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Regulatory frameworks for cell-based food and precision fermentation-derived food products

An overview of legal issues and solutions

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Abbreviations

CAC	Codex Alimentarius Commission
CBD	Convention on Biological Diversity
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
GDI	Gottlieb Duttweiler Institute
GM	genetically modified
GMO	genetically modified organism
GMP	good manufacturing practices
GCCP	good cell culture practices
GHP	good hygiene practices
ICESCR	International Covenant on Economic, Social and Cultural Rights
LMO	living modified organism
NFPS	new food sources and production systems
SDGs	Sustainable Development Goals
SPS	sanitary and phytosanitary measures
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
USDA	United States Department of Agriculture
WFO	World Farmers' Organisation
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

This Legal Paper developed by the Food and Agriculture Organization of the United Nations (FAO) explores the legal issues surrounding cell-based food and precision fermentation-derived food products, focusing on international, as well as regional and national regulatory frameworks. As these innovative food products emerge in different markets, legal uncertainties are arising in terms of the application of rules governing their safety, marketing, and trade.

Drawing on existing **international frameworks** such as the Codex Alimentarius and World Trade Organization (WTO) agreements, among others, the paper highlights gaps and challenges in regulating these new food technologies and examines their broader societal and ethical implications, particularly for sustainable development, human rights, and environmental sustainability. The paper also notes that while the Codex Alimentarius has begun to consider cell-based and precision fermentation-derived foods within its work on novel food production systems, concrete international standards for these products remain at a formative stage, with discussions focusing on definitions, risk assessment principles, and hygienic practices.

Existing **national and regional regulatory frameworks** already cover many aspects relevant to cell-based and precision fermentation-derived food products, often through laws on novel food production systems (NFPS) or genetically modified foods. In many cases, entirely new regulatory regimes are not necessary. However, food safety authorities must clarify how current rules apply to these emerging products to ensure legal certainty, protect consumers, and enable market access, innovation and international trade.

Five priority actions for countries and regions are recommended:

1. **Clarify existing frameworks:** Review and clarify how existing laws apply to cell-based and precision fermentation-derived foods, removing ambiguities and ensuring that appropriate standards are consistently applied or adapted where necessary.

2. **Evaluate pre-marketing authorisation requirements:** Consider whether additional approval processes are necessary beyond general food safety regulations.

3. **Update and develop regulatory elements:** Amend existing rules on labelling, permissible additives, enzymes, and processing aids, and develop guidance on manufacturing, hygiene, and good practices tailored to these new production methods.

4. **Promote international harmonisation:** Engage with bodies such as Codex Alimentarius to align standards globally, improving food safety, reducing legal uncertainty and facilitating trade.

5. **Ensure broad stakeholder engagement:** Include producers, consumers, civil society, environmental groups, ethical bodies, trade associations, and public health authorities to ensure regulations address safety, ethics, transparency, sustainability, and socio-economic impacts.

Introduction

1. Legislating cell-based and precision fermentation-derived food products

The growing global demand for animal-sourced protein,[1] and the objective to ensure sustainable food production systems,[2] have accelerated biotechnological research into new types of food. Particularly noteworthy are the *in vitro* cultivation of animal cells, known as **cell-based food**[3] (or cultured food products) and the use of **precision fermentation** to make food or food ingredients and supplements. Cell-based food products include cultivated meat such as beef, chicken, pork, or fish derived from animal muscle cells, as well as cell-based milk produced from cultured mammary cells or through synthetic biology processes that replicate traditional dairy. Other examples include cultured fats, used to enhance flavour and texture in plant-based or hybrid products or seafood. Precision fermentation has been utilized to produce proteins such as casein or whey for dairy analogues, enzymes like chymosin for cheese-making, and lipids such as omega-3 fatty acids for supplements or fortified foods.

Unlike plant-based alternative proteins, where most of the ingredients are already widely accepted and traded, all cell-based food products and most precision fermentation-derived food products are completely new food sources and production systems (NFPS). Therefore, there is often a need to develop consumer confidence and public trust, as well as related scientific evidence concerning the safety of such products, and agreements on their proper naming. As this industry evolves, regulators will want to evaluate the suitability of laws and policies to address food safety, consumer information and protection, and other regulatory challenges for these products. Furthermore, establishing consistent terminology for these products is crucial for effective communication and regulatory purposes. Clarity on these issues can also help to bring security to public and private entities to invest in further research and development regarding these products and to steer innovation in certain directions that are socially desirable in terms of public health, agricultural policies and environmental or climate considerations.

The governance of cell-based food and precision fermentation is not just a technical issue, but also a political and a legal one. Notably, legislation is a critical tool for countries as it can provide the ability to control the market entry of these products. Through legislation, countries can set the framework to implement conscious policy decisions over the direction of development of cell-based food and precision fermentation-derived food products at the national, regional and international levels, based on their values, societal needs and plans for the future.

However, there is currently relatively little guidance on legislation relevant to cell-based food and precision fermentation. For example, the predominant focus within current literature concerns the governance of cell-based food and the naming conventions of such products, particularly as they relate to those of animal origin. This encompasses inquiries into nomenclature and trademark issues. In contrast, the literature provides only limited exploration of food safety and premarket approval processes. Where these topics are addressed, the focus tends to be on NFPS regulatory frameworks, primarily those that were adopted in a few high-income and upper-middle-income countries, which vary considerably across jurisdictions.

Notably absent from the current literature is a substantial analysis of how cell-based food products integrate into general systems of food law and food safety regulation. There is little or no research on the impact of product-specific regulatory frameworks or necessary adaptations for food operators. Similarly, research on the socio-economic, trade, and investment law dimensions, as well as intellectual property rights, ethical concerns, and the environmental and climate-related impacts of cell-based food products, remains sparse. Where available, legislative studies have predominantly concentrated on the United States of America, the European Union, Singapore, and Israel, as these are the markets and regulators where there is most development or marketing of these products. Conversely, the literature is markedly silent on legal frameworks and impacts of other countries. Moreover, while a lot of the available literature is focused on consumer acceptability and awareness, little is focused on consumer information and protection. There is even less available literature when it comes to governance and regulation of precision fermentation-derived food products.

2. Objective and scope of this paper

Aimed at policymakers and regulators, this paper explores selected legal issues surrounding cell-based food and precision fermentation-derived food products. It excludes broader topics like naming conventions for alternative proteins, biomass fermentation, and in-depth discussions on regulatory frameworks for genetically modified organisms (GMOs) or food produced with GMOs. Additionally, policy and technical matters without direct legal consequences or those limited to non-legal guidelines are generally beyond its scope. Thus, this paper primarily provides an outline of current legal developments and identifies potential conflicts and uncertainties that may arise in the legal frameworks governing these technologies.

The paper is organized into two main parts. Part A focuses on matters of **international law**, including for example, relevant legal obligations on countries when it comes to international trade, biosafety, intellectual property, human rights, and the environment. Part B focuses on matters of **national legislation** and where applicable, regional legislation. It highlights several issues and elements from national and regional legislation that could be particularly relevant to consider in understanding (or introducing reforms to) a country's relevant legal framework applicable to cell-based food and precision fermentation.

Part A – International law: an overview of legal issues

1. Codex Alimentarius and international food safety standards

The Codex Alimentarius is an international food standards programme jointly established by FAO and WHO. Its primary function is to harmonize global food safety and quality standards to facilitate fair trade practices and protect consumer health. Although Codex standards are not legally binding in of themselves, they significantly influence national and regional food legislation.[1]

Cell-based food and precision fermentation-derived food products fall under Codex's general standards on food safety, labelling, hygiene, risk assessment procedures, food additives, contaminants, residue limits, nutrition labelling, and halal and organic food standards, etc. Moreover, various standards and documents have been produced on biotechnology more broadly, which pertains to cell-based food through its stem cells or growth medium and to most precision fermentation through the organism used (see Part B).

In addition, thus far, cell-based food and precision fermentation-derived food products have mainly been dealt with in terms of NFPS. In 2021, FAO and WHO asked the Codex Alimentarius Commission (CAC) how it would approach new food products.[4] Subsequently in 2021, following discussions at the Executive Committee of the Codex Alimentarius Commission (CCEXEC81) and the Forty Fourth Session of the Codex Alimentarius Commission (CAC44), a Sub-Committee on New Food Sources and Production Systems was established to deal with the cross-cutting nature of NFPS.

