaliya et al. 2024).

Innovative nutraceutical development

In nutraceutical development, improving bioactivity is key. Fermentation addresses microbiome imbalances that may limit nutrient absorption.

Advanced fermentation technology now allows controlled production of highly bioactive metabolites in fermented ingredients. Examples include 6-paradol from fermented ginger (Choi et al. 2017) and bioavailable withanolides from Ashwagandha (Devkar et al. 2015).

Controlled fermentation of raw ingredients like fruits, vegetables, and medicinal plants with specific probiotics triggers enzymatic reactions that convert complex molecules into bioactive metabolites, maximizing nutrient potential.

Fermentation vs. fiber: New insights

A 2021 study by Stanford researchers compared high-fiber and high-fermented food diets on gut health (Wastyk et al. 2021).

While both benefited gut health, the high-fermented food diet notably increased microbiome diversity and reduced inflammatory markers, unlike the fiber-only diet.

This highlights fermented foods' unique role in promoting a diverse, balanced microbiome. Researchers observed that fermented fruits and vegetables, rich in fiber, polyphenols, and postbiotic metabolites, significantly enhanced gut-immune function.

This underscores the value of fermented ingredients like

Fibriotics® and Berriotics® in supporting microbiome diversity and overall health (Wastyk et al. 2021).

Unlocking bioactive metabolites through fermentation

Fermented foods enhance digestive health by increasing microbial diversity and activating secondary plant metabolites.

6-Paradol: Ginger's potent metabolite

Raw ginger contains bioactive compounds, such as 6-gingerol and 6-shogaol, which undergo further conversion during fermentation. Specifically, 6-gingerol transforms into 6-shogaol, and eventually into 6-paradol.

Research shows that 6-paradol has enhanced anti-inflammatory effects, stability, and bioavailability compared to its precursors (Tokuhara et al. 2013). Fermented ginger products standardized for 6-paradol, like Ferzinger®, optimize ginger's digestive and anti-inflammatory benefits (Ballester et al. 2022; Rafeeq et al. 2021).

Fermented turmeric: Unleashing anti-inflammatory potential

Fermentation enhances turmeric's curcuminoid levels and releases volatile oils, preserving its beneficial metabolites. Fermented turmeric, specifically Fermeric®, shows a 17-fold increase in bioavailability in vitro, significantly enhancing absorption and anti-inflammatory effects compared to unfermented turmeric (Salve et al. 2023).

Fermedics: Leaders in targeted fermentation

Fermedics specializes in fermentation to improve bioavailability of standardized botanicals, maximizing the absorption and effectiveness of natural ingredients. Based in Belgium, Fermedics provides fermented ingredients supporting cardiovascular, metabolic, and gut health. Products include Berriotics®, Fibriotics®, Ferzinger®, Fermbucha®, and Fermeric®, each standardized for digestive and health benefits.

Postbiotics and their health impact

Controlled fermentation produces postbiotics-heat-killed bacteria and metabolites like short-chain fatty acids (SCFAs) and organic acids. SCFAs, such as butyrate, acetate, and propionate, are key to gut health, supporting barrier integrity, reducing inflammation, and promoting beneficial bacteria growth (Ma et al. 2023; Nogal et al. 2021).

Additionally, standardized products like Fermbucha®, rich in glucuronic acid, aid in detoxification and offer antimicrobial benefits (Massoud et al. 2024; Ho et al. 2019).

Conclusion

Fermented ingredients enhance product efficacy in food, dietary supplements, and nutraceuticals by unlocking nutrient activity. Scientific research affirms the benefits of fermentation, making it a powerful tool for product innovation.

Companies like Fermedics combine traditional fermentation practices with modern science to maximize ingredient potential, advancing consumer health through nutrition and wellness.

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Standards and certifications

Integrating sustainability, safety, and organizational culture in food management systems

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Abstract

The global food system is at a crossroads, facing unprecedented challenges from climate change, resource scarcity, geopolitical instability, and evolving consumer demands. To navigate these complexities, the food industry must adopt a holistic approach that integrates sustainability, safety, and organizational culture into its management systems.

This article explores key strategies for achieving food integrity—ensuring that food is safe, nutritious, authentic, ethical, and planet-friendly—while addressing the pressing risks and opportunities of our time.

Introduction

The modern food system is under immense pressure. Climate change, population growth, and shifting socio-economic dynamics are reshaping the way food is produced, distributed, and consumed. At the same time, consumers are increasingly demanding food that is not only safe and nutritious but also sustainable and ethically produced. To meet these challenges, the food industry must rethink its approach to management systems, moving beyond compliance with standards to foster a culture of continuous improvement, social responsibility, and innovation.

One of the most pressing challenges facing the food

The impact of global risks on food safety

Industry is the impact of global risks on food safety. Rising global temperatures, for example, are creating new vulnerabilities in the food supply chain. Higher temperatures can increase the prevalence of food- and waterborne pathogens, promote the uptake of toxic heavy metals in crops, and expand harmful algal blooms, which threaten seafood safety.

Additionally, climate change is driving plant pests into new regions, potentially leading to the overuse of pesticides and making crops more susceptible to fungal infections and mycotoxins.

To address these risks, the food industry must adopt adaptive strategies that integrate climate resilience into food safety management systems.

This includes investing in research and development to create more resilient crop varieties, improving monitoring and early warning systems for foodborne hazards, and promoting sustainable agricultural practices that reduce reliance on chemical inputs.

The role of standards and organizational culture

While standards such as ISO 9001 (Quality Management), ISO 14001 (Environmental Management), and ISO 22000 (Food Safety Management) play a critical role in ensuring

food safety and sustainability, their proliferation can sometimes lead to confusion and inefficiency. The key is not just to comply with these standards but to embed them within a broader organizational culture that prioritizes continuous improvement and social responsibility.

As Peter Drucker famously said, “Culture eats strategy for breakfast.” In the context of food management systems, this means that the success of any strategy - whether it’s reducing food waste, improving supply chain transparency, or enhancing product quality - depends on the culture of the organization. Companies must foster a culture where employees at all levels are empowered to take ownership of sustainability and safety initiatives, where innovation is encouraged, and where ethical behavior is the norm.

Social responsibility in the agrifood sector

Social responsibility is no longer a peripheral concern for the food industry; it is a core component of sustainable food systems.

The seven fundamental questions of social responsibility, as outlined in ISO 26000, provide a useful framework for addressing key issues in the agrifood sector. These include consumer protection, fair labor practices, environmental sustainability, and respect for human rights.

Transparency and ethical conduct are essential for building trust with consumers and stakeholders. Companies must be accountable for their actions, from sourcing raw materials to labeling and marketing their products.

This includes ensuring that supply chains are free from exploitation, that workers are treated fairly, and that environmental impacts are minimized. By aligning their operations with the Sustainable Development Goals (SDGs), food companies can contribute to a more equitable and sustainable global food system.

Governance, leadership, and stakeholder engagement

Effective governance and leadership are critical for integrating sustainability into food management systems. Leaders in the food industry must understand the complex social, economic, and environmental contexts in which they operate and be willing to engage with a wide range of stakeholders, including governments, civil society organizations, and local communities. Science and technology play a vital role in addressing food security challenges, from developing innovative farming techniques to improving food processing and distribution. However, technological solutions must be accompanied by strong leadership that prioritizes long-term sustainability over short-term profits. This requires a commitment to transparency, collaboration, and shared value creation.

Continuous improvement and the path forward

The journey toward sustainable, safe, and ethical food systems is ongoing. Companies must embrace a mindset of continuous improvement, using tools such as the PDCA (Plan-Do-Check-Act) cycle to evaluate and enhance their performance.

This involves setting clear goals, implementing effective processes, monitoring outcomes, and making adjustments as needed.

Integration is key. Sustainability, safety, and organizational culture cannot be treated as separate silos; they must be woven into the fabric of the organization.

This means aligning strategic objectives with operational practices, investing in employee training and development, and leveraging data and technology to drive decision-making.

Conclusion

The challenges facing the global food system are daunting, but they also present opportunities for innovation and transformation.

By integrating sustainability, safety, and organizational

culture into their management systems, food companies can not only mitigate risks but also create value for consumers, employees, and society at large. As the industry moves forward, it must remain committed to the principles of integrity, transparency, and social responsibility, ensuring that the food of the future is not only safe and nutritious but also sustainable and ethical.

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Potentials of implementing “Zero residue” concept in primary food production

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Introduction

There are several initiatives on how to decrease the use of plant protection products (PPPs) in agricultural practices as their reduction may have a positive effect on food commodities and environmental protection (Djekic et al. 2023). To control the health effects of PPPs, regulatory agencies set maximum residue levels (MRLs) for all types of agricultural commodities (Galani et al. 2020).

MRL represents the maximum concentration of a pesticide residue that is legally permitted to be found in food commodities and/or animal feeds. It is expressed as mg/kg of a certain chemical. These MRLs are derived from scientific studies and confirm that products with pesticide residues below MRL are toxicologically acceptable. Bearing in mind how the agricultural production depends on the use of PPPs, its reduction is not an easy task and raises various challenges (Jacquet et al. 2022). It is worth mentioning that some retailers in the European Union have more strict demands related to MRLs for the agricultural commodities sold in Central Europe ranging between 33% and 70% (Germany, the Netherlands, Austria, Belgium), or the UK and Switzerland (Lambrechts 2017), subject to successful on-site certification of good agricultural practices. In parallel with the enforcement of various legal requirements and

regulations, new food safety standards associated with the level of pesticides are introduced, such as pesticide free certification standard (SCS 2018) and zero/controlled pesticide residue (BAC 2020) combining assessment of good agricultural practice and testing of agricultural products in accredited laboratories (Djekic et al. 2024). A “Zero Pesticide Residue” initiative was initially developed in France in 2018 by the “Nouveaux Champs” (diverging from both conventional and organic farming) and by 2019, the “Zero Pesticide Residue” label was adopted by 52 companies and more than 3,000 producers in France. Similar concepts were developed in Spain and Italy. This concept has a main requirement, that the agricultural commodities upon harvesting do not have any residues of PPPs or the quantities are not detectable by analytical instruments performed in accredited laboratories where the main criterion is known as “less than or equal to 0.01 mg/kg” (SCS 2018). To achieve certification of this concept it is necessary to have a positive outcome from auditing the good agricultural practice and laboratory testing of grown commodities (Djekic et al. 2023). The entire certification process should be aligned with food safety system audits (ISO 2022).

Joint with improved environmental footprint and the health benefits, the “Zero residue” certified products are also an added value to modern consumers (Djekic et al. 2023). Its main benefits intertwine with three dimensions: (i) food safety achieved by implementing this agricultural practice, (ii) health issues associated with food consumption and (iii) environmental concern regarding primary food production, *Fig. 1*.



Fig. 1. Triumvirate of “Zero residue” benefits.

Food safety aspect

To verify a successful implementation of this concept, it is important to perform a food safety third-party assessment known as certification. Main risks in implementing and certifying this concept are the use of unregistered PPPs, inadequate sampling plan for controlling the growing process, and use of inappropriate laboratory methods for analysing the products, but also water and/or soil (Djekic et al. 2023). The “Zero residue” certification procedure consists of various stages, as follows: certification request submitted by the agricultural producer growing products under this

concept; verification of the plant protection and self-control plans for all commodities grown under the “Zero residue” concept; on-site assessment of good agricultural practice performed by competent auditors, laboratory testing of commodities confirming that they comply with the “ ≤ 0.01 mg/kg” requirement and granting declaration of conformity (Djekic et al. 2023). This concept has started in Serbia starting from 2023. During the last two years (2023 and 2024), five agricultural producers with 11 different types of fruits and vegetables (and 23 varieties) were subject to the “Zero residue” certification process. During this period, all producers have successfully passed the third-party assessment of good agricultural practises with two varieties failing the laboratory analysis (i.e. they failed to comply with the “ ≤ 0.01 mg/kg” requirement). All of the certified companies previously had a GlobalGAP certificate, in line with the Global Food Safety Initiative, as this certification scheme is considered being the most trustful for agricultural production (GFSI 2022). Overall, the main nonconformities revealed during these audits were related to traceability issues when the producers have commodities grown under “Zero residue” concept and under other agricultural practices, as well inadequate control of risks associated with the surrounding producers and their use of PPPs.

