CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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CODEX ALIMENTARIUS COMMISSION

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FOOD SAFETY ASPECTS OF CELL-BASED FOOD AND PRECISION FERMENTATION DERIVED FOOD PRODUCTS

(Prepared by FAO and WHO)

Background

Cell-based food production[1] involves using cells isolated from animals, plants or microorganisms to produce food products, ingredients or additives. Often times the products can be seen as comparable to the existing animal-source products, such as meat, poultry, aquatic products, dairy products and eggs.

Precision fermentation often refers to a process that utilizes microorganisms such as bacteria, yeast, or fungi to produce specific target products through controlled production systems. A wide range of products such as proteins, enzymes, vitamins or other bioactive substances can be produced through precision fermentation.

As the global demand for proteins and specific nutrients grows, various efforts have been initiated to investigate the feasibility of expanding the scope of diverse food production systems that can be safe, environmentally sustainable, nutritionally sound and profitable. Therefore, many food safety authorities are working to address the potential food safety implications so that appropriate regulatory frameworks can be identified to protect consumers. FAO and WHO, together with the competent authorities, engage many other stakeholders to collaborate in this space to advance our collective knowledge.

Sharing regulatory information across countries and regions

Following up on the rich discussions held at CAC46 and several recommendations made (REP23/CAC Paragraph 198b), FAO, together with WHO, has strengthened the informal Technical Working Group[2] which was established in 2021, to establish a mechanism to share the current regulatory approaches and risk management measures to assure the safety of cell-based foods and precision fermentation derived food products across countries and regions.

As of September 2024, the TWG has more than 110 individuals from 35 Codex Members, and the participating Codex Members include: Argentina, Australia, Bangladesh, Brazil, Canada, Chile, China, European Union, Estonia, France, Germany, Greece, Guatemala, Hungary, Indonesia, Iran (Islamic Republic of), Israel, Italy, Japan, New Zealand, North Macedonia, Oman, Qatar, Republic of Korea, Saudi Arabia, Singapore, Spain, Sudan, Switzerland, Thailand, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United States of America, Uruguay and Yemen.

Regulatory snapshot 2024: cell-based foods

The informal TWG has held two virtual meeting sessions followed by email exchanges on the latest development of the regulatory activities with regard to food safety assurance of cell-based foods and precision fermentation derived food products. Table 1 illustrates the summary of the current regulatory status related to cell-based foods. The original table was developed in 2022 and published as Table 4 (Page 31) of the FAO/WHO publication entitled "Food safety aspects of cell-based foods[3]" (FAO and WHO, 2023) and the TWG members updated the relevant information in September 2024.

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[1] FAO Food Safety and Quality website. 2022. Scientific advice – cell-based food and precision fermentation. https://www.fao.org/food-safety/scientific-advice/crosscutting-and-emerging-issues/cell-based-food/

[2] Those who wish to join the TWG can contact their country/jurisdiction's Codex Contact Point, who can then contact the FAO facilitator.

[3] FAO & WHO. 2023. Food safety aspects of cell-based food. Rome. https://doi.org/10.4060/cc4855en

Table 1. Developments in different countries relevant for cell-based food products and their safety (Note the information is strictly time-bound and is as of September 2024)

Country/ economic zone	Competent authority	Legislative/ standard-setting bodies	Cell-based food product on the market?	Cell-based food-specifically addressed in food safety regulations and/or safety guidelines/ instructions?
Argentina	National Service for Agrifood Health and Quality (SENASA)	National Service for Agrifood Health and Quality (SENASA)	No	No
Australia and New Zealand	Food Standards Australia New Zealand	Food Standards Australia New Zealand and Ministry for Primary Industries	No	Pending 2025
Bangladesh	Bangladesh Food Safety Authority	Bangladesh Food Safety Authority	No	No
Brazil	Brazilian Health Regulatory Agency/Ministry of Agriculture and Livestock/National Technical Commission on Biosafety	Brazilian Health Regulatory Agency/Ministry of Agriculture and Livestock/National Technical Commission on Biosafety	No	No
Canada	Health Canada	Health Canada	No	No
Chile	Ministry of Health	Congress, Ministry of Health	Unknown	No
China	National Health Commission (NHC); China National Center for Food Safety Risk Assessment (CFSA)	People's Congress; the State Council; National Health Commission (NHC), State Administration of Market Regulation (SAMR)	No	No
European Union / European Economic Area	European Food Safety Authority; European Commission (issuing institution) European Union (EU) / Federal Food Safety and Veterinary Office (Switzerland) / Mattilsynet (Norway) / Matvælastofnun (Iceland)	European Parliament, Council, European Commission, national ministries	No	Yes [Link to be available in September 2024]
Guatemala	Ministry of Agriculture, livestock and food	Food Safety	No	No
Indonesia	Ministry of Agriculture/ Ministry of Marine Affairs and Fisheries/ National Agency of Drugs and Food Control/ Ministry of Trade/Ministry of Industry /Ministry of Health /National Standardization Agency of Indonesia	Ministry of Agriculture/ Ministry of Marine Affairs and Fisheries/ National Agency of Drugs and Food Control/ Ministry of Trade/Ministry of Industry/Ministry of Health /National Standardization Agency of Indonesia	No	No
India	Food Safety and Standards Authority of India	Food Safety and Standards Authority of India	No	No
Iran (Islamic Republic of)	Food and Drug Administration (FDA) of Iran (Islamic Republic of)	FDA of Iran (Islamic Republic of) and INSO (Iran National Standards Organization)	No	No
Israel	National Food Service	Ministry of Health	Authorized, not yet on the market	Yes [to be published by the end of 2024]