Furthermore, during CAC44, it was requested that the Codex Secretariat issue a Circular Letter to collect information from Members and observers on ongoing developments related to NFPS.[5] This request was followed up by a Circular Letter on NFPS that included cultivated meat, seafood, and dairy, fermentation-derived ingredients, plant-based protein alternatives, seaweed, edible insects, 3-D printed foods, and microalgae.[6]

Through the Circular Letter, the Sub-Committee collected information from Members and observers about current practices and concerns related to NFPS. In its 2022 interim report, it highlighted that it is important to:

> *Carefully assess the need to develop standards/guidelines/codes of practice to allow for safe consumption and fair trade of foods arising from new food sources and production systems. In this context, it was noted that this was a fast-moving industry, and it was also important that any approach or regulatory frameworks considered should not stifle innovation in this sector.*[7]

[1] For information on the Codex Alimentarius, see www.fao.org/fao-who-codexalimentarius

During the 2023 meeting of the Codex Alimentarius Commission (CAC46), Codex Members and observers shared the following comprehensive list of ideas on the types of work that could be undertaken on cell-based food and precision fermentation-derived food products and other NFPS:

a. developing a definition of NFPS since the term was very broad and there was a need for Codex to define the areas in which it could add value;

b. focusing on cell-based meat and seafood and precision fermentation to promote consistent regulatory approaches and risk management measures to these new foods across countries and regions;

c. developing general principles on risk analysis of NFPS to support national authorities in the management of NFPS;

d. addressing food safety aspects of seaweed as there had been an increase in global trade and an absence of standards;

e. developing food hygiene guidelines and a code of practice on the production of new foods;

f. reviewing existing horizontal texts to identify gaps that might need to be addressed to ensure they would also be applicable to NFPS;

g. addressing novel risks introduced by NFPS;

h. considering halal requirements in any discussions regarding NFPS;

i. using an analysis of the national legislation, regulation and risk management measures to determine key work areas; and

j. identifying those products that had a history of consumption in some countries compared to those that did not to better define work areas and approaches.[8]

The Codex Alimentarius Commission (during CAC46) also urged Members to submit discussion papers or new work proposals to relevant Codex committees or the Executive Committee via the Codex Secretariat.[8] In response, thus far Singapore has made indications on its plans to submit two new work proposals to Codex: i) a proposal to develop guidelines for the safety assessment of cell culture media for consideration by the Codex Committee on Food Additives (CCFA); and ii) a proposal for the development of a code of hygienic practice for the production of cell-based food to Codex Committee on Food Hygiene (CCFH). Discussions are ongoing.

2. International trade law

International trade law becomes a relevant consideration when cell-based food and precision fermentation-derived food products are traded across borders. Note that the Codex standards discussed in the prior section also serve as a reference point in international trade disputes under World Trade Organization (WTO) frameworks, encouraging countries to align their food laws with international norms to reduce trade barriers. With 164 members, the WTO agreements cover 96 percent of global trade.[9] One of the core aims of the WTO's legal trade regime is to reduce barriers to trade, as embodied in the *General Agreement on Tariffs and Trade (GATT)*.[10] The Agreement on the *Application of Sanitary and Phytosanitary Measures (SPS)* allows WTO members to set their own standards on food safety and animal and plant health, but these standards must be based on science, applied only to the extent necessary to protect human, animal or plant life

or health, and not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail (Article 2 of the SPS Agreement).[11]

Further exploration of international trade law could be crucial to NFPS legal frameworks because members can only restrict the import of cell-based food and precision fermentation-derived food products if their import requirements align with WTO law. To date, there is limited or no trade in cell-based food and limited trade in precision fermentation-derived food and food ingredients. Discussions have not yet arisen at WTO bodies, such as the SPS Committee, on these topics. Countries aiming to create trade and food safety positions currently have to do that on limited publicly available scientific knowledge on the issue, and as a result, various legal questions will likely arise in the future. These issues could relate to labelling, from a trade perspective one of the least intrusive methods of regulating cell-based food and precision fermentation-derived food products, but disagreements might more likely arise on other methods that impact trade more significantly, such as banning the import of cell-based food products or effectively banning these products through convoluted import standards.

Members of the WTO are encouraged to use the standards, guidelines and recommendations set up by selected international standard-setting bodies (Article 3 and Annex A of the SPS Agreement), but may adopt higher levels of protection if there is scientific justification for it, or if they are based on appropriate assessment of risks. For food safety, it explicitly mentions the Codex Alimentarius Commission as the main standard setting body. Food safety measures that countries undertake with regards to cell-based food and precision fermentation-derived food products can only be taken if they are in line with the definition of "sanitary or phytosanitary measure" and the related objectives as defined in Paragraph 1 of Annex A to the SPS Agreement.

Article 5.1 of the SPS Agreement obliges Members to base their sanitary or phytosanitary measures on a risk assessment that is suitable to the specific circumstances, considering the risks to human, animal, or plant health, and incorporating risk assessment techniques established by relevant international organisations. Article 5.7 of the SPS Agreement also permits Members to provisionally adopt sanitary or phytosanitary measures when relevant scientific evidence is insufficient, provided that they base these measures on available pertinent information, actively seek additional data to reassess the risk, and review the measures within a reasonable timeframe to ensure they remain appropriate.

Cases such as *EC-Hormones* (WT/DS26, 1997),[12] *EC-Biotech* (WT/DS291, 2006),[13] and *EC-Hormones Suspension* (WT/DS320, 2008)[14] in front of the WTO Appellate Body, however, have shown the complexity of dealing with public confidence and opinion as well as oftentimes limited data or divergent scientific views. Although WTO dispute settlement bodies' decisions do not set a binding precedent, it is worth noting that the WTO ruling in *EC-Biotech* found that the European Communities' de facto moratorium on GMOs violated WTO rules due to undue delays and insufficient scientific justification under the SPS Agreement. Therefore, a long-term and full moratorium on cell-based food or precision fermentation-derived food products would likely need to be well constructed with sufficient care for argumentation and evidence of food safety risks.

Members can also limit certain products based on cultural reasons under Article XX of the GATT, which allows measures necessary to protect public morals and national treasures, provided they do not constitute arbitrary or unjustifiable discrimination or a disguised restriction on trade. This was exemplified in two *EC-Seal Products* (WT/DS400 and WT/DS401, 2014)[15, 16] where the European Union's ban on seal products was justified on public moral grounds concerning animal welfare.

3. Biosafety law

As of 2024, 173 countries are parties to the *Cartagena Protocol on Biosafety (2000)*,[17] a supplementary agreement to the *Convention on Biological Diversity (CBD) (1992)*,[18] that specifically relates to the transboundary movement, handling, and use of living modified organisms (LMOs) derived from modern biotechnology. The Protocol's scope, defined under Article 4, primarily covers LMOs that may have adverse effects on biodiversity and human health. Here, the applicability of the Protocol to cell-based food and precision fermentation-derived food products could be an uncertain question going forward. While most precision fermentation relies on LMOs, not all cell-based foods do; some methods use unmodified cell cultures and serum, which would place these outside the Protocol's regulatory scope. In the cell-based food and precision fermentation-derived food production that do use LMOs, they are used within a closed system and generally are not present in the final product.[3]

Where LMOs are traded, they would fall under the Protocol's risk assessment and management requirements, as stipulated in Articles 15 and 16. This distinction highlights the need for legal clarity regarding the application of biosafety regulations to these innovative food technologies. Currently, LMOs intended for food, feed, or processing must be accompanied by documentation indicating that the shipment "may contain" LMOs. According to Article 18(2)(a) of the Protocol, the documentation must also specify that the shipment is solely intended for food, feed, or processing, and include contact information for further inquiries.

It is important to note that some of the main countries working on cell-based food, such as Canada, Israel, the United States of America, and Singapore, are not parties to the *Cartagena Protocol on Biosafety*. The Cartagena Protocol operates outside the WTO framework. It is a separate treaty under the CBD, and while it deals with biosafety issues, particularly regarding LMOs, it does not hold the same status as the Codex Alimentarius within the WTO system. While the Cartagena Protocol, for instance, allows countries to take precautionary measures to protect biodiversity and human health from the potential risks of LMOs, the WTO requires more stringently that such measures be scientifically justified and not unnecessarily restrictive of international trade.

4. Intellectual property law

Cell-based food and precision fermentation-derived food products may raise questions regarding their protections under intellectual property law. The *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* prohibits unjustifiable encumbrances on trademark use in trade.[19] The TRIPS framework intersects with regulatory measures and labelling requirements, which can impact market access and consumer perceptions of cell-based food products. Labelling restrictions that limit the use of terms normally used for traditional animal products may infringe on the trademark rights of cell-based food producers, potentially violating Article 20.

The TRIPS Agreement also mandates that Members provide patent protection for inventions that are new, involve an inventive step, and are capable of industrial application (Article 27). This has facilitated the patentability of processes and technologies in the biotechnological agriculture sector, where human intervention is essential. Article 27.3(b) of the TRIPS Agreement provides WTO members with the option to exclude from patentability plants, animals, and essentially biological processes for the production of plants or animals, but it mandates the protection of

plant varieties through patents, an effective *sui generis* system, or a combination thereof, thus leaving room for significant flexibility in national implementations while triggering debates over biodiversity, farmers' rights, and the commercialization of life forms.