Health aspect

Use of various PPPs during agricultural production have negative health effects as these active substances may have carcinogenic, reprotoxic, immunosuppressive and endocrine-disrupting effects when found in food products (Goodson III et al. 2015; Rizzati et al. 2016). Therefore, the absence/reduced presence of pesticide residues in agricultural commodities has the potential to satisfy demanding health-oriented food consumers. To address the negative effects of PPPs on human health, the European Food Safety Authority has developed a scientifically sound methodology for analysing the

cumulative effects of different chemicals derived from pesticide residues (More et al. 2019). An exposure assessment study on cumulative effects of pesticides that have chronic effects on the thyroid gland through consumption of fresh fruits and vegetables confirmed the positive health effects of the “Zero residue” concept (Djekic et al. 2024). This study analyzed pesticide residues in over 2,300 samples of fruits and vegetables joint with dietary habits of the Serbian young population regarding consumption of these commodities vegetables. Results from this research depicted that when products have pesticide residues below 70% of the maximum residue levels, the risk indicator reduces two times while the implementation of “Zero residue” reduces the risk three times.

This concept has a strong relation with the “One Health” approach introduced by the World Health Organization. It is considered as an “integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems” (WHO 2021).

Environmental aspect

From an environmental point of view, there are some frameworks, like the European Green Deal, that promote food sustainability from farm to the fork (EC 2022).

It supports lower use of pesticides and fertilization in primary production (EC 2020). One of the main challenges associated with agricultural production is climate change, as on one side it can trigger additional use of PPPs to mitigate potential losses of crops and yield decrease as a result of unfavourable weather conditions, and on the other side the extensive use of PPPs has a direct impact on emission of greenhouse gasses (Djekic et al. 2021). When it comes to environmental impacts of the usage of PPPs, comparison of conventional primary production and “Zero Residue” concept for eight products (watermelons, melons, raspberries, apples, cherries, pumpkins, parsnip, and salads) confirmed a significant decrease of greenhouse gasses (GHG).

Reductions in GHG emissions were confirmed for all products that implemented the “Zero Residue” concept, and depending on the product, these reductions reached up to 33%. The functional unit that was used for the calculation was kg CO₂e per hectare.

The calculation of carbon footprint of the products grown under this concept was performed in line with the methodology outlined in ISO 14067 (ISO 2018). All agricultural producers provided data on the use of PPPs (type and quantity of pesticides - insecticides, herbicides and fungicides) during 2023 and 2024.

To compare the results with conventional production, producers provided data from previous years (mainly 2022) when they produced the commodities using conventional practices. However, as during conventional production the crop yield per hectare (as the fundamental agricultural indicator measuring the amount of crop produced on a specific unit of land) is higher compared with the “Zero Residue” concept, the carbon footprint per kg of product is not always on the “Zero Residue” side of the coin.

Nevertheless, the “Zero residue” concept can be considered as a mitigation solution for combating climate change issues in primary production.

Conclusion

The main idea behind “Zero residue” concept is to promote its implementation and certification by primary agricultural producers voluntarily and it does not replace any regulatory requirements (Djekic et al. 2023).

Knowing the great importance of achieving sustainable development goals of the United Nations (FAO 2015), this concept may pave the way for improving agricultural production of small producers that produce over 70% of food (Lowder et al. 2016).

It has the potential of promoting sustainable agriculture, serving as a tool for primary food producers, as it aligns with the UN sustainable goals #12 “Responsible consumption and production” and #13 “Climate action”.

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Standards and certifications

Empowering consumers with front of pack labelling to promote healthy diets and sustainability

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Summary

The overconsumption of foods and drinks high in fats (including saturated and trans fats), sugars (both added and refined), and sodium is strongly associated with an increased risk of obesity and noncommunicable diseases (NCDs). Without targeted policy interventions to improve the food environment, these health risks will continue to grow worldwide. Apart from causing public health problems, the food system also contributes to a larger number of environmental issues such as: climate change, deforestation, biodiversity loss, irrigation problems, and pollutants.

One effective, evidence-backed strategy to address these issues is the implementation of front-of-package (FOP) nutrition and sustainability labels. These labels can help guide consumers toward healthier and more sustainable choices and motivate the food industry to enhance the quality of their products and processes in order to produce healthier foods in a more sustainable manner.

While various types of FOP labels are used around the world, the strongest evidence supports labels that are: (i) mandatory; (ii) based on a scientifically validated nutritional or environmental profiling system; (iii) simple, clear, and easily visible; and (iv) interpretive, meaning they provide guidance to consumers based on a product's

information, rather than just listing nutrition content without offering actionable advice or recommendations.

Introduction

One of the tools available for authorities to help consumers to make the healthy and/or sustainable food choice is Front-of-pack nutrition and sustainability labelling (FOPL). Nutrition labelling is simplified nutrition information provided on the front of food packaging aiming to help consumers with their food choices (EU Commission 2020). Under the current EU rules, the indication of nutrition information on the front-of-pack is not mandatory but could be provided on a voluntary basis. FOPL can also be defined as Front-of-package warning labeling, which is a simple, practical and effective tool to inform the public about products that can harm health and help guide purchasing decisions (Pan American Health Organization 2020).

Nutrition labelling is recommended by the WHO as one of the 'best-buy' measures to help prevent Noncommunicable diseases (NCDs) (Farrand 2021). NCDs – mainly cancer, cardiovascular disease, chronic respiratory diseases, and diabetes – are the #1 cause of death and disability worldwide (NCD Alliance n.d.). NCDs could be largely prevented if action is taken to address their

common risk factors including tobacco use, unhealthy diet, physical inactivity, harmful use of alcohol, and air pollution. FOPL involves nutrition labelling to reduce total energy intake (kcal), sugars, sodium and fats (WHO 2024). Other recommended interventions from WHO guidance are: (i) implement subsidies to increase the intake of fruits and vegetables, (ii) replace trans-fats and saturated fats with unsaturated fats, through reformulation, labelling, fiscal policies or agricultural policies, and (iii) implement nutrition education and counselling in different settings (for example, in preschools, schools, workplaces and hospitals) to increase the intake of fruits and vegetables.

In recent years many LCA-based FOPL systems on food (further on called ecolabels) have been introduced that make it possible to assess and communicate on the environmental impact of all food, instead of only the products that are certified according to that specific scheme (Boone et al. 2023). Ecolabels can be a game changer in making food more sustainable as they are fully based on measuring impacts (e.g. greenhouse gas emissions, water use).

Consumers are faced by many sustainability claims. Some of these really indicate superior sustainability performance but for many of them the improved sustainability performance remains a challenge to quantify (WBCSD 2021). This, and the enormous amount of certification schemes and claims, leads to consumers facing misleading commercial practices related to the sustainability of products.

Ecolabeling systems have the potential to support consumers both in the selection between product categories and within a product category.

Producers are only slightly stimulated to make their products more sustainable and are hesitant to start investments because it is hard to convince consumers that their product is more sustainable than competing alternatives.

Nutrition and ecolabelling

According to the World Bank, our global food system generates US\$12 trillion in hidden social, economic and environmental costs each year, and is unfit to provide healthy diets to 10 billion people by 2050 without massively increasing the sector's carbon footprint and generating further natural capital loss (World Bank Group n.d.). These hidden costs are currently not incorporated in the food prices. True Cost Accounting (TCA) is an evolving holistic and systemic approach to measure and value the positive and negative environmental, social, health and economic costs and benefits to facilitate business, consumer, investor and/or policy decisions (TCA n.d.). Business and government leaders around the world are employing True Cost Accounting as a tool to provide more accurate assessments of social, economic and environmental conditions. These assessments can inform policy and business decisions that make healthy, sustainably grown food the norm for all.

This brings us to the important role for governments to take action. Currently we have the situation that the hidden costs of our food system are not incorporated and paid for by the food prices. This means that the tax payer via the government has to carry the costs for repairing the negative impact of the food sector. Authorities have at least two sets of actions at their disposal: (i) introduce new laws and regulations, and (ii) take actions to create a food environment that is supportive for public health and the food environment (WBCSD 2021). The introduction of new laws as the Corporate Sustainability Due Diligence Directive (CSDDD), the Forced Labour Regulation (FLR), the EU Deforestation Regulation (EUDR) and the Green Claims Directive (GCD) are examples of this. Actions to regulate the food environment are less common.

Nutrition and ecolabels are important means to communicate with the consumer.

Currently, there is a large number of labels available which might seem positive, but could also lead to label-tiredness of the consumer (Global Food research Program 2025).

This is why in my presentation I paid special attention to those labels that are the most important for the food sector: FAIRTRADE, ORGANIC, MSC, V-label, and B-Corp. Special attention was given to the German NON-GMO label, which has proven to be highly successful. German consumers have now embraced the scheme with the result that more than 75% percent of all German milk today is from cows without GMO feed in the trough (VLOG 2024).

To be able to make reliable food labels and product evaluations we need facts (WHO 2024; Boone et al. 2023). Open Food Facts is a French organization that collects food facts together with volunteers and makes them available for parties that would like to make use of them (Open Food Facts n.d.). The data from Open Food Facts are used in education, for products and services and in science. Other databases (that focus more on sustainability aspects) are CarbonCloud from Sweden (Carbon Cloud n.d.) and the Concito Big Climate Database from Denmark (Concito 2024). Carbon budgets – that measure how much CO₂ is produced by industry, homes and all other parts of the economy to calculate by how much emissions must be cut in the future – offer a way to benchmark the progress of governments in meeting their climate goals (Word Economic Forum 2024). The aim is to reach net-zero emissions – striking an equal balance between the carbon released into the atmosphere and that removed from it. CarbonCloud proposes to give consumers a CO₂ budget for shopping which helps them to make sustainable food choices (Carbon Cloud 2021).

Several aspects have to be taken into account when developing and implementing a nutrition and ecolabel for food, like the topics to be addressed (nutrition, processing, environment, origin). As indicated, the

quality of the underlying dataset is crucial. Important questions are “what is the methodology to calculate the scores” and “how transparent is this methodology”.

Very important aspects to discuss are (i) if all products get a label/score or only the ones with a positive score or a negative score – which is the case for a warning label – and (ii) if the label is voluntary or mandatory. Both these aspects strongly influence the willingness to participate of the industry. Front-of-package labels can nudge consumers and industry towards healthier products, but mandatory Front-of-package labels especially those with negative scores, can limit the enthusiasm of the industry to participate (Global Food Research Program 2025). Lastly, key for the effectivity is the design of the label which includes aspects of recognition and colour use (Farrad 2021; Global Food Research Program 2025). Examples of nutrition FOPLs are NutriScore, The Keyhole, The UK Multiple Traffic Light label, and Latin American warning labels (National Institute for Public Health and the Environment 2020; Farrad 2021; Global Food research Program 2025). Examples of sustainability labels are Eco-score, Enviroscore, Planetscore (Boone et al. 2023) and the last proposal from Le Collectif en Verite which combines NutriScore, Planetscore with data on origin (En-verite n.d.). The latter was driven by the French government. Eco-score and Enviroscore are both based on data collected by Life Cycle Assessment (LCA) (Boone et al. 2023). The name Eco-score could create confusion with organic production, which is in fact not included in this score (Colruytgroup n.d.). Planetscore fills this gap by giving scores for use of pesticides and the impact on biodiversity in combination with data on climate impact (Planetscore n.d.). Numerous apps are available that share information on food products with consumers on nutrition and sustainability aspects. Open Food Facts has their own app, but also shares data with Yuka, for instance (Yuca n.d.). CodeCheck is an independent App which covers German speaking countries (Codecheck-app n.d.). A specific case is the Greenhabit app, which helps

consumers in an engaging way to adopt a more healthy and sustainable life-style (Green Habit n.d.).

A special word about NutriScore. This label is based on the previous work done on in the UK on HFSS foods (High in Fat, Sugar and Salt) (Drewnowski and Fulgoni 2008). The scores are based on the composition of the products, the scoring system is designed by an independent scientific panel and thus completely transparent (Eurofins 2024), meaning the scores are fact-based and science-based and calculated without industry involvement. Multiple human trials have shown positive effects on years of healthy life when staying away from NutriScore D and E products (Donat-Vargas et al. 2021). Additionally, in France NutriScore has strongly stimulated the food processors to reformulate their recipes to get a higher score (Bauner and Rahman 2024).

Additionally, NutriScore is highly appreciated by French consumers (Santé publique France 2021). Despite these positive evaluations, the food processing industry is not always too eager to implement NutriScore, most likely because of the fact that NutriScore is not only giving positive scores (like A, B or C), but also giving warning negative scores (like D and E). This is a difference with the Scandinavian KeyHole label that is only putted on the label of products that are contributing positively to health, and maybe for this reason is highly supported by the food industry. The retail sector appears to have a more positive attitude against NutriScore and sees an opportunity to help consumers to choose a healthier diet and to improve systematically their product offer.

I would like to introduce two initiatives from the TITAN project that relate to the topic of this paper (Sliwinski 2024). One is the pilot run by QUB on the development of the Sus-Health index, a combined measure for describing environmental impact and nutritive value of foods and meals (Thomas et al. 2024). The pilot focuses on demonstrating the utility of the Sus-Health index, which combines both health and environmental impact metrics

to assess foods and meals. This approach aims to influence consumer preferences towards healthier and more sustainable food choices. Key achievements include the co-design of the Sus-Health index with stakeholders and the completion of a pilot living lab. Stakeholder engagement and the completion of a detailed index assessment mark significant milestones in the project.

The second one is Envirodigital which is a digital tool developed by AZTI, partner in TITAN, to help companies to reduce the environmental impact of their food products (Envirodigital n.d.). The EnviroScore calculation is based on the Product Environmental Footprint (PEF), a methodology accepted, standardised and recommended by the European Commission. It calculates in a single final score the environmental impacts generated throughout all stages of production and consumption of a kilogram of packaged product, including, among others, the potential for climate change, ozone layer depletion, water pollution or the depletion of fossil resources.

Concluding remarks

High blood pressure, high fasting blood sugar levels (measured as fasting plasma glucose), and overweight/obesity are among the top three risk factors for mortality in the western world. Unhealthy eating is closely linked to these top three risk factors, driven largely by excess intake of sugars, total fats, saturated fats, trans fats, and sodium — which are referred to as the “critical nutrients” of public health concern. Interpreting back-of-pack nutrition facts tables requires nutritional knowledge, literacy, and numeracy skills; accordingly, their use varies significantly depending on consumers’ education and income level. On the contrary, simple, clear front-of-package labels are an evidence-based policy tool, backed by decades of research showing how they can effectively nudge consumers towards healthier foods and drinks while also encouraging industry to improve the

nutritional profile of the products they sell. Therefore, the regulatory objective of a FOPL system should aim at allowing consumers to correctly, quickly, and easily identify products that contain excessive amount of sugars, total fats, saturated fats, trans fats, and sodium. The introduction of LCA-based ecolabelling initiatives for all food could be a game changer for making the food sector more sustainable. Ecolabelling is expected to help consumers to choose more sustainable products, resulting in positive business cases and incentives for producers to make food more sustainable. Governments together with all supply chain partners can use the environmental impact data of food to set quantitative time-bounded goals.

Disclaimer

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Food waste reduction and recycling

Is it time for a new food waste hierarchy?

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The waste hierarchy is a guiding principle that establishes a priority order for waste management strategies based on their expected environmental impact. It is thought to have emerged around 1980, with an emphasis on reducing, reusing, and recycling hazardous waste rather than treating or disposing of it (Van Ewijk and Stegemann 2016). Over the years, this framework has been adapted to manage various waste streams, including food waste. In all versions of the adapted waste hierarchy, prevention is the highest priority, while disposal without deriving any value from waste is typically the least preferred option. The steps in between represent various valorisation routes, aiming to extract value from materials that would otherwise remain unused.

The current food waste hierarchy

REFRESH (2015 - 2019), a European Commission-funded project focused on reducing food waste, proposed a version of the waste hierarchy suitable for managing food waste. Several Union-level as well as Member State-level policy and legal documents now refer to this hierarchy when discussing matters pertaining to food waste. *Fig. 1* is an illustration of this framework.

According to the REFRESH hierarchy, the most preferred valorisation option is the redistribution and reprocessing of safe, edible surplus food for human consumption. Redistribution is typically carried out by hunger relief

organisations and social enterprises, which collect surplus food from retailers and distribute it to those in need. However, two major challenges hinder this process: taxation and food safety liability.

Under normal circumstances, value-added tax (VAT) is paid by consumers upon purchasing food products. However, if food is donated, retailers must still pay VAT unless Member State (MS)-level legislation provides an exemption (Eriksson et al. 2020). Food safety is another critical concern. When retailers or suppliers donate food, they often have limited or no control over its handling and storage. However, under European General Food Law, Food Business Operators (FBOs) remain legally responsible if food safety issues arise, potentially exposing them to serious legal and reputational risks. Consequently, discarding surplus food or removing it from the food supply chain is often a cheaper and easier alternative to donation (Eriksson et al. 2020).

The next preferred valorisation pathway involves repurposing food waste as animal feed, offering a dual environmental benefit: mitigating the impact of meat production while reducing food waste. In the EU, various food processing by-products – such as spent grains, fresh produce trimmings, and oilseed meals – are already successfully incorporated into animal feed (Rao et al. 2021). Additionally, surplus food from different stages of the supply chain, known as former food products, is also

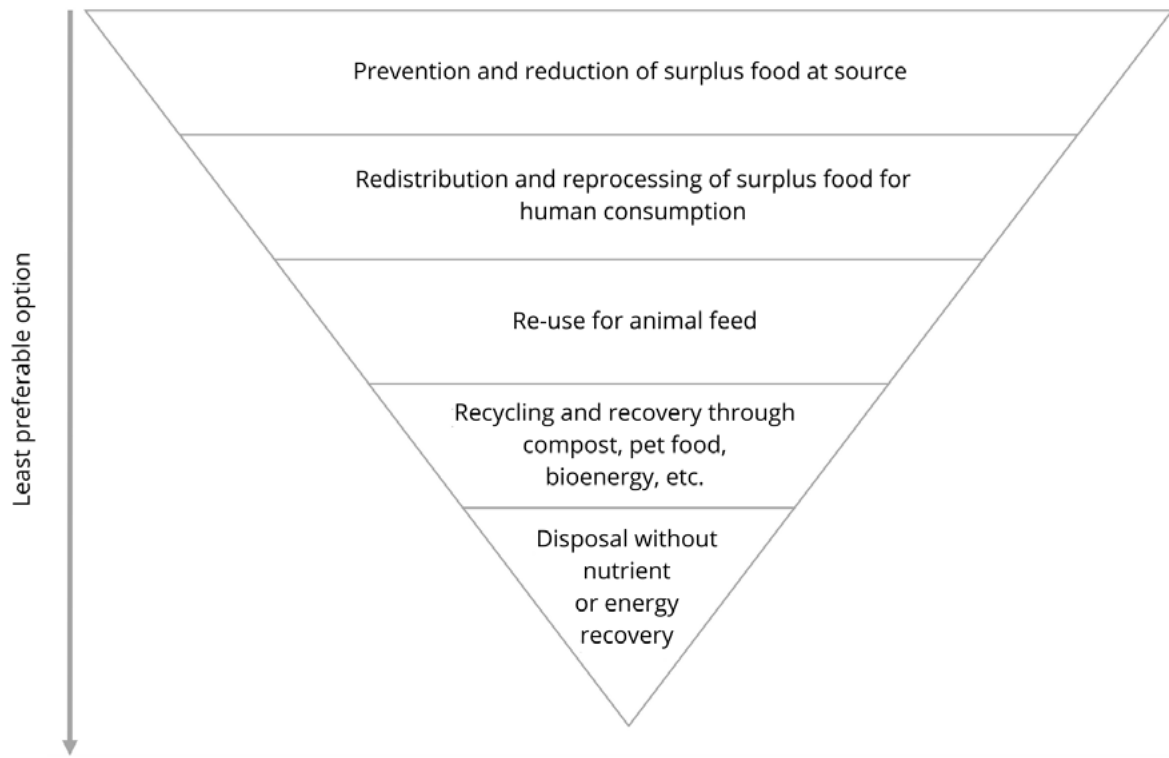


Fig. 1. The food waste hierarchy as presented by the REFRESH project.

redirected for this purpose (Luciano et al. 2020).

This approach ensures that surplus biomass partially fulfils its original role by remaining within the food system. However, not all surplus food and by-products are suitable for animal feed due to strict EU feed regulations designed to prevent prion and other animal-borne diseases. These regulations impose stringent limits on using animal-derived ingredients in feed, affecting not only meat processing by-products but also household food waste and leftovers from catering, where the presence of meat cannot be verified. Consequently, despite their high nutritional value, only a small fraction of materials that could contain animal by-products are currently used in livestock feed (Jedrejek et al. 2016).

The next step of the hierarchy involves recycling or

recovery through converting food waste into energy, compost, and pet food among other products.

Due to constraints imposed by EU food and feed law as well as risks connected to safety, these options are often favoured by FBOs. Fiscal incentives encouraging FBOs to divert waste toward energy recovery often make it a more attractive option (O'Connor et al. 2014). Bowman et al. (2020) highlight that in 2017-18, the UK's largest food retailer sent 19,898 tonnes of food, still fit for human consumption, to anaerobic digestion instead of redistribution.

Some MSs even prioritise waste-to-energy strategies over surplus food redistribution, despite its potential to enhance food security. Sweden, for example, frames food waste as an economic and environmental issue,

largely overlooking its social dimension when shaping policies (Johansson 2021). To address these differences, the European Commission issued guidelines on food donation in 2017, aiming to clarify relevant EU legislation and foster a unified interpretation across MSs and regulatory authorities (European Commission 2017). However, these guidelines remain non-binding, leaving it to individual MSs to revise their legislation and create conditions where donating or reprocessing surplus food for human consumption becomes the preferred valorisation route.