Patent-related issues in this domain also extend to intricate biotechnological processes, machinery, and inputs, possibly creating a highly privatized production system for cell-based food and precision fermentation-derived food products, predominantly controlled by actors in high-income countries (HICs). Article 66.2 of TRIPS could mitigate this as it encourages developed countries to promote technology transfer to least-developed countries, and successful implementation of this provision is critical for cell-based food and precision fermentation-derived food products as innovation is currently concentrated in HICs.

5. Human rights, the right to food and food sovereignty

The development of cell-based food and precision fermentation-derived food products intersects with the right to adequate food, enshrined in the *Universal Declaration of Human Rights (UDHR)*,[20] and the *International Covenant on Economic, Social and Cultural Rights (ICESCR),*[21] and aligns with key Sustainable Development Goals (SDGs) such as Zero Hunger (SDG 2), Responsible Consumption and Production (SDG 12), and Climate Action (SDG 13). However, they also raise ethical concerns about equity and access, as highlighted by SDG 10 (Reduced Inequalities).[22] Evaluating these innovations through the lens of human rights and the SDGs is crucial to ensuring they contribute to a more sustainable and just future.

Some ethical aspects of cell-based food and precision fermentation-derived food products fall within the context of the right to adequate food. The right to food has clear operational aspects that can improve the impacts of interventions in a variety of domains, such as economic, environmental and social policies, at both the national and international levels. Countries have the obligation to respect, protect, and fulfil this right, which includes the duty to carefully consider the use of new technologies and facilitating access to new foods. By evaluating and potentially adopting innovations such as cell-based food and fermentation-derived food products (once readily available), countries could in the future, potentially address food security, nutritional needs, and environmental sustainability. This consideration must involve thorough assessments of safety, affordability, and cultural acceptability to ensure that advancements contribute positively to the right to food for all individuals. Decision-making processes, monitoring, and evaluation should also align with the human rights principles of participation, accountability, non-discrimination, transparency, empowerment and the rule of law.

Moreover, the *United Nations Declaration on the Rights of Peasants and Other People Working in Rural Areas* that was adopted by the United Nations General Assembly in 2018, notes the important role that peasants and people working in rural areas have and their vulnerable positions in relation to global markets.[23] It highlights the importance of allowing them to "participate in decision-making processes on food and agriculture policy" (Article 15). Moreover, the Declaration advocates for the strengthening of local food systems and the promotion of sustainable farming (Article 16).

At the same time, many countries face significant constraints in exercising the policy space necessary to advance food sovereignty – a concept rooted in the rights of peoples to define

their own food systems in ways that are ecologically, culturally, and economically appropriate. According to FAO, food sovereignty emphasizes the central role of small-scale food producers, indigenous communities, and local markets in feeding the majority of the world's population.[24] However, this vision is increasingly challenged by global trade rules, corporate concentration in agrifood systems, and policy environments that prioritize industrial agriculture. These dynamics can limit national policy space on food sovereignty, including protecting traditional knowledge, and ensuring democratic participation in food governance. As countries consider integrating cell-based food and precision fermentation-derived food products, it is essential that such innovations do not further erode local control or marginalize rural communities. Instead, policies should be designed to reinforce food sovereignty by enabling inclusive decision-making, protecting biodiversity, and fostering resilient local food systems.

6. Environmental law, biodiversity law and climate law

International environmental law, biodiversity law, and climate law set out obligations on countries for global cooperation in addressing environmental degradation, the loss of biodiversity, and the impacts of climate change, while balancing the interests of development and environmental protection. Notable treaties include the Paris Agreement which seeks to mitigate climate change by limiting global warming,[25] the CBD which aims to conserve biological diversity, and the Kyoto Protocol which addresses greenhouse gas emissions.[26] Countries, under these agreements, are obligated to incorporate sustainable practices and innovations into their national policies. It could be argued that this includes the careful consideration of emerging technologies such as cell-based food and precision fermentation-derived food products.

Part B – National and regional law: an overview of legal issues

At the national level (and where applicable, the regional level), the legislative framework for cell-based food and precision fermentation-derived food products is generally built on traditional food law and food safety governance, with no country or region at this moment having specific, standalone regulatory frameworks for these products. **In most cases, existing broader laws and regulatory mechanisms are sufficient to cover these ingredients and/or products, particularly when provisions already exist for NFPS, as well as for biotechnologies.** This framework may be supplemented with additional regulations, guidelines or technical oversight, particularly for cell culture practices or microbiological laboratory practices.

Thus, these products require careful evaluation of how existing food legislation, especially those provisions governing animal-based products, applies to ensure consumer safety and accurate naming and labelling. However, these regulatory questions largely overlap with other plant-based products and are not specific to cell-based food and precision fermentation-derived food products. Besides that, many issues covered by these regulations are language- and culture-specific. Beyond food legislation, a number of other domains may also be relevant to consider in certain circumstances. For example, consumer rights laws could play an essential role in ensuring transparency and informed decision-making. Transparency and accountability around animal welfare and environmental impact are equally important, given the promises that currently drive the development of these technologies in the first place.

Thus, the governance of cell-based food and precision fermentation-derived food products is characterized by evolving and diverse regulatory frameworks, which reflect the emerging stage of these technologies. However, a number of common critical legal issues and elements are arising. The following sections highlight several of these critical legal issues and feature key elements from national and regional legislation relevant for cell-based food and precision fermentation-derived food products.

1. Institutional frameworks and coordination of competent authorities

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 82-2013	Principles and Guidelines for National Food Control Systems	CCFICS	2013

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

As a starting point, legislation should clearly define which authority is (or which authorities are) competent to regulate, monitor, and control the safety and quality of cell-based food and precision fermentation-derived food products. This includes the development and oversight of food safety

standards, quality assurance, and the approval processes necessary for market authorization. Depending on the context, this competence may fall under a single, dedicated body (such as a food safety agency with expertise in biotechnology), or multiple bodies across different agencies (for instance one for food safety in general and one for food safety of animal-derived products) or levels of government (e.g. central or federal, and decentralized or local).

Where multiple institutions are involved, in some contexts, a single entity is appointed to coordinate oversight, ensuring comprehensive regulatory alignment across the entire production process – from cell culture and fermentation inputs to final product distribution – consistent with the Codex Alimentarius text on *Principles and Guidelines for National Food Control Systems (CXG 82-2013)*. Alternatively, at least an agreement must be made between institutions to streamline the food safety process between agencies. Legislation may also empower the competent authority to delegate specific tasks, such as risk assessment and inspection, to specialized public or private entities, and to establish a regulatory framework for designating official and reference laboratories with the technical capacity to test and certify the safety of cell-based food and precision fermentation-derived food products.

In terms of current trends, national and regional laws generally place food safety authorities at the forefront of oversight, leveraging existing food laws while adapting to new biotechnologies and production technologies. The coordination of cell-based food products however remains rather ambiguous in many countries due to its predominantly theoretical existence. A key question is the oversight over the biotechnological stage of cell-based food production versus the oversight over the regular food production process. It is often the case that there is no clarity on the oversight over the laboratory or bioreactor phase in the food sector, that specific standards for laboratories apply, or that standards similar to those applied in the pharmaceutical sector are applied that can be unrealistic, or at least not cost-effective, in food production.

However, jurisdictional uncertainties and overlapping authorities pose challenges, often requiring coordination among multiple agencies with conflicting goals. Key elements that cause governance complexities are the questions that arise over conflicting governance that may exist with governance of animal products, governance of biotechnology and cell culturing, and governance of genetically modified cells and organisms that can form the basis for cell-based food products. Transparency and cooperation between regulatory agencies, as well as food business operators, are essential to bridge knowledge gaps and foster mutual understanding.

Box 1. Country case study: the United States of America

In 2019, the Food Safety and Inspection Service of the United States Department of Agriculture (USDA), and the Food and Drug Administration (FDA) of the United States Department of Health and Human Services, formalized an agreement delineating their respective regulatory responsibilities to ensure that human food made with cultured animal cells derived from a USDA-amenable species (i.e. livestock, including fish of the order of Siluriformes, and poultry) that enters the United States market are safe for consumption and properly labelled. This agreement clarified the specific roles each agency would play within the regulatory process, thus providing industry with a clearer understanding of the requirements for producing, distributing, and selling their products in the United States. Under this agreement, the FDA is charged with overseeing the "pre-harvest" phase of production for all human food made with cultured animal cells. This includes the oversight of cell collection, banking, and the proliferation and differentiation of cells through harvest (i.e. the point at which the cells are no longer viable), across all categories of cultivated meat, poultry, and seafood. During harvest, for cell lines derived from amenable species, the FDA coordinates the transfer of regulatory oversight to the USDA, which then assumes responsibility for the regulation of cultivated livestock (including fish of the order of Siluriformes), and poultry. The USDA exclusively manages the post-harvest

Box 1. *cont.*

processing, packaging, and labelling of cultivated livestock (including fish of the order of Siluriformes), and poultry. For non-amenable species (i.e. those not regulated by the USDA), such as cultivated seafood (other than fish of the order of Siluriformes) and game meat, the FDA retains jurisdiction over post-harvest processing, packaging, and labelling.