Competing valorisation pathways

Marie Mourad’s research on competing hierarchies of food waste solutions provides valuable insights into how different valorisation pathways are perceived and prioritised (Mourad 2016). As illustrated in Fig. 2, her findings suggest that the preferred approach to food waste management largely depends on the perspective from which the issue is examined. Within the context of environmental sustainability, waste-to-energy solutions are often considered more favourable than alternatives such as food donation or discounting surplus food. This preference arises because different valorisation methods

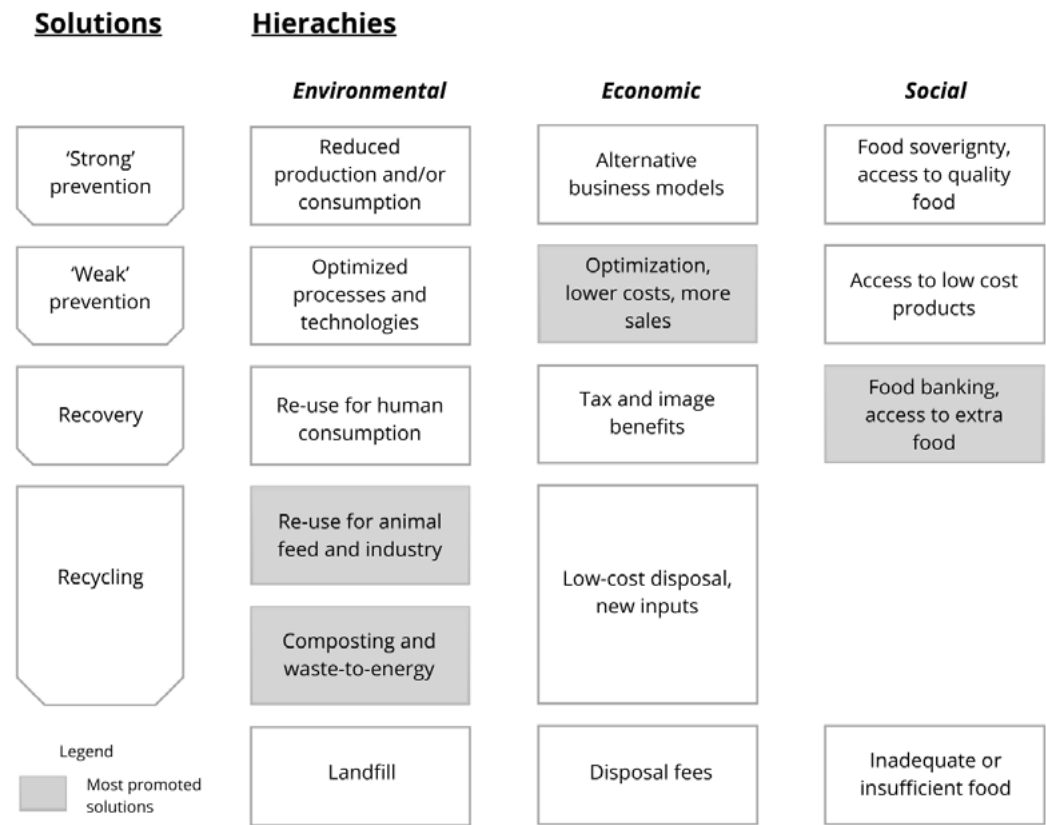


Fig. 2. Competing hierarchies of solutions to food waste as presented by Mourad (2016).

are assessed using distinct criteria. For example, environmental impact is typically evaluated based on carbon emissions and effects on soil and water, while social impact is measured in terms of nutritional value and accessibility, and economic impact by cost savings or profitability (Mourad 2016).

Mourad's study also highlights that despite being positioned at the bottom of the waste hierarchy, waste-to-energy solutions are often favoured by businesses and municipalities. One reason for this preference is the ease with which their impact can be quantified - waste diverted from landfill can be directly measured, offering a tangible indicator of success (Mourad 2016). Additionally, legislative efforts to promote renewable energy targets have incentivised the use of waste, including food waste, for energy production. As a result, several Member States have introduced tax incentives to encourage businesses to channel waste into energy recovery (Mourad 2016; Wunder et al. 2018). Mourad ultimately argues that social, environmental, and economic considerations place different valorisation methods in competition with one another when arranged hierarchically. This raises the broader question of whether a rigid ranking system for valorisation options is appropriate at all.

Nadine Arnold's work on competition within the food waste hierarchy examines this issue through the lens of organisation theory (Arnold 2021). A key distinction in food waste valorisation, she notes, is that actors engaged in lower-ranking processes do not necessarily strive to move up the hierarchy (Arnold 2021). In her study of Swiss biogas plants, Arnold observes that bioenergy producers actively distance themselves from the broader discourse on food waste by establishing a separate sub-field focused on waste recovery (Arnold 2021).

Through strategic language choices, these actors shape the narrative of their industry to reinforce their legitimacy (Arnold 2021). In the Swiss context, terms associated with food waste - such as *Verschwendung* (German) and

gaspillage (French), meaning 'wastage' - are deliberately avoided. Instead, terms like *Abfall* (German) and *déchets* (French), which translate to 'discarded material' or 'waste,' are used to frame their work as a transformation of worthless by-products into valuable resources (Arnold 2021). Although bioenergy derived from food waste is ranked low within the hierarchy, it is perceived more favourably when compared to other energy sources.

This suggests that competition does not necessarily occur between the actors operating within different valorisation pathways. Rather, it is FBOs that experience pressure to select and defend the most sustainable option, often navigating tensions between social (people), environmental (planet), and economic (profit) priorities. It is, however, worth questioning whether the people-planet-profit framework - also known as the triple bottom line - is an effective approach for designing policies to optimise food waste valorisation.

Originally introduced by John Elkington as a way to operationalise corporate social responsibility (Elkington 1994), the triple bottom line remains a widely used framework in sustainability discussions. However, Kuhlman and Farrington (2010) argue that separating environmental considerations from social and economic factors may provide a clearer and more practical approach when evaluating sustainability policies. Their reasoning is that while social and economic sustainability focus on present-day needs, environmental sustainability is concerned with long-term impacts. Consequently, they propose distinguishing these dimensions by referring to the former as well-being and the latter as sustainability (Kuhlman and Farrington 2010).

Proposal for a new food safety-based hierarchy

Applying this reasoning to food waste management, we propose a differentiated approach that prioritises management strategies based on whether or not food by-products or surpluses are safe for human consumption. The fundamental principle guiding this approach is that when food retains its status as a

marketable commodity with nutritional value, its role in addressing immediate food security concerns takes precedence. At this stage, the highest priority must be placed on preventing food from becoming waste in the first place. This necessitates a dual strategy: 'strong' prevention measures aimed at systemic change complemented by 'weak' prevention strategies focused on process optimisation (Mourad 2016).

However, when prevention is unsuccessful, efforts should be directed towards redistribution and donation, ensuring that food remains within food supply chains for as long as possible. To facilitate this, supportive legal frameworks and logistical infrastructure must be in place to remove barriers and encourage widespread participation in food donation initiatives. In cases where food processing by-products can be safely repurposed into new food products, this should be considered alongside or immediately after redistribution efforts.

Once food is no longer safe for human consumption, the priority must shift towards environmental sustainability, as the methods used to manage this biomass will have long-term environmental implications. From a sustainability and circular economy perspective, repurposing food waste as animal feed should be the preferred option wherever it is deemed safe and nutritionally viable. This approach offers significant environmental benefits compared to alternative valorisation methods, particularly energy recovery (Salemdeeb et al. 2017).

If the biomass is unsuitable for use in animal feed, alternative valorisation methods must be considered. One key option is energy recovery, prioritising anaerobic digestion, which enables the extraction of biogas while reducing waste volumes. If anaerobic digestion is not feasible, incineration with energy recovery may be pursued as a secondary option (Papargyropoulou et al. 2014). At the same stage, composting presents another viable pathway, particularly for food waste that retains its biological integrity but is unfit for consumption or

animal feed. Composting allows organic waste to be converted into nutrient-rich soil amendments, supporting agricultural and horticultural systems while reducing reliance on synthetic fertilisers. Additionally, emerging bio-material applications for food waste, such as bio-based packaging or bioplastics, offer further opportunities to close resource loops and minimise waste.

Finally, the least desirable stage in this hierarchy is the disposal of food waste without any form of nutrient or energy recovery. Landfilling or other forms of direct disposal should be considered only as a last resort, as they contribute to greenhouse gas emissions, soil degradation, and long-term environmental harm. Preventing food from reaching this stage is crucial for both sustainability and resource efficiency.

Fig. 3 illustrates this bifurcated hierarchy, outlining the sequential decision-making framework that prioritises food waste reduction, redistribution, and sustainable repurposing before resorting to energy recovery, composting, or, as a last resort, disposal.

Conclusion and way forward

In the European Union, the fragmented legal landscape governing food waste valorisation is gradually being replaced by more harmonised legislation. However, the prevailing food waste hierarchy, which underpins legislative developments in this area, may inadvertently create competition between different valorisation pathways. For instance, although energy recovery is ranked lowest among valorisation options, FBOs may still favour it over reuse as food or feed due to its role in diverting waste from landfills while avoiding safety risks and associated costs. To mitigate such competition, the bifurcated food waste hierarchy proposed earlier in this article presents a potential solution. By prioritising economic and social well-being when food remains fit for consumption and environmental sustainability once it is no longer suitable for human use, conflicts between

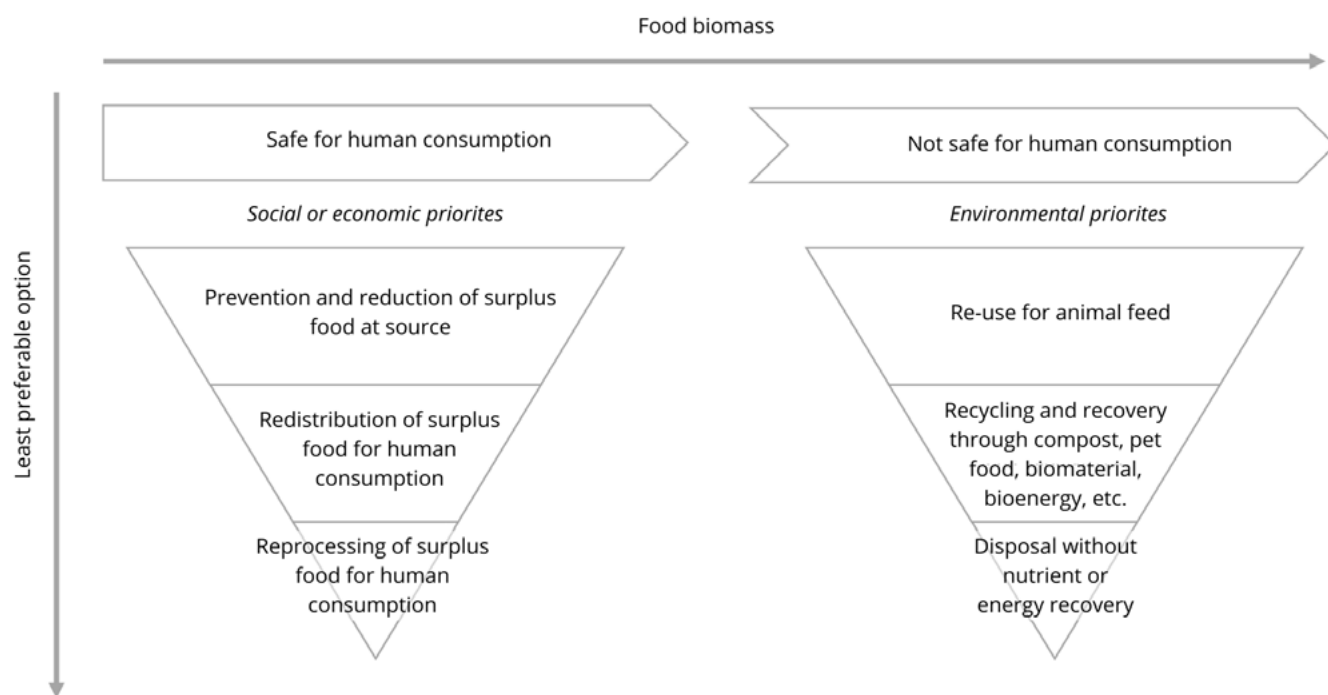


Fig. 3. Bifurcated food waste hierarchy

FBOs' financial, social, and environmental priorities can be minimised.

However, even if this new model of the food waste hierarchy was to be implemented, businesses are likely to need additional guidance in determining the most appropriate use for their food surplus or waste. In the food sector, public law permits private actors to self-regulate certain aspects of decision-making and compliance.

Voluntary standards, as a form of private regulation, could provide a framework for the sustainable and equitable valorisation of food waste. To facilitate this transition, private standards governing food, feed, energy, and other sectors involved in food waste valorisation must align more effectively, thereby ensuring that biomass at the end of its lifecycle in one supply chain can be safely repurposed in another.

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New food products – Risk management

Benefits and risks of novel foods - Anticipating the unknown unknowns

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Prospects for novel foods

The market for novel foods is expected to experience exponential growth over the next three to five years. This expansion is fuelled by advancements in biotechnology, a shift towards climate-smart agricultural practices, and growing consumer demand for sustainable and eco-friendly dietary options. However, the rapid introduction of novel foods is likely to bring about a host of new challenges, particularly concerning safety and regulatory oversight.

Advanced methods for risk reduction

1. Predictive modelling and enhanced detection

The integration of predictive models leveraging genomic and proteomic datasets represents a significant advancement in ensuring food safety.

These models facilitate the early identification of potential risks, such as the presence of hazardous compounds or harmful microorganisms, during the development of innovative food products. This pre-emptive approach enables manufacturers to address safety concerns before products enter the supply chain. Complementing these models, advanced detection technologies such as high-resolution mass spectrometry (HRMS) and near-infrared (NIR) spectroscopy offer high precision in identifying contaminants, allergens, and

adulterants at trace levels. By incorporating data-driven tools, real-time analysis becomes feasible, supporting swift and decisive interventions. These technologies, when paired with advanced computational methods, allow continuous improvement in safety standards and provide critical insights that mitigate risks efficiently.

2. On-site analysis and automation

The advent of compact diagnostic devices has revolutionised the capacity for on-site monitoring and analysis. Portable technologies such as surface-enhanced Raman spectroscopy (SERS) and next-generation sequencing (NGS) provide rapid detection of proteins, sugars, fats, and a range of contaminants. Their portability ensures that these assessments can be conducted at various stages of production and distribution, reducing the reliance on centralised laboratories. Furthermore, the ease of use of these devices means non-experts can perform reliable analyses, empowering more personnel across the supply chain to take corrective action when needed. Integrating these diagnostic tools with automated systems for quality control ensures consistent monitoring and enhances the overall safety of production processes. Automation reduces human error, improves data accuracy, and facilitates compliance with stringent

safety regulations.

3. Enhancing traceability and supply chain resilience

The increasing globalisation of food supply chains introduces significant complexities in maintaining transparency and traceability.

Ingredients sourced from geographically dispersed regions often pass through multiple intermediaries before reaching the end consumer.

Blockchain technology, along with similar decentralised ledger systems, provides a robust mechanism for recording and verifying the origins, handling, and processing of these ingredients.

By ensuring that these records are tamper-proof, these systems bolster confidence among stakeholders. Furthermore, they help pinpoint vulnerabilities in the supply chain, such as the substitution of high-quality ingredients with inferior alternatives or instances of contamination. Adopting such technologies on a wider scale will require updated regulatory frameworks, which should compel their use, particularly in sectors dealing with high-risk or novel food products. The combination of technology and regulation can significantly enhance consumer confidence and supply chain resilience.

Gene-edited ingredients

Gene-editing and precision fermentation technologies have the potential to redefine the food landscape by introducing a range of customisable products. For instance, proteins engineered to enhance nutritional content or mimic the taste and texture of traditional animal-based products are poised to gain popularity. Yet, these developments also introduce new risks. Altered genetic profiles may lead to unforeseen health implications, such as changes in allergenic properties or complex metabolic interactions that could affect long-term health outcomes. Addressing these uncertainties will require rigorous validation and approval frameworks, underpinned by comprehensive research on the safety and nutritional implications of these products.

Climate-driven risks

The effects of climate change on agricultural systems are becoming increasingly evident, influencing both the quality and safety of food products.

Warmer temperatures and shifting climatic patterns are causing toxin-producing organisms, such as algae, and invasive plant species to spread to new regions.

For example, the migration of *Datura stramonium*, a plant associated with tropane alkaloid contamination, poses a growing threat to cereal crops in Europe.

Addressing such risks will necessitate continuous monitoring and the development of adaptive strategies to mitigate contamination risks. Collaborative efforts between agricultural experts, environmental scientists, and food safety authorities will be critical to managing these emerging threats.

Circular bioeconomy and emerging practices

The push towards sustainability in food production has led to the adoption of alternative practices under circular bioeconomy models.

Methods such as water-saving irrigation techniques are being implemented to conserve resources, particularly in water-intensive crops like rice. However, these practices may inadvertently heighten the risk of heavy metal uptake, such as cadmium, in edible plants.

Similarly, no-till farming methods, which are promoted for their ability to reduce greenhouse gas emissions, can alter soil microbial activity, potentially increasing the levels of harmful mycotoxins.

Achieving a balance between ecological benefits and food safety will require interdisciplinary collaboration, combining expertise from agronomy, environmental science, and food technology.

Evolving risk communication strategies

Effective communication will be indispensable in alleviating public concerns about the safety and sustainability of novel foods. Transparency in safety

protocols and traceability measures must become standard practice to build and maintain consumer trust. Leveraging digital platforms to share critical data on food safety, ingredient sourcing, and sustainability credentials can significantly enhance public engagement. Regulatory agencies, too, must expand their outreach to ensure that emerging risks are communicated in a clear and accessible manner. Public education campaigns, coupled with robust regulatory frameworks, will play a vital role in aligning consumer perceptions with scientific realities.

By addressing these challenges with foresight and a commitment to safety, the novel food industry can continue to grow sustainably. The integration of advanced technologies, coupled with comprehensive oversight and public engagement, will be crucial in ensuring that this dynamic sector meets both consumer expectations and safety standards.

New food products – Risk management

Navigating the promise and peril of novel foods: Mitigating fraud risks through innovative analytical methods and regulatory compliance

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In recent years, the food industry has witnessed a surge in interest surrounding novel foods – products that have not been significantly consumed by humans in the European Union (EU) prior to May 15, 1997. This category encompasses newly developed food items, those produced using innovative technologies, and foods traditionally consumed outside the EU. As consumer demand for sustainable and health-conscious options grows, the market for novel foods is projected to expand significantly, with the global plant-based food market expected to reach USD 74.2 billion by 2027.

Growth of novel foods market

One of the primary drivers behind the rise of novel foods is the increasing consumer awareness about health and environmental sustainability. Consumers are seeking out alternative protein sources, such as plant-based meat substitutes, insect-based products, and cultured meats, to reduce their environmental footprint and improve their health. Additionally, advancements in food technology have made it possible to produce these novel foods at a scale and cost that were previously unimaginable. Innovations in biotechnology, for example, have enabled the development of lab-grown meat, which promises to revolutionize the food industry

by providing a sustainable alternative to traditional animal farming.

The risks of food fraud

However, with the promise of novel foods comes the peril of food fraud. Food fraud is defined as the deliberate and intentional substitution, mislabeling, adulteration, or counterfeiting of food products for economic gain. The unique characteristics of novel foods—such as their high demand, value-added claims, and often complex supply chains—make them particularly susceptible to fraudulent activities. This susceptibility is exacerbated by knowledge gaps regarding new ingredients and processing methods, which can create increased tolerance for deviations from known fraud indicators.

The consequences of food fraud are far-reaching, impacting both consumer trust and the economy. Erosion of consumer confidence in novel foods can lead to financial losses for legitimate businesses, as they face unfair competition from fraudulent products. Additionally, market instability can arise from a lack of trust, further complicating the landscape for both consumers and producers. Beyond economic losses, food fraud can also pose significant health risks, as adulterated or mislabeled products may contain harmful

substances or allergens that can endanger consumers.

Advanced analytical methods

To combat these challenges, advanced testing techniques are essential. Expert laboratories specialize in verifying the origin and authenticity of food products through modern, high-tech analytical methods. Such tools include fraud prevention strategic consulting, fraud intelligence, and risk assessment, all aimed at ensuring the integrity of food products in the market. Advanced analytical methods, such as isotopic analysis, DNA barcoding, and mass spectrometry, allow for precise identification and verification of food components, helping to detect and deter fraudulent activities.

Isotopic analysis, for instance, can be used to determine the geographical origin of food products, ensuring that items labeled as “organic” or “locally sourced” genuinely meet those criteria.

DNA barcoding enables the identification of species in mixed or processed food products, which is particularly useful in detecting the presence of unauthorized ingredients or species substitutions. Mass spectrometry, on the other hand, provides detailed information about the molecular composition of food products, helping to identify adulterants and contaminants that may not be detectable through traditional methods.

Regulatory compliance

The regulatory landscape surrounding food safety and fraud prevention is also evolving. Key regulations, such as the FDA FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration and the EU Green Claims Directive, are designed to enhance food safety and protect consumers from fraudulent practices. Compliance with these regulations is crucial for businesses operating in the novel foods sector. Companies must not only adhere to these regulations but also stay informed about emerging legal requirements and best practices to ensure ongoing compliance.

In the EU, the European Food Safety Authority (EFSA) plays a critical role in assessing the safety of novel foods before they can be marketed. This rigorous evaluation

process includes reviewing scientific data on the nutritional content, potential toxicity, and allergenicity of novel foods, as well as assessing their overall safety for consumption. By ensuring that novel foods meet these stringent safety standards, regulatory bodies help protect consumers from potential health risks and build trust in the novel foods market.

Future outlook

As the novel foods market continues to grow, collaboration between industry stakeholders, regulatory agencies, and science-based service providers is vital. By working together, these entities can create a resilient and ethical food system for the future. The urgent need for proactive steps in mitigating fraud risks and ensuring food integrity cannot be overstated.

Initiatives such as industry-wide standards for novel foods, public-private partnerships for research and development, and consumer education campaigns can all contribute to a more transparent and trustworthy food industry.

Conclusion

In conclusion, while novel foods present exciting opportunities for innovation and sustainability, they also pose significant challenges related to food fraud.

By leveraging advanced testing techniques and fostering collaboration across the industry, we can navigate these challenges and build a trustworthy food system that benefits consumers and producers alike.

The continued evolution of analytical methods and regulatory frameworks will be essential in maintaining the integrity of the novel foods market and ensuring that consumers can confidently enjoy the benefits of these innovative products.

Plenary Session III: Toolbox for the future

Food system microbiomes and their implications for sustainable, safe, and healthy food

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Microbiomes, dynamic communities of microorganisms including bacteria, fungi, viruses, and archaea, inhabit virtually every part of the food system, from soil and plants to livestock and human digestive systems (Berg et al. 2020). These microbial ecosystems play a pivotal role in nutrient cycling, plant growth, food safety, and animal and human health. Understanding and harnessing these interactions offers immense potential for creating resilient, sustainable, and safe food systems (d'Hondt et al. 2021; Callens et al. 2022). However, achieving this vision requires addressing significant scientific, regulatory, and societal challenges.

Microbiome applications: success stories

Microbiome-based innovations have shown transformative potential across food systems, as recently illustrated by the 14 success stories summarized by Olmo et al. (2022) spanning plant health, feed products and livestock health, food production and human health applications. These stories were selected based on a strict set of criteria. However, scientific literature showcases the even bigger potential of microbiome-based applications.

For example, in agriculture, microbial inoculants such as

Rhizobium spp. for legumes and arbuscular mycorrhizal fungi for cereals and other crops have improved nitrogen fixation and phosphorus uptake, reducing dependency on chemical fertilisers and enhancing soil health (Goyal et al. 2021; Fasusi et al. 2023). Biocontrol agents, including *Bacillus* and *Trichoderma* species, have effectively suppressed plant pathogens such as *Fusarium* spp. and *Phytophthora* spp., reducing crop losses in bananas, tomatoes, and other key staples (Zhang et al. 2023; Asad 2022).

Microbial consortia tailored to specific environmental stresses have also been used to enhance crop resilience to drought and salinity, addressing challenges associated with climate change (Compant et al. 2024).