Source: U.S. Food and Drug Administration. 2019. Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species, 7 March 2019.

2. Food safety law and marketing authorization

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXC 1-1969	General Principles of Food Hygiene	CCFH	2022
CXG 82-2013	Principles and Guidelines for National Food Control Systems	CCFICS	2013

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

General considerations

To ensure no gaps arise in the food safety control system and to consider all possible stages where risks occur, legislation should follow the whole food chain approach according to the Codex Alimentarius text on *General Principles of Food Hygiene (CXC 1-1969)* (Principle 2). This approach ensures applicability to all food business operators at all stages of production and distribution, including the production of inputs such as feed for food-producing animals, encompassing the entire process "from farm to fork", encompassing every stage from the extraction of starter cells and the cultivation in a bioreactor to the final distribution of the food product.

In many countries, food safety and quality legislation typically does not include specific provisions or adjustments for cell-based food or precision fermentation-derived food products. However, existing provisions can often provide adequate legislative entry points to regulate all food products and processing methods, addressing emerging hazards associated with these products. Up to this point, no country has established a pre-marketing authorization process or legal framework **specifically** for cell-based food or precision fermentation-derived food products.

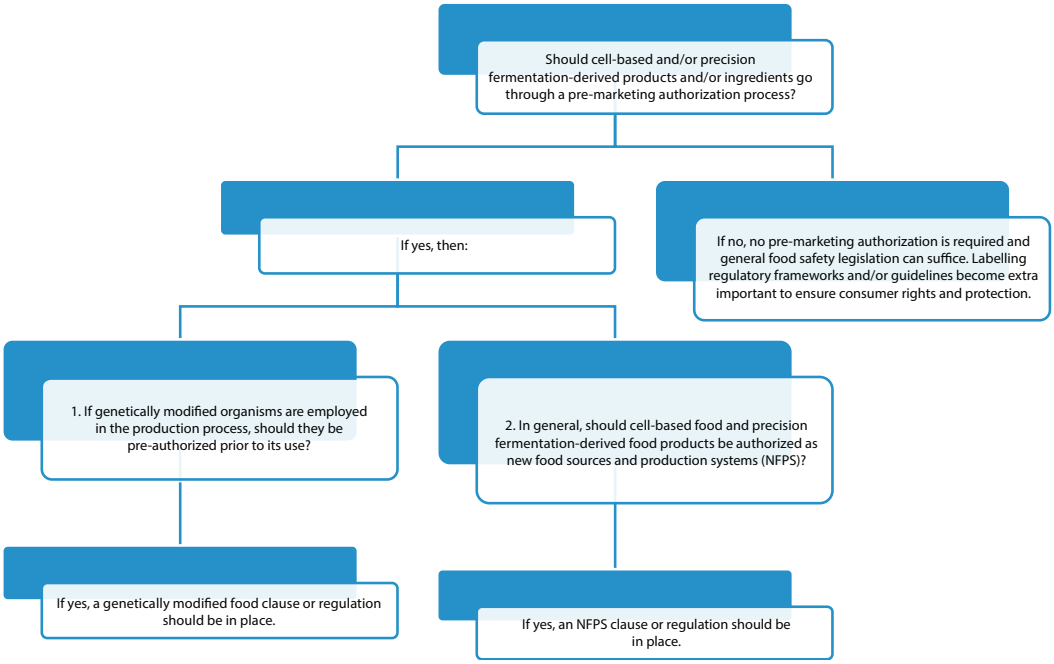
However, these products may be subject to broader requirements for a pre-marketing authorization process as cell-based food products and most precision fermentation-derived food products use new *in vitro* cultivation technologies and create food products that have never been consumed before, necessitating regulatory safety evaluations to ensure it poses no health risks and meets public health standards. Some cell-based food products and most precision fermentation-derived food products also make use of GMOs for a part of the process. Thus, depending on the context, one or multiple pre-marketing authorization processes could cover this.

Numerous countries have introduced a pre-marketing authorization process for new food sources and production systems (NFPS). There is no agreed harmonized definition for NFPS in the context of the Codex Alimentarius. At the national level, the definition of NFPS varies widely across countries. For the purposes of this publication, we understand NFPS as follows, acknowledging that the definition is evolving:

> *New food sources denote those that have not been widely consumed, either because their consumption has been historically restricted to certain regions in the world or they have recently emerged in the global retail space thanks to technological innovations. […] New food production systems reflect novel innovations or advancements in preexisting food technologies that are involved in producing some of the new foods that are finding their way into the mainstream.*[27]
>
> *Source:* FAO. 2022. *Thinking about the future of food safety – A foresight report*. Rome. https://doi.org/10.4060/cb8667en

Sometimes, NFPS are covered as a separate section within food safety law or as a separate legal framework. Some countries also have a separate process and respective legal framework for genetically modified food that may in some cases apply to cell-based food and precision fermentation-derived food products. Figure 1 illustrates one possible decision tree to help understand if pre-marketing authorization requirements for NFPS or GMOs could apply.

Figure 1.
Regulatory frameworks tree for cell-based food and precision fermentation-derived food products



Link to the pre-marketing authorization of new food sources and production systems

As mentioned, there is significant diversity in legal definitions of NFPS across jurisdictions. Common criteria include the lack of significant past use, new production processes, and the absence of existing standards for foods. Some countries focus on the history of consumption within their borders, while others emphasize the current market presence or the innovative nature of the

production process. Notably, the inclusion or exclusion of GMOs and traditional foods varies widely. While definitions differ, overall cell-based food products are often obliged to go through the NFPS regulatory pathway (where present), but depending on the country, they might have to pass through an alternative regulatory pathway for biotechnological products or GMOs (Figure 1).

Some precision fermentation-derived food products or ingredients have been marketed for much longer and can fall outside of the NFPS scope. New precision fermentation-derived food products can be NFPS, or depending on regulations, fall within the alternative regulatory pathway for biotechnological products or GMOs.

Box 2. Case study: the European Union, Sierra Leone, Thailand and Bangladesh

The European Union has several decades of experience regulating new food sources and production systems (NFPS) at the regional level. The current main instrument, *Regulation (EU) 2015/2283 on novel foods,* is binding and applies directly in the 27 EU Member States. This Regulation defines an NFPS by creating 10 categories of foods that are regulated by it. Cell-based food is regulated by a separate category in Article 3: "(vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae." Precision fermentation-derived food is covered by another category in Article 3: "(ii) food consisting of, isolated from or produced from microorganisms, fungi or algae." To be approved, NFPS must meet three main conditions stated in Article 7:

(a) the food does not, on the basis of the scientific evidence available, pose a safety risk to human health; (b) the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value; (c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

It is specified in Article 2(2)(a) of this Regulation that genetically modified organisms (GMOs) are excluded from its scope. Rather, GMOs are specifically referred to in *Regulation (EC) No 1829/2003 on genetically modified food and feed*, which indicates that GMOs are regulated under a separate pathway and are not considered under the novel food framework.

Sierra Leone, in Section 1 of its *Food and Feed Safety Act 2017*, takes another approach looking only at past use, as it defines NFPS as "food or food ingredients that have not been previously used for human consumption to a significant degree." **Thailand**, in its *Notification of the Ministry of Public Health (No.376) B.E 2559 (2016) Re: Novel Food*, uses a clear temporal scope, stating that an NFPS is any substance used as food or food ingredients which have been significantly used for human consumption for *less than 15 years* based on scientific or reliable evidence. **Bangladesh**, in Section 31(a) of the *Food Safety Act 2013*, takes another approach focused on food standards, defining NFPS as "*any food for which no standard is yet specified but is not unsafe and which does not contain any substance or matter prohibited by regulations*."

Sources: European Union, *Regulation (EU) 2015/2283 on novel foods*, 25 November 2015; European Union, *Regulation (EC) No 1829/2003 on genetically modified food and feed*, 22 September 2003; Sierra Leone, *Food and Feed Safety Act 2017*; Thailand, *Notification of the Ministry of Public Health (No.376) B.E 2559 (2016) Re: Novel Food*, 29 June 2016; Bangladesh, *Food Safety Act 2013*, 10 October 2013.

As per the examples given, there are numerous ways to regulate NFPS. Different regulatory options can include/exclude long-used precision fermentation-derived food products or ingredients. All current definitions appear to include cell-based food products and new precision fermentation-derived food products. Depending on the legislation, GMOs can be included or have a separate or parallel regulatory process.