In livestock, probiotics like lactobacilli strains have improved gut health in poultry and cattle, enhancing feed efficiency and reducing the need for antibiotics, which aligns with efforts to combat antimicrobial resistance (Anee et al. 2021; Elshaghabee and Rokana 2022). Similarly, in aquaculture, probiotics and tailored microbiome management strategies have improved water quality and disease resistance in farmed fish and shrimp, contributing to more sustainable practices (El-Saadony et al. 2021). Microbial applications in food

processing have enhanced product safety and quality; for instance, lactic acid bacteria (LAB) used in yogurt and cheese production inhibit pathogens and extend shelf life (Zapasnik et al. 2022), while sourdough fermentation with specific microbial strains enhances flavour and texture without synthetic additives (Arora et al. 2021). In addition to production and processing, microbiomes have been harnessed to create functional foods, such as fermented products enriched with probiotics that promote gut health and overall well-being (Obayomi et al. 2024). Waste management has also seen microbiome innovations, such as using microbial consortia to convert agricultural byproducts into biogas or biofertilizers (Kiruba and Saeid 2022), contributing to circular economy practices. Nevertheless, as emphasised by Olmo et al. (2022), the success and scalability of these innovations rely on addressing knowledge gaps, fostering microbiome literacy, and creating multidisciplinary collaborations.

Challenges in harnessing food system microbiomes

Despite the significant potential of microbiome-based innovations in food systems, several challenges must be addressed to fully harness their benefits and ensure the successful transition from research & development into implementation and impact achievement.

One of the primary challenges is the existing knowledge gaps regarding the complex interactions within microbiomes. Microbial communities are influenced by a range of factors, including environmental conditions, host species, and human interventions, which contribute to their variability. This variability and inherent interconnectedness of microbiomes complicate efforts to standardize and scale microbiome-based solutions (Sessitsch et al. 2023). A deeper, long-term commitment to interdisciplinary research is essential to unravel these complexities and develop predictive models that can better anticipate microbiome behaviour. At the same time, it is crucial to transition from descriptive,

taxonomy-focused research that unveils correlations, toward functional, multi-omics studies that uncover causative mechanisms (Ferrocino et al. 2023). Moreover, the integration of data from diverse ecosystems through global collaborations will be necessary to generate actionable insights that can guide the application of microbiome technologies across different food system contexts (Meisner et al. 2022).

The growing complexity and scale of microbiome data present both a challenge and an opportunity. Microbiome research generates vast amounts of data, but this data must be standardised, organised and analysed effectively to extract actionable insights (Cernava et al. 2022). To address this, the principles of FAIR (Findable, Accessible, Interoperable, and Reusable) data must be embraced. FAIR data allows researchers to share and access microbiome data easily, enabling more efficient collaboration and accelerating discoveries. Additionally, the integration of artificial intelligence (AI) and machine learning (ML) approaches can play a key role in making sense of big microbiome data (Kumar et al. 2024). Machine learning algorithms can identify patterns and predict microbiome behaviour, which can be used to develop precision applications in agriculture, food safety, and medicine. AI-powered tools can help design microbiome-based solutions tailored to specific environmental or host conditions, improving their effectiveness and minimising unintended consequences. The importance of data availability and the potential of data integration was recently showcased in the example of the curated Food Metagenomic Data (cFMD; Carlino et al. 2024). This resource advances our understanding of food system microbiomes and their influence on the human microbiome and paves the way for future applications of metagenomics in food quality, safety, and authentication.

The potential of microbiomes revealed through “big data” analyses can only be fully realized if corresponding biological resources are accessible. Biobanks are crucial

for microbiome research, preserving microbial isolates, ensuring long-term access, and preventing biodiversity loss caused by environmental changes and human activities (Sonnenburg and Sonnenburg 2019; Berg and Cernava 2022). However, as Ryan et al. (2020) highlighted, biobanking infrastructure is fragmented and poorly equipped for the preservation of microbiomes. A key challenge is developing methods to preserve microbiomes while maintaining their composition and functionality, alongside reliable assessments of preservation success. Furthermore, the diversity and complexity of microbiomes across environments necessitate careful consideration of what should be conserved and why, accounting for scientific, economic, social, and environmental perspectives.

Another critical issue that needs to be addressed is the growing need for education and capacity building to support the effective integration of microbiome-based innovations into food systems. Olmo et al. (2023) identified critical educational needs for stakeholders in agriculture, food production, policy, and the general public. They stress that building microbiome literacy is essential for overcoming regulatory barriers, improving public acceptance, and enhancing the application of microbiomes to improve food security, sustainability, and safety. The study advocates for targeted educational initiatives to foster understanding and engagement, enabling the development of more resilient and sustainable food systems. Additional publications, such as those by Timmis et al (2019; 2024) and Kokkinias et al. (2024) further support the importance of education and collaboration in advancing microbiome science. In parallel, there is an inherent need to strengthen and improve the communication from the scientific community towards other stakeholders (Schelkle and Galland 2020). This will ensure effective knowledge transfer, support the establishment of realistic expectations and enable informed decision-making. The regulatory environment for microbiome-based

applications presents a significant barrier to innovation. Existing regulatory frameworks often fail to account for the unique complexities of microbiomes, resulting in lengthy approval processes and uncertainty around safety and efficacy. Regulators must develop new, flexible policies that are tailored to microbiome technologies while ensuring safety and minimizing risks. This includes establishing clear guidelines for the approval of microbial products like biopesticides, probiotics, and biofertilizers. At the same time, regulatory agencies must remain vigilant to the potential risks of microbiome technologies, such as unintended ecological consequences or health impacts, and establish appropriate monitoring systems.

Conclusions

Setting realistic expectations about the potential and limitations of microbiome applications is crucial for ensuring their long-term success and meaningful impact on food systems. While microbiomes present exciting opportunities, the field remains in its early stages, with much still to be understood about their full capabilities and complexities. Expectations must be grounded in current scientific knowledge, recognizing that microbiome-based solutions are not universal or immediate fixes. A balanced approach is needed from researchers, policymakers, and industry stakeholders, who must weigh both the transformative potential and challenges, including the need for robust evidence, scalable methods, and clear regulatory frameworks. Overhyping microbiome technologies risks fostering disillusionment, misuse, or unintended consequences. Instead, transparent communication about their realistic applications and limitations, supported by interdisciplinary collaboration and ongoing education, is essential for driving innovation, building trust, and achieving sustainable progress in microbiome science. The MicrobiomeSupport association can play a pivotal role in achieving these goals by serving as a collaborative platform that brings together researchers, industry

leaders, policymakers, and educators to advance microbiome science. By fostering dialogue, promoting microbiome literacy, and driving the development of standardized methodologies and policies, the association helps align innovations with evidence-based practices and realistic expectations. This collective approach ensures that microbiome solutions are sustainably integrated into food systems, maximizing their potential benefits while addressing key challenges.

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*Toolbox for the future*

Building bridges between habit and health: The nutritional value of plant-based meat and milk alternatives

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The growing popularity of plant-based meat and milk alternatives reflects an increasing awareness of their potential to support healthier diets and a more sustainable food system (Clark et al. 2022; Ritchie et al. 2018). With concerns mounting over the environmental and health impacts of animal agriculture, plant-based products are increasingly seen as viable dietary alternatives.

However, questions remain about their nutritional value – can these alternatives compete with traditional meat and dairy in terms of health benefits, and do they align with global dietary recommendations?

The shift towards plant-rich diets is not just a trend but a necessity for safeguarding human and planetary health. Plant-based meat and milk alternatives represent a critical step on this path, offering scalable and sustainable solutions to some of the most pressing challenges of our time. These products have the potential to reshape food systems by reducing environmental impacts while making the transition towards a more plant-rich diet easier and more convenient.

ProVeg International recently conducted a comprehensive study to evaluate the nutritional profiles of a wide range of plant-based meat and milk alternatives and compared them with their animal-based

counterparts. The findings include an analysis of 422 plant-based meat products and 251 plant-based milk products, collected from 11 countries around the world. The study highlights the varying degrees of market maturity and the varying availability of plant-based alternatives in diverse regions, including Europe, North America, Asia, and South Africa.

Methodology

Countries were selected to reflect varying levels of market maturity for plant-based products, including Belgium, the Netherlands, Italy, Czechia, Spain, Poland, Germany, the UK, the United States, South Africa, and Malaysia.

Nutritional assessments were conducted through a scoring system we developed, based on internationally recognised frameworks, including the WHO Nutrients Profile model (NPM) (WHO 2023), the Netherlands Nutrition Centre (Nutrition Centre 2018) and the EFSA nutrition claim legislation (EFSA 2006). These guidelines provided clear benchmarks for assessing the healthiness of plant-based products, based on their levels of protein, fibre, saturated fats, added sugars, and micronutrients. One score was created for plant-based and animal-based meat products, and another for plant-based and

animal-based milk. The scores were used to evaluate plant-based milk and meat alternatives and their animal-based counterparts in order to better compare their nutritional profiles. In addition to quantitative data, qualitative insights were gathered through interviews with industry professionals, nutritionists, and public-health experts. These insights explored the challenges inherent in product formulation, consumer adoption, and regulatory frameworks. This combination of quantitative and qualitative methods ensured a comprehensive analysis of products' nutritional profiles as well as the broader systemic challenges facing plant-based products.

The key findings - Plant-based meat alternatives

- **Nutritional profile:** The plant-based meat alternatives we studied contained, on average, significantly less saturated fat than their animal-based counterparts. With an average nutritional score of 5.32 out of 8, compared to 4.50 for animal-based meats, plant-based

meat alternatives performed slightly better than their counterparts. However, there is still room for improvement (*Fig. 1*).

- **Protein content:** These products generally also provide comparable protein content to traditional meats when formulated with high-protein ingredients such as pea or soya protein. We found that the average protein content of plant-based meat alternatives ranges from 11.2 g to 19.6 g per 100 g of product.

In comparison, the average protein content of animal-based meat typically ranges from 15 g to 19.5 g per 100 g of product. This makes plant-based meat alternatives, in general, a viable option for meeting dietary protein requirements, particularly for individuals seeking plant-based alternatives.

- **Saturated fat content:** Plant-based meat alternatives contain significantly lower levels of saturated fat than their animal-based counterparts - and they do not contain cholesterol, possibly contributing to better

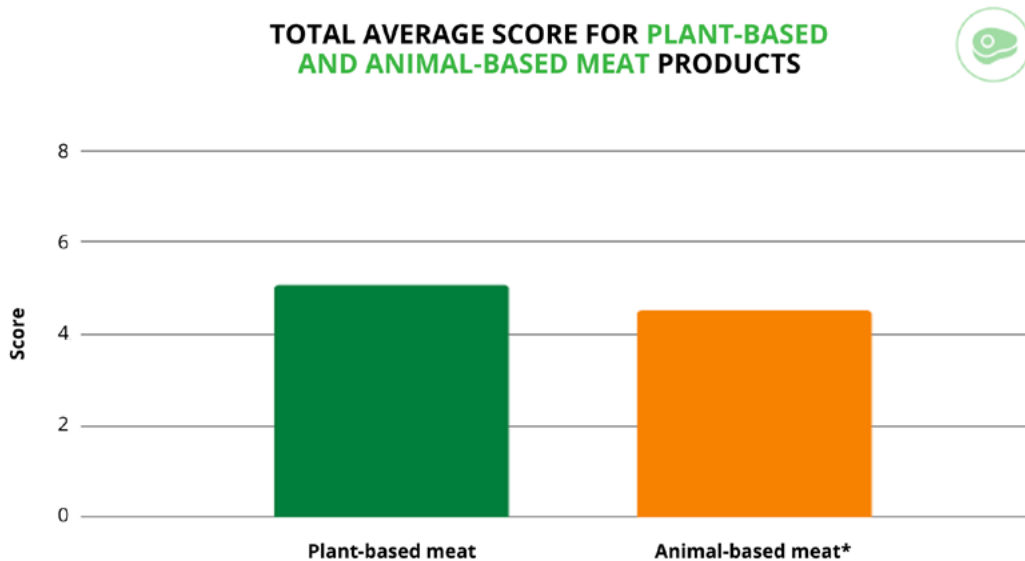


Fig. 1. Overall total average score of plant-based meat alternatives and animal-based meat products. *Average nutritional value of animal-based products from USDA Food Data Central and UK Food Composition Database

cardiovascular health. Depending on the product type, saturated-fat content ranges from 0.7 g to 2.3 g per 100 g, compared to 4 g to 8 g per 100 g in animal-based meats. This reduction positions plant-based alternatives as a healthier choice for heart health (Fig. 2).

- Fibre content: Plant-based meat alternatives contain

significantly higher fibre content than animal-based meats. On average, these products range from 3.5 g to 6.7 g of fibre per 100 g of product, whereas animal-based meats don't naturally contain fibre. This makes plant-based alternatives a valuable addition for those people who want to improve their fibre intake (Fig. 3).

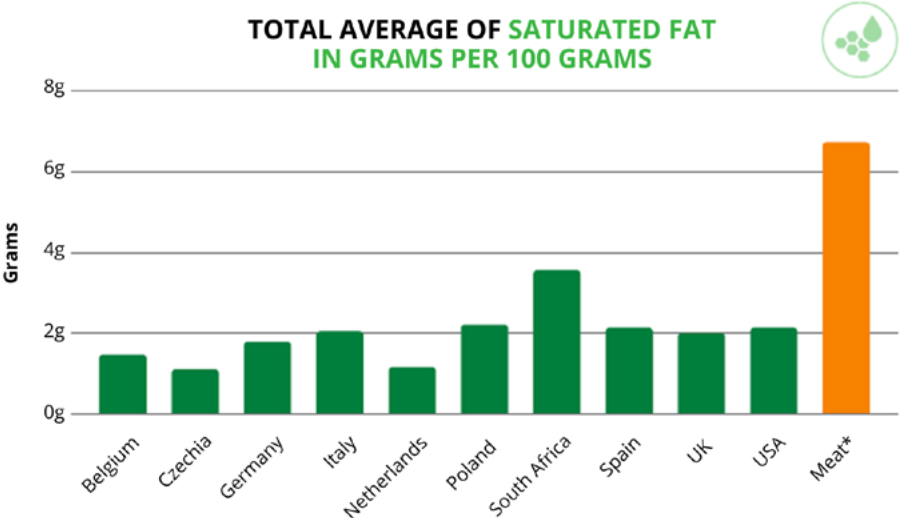


Fig. 2. Total average content of saturated fat in g per 100 g of plant-based meat alternatives and animal-based meat products. *Average nutritional value of animal-based products from USDA Food Data Central and UK Food Composition Database.

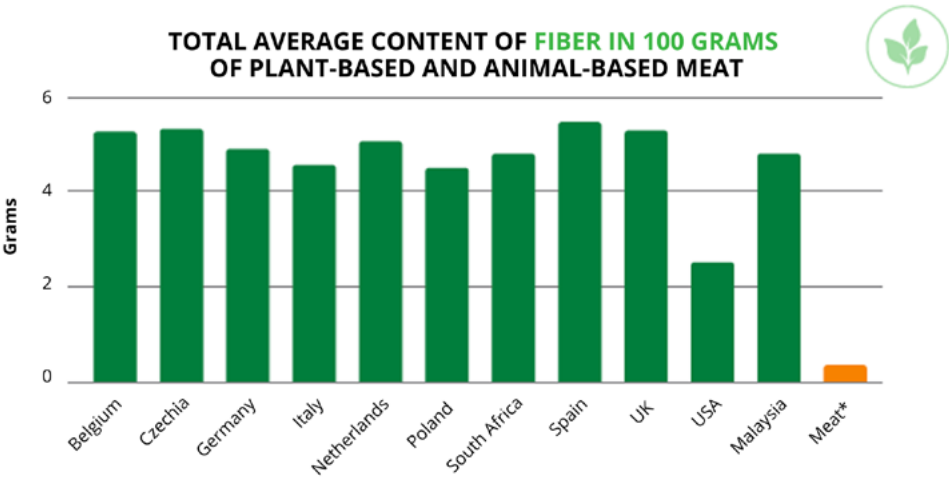


Fig. 3. Total average content of fibre in g per 100 g of plant-based meat alternatives and animal-based meat products. *Average nutritional value of animal-based products from USDA Food Data Central and UK Food Composition Database.

- **Micronutrient fortification:** Fortification practices vary widely across regions. In countries such as the Netherlands and Belgium, 70-90% of plant-based meat alternatives are fortified with iron and vitamin B12, compared to less than 20% in Malaysia and South Africa.
- **Salt content:** Salt levels remain a concern, with most plant-based meat alternatives exceeding the recommended limit of 1.1 g per 100 g. This highlights the need for reformulation in order to reduce salt content without compromising taste.
- **Best-performing regions:** The Netherlands emerged as the leader, with plant-based meat alternatives achieving high scores due to their fibre content, low saturated fats, and widespread fortification. Other countries that performed well were Belgium, Spain, the USA and the UK, with plant-based meat alternatives containing less total saturated fat and significantly more fibre than their animal counterparts, sufficient to qualify them as a

source of fibre, according to EU regulations. This confirms the results of previous studies (FoodFrontier n.d.; Andreani et al. 2022; Bryngelsson et al. 2022; Gibbs and Leung 2023).

The key findings - Plant-based milks

Comparison to cow's milk: Plant-based milk generally outperformed cow's milk in terms of lower saturated fat and sugar content. We found that the plant-based milk alternatives contained less total fat and less saturated fat, consistent with findings from other studies (ProVeg International 2019; Craig and Fresán 2021; Fructuoso et al. 2021; Johnson et al. 2024) (Fig. 4). Soya milk stood out for its high protein content (approximately 3 g per 100 ml), which matches cow's milk, as well as its lower saturated fat content, which makes it a healthier choice compared to cow's milk.

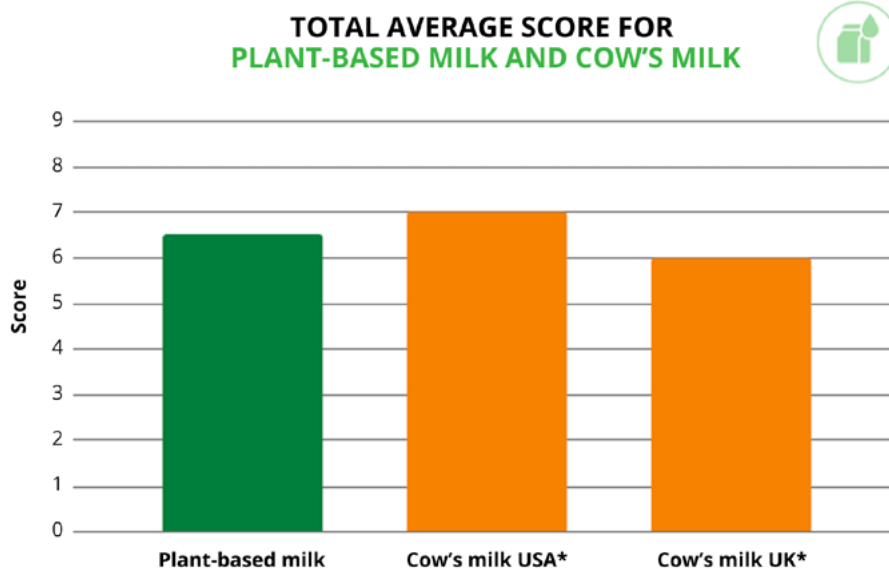


Fig. 4. TGrand total average score of plant-based milk alternatives and cow's milk. *Average nutritional value of animal-based products from USDA Food Data Central and UK Food Composition Database.

- **Calcium and vitamins:** Most plant-based milks are fortified with calcium, often matching the 120 mg per 100 ml found in cow's milk. However, fortification with vitamins B12, B2, and D remains less common, and varies significantly across regions (Fig. 5).
 - **Protein content:** Soya milk provides a level (approximately 3 g per 100 ml) and quality of protein that is comparable to cow's milk, (Fig. 6) making it a nutritionally robust option (Fig. 7).
- In contrast, alternatives such as oats, almonds, and coconut milk generally contain lower levels of protein. Some producers are exploring the use of higher-protein bases, such as pea protein, to enhance the nutritional profiles of their milk alternatives.

- **Saturated fat content:** Plant-based milks consistently contain lower levels of saturated fat, compared to cow's milk, and do not contain cholesterol. On average, the levels of saturated-fat in plant-based milks range from 0.1 g to 0.5 g per 100 ml, whereas cow's milk ranges from 1.5 g to 2.5 g per 100 ml. This makes plant-based options a preferable choice for reducing saturated fat intake.
- **Fibre content:** Here plant-based milks clearly outperform cow's milk, which contains no dietary fibre. Depending on the product, plant-based milks provide between 0.8 g and 1.2 g of fibre per 100 ml, contributing modestly to daily fibre.
- **Sugar and salt:** Most plant-based milks are classified as being low in sugar (Fig. 8), contrary to what is often said

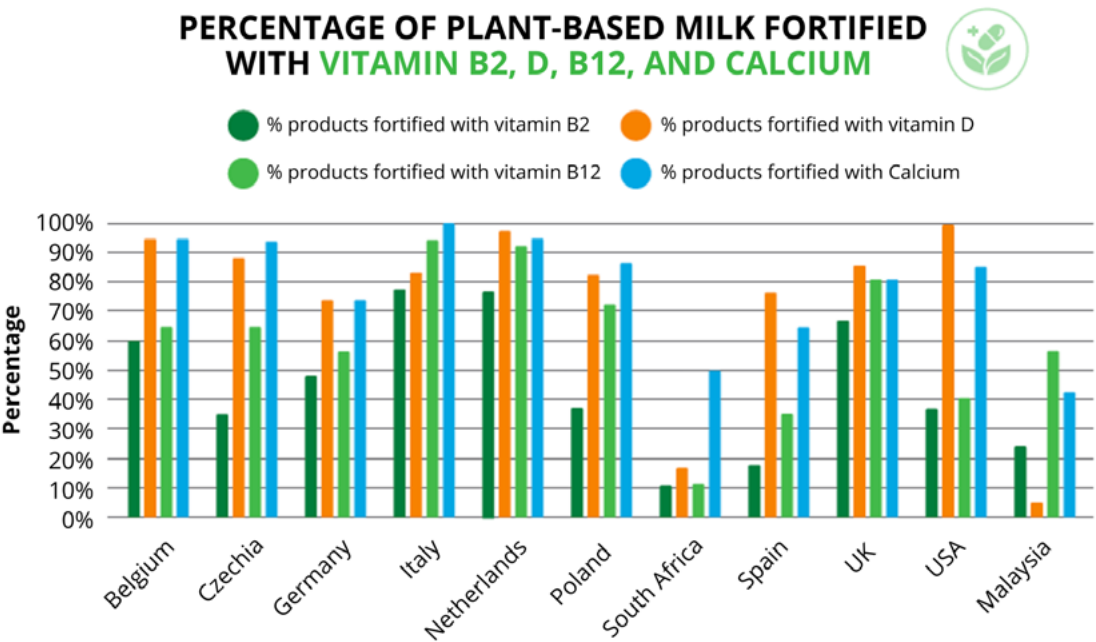


Fig. 5. Percentage of plant-based milk alternatives that are fortified with vitamins B2, D, B12, and calcium.