Link to the pre-marketing authorization for biotechnology and genetically modified (GM) foods

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 44-2003	Principles for the Risk Analysis of Foods Derived from Modern Biotechnology	TFFBT	2011
CXG 45-2003	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	TFFBT	2008
CXG 46-2003	Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms	TFFBT	2003
CXG 68-2008	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals	TFFBT	2008
CXG 74-2010	Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Foods	CCMAS	2010
CXG 76-2011	Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology	CCFL	2011

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

The Codex text in *CXG 44-2003* defines "modern biotechnology" in p. 1 as "the application of: i) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or ii) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection."

The *CXG 44-2003* lays out general principles for the risk analysis of foods derived from modern biotechnology. The principles emphasize the need for a science-based assessment that compares such foods to their conventional counterparts to identify any potential hazards or nutritional differences. Risk management should be proportional to the identified risks, incorporating measures such as food labelling and post-market monitoring, while maintaining transparency and effective communication throughout the process. Additionally, there is an emphasis on consistency in regulatory approaches and the importance of capacity building, particularly for developing countries, to ensure they can effectively manage and communicate risks associated with these foods.

In addition, the Codex Alimentarius guidelines relevant to biotechnology processes which might be applicable to cell-based food products and precision fermentation include several other key documents. Guideline *CXG 46-2003* provides a framework for assessing the safety of foods

produced using recombinant-DNA microorganisms, directly applicable to precision fermentation technologies. Guideline *CXG 68-2008* focuses on the safety assessment of foods derived from recombinant-DNA animals, relevant to cell-based meat production. Guideline *CXG 76-2011* also provides a compilation of Codex texts on labelling foods derived from modern biotechnology, ensuring transparency and consumer awareness regarding these innovative products.

National legislation governing genetically modified (GM) foods exhibits considerable variation across countries. As mentioned, pre-marketing processes can be distinct from the traditional or NFPS pathway, or standards can be supplementary. Where legislation exists, the primary focus tends to be on assessing risks to consumer health. These regulatory provisions often extend to GMOs more broadly, incorporating considerations of health, environmental impacts, and trade-related issues such as testing and labelling requirements. As the debate surrounding GM foods continues to evolve, so too is the legislative landscape. This is particularly relevant as emerging food technologies like cell-based food, which may involve GM cells and precision fermentation, inherently reliant on GM microbes. Therefore, it is important to assess what exactly regulatory frameworks should cover. Depending on the food safety and legal traditions, some countries or regions focus on the production process including products that are classified as "derived from GMOs" rather than "containing GMOs". Other countries or regions focus more on the final product and would only include products "containing GMOs" in the distinct process.

Box 3. Country case study: China and the European Union

China's *Regulation on the Safety of Agricultural Genetically Modified Organisms (2001)* primarily governs genetically modified organisms (GMOs), encompassing animals, plants, and microorganisms whose genomes have been altered using genetic engineering techniques (Article 3). While cell-based food and precision fermentation-derived food products are not explicitly mentioned, they would be subject to regulation only if they contain or were derived from GMOs or their products. Under Article 3, Clause 4 clarifies that products containing GM ingredients must fall under this regulatory framework. Therefore, if the final product no longer contains the GMO (such as serum-free cell culture or precision fermentation without GM material), it may not be classified under these provisions. However, if GMOs remain present in the final product, it would likely require evaluation and labelling according to the regulations. This nuanced coverage necessitates a case-by-case determination based on the presence of GM components in the final product.

In contrast, the European Union *Regulation (EC) No. 1829/2003 on genetically modified food and feed* (2003) applies to foods "produced from GMOs". The European Union framework includes any food derived from GM processes, even if the genetic modification does not persist in the final product (Article 3(1)). This ensures broader coverage, particularly for precision fermentation-derived food products, which may not retain GM material but are still "produced from" GMOs, thereby falling under European Union regulations.

Sources: China, *Regulation on the Safety of Agricultural Genetically Modified Organisms (2001)*, 23 May 2001; European Union, *Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance)*.

Pre-marketing authorization processes and the issue of pre-approval tastings

In some countries where pre-marketing authorization processes are in place and applicable to cell-based food and precision fermentation-derived food products, pre-approval tasting is currently not accounted for or there is a lack of clarity around the process. Pre-approval tastings of cell-based food deserve special attention as a legal issue because they represent a critical juncture in the intersection of innovation and regulation, serving as a provisional bridge between experimental production and market entry.

Box 4. Country case study: Netherlands (Kingdom of the)

On 1 July 2023, the Kingdom of the Netherlands introduced the *Code of Practice for Safely Conducting Tastings of Cultivated Foods Prior to EU Approval*. This code of practice outlines the process by which companies in the country may conduct tastings of cultivated meat, providing a framework for ensuring the safety of participants and compliance with legal standards. The code applies to companies that produce cultivated meat and wish to organize tastings before submitting their products for formal authorization under European Union novel food regulations.

The code permits companies to conduct tastings under controlled conditions, with approval from an independent Expert Committee. This allows for limited tastings prior to European Union approval, enabling companies to assess public perception and make adjustments before formally applying for market authorization.

The code is limited in scope, allowing a maximum of 10 tastings per company per year, with each tasting capped at 30 participants. It is designed as a pilot programme, initially in force for 1 year, with the potential for extension. The Kingdom of the Netherlands is the first Member State to regulate tastings of cultivated meat in this manner, although similar initiatives have occurred in other European Union countries.

Source: Kingdom of the Netherlands, *Code of Practice for Safely Conducting Tastings of Cultivated Foods Prior to EU Approval*, 1 July 2023.

Prohibitions of cell-based food and precision fermentation-derived food products

To date, a few countries have considered some form of prohibition or restriction of certain (or all) cell-based food or precision fermentation-derived food products. Depending on the context, countries may try to justify these restrictions based on various reasons, for example, as a precautionary measure in the absence of sufficiently comprehensive risk assessments, awaiting regulatory or scientific risk-assessment precedents from other nations. However, these country decisions and grounds must align with the country's international and/or regional legal obligations (see Part A).

Box 5. Country case study: Italy

In 2023, Italy became the first country in the European Union to ban cell-based food and feed, citing the need to protect traditional food culture and heritage. The Italian legislation *Legge 1 dicembre 2023, n. 172* based itself on the precautionary principle as defined in Article 7 of *Regulation (EC) no. 178/2002 of 28 January 2002*. Under this ban, operators in the Italian food and feed sectors have been prohibited from using in the preparation of food, beverages, and feed, selling, possessing for sale, importing, producing for export, serving or distributing for human consumption, or promoting for these purposes, food or feed composed of, isolated from, or made from cell cultures or tissues derived from vertebrate animals.

Source: Italy. *Legge 1 dicembre 2023, n. 172, Disposizioni in materia di divieto di produzione e di immissione sul mercato di alimenti e mangimi costituiti, isolati o prodotti a partire da colture cellulari o di tessuti derivanti da animali vertebrati nonché di divieto della denominazione di carne per prodotti trasformati contenenti proteine vegetali*. Official Gazette of the Italian Republic, no. 281, 1 December 2023.

3. Food production and processing methods

The production and processing of cell-based food and precision fermentation-derived food products have the potential to raise several legal issues. Focusing on cell-based foods as an example, this could include issues related to cell sourcing, cell isolation and cultivation.

Cell sourcing

For cell-based foods, the sourcing and isolation of animal cells for cultivation involves several key legal and safety considerations. The process begins with selecting the appropriate cell types (such as stem cells or muscle precursor cells) from animals, often via biopsies. This raises issues around animal health (for example, concerns about the potential for zoonoses) and welfare, as regulators will likely require that animals are in good health before any cells are taken. Standards for confirming the health of animals prior to cell extraction are crucial and may be linked to broader animal welfare laws that govern how animals are treated during and after the sourcing process.

The use of primary cell sources for research and medical use to create cell-based food products, while providing insights into the myogenic characteristics of a specific species, already poses significant ethical, health, cultural and regulatory challenges. Of course, this is even more so in the context of cultivating human tissue (for instance breast milk). Regulatory frameworks must address cellular agriculture involving species that are usually not consumed, by considering ethical, social, and safety implications across various production scales. The choice of species for cell-based food products however is even more complex, with public and regulatory acceptance uncertain, especially for unconventional sources such as extinct animals or wildlife whose consumption is discouraged and could be normalized through cell-based production. On the other hand, replacing endangered species that are commonly eaten already with cell-based food products could contribute to mitigating their overexploitation and illegal trade. Also, notably, the concept of *in vitro* meat-like products from human cells could raise ethical concerns and potential legislative responses, to prevent scenarios akin to "victimless cannibalism".

Cell isolation and cultivation

For cell-based foods, food safety becomes particularly pertinent during the *cell isolation* stage. Here, the use of enzymes such as *trypsin* or *collagenase* to digest tissue and release cells presents a critical issue. These enzymes, while facilitating cell isolation, must be controlled to prevent contamination or unintended degradation of cells. There are legal implications tied to the use of these enzymes, as they must comply with food safety regulations concerning the permissible use of enzymes in food production processes. Any residues or unintended interactions must be managed to ensure the final product is safe for consumption. Lists of permitted or authorized food enzymes might have to be adapted and could be harmonized.