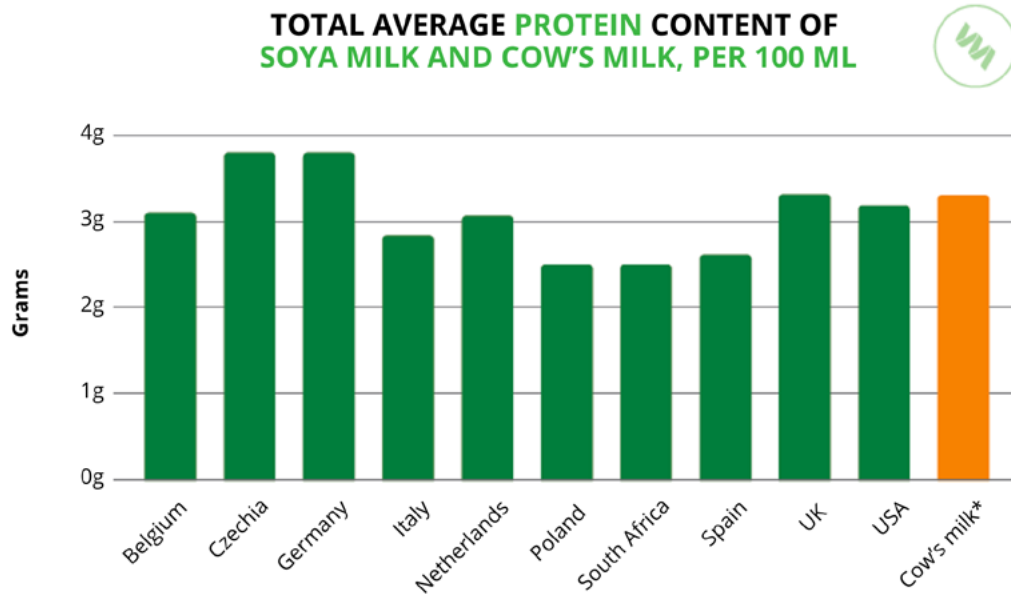


Fig. 6. Average protein content in g per 100 ml of soya milk and cow's milk. *Average nutritional value of animal-based products from USDA Food Data Central and UK Food Composition Database.

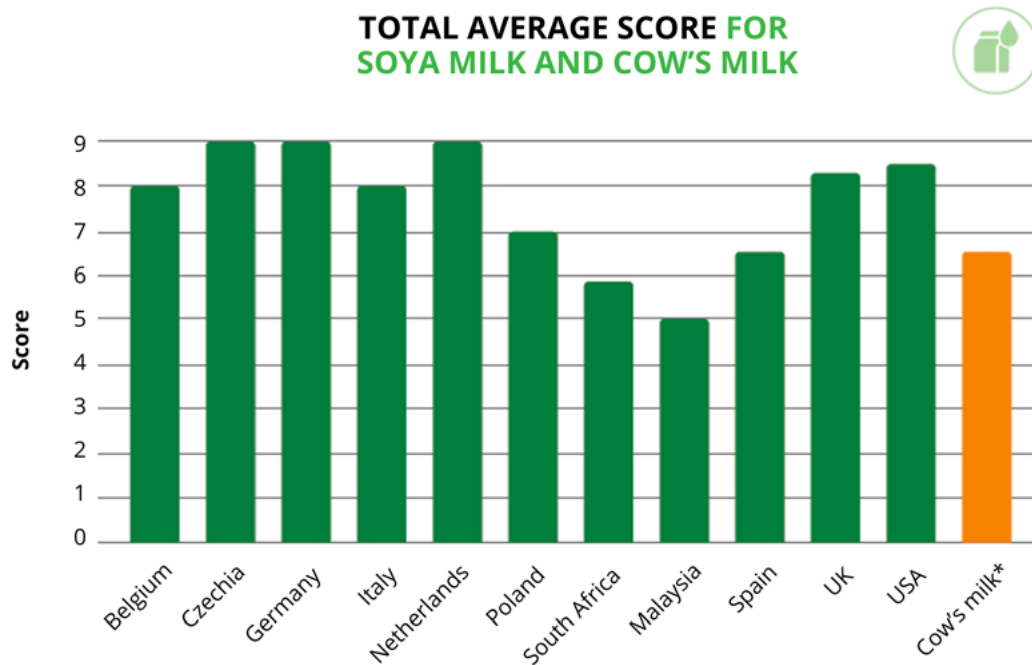


Fig. 7. Total average score of plant-based soya milk and cow's milk. *Average nutritional value of animal-based products from USDA Food Data Central and UK Food Composition Database.

about these alternatives, while salt content remains below public-health thresholds across the category.

Challenges and opportunities

Both plant-based alternatives to meat and milk provide substantial health and sustainability benefits. However, these products face several distinct challenges that need to be addressed in order to optimise their impact on the global food system. By understanding and overcoming these challenges, both plant-based meat and milk alternatives can better align with consumer needs and dietary goals.

Key considerations for plant-based meat alternatives

Plant-based meat alternatives have clear health and environmental advantages, but there are challenges that must be addressed:

- 1. Salt reduction: High levels of salt in plant-based meat alternatives, especially in processed products such as sausages and burgers, are a key concern in terms of health. Salt plays an important role in flavour, preservation, and texture, making reformulation challenging. Innovative approaches-such as using potassium chloride or natural flavour enhancers-could help to reduce salt content without sacrificing taste or functionality.
- 2. Micronutrient fortification: While plant-based meat alternatives often contain more fibre and less saturated fat than their animal-based counterparts, fortification with essential nutrients such as iron and vitamin B12 varies widely across countries and brands. Standardising fortification practices globally could help to ensure consistent nutritional benefits.
- 3. Consumer perceptions and education: Despite their growing popularity, many consumers remain sceptical of

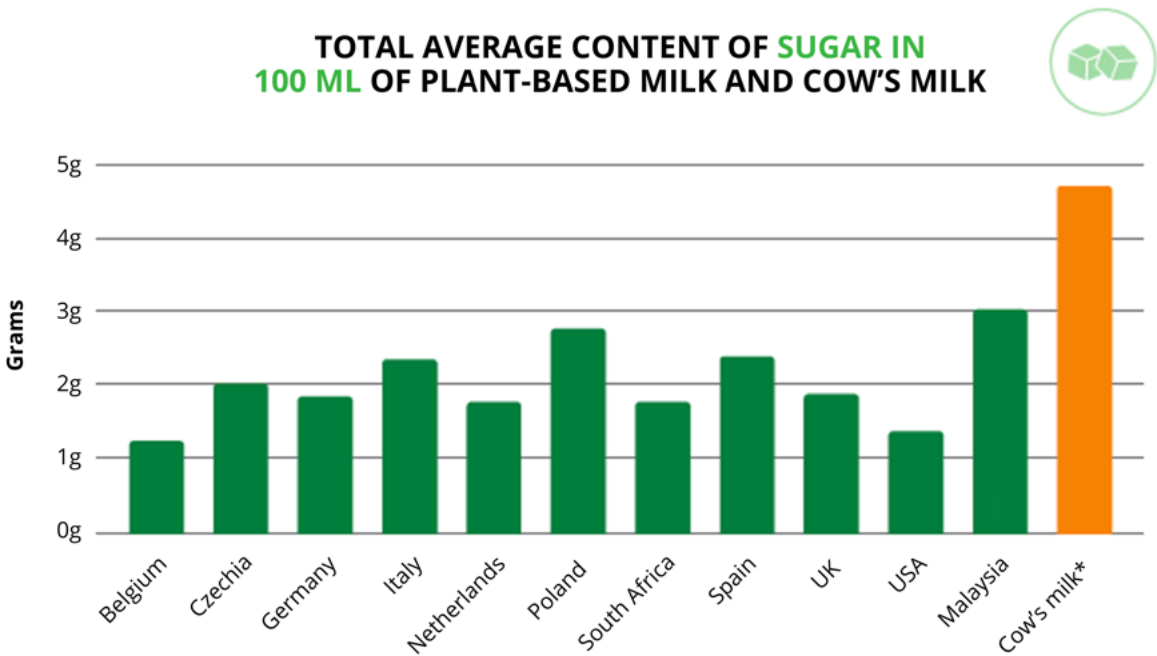


Fig. 8. Total average score of plant-based soya milk and cow's milk. *Average nutritional value of animal-based products from USDA Food Data Central and UK Food Composition Database.

plant-based meat alternatives, associating them with processed foods, which are widely seen as unhealthy. Effective education campaigns are needed to highlight the nutritional and environmental benefits of plant-based meat alternatives as part of a balanced diet, particularly those that are fortified.

4. Economic and policy barriers: Plant-based meat alternatives are often taxed as luxury items, particularly in lower-income regions, thus limiting their accessibility. Additionally, the lack of clear regulatory standards for plant-based meat alternatives results in inconsistencies in product quality and nutritional content. Governments can support plant-based meat alternatives by introducing tax incentives, subsidies, and harmonised regulations in order to ensure consistency in product quality, accessibility, and availability.

Key considerations for plant-based milks

Plant-based milks offer a range of health and sustainability benefits. However, as with plant-based meat, there are several distinct challenges to overcome:

1. Micronutrient fortification: Although many plant-based milks are fortified with calcium, the inclusion of other key nutrients such as vitamin B12, vitamin D, and riboflavin (B2) is inconsistent. Standardising fortification practices across brands and regions would address this issue.
2. Protein content: While soya milk offers protein levels that are comparable to cow's milk, other plant-based milks, such as almond, oats, and coconut milk, are lower in protein, which can limit their ability to meet dietary protein requirements. Producers could explore the use of higher-protein plant bases, such as peas, in order to create more nutritionally complete products.
3. Consumer perceptions and education: There is a perception among some consumers that plant-based milks are nutritionally inferior to cow's milk. Targeted consumer education that highlights the benefits of fortified products, as well as the environmental

advantages of plant-based milks, could help to shift these perceptions.

4. Economic and policy barriers: As with plant-based meat alternatives, plant-based milks are often more expensive than their animal-based counterparts, creating affordability challenges. Policies such as reduced VAT rates, subsidies, or tax incentives could help to make plant-based milks more accessible to a wider range of consumers.

Recommendations for producers

1. Improve nutritional profiles: Incorporate fortification strategies for micronutrients such as calcium, vitamin D, vitamin B12, and iron in order to ensure that plant-based meat alternatives and plant-based milks provide comparable benefits to animal-based products.
2. Reformulate to reduce salt and saturated fats: Replace coconut oil with healthier fats such as olive in order to reduce their saturated fat content and improve the overall health profile of plant-based products.
3. Transparent labelling: Provide clear, consumer-friendly information about the nutritional benefits of plant-based products as a way to build trust and encourage informed purchasing choice.

For retailers

1. Increase visibility: Position plant-based meat alternatives and plant-based milks alongside traditional meat and dairy products in order to normalise their consumption and make them easier for consumers to discover and access.
2. Price parity: Ensure that plant-based meat alternatives and plant-based milks are priced competitively with their animal-based counterparts in order to remove cost barriers.
3. Staff training: Educate retail employees about plant-based meat alternatives and plant-based milks, including their nutritional and environmental benefits, in order to enhance consumer support and guidance.

For governments

Governments have a key role to play in shaping the future of plant-based meat alternatives and plant-based milks. By creating supportive policy environments and investing in research and innovation, they can accelerate the adoption of plant-based diets:

1. Policy frameworks: National governments should develop comprehensive guidelines for plant-based meat alternatives and plant-based milks, including standards for fortification, labelling, and nutrient thresholds. Adopting a standardised approach can ensure that consumers have access to products that meet minimum nutritional requirements.

2. Tax reforms: Implementing reduced VAT rates and subsidies for plant-based meat alternatives and plant-based milks can make them more affordable and competitive with animal-based products.

This aligns with broader public health and environmental goals by encouraging consumers to make more sustainable choices.

3. Research funding: Governments should allocate funding for research into innovations in plant-based meat alternatives and plant-based milks.

This could include developing new ingredients with higher nutritional profiles or improving production processes to enhance product quality. Investing in plant-based alternatives will support both public health goals and sustainability efforts.

Conclusion

The nutritional profiles of plant-based meat and milk alternatives have shown significant improvements, with many products outperforming their animal-based counterparts in terms of fat, fibre, and sugar content. However, challenges remain, particularly around salt reduction, fortification consistency, and consumer perceptions.

By addressing these challenges through reformulation,

clearer labelling, and better education, both producers and consumers can benefit from these healthier and more sustainable options.

With continued innovation, strategic public-private partnerships, investment in research, and supportive policy frameworks, plant-based alternatives have the potential to play a vital role in the global shift towards more sustainable and health-conscious food systems.

As consumer demand grows, these products can help to bridge the gap between habit and health, contributing to a better future for people and the planet.

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