A strong focus is required on contamination control and sterility during the production process, with strict oversight of the manufacturing environment, including air quality, temperature, and humidity, which must be meticulously monitored to prevent contamination and ensure product stability. Equipment used in the manufacturing process, such as bioreactors, must undergo regular cleaning, calibration, and validation to maintain consistency in product quality. Furthermore, procedures around the use of reagents, growth media, and all inputs must be verified and validated to comply with safety standards. The focus on contamination control is critical since these products

are not terminally sterilized, meaning they cannot be fully treated at the end of production to remove any microbial threats. However, the lack of specific technical regulations and standards for the aforementioned laboratory practices poses significant challenges in many countries.

4. Food business operators and good practices

As a general foundational requirement, legislation should place the primary responsibility for food safety on food business operators (FBOs), including those involved in producing, processing, and distributing cell-based food and fermentation-derived food products or any other step in the food chain, in line with *Principles and Guidelines for National Food Control Systems (CXG 82-2013)*. One mechanism for controlling FBOs is the requirement of registration or a license to operate issued by the competent food authority, and a requirement of this nature could be applied for this context.

In some cases, legislation may impose specific conditions or requirements for cell-based food and fermentation-derived food products. In other cases, related processes may be imposed on FBOs through any regulatory mechanism that ensures the provision of safe food (e.g. compliance with hygiene requirements, food-handler training, etc.). For example, to further ensure the safety and quality of cell-based food and fermentation-derived food products, the development of guidelines such as Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP), Good Cell Culture Practices (GCCP), and/or Hazard Analysis and Critical Control Points (HACCP) is essential. However, to date, very few countries have published good practices that are specific to cell-based food and precision fermentation-derived food products.

Box 6. Country case study: United States of America

Facilities required to register with the Food and Drug Administration (FDA) of the United States Department of Health and Human Services must comply with: 21 Code of Federal Regulations (CFR) part 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food*; and 21 CFR part 123, *Fish and Fishery Products* for cell lines derived from seafood (excluding fish of the order of Siluriformes). These regulations cover a range of requirements, including building structure, size, design, cleanliness, and sanitization of food-contact surfaces, as well as stipulations regarding water supply, plumbing, sewage, and trash disposal. In addition, they mandate strict quality control measures throughout various stages of food production – receiving, transporting, segregating, preparing, manufacturing, packaging, and storage of both raw materials and finished food products.

The provisions related to preventive controls in 21 CFR Part 117 (primarily located in subparts C and G) require certain domestic and foreign facilities (including manufacturers of food made with cultured animal cells) to establish and implement a written food safety plan, to ensure the safety of human food products. The facilities must conduct a hazard analysis to determine which biological, chemical, and physical hazards require a preventive control. They must then establish and implement risk-based preventive controls addressing these hazards including (as applicable) process, allergen, sanitation, supply chain, and other controls. The food safety plan must also include (as required) management components (procedures for monitoring, corrective action, and verification) as well as a recall plan. The implementation of the food safety plan must be documented.

In general, the preventive control requirements apply to facilities that manufacture, process, pack, or hold food for human consumption in the United States and must register with the FDA as a food facility, unless an exemption in 21 CFR 117.5 applies. An establishment may also be subject to the Current Good

Box 6. *cont.*

Manufacturing Practice requirements (primarily located in subpart B of 21 CFR Part 117); those requirements are not dependent on whether a facility is required to register.

Source: 21 CFR part 117, *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls*, 17 September 2015; and 21 CFR part 123, *Fish and Fishery Products*, 18 December 1995.

5. Food processing aids and food additives

Relevant Codex Standards

Reference	Title	Committee	Last modified
CXG 3-1989	Guidelines for Simple Evaluation of Dietary Exposure to Food Additives	CCFA	2014
CXG 75-2010	Guidelines on Substances used as Processing Aids	CCFA	2010

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

The Codex databases provide internationally recognized numerical standards for maximum residue levels of food additives.[2] It is possible that new food additives could be used by industry to improve taste and texture when converting cell-based food and precision fermentation ingredients into final food products. For new additives or new uses of an existing additive, it may be necessary to first generate data and then obtain acceptance of the information that establishes the safety of the use, as well as authorization as prescribed.

For example, processing aids in cell-based food and precision fermentation-derived food products, such as growth media and scaffolding materials, often comprise substances not traditionally encountered or previously used in food manufacturing. Yet, these aids are essential for cell proliferation and the structural integrity of these products. Scaffolding materials might fall under the legal definition of "food additive" and be subject to related provisions if they remain integral to the final product, often necessitating rigorous safety evaluations to meet regulatory standards. Identifying the media components that are common across all platforms, such as amino acids, sugars, vitamins, and salts, would support more efficient evaluation and provide more confidence in establishing "safe" levels (e.g. by establishing maximum use or residue limits).

Similarly, many chemical and biological components, along with their residues, are removed during cell harvesting or destroyed in later processing steps, such as heating. However, harvesting can also introduce substances like protease enzymes, non-enzymatic agents; as such, the entire process needs to be covered, and updates to additive lists may be needed.

[2] For Codex databases, see https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/en

6. Food supplements

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 55-2005	Guidelines for Vitamin and Mineral Food Supplements	CCNFSDU	2005

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

Food supplements are typically governed either under food or medicine law, or under specific dedicated legislation, often requiring authorization to be placed on the market. When considering the applicability of food supplement regulations to cell-based food and precision fermentation-derived food products, several key considerations emerge. Such supplements, often developed using techniques that did not previously exist in the market, raise questions regarding their classification, safety, and labelling. In some cases, such innovations may necessitate updates to existing regulatory frameworks to ensure consumer safety and transparency.

For instance, certain supplements may be based on human cells or ingredients akin to breast milk, or they might contain new proteins and allergens that are distinct from those in traditional supplements. Some also can have significant therapeutic impact. New potential allergens that these supplements may introduce must be assessed and authorized, as traditional allergen labels may not capture the new proteins present. Furthermore, regulations surrounding labelling will need to reflect the origins and production methods of these supplements, particularly when they are derived from human or animal cells, to ensure that consumers can make informed decisions.

New legislative approaches may also be required to address broader safety concerns, considering that these supplements could introduce unique compounds and nutritional profiles that were not previously regulated, and that consumers are not aware of. Thus, the intersection of biotechnology and food supplements calls for robust legal frameworks to manage the influx of innovative products, ensuring they are both safe and correctly communicated to the public.

7. Pesticide and veterinary medicinal product maximum residue limits

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXC 61-2005	Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance	TFAMR	2021
CXG 77-2011	Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance	TFAMR	2021
CXG 94-2021	Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance	TFAMR	2021

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

The regulation of Maximum Residue Limits (MRLs) for pesticides and Veterinary Medicinal Products (VMPs) is critical to public health due to their potential toxicity and the risk of contributing to antimicrobial resistance (AMR). Traditionally, MRLs are determined within the framework of food safety, public health, pesticide management, and agricultural production legislation. This regulatory landscape ensures that residues remain within safe limits, tailored to local dietary habits and consumption data. The Codex Alimentarius provides international guidelines for setting these MRLs, thus facilitating uniformity and safety in global food standards. The Codex databases provide internationally recognized numerical standards for maximum residue levels of veterinary drugs, and pesticides.[3]

When considering the applicability of MRL regulations to cell-based food and precision fermentation-derived food products, several key considerations emerge. These new food production methods involve different risk profiles compared to conventional agricultural practices.[28] Nevertheless, they are not exempt from potential contamination with pesticides or antimicrobials used during the production process. Despite the innovative nature of these products, the legislative frameworks governing MRLs for traditional foods could be extended to ensure their safety. This includes setting acceptable maximum levels of all pesticides (from plant-based growth media or from cleaning products) and antimicrobial residues in the growth media specific to these emerging technologies.

While standards on antimicrobial resistance have recently been developed and updated, they focus on the use of antibiotics in plant or animal production. However, the production processes for cell-based food and precision fermentation-derived food products might also involve the use of antimicrobials. These substances could be integral to maintaining sterile environments or optimizing cell growth, but could also pose new risk of development and spread of new resistance mechanisms. Therefore, it is important that the legislative focus expands to encompass these new production methods, ensuring comprehensive risk assessments and appropriate MRLs to mitigate the risk of AMR development.

8. Microbiological criteria

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 21-1997	Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods	CCFH	2013
CXG 30-1999	Principles and Guidelines for the Conduct of Microbiological Risk Assessment	CCFH	2014
CXG 33-1999	Recommended Methods of Sampling for the Determination of Pesticide Residues for Compliance with MRLs	CCFH	1999
CXG 63-2007	Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)	CCFH	2008

[3] For Codex databases, see https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/en

Relevant Codex Standards *cont.*			
Reference	**Title**	**Committee**	**Last modified**
CXG 79-2012	Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food	CCFH	2012

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

The issue of microbiological criteria (e.g. criteria for bacteria, fungi, viruses, prions) can also be relevant to cell-based foods and precision fermentation-derived food products, but special attention should be taken to account for the specific nature of their production processes. In some cases, this may require developing new or modified criteria to ensure comprehensive safety assessments.

9. Product-specific (vertical) food safety standards

Vertical food safety standards based on conventional agriculture

The Codex Alimentarius has developed a wealth of standards that pertain to conventional agricultural products, such as meat and milk. Similarly, national and regional food safety laws often have product-specific standards. The integration of cell-based food into existing product-specific frameworks can pose a significant and complex challenge. These frameworks were originally established with conventional agriculture in mind, and their definitions of "meat" and "milk" are deeply rooted in traditional production methods and biological processes. Cell-based food, which is derived from animal cells but does not involve the raising or slaughtering of animals in the traditional sense, disrupts these categories and raises profound questions about how such products should be classified and regulated.

Thus, food safety regulators will have to evaluate and decide whether cell-based food and precision fermentation-derived food products should adhere to the same standards as conventional animal-derived food products (or in some contexts, only to certain sections of the standards). In some cases, clarification from regulators may be needed regarding how they intend to apply or interpret the existing legal framework.

The case of breast milk substitutes, infant and therapeutic foods

In some cases, countries and regions have taken specific and additional measures regarding NFPS foods, or cell-based food and precision fermentation-derived food products, specifically regarding their use in breast-milk substitutes and infant and therapeutic foods, or they have created additional risk assessment requirements to protect especially vulnerable groups.

For breast-milk substitutes and infant food, the *International Code of Marketing of Breast-milk Substitutes*, established by WHO in 1981 (updated 2017), sets forth guidelines to ensure the safe and appropriate marketing and use of breast-milk substitutes, thereby protecting and promoting breastfeeding.[29] This code applies to any product intended to replace breast milk, including those made via cell-based food production and precision fermentation. Thus, precision fermentation, which replicates proteins or carbohydrates identical to those in human milk, would likely fall under this code when marketed as breast-milk substitutes. Article 9 mandates clear labelling,

emphasizing the superiority of breastfeeding and warning against improper use, to prevent misleading consumers or undermining breastfeeding.

10. Labelling, naming and certifications

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 2-1985	Guidelines on Nutrition Labelling	CCFL	2021
CXG 76-2011	Compilation of Codex texts relevant to the labelling of foods derived from modern biotechnology	CCFL	2011

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

Accurate and transparent labelling and marketing are key in the context of cell-based food and precision fermentation-derived food products, to prevent consumer confusion and misinformation.[30] Key issues around labelling include the terminology used to describe the product to make clear that it is produced through these methods, the naming of the species that was used, conveying increasingly complex messages about allergens, ingredients used in production and the involvement of GMOs.

For example, there is an ongoing debate regarding the use of terms like "meat" and related terminology in the naming or labelling of non-meat products, as well as similar issues concerning dairy and other animal-derived products which is relevant for cell-based food and precision fermentation. Questions arise over whether these alternatives should be displayed alongside their traditional counterparts in stores and how products such as cultured meat and plant-based dairy should be labelled based on their production methods. These issues highlight inherent ambiguities as the definitions of these foods evolve.

Box 7. Country case studies: Singapore and the United States of America

In Singapore, the Singapore Food Agency requires that cell-based meat products be labelled such that their nature can be clearly conveyed to consumers, allowing various terms, such as "cultivated meat", "cell-based meat" or "cultured meat". This is in line with the labelling of traditionally available "mock meat" products which are made of soy or wheat proteins.[i]

In the United States of America, the United States Department of Agriculture (USDA) is currently in the process of developing regulations for labelling cultivated meat and poultry products, and all product labels will be required to be pre-approved by the USDA before the products may be sold in restaurants and stores. To date, USDA has permitted two cultivated chicken companies to label their products as "cell-cultivated chicken".[ii]

However, on a general basis, industry stakeholders are primarily using the term "cultivated" to describe these sorts of proteins, which research indicates is more familiar to consumers than terms such as "cell-cultivated" or "cell-based."[iii]

Sources:

i. Singapore Food Agency. 2024. *A Guide to Food Labelling and Advertisements.* https://www.sfa.gov.sg/docs/default-source/food-manufacturing-and-storage/a-guide-to-food-labelling-and-advertisements.pdf;

Box 7. *cont.*

ii. Good Food Institute. Interview by Maarten van der Heijden [personal interview]. 16 August 2024; and

iii. Good Food Institute. 2022. *Cultivated meat consumer insights - Findings from a recent study by Embrapa, commissioned by the Good Food Institute.* https://gfi.org/wp-content/uploads/2023/01/CM-consumer-insights-and-nomenclature-insights-2.pdf

Allergens

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXC 80-2020	Code of Practice on Food Allergen Management for Food Business Operators	CCFH	2020

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

Usually, existing allergen regulatory frameworks can apply in the context of labelling, naming and certification. However, in some cases, regulators may need to clarify that the list of allergens that should be labelled, also applies to cell-based food or precision fermentation-derived ingredients or food products. Proper allergen labelling is crucial, as these foods may pose similar allergy risks as conventional products. The term used to describe a product, such as "salmon" in "cultured salmon", may convey important information for people who are allergic to the traditional version of the product. Modifiers, like in "cell-based artificial salmon product", should not obscure this and regulatory frameworks for food safety in these cases should align with those for labelling.

Religious certifications

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 24-1997	General Guidelines for Use of the Term "Halal"	CCFL	1997

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

Depending on country context, the issue of religious certifications for cell-based food and precision fermentation-derived food products can fall under private standards, when accompanied by third party certification and labelling requirements, or be embedded in national legislation. Notable private certifications include Halal, which requires that source cells come from animals slaughtered according to Islamic law or not slaughtered at all, ensuring no prohibited substances like alcohol or pork derivatives are used; and Kosher, which scrutinizes the kosher status of growth media and processes, ensuring compliance with Jewish dietary laws. National legislation may incorporate these religious standards to varying extents, depending on the country. For instance, some Muslim-majority countries have national Halal standards enforced by law, while others rely on private certification bodies. Hindu and Buddhist dietary certifications focus primarily on non-violence and respect for all living beings, in line with vegan and vegetarian certifications. Discussions about the acceptability of cell-based food and precision fermentation-derived food products within these frameworks are ongoing, with a focus on aligning production methods with traditional dietary and ethical principles.

Other certifications (vegan, vegetarian, organic)

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 32-1999	Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods	CCFL	2013

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

Organic: Cell-based food and precision fermentation-derived food products face significant regulatory barriers to being classified as organic. Organic food standards are largely harmonized via the private standards of the International Federation of Organic Agriculture Movements (IFOAM). The Codex Alimentarius *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32-1999)* provides a framework for organic certification, but applying these to cell-based food and precision fermentation-derived food products presents significant challenges. For example, traditional organic food concepts like the transition period (for instance in Section 3.7 of the guidelines) do not fit cell-based food and precision fermentation technologies, as these do not involve conventional land use or crop/livestock management. Specifically, Article 1.5 prohibits the use of genetically engineered or modified organisms in organic production, which directly impacts precision fermentation processes if they rely on GMOs. Furthermore, Article B.7 stipulates that organic livestock must be raised according to traditional farming methods, rendering cell-based meat incompatible with organic labelling. Additionally, Article 2.1 emphasises that organic products must be derived from natural farming systems, reinforcing the exclusion of cell-based food products and precision fermentation-derived food products that involve GMOs. Thus, while precision fermentation products might theoretically qualify as organic if non-GMO microorganisms are used, both cell-based food and most current precision fermentation processes face significant challenges under these guidelines.

Box 8. Regional case study: European Union

Under *Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products*, cell-based meat cannot be classified as organic, as organic production requires livestock to be "born and raised on organic holdings" (Article 14) and relies on "natural substances and processes" (Article 3). Precision fermentation products could only qualify if no genetically modified organisms (GMOs) are used, as Article 5 prohibits GMOs in organic production.

Source: European Union, *Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products*.

Vegan and vegetarian: In some cases, there may be uncertainty in the applicability of vegan and vegetarian labelling requirements. National laws on vegetarian and vegan labelling typically emphasize the absence of animal-derived ingredients and animal testing, or even any processing aids of animal origin that have been added or used during the manufacturing process, preparation, treatment or placing on the market of foods. For cell-based food products, which originate from animal cells, they generally do not qualify for vegan labelling due to their animal origin, despite the lack of traditional farming or slaughter. Some countries' regulations align with this perspective, requiring products to be entirely free from animal origins to qualify as vegan.

Precision fermentation-derived milk, on the other hand, could be interpreted to have a more favourable position under vegan labelling laws. If the fermentation process uses microbial feedstocks free from animal-derived substances and the final product contains no animal ingredients, it can often be deemed eligible for vegan labelling.

The requirements for vegetarian labelling tend to be somewhat less stringent than for vegan labelling. Commonly, products labelled as "suitable for vegetarians" must not contain any ingredients derived from killed animals but can include animal by-products like milk, eggs, and honey. Thus, cell-based meat typically would not meet vegan labelling standards due to its origin from animal cells. However, precision fermentation-derived milk can qualify as vegetarian, provided it adheres to the absence of animal slaughter in its production.

Similarly, the claim or label "animal-free" for cell-based meat and precision fermentation is complicated by the fact that while these products do not involve the slaughter of animals, they often rely on animal-derived cell culture media, processing aids, or cells from animals will be used as donors in the initial stage.

11. Health and nutrition claims

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 1-1979	General Guidelines on Claims	CCFL	2009

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

The application of broader rules on health and nutrition claims can also sometimes pose challenges in this context. For example, due to the variability inherent in cell-based food products, the application of traditional food claims is not straightforward. Food claims, particularly those related to specific attributes of conventional foods, do not automatically extend to cell-based equivalents. This is because the production processes and nutritional profiles of cell-based foods can differ significantly from their conventional counterparts, necessitating a case-by-case evaluation to ensure that claims are substantiated for these new products. Changes in the law are not *per se* necessary, but clarification from authorities whether food claims can be directly applied or need additional evidence could improve predictability here.

12. Food import/export controls and certification

Relevant Codex Standards			
Reference	**Title**	**Committee**	**Last modified**
CXG 20-1995	Principles for Food Import and Export Inspection and Certification	CCFICS	1995

Relevant Codex Standards *cont.*			
CXG 25-1997	Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods	CCFICS	2016
CXG 26-1997	Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems	CCFICS	2010
CXG 27-1997	Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food	CCFICS	2006
CXG 34-1999	Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems	CCFICS	1999
CXG 47-2003	Guidelines for Food Import Control Systems	CCFICS	2006

Source: FAO and WHO. Codex Alimentarius. In: *FAO*. [Cited 28 May 2025].

The international trade of cell-based food and precision fermentation-derived food products is governed by evolving regulatory frameworks. In addition, the international shipment of materials required to produce cell-based food and precision fermentation-derived food products presents significant import and export challenges, particularly due to the novel nature of these products. Transporting cell lines, biomass, and final products across borders may be complicated by uncertainty. Also, in import/export, product-specific legislation can form a barrier (for instance, if customs officials request documentation that is impossible to provide, such as health certificates for animals where the food producer does not know the origin of the animal but only the cell).

With the principle of equivalence playing a key role in determining market access, countries and regions must demonstrate that their food safety and production standards offer a level of public health protection comparable to importing countries' requirements, as seen with traditional meat. As regulatory agencies worldwide address the challenges posed by cell-based foods, equivalence allows diverse regulatory systems to be recognized, facilitating the expansion of this emerging sector while ensuring consumer safety. In practice so far, however, because of the lack of standardization and evolving nature of regulation and guidelines, equivalence is hard to assess, and trade remains very limited.

13. Inspection, incident management and enforcement

Cell-based food and precision fermentation-derived food products will also generally be subject to broader rules for aspects such as inspection, traceability, incident management, and enforcement, typically regulated under food safety legislation. For example, traceability of cell-based food and precision fermentation-derived food products is essential to ensure transparency across the supply chain, from production in controlled lab environments to final consumer markets. In addition, given the nature of these products and production methods, traditional food inspection

frameworks may have to adapt to new production processes involving bioreactors and tissue culture rather than conventional slaughterhouses and food packaging plants. This may require new analytical methods to detect fraudulent or otherwise non-compliant products alongside specific documentary requirements to assess authenticity and traceability. In many country contexts, no new changes in legislation are necessary for this, but in some cases, statements or guidelines from relevant authorities can help to facilitate implementation and the application of existing rules to cell-based food and precision fermentation-derived food products.

Conclusions and next steps

In many cases, existing national and regional regulatory frameworks may address many of the legal areas necessary to regulate cell-based food and precision fermentation-derived food products, particularly through regulatory frameworks that already cover NFPS and those governing GM foods. Specific regulatory frameworks or sections on cell-based food and precision fermentation-derived food products are not necessarily required. However, there is a pressing need for food safety authorities to clarify how existing food laws apply to these products, facilitating market entry (e.g. do food safety standards for traditional meat and milk apply to cell-based food and precision fermentation-derived similar food products?) and protecting consumers (e.g. do lists of allergens apply to cell-based food and precision fermentation-derived similar food products?). Lists of food additives, enzymes, and processing aids must also be updated to include those used in these new food production methods. Moreover, harmonization of these frameworks is crucial for enabling regional and international trade.

Thus, even where developing new specific regulatory frameworks is not required, declarations from food safety authorities on the applicability and interpretation of existing regulatory frameworks, as well as guidelines and good practices, are essential to govern and inspect these new production processes from "lab to fork". Moving forward, transparency, stakeholder engagement, and scientific evidence are all important for countries to incorporate in shaping future governance in this rapidly evolving sector.

Five Actions for Countries to Prepare Regulatory Frameworks for Novel Foods

Five actions that countries/regions may want to undertake to prepare their regulatory frameworks for cell-based food and precision fermentation-derived food products:

1. **Assessing and clarifying the applicability and suitability of existing regulatory frameworks:** Food safety authorities should assess existing food regulatory frameworks for preparedness for cell-based food and precision fermentation-derived food products. It may be necessary to clarify those cases where existing regulations have some ambiguity about their application to cell-based food and precision fermentation-derived food products. This is essential to provide legal certainty for food producers, ensuring that food safety standards for conventional products are appropriately applied or adjusted.
2. **Evaluating whether legal frameworks for pre-marketing authorization for new food sources and production systems (NFPS) and/or genetically modified food are required:** If countries wish to implement pre-marketing authorization processes supplementary to the general food safety framework, various modalities and options can be considered.
3. **Developing new regulatory elements and/or guidelines:** In some cases, specific elements of the food regulatory framework might have to be developed or updated. This could include, for example, regulations relating to food labelling and naming, as well as issues such as updating lists of permissible additives, enzymes, and processing aids, ensuring they reflect the needs of these food technologies. In some cases, in addition to other options, authorities may want to develop clear supporting guidelines for the production, labelling, and market authorization of these products, as well as producing good manufacturing practices, good cell culture practices and, good hygiene practices to help guide producers and set standards.

Five Actions for Countries to Prepare Regulatory Frameworks for Novel Foods *cont.*

4. **International and regional harmonization of standards:** International bodies like the Codex Alimentarius should continue their discussions regarding clear definitions and guidelines for cell-based food and precision fermentation-derived food products, particularly concerning food safety and labelling. This will facilitate smoother international trade and reduce legal uncertainties for food producers. Harmonization of new food sources and production systems (NFPS) might be an important pathway to consider.
5. **Broad stakeholder engagement:** Regulatory frameworks must be developed through broad consultations to reflect all relevant perspectives. Beyond producers, consumers, industry, civil society, and governments, it is essential to involve environmental organizations to assess sustainability, ethical groups to address animal welfare concerns, and agricultural workers and unions to examine socio-economic impacts on traditional sectors. Input from biotechnology experts, public health authorities, and trade associations will ensure the inclusion of innovation, health assessments, and smooth market integration. This approach ensures that regulations align with societal values and address key concerns around safety, transparency, ethics, and sustainability.

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How should legal systems respond when novel food technologies challenge the boundaries of existing regulation? As cell-based and precision fermentation-derived foods enter global markets, governments and regulators face the task of applying existing laws to technologies that challenge traditional notions of food production. This Legal Paper, developed by the Food and Agriculture Organization of the United Nations (FAO), examines the legal questions these products raise across international, regional, and national frameworks. It draws on instruments such as the Codex Alimentarius and World Trade Organization agreements to explore regulatory gaps, ambiguities, and broader implications for sustainability, human rights, and trade.

While most countries already regulate food, novel foods and genetically modified organisms, clarity is urgently needed on how these rules apply to cell-based and precision fermentation-derived products. Issues such as labelling, safety assessments, and permissible additives require clarification on their use and applicability, and, in some cases, reform. Internationally, efforts to develop harmonised standards remain at a formative stage, focusing on definitions, risk assessment, and good manufacturing practices.

To guide policymakers, the paper recommends five current priority actions: clarify existing rules, assess authorisation requirements, update regulatory elements, promote international harmonisation, and ensure broad stakeholder engagement. Together, these measures help provide legal certainty, protect consumers, enable innovation, and support equitable and sustainable trade in a rapidly evolving food landscape.

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