Country/ economic zone	Competent authority	Legislative/ standard-setting bodies	Cell-based food product on the market?	Cell-based food-specifically addressed in food safety regulations and/or safety guidelines/ instructions?
Japan	Food Safety Committee Consumer Affairs Agency Ministry of Health, Labour and Welfare Ministry of Agriculture, Forestry and Fisheries	Consumer Affairs Agency Ministry of Health, Labour and Welfare	No	No
North Macedonia	Food and Veterinary Agency	Food and Veterinary Agency	No	Yes/Cell based foods are a category of novel foods and regulated by the Rulebook on the specific safety requirements for novel foods[4]
Qatar	Ministry of Public Health	Qatar General Organization for Standards and Metrology and Gulf Cooperation Council Standardization Organization	No	No
Republic of Korea	Ministry of Food and Drug Safety	Ministry of Food and Drug Safety	No	Yes [Standards for recognition of Temporary Standards and Specifications for Foods][5]
Saudi Arabia	Saudi Food and Drug Authority	Saudi Food and Drug Authority	No	Yes [Technical regulation SFDA.FD 5013 "General Requirements for Novel Foods"; Guideline to Apply for the Approval of Novel Foods][6]
Singapore	Singapore Food Agency	Singapore Food Agency	Yes Processed comminuted poultry products containing cultivated chicken or quail cells	Yes [Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients][7]
Thailand	Ministry of Public Health	Food and Drug Administration	No	No
United Arab Emirates	Ministry of Climate Change and Environment	Ministry of Climate Change and Environment / Ministry	No	Cell based food fall under UAE.S 5048:2021: General

[4] North Macedonia. 2020. Rulebook on the specific safety requirements for novel foods. https://drive.google.com/file/d/1ySmxE9hUzHf-NOeWOECnaeVGqjn3FAx_/view

[5] Republic of Korea. 2024. Standards for Recognition of Temporary Standards and Specifications for Foods (No. 2024-13). https://www.mfds.go.kr/eng/brd/m_15/view.do?seq=72449

[6] Saudi Arabia. 2021. Guidelines to Apply for the Approval of Novel Foods. https://www.sfda.gov.sa/sites/default/files/2021-07/Foodjh45.pdf

[7] Singapore. Updated on 20 July 2023. Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients. https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-foods-and-novel-food-ingredients.pdf

Country/ economic zone	Competent authority	Legislative/ standard-setting bodies	Cell-based food product on the market?	Cell-based food-specifically addressed in food safety regulations and/or safety guidelines/ instructions?
		of Industries and Advanced Technologies		Requirements for Novel Foods
United Kingdom of Great Britain and Northern Ireland	Food Standards Agency	Food Standards Agency	No	Yes [Cell-cultivated products | Food Standards Agency][8]
Uruguay	Ministry of Livestock, Agriculture and Fisheries, Ministry of Industry, Energy and Mining, Ministry of Public Health, Ministry of Foreign Affairs, Ministry of the Environment, National Council of Innovation, Science and Technology	Ministry of Livestock, Agriculture and Fisheries, Ministry of Public Health	No	No
United States of America	United States Department of Health and Human Services Food and Drug Administration (HHS-FDA) / United States Department of Agriculture Food Safety and Inspection Service (USDA-FSIS)	HHS-FDA /USDA-FSIS	Yes	Yes
Yemen	Yemen Standardization Metrology and Quality Control Organization	Yemen Standardization Metrology and Quality Control Organization	No	No

Argentina

The National Service for Agrifood Health and Quality (SENASA) is the regulatory agency responsible for food safety in Argentina. Its role includes the development and enforcement of specific regulations related to animal and plant health and quality, as well as the safety of foods under its jurisdiction, including those of biotechnological origin or novel food.

Cell-based food is a novel concept in our country that still needs to be clearly defined in order to differentiate it from traditional meat products. As a result, potential regulations are currently under discussion.

While SENASA has specific regulations to ensure the quality and safety of meat products, there is currently no specific regulation for foods derived from cell-based foods. However, SENASA has extensive experience in the regulation and risk assessment of foods derived from genetically modified organisms, based on the guidelines of the Codex Alimentarius and the conceptual criteria developed by the OECD. This expertise could serve as a foundation to address novel cases of cell-based foods or to develop specific regulations in this area. Additionally, the applicability of current regulations on GMO safety could be analyzed for these kinds of products.

Australia and New Zealand

All food sold in Australia and New Zealand must comply with food standards. Food Standards Australia New Zealand (FSANZ) assesses applications to amend the Code and prepares proposals to vary existing standards or develop new ones. These standards are compiled in the Australia New Zealand Food Standards Code (the Code). The Code covers labelling and other information requirements, substances added to or present in food such as food additives, processing aids and vitamins and minerals, contaminants and residues in foods, foods requiring pre-market clearance such as novel foods, foods produced using gene technology, irradiation of food,

[8] United Kingdom of Great Britain and Northern Ireland. Food Standards Agency. 2024. Cell-cultivated products. https://www.food.gov.uk/business-guidance/cell-cultivated-products

microbiological limits and processing requirements, food standards for general foods, plus food safety standards (Australia only) and primary production standards (Australia only).

The Code does not currently contain specific permissions or requirements for cell-based meats (FSANZ, 2021), however an assessment is underway on one type of cell-based food. Currently a cell-based food will be considered a novel food in the Code, being a non-traditional food that requires an assessment of the public health and safety considerations. A non-traditional food means: (a) a food that does not have a history of human consumption in Australia or New Zealand; or (b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or (c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand (FSANZ, 2017).

FSANZ's current assessment of a cell-based food would be covered by the existing standards in the Food Standards Code and require pre-market approval in the future (FSANZ, 2021). Depending on the composition of cell-based foods, these standards may include those for: (i) novel foods - foods without a history of traditional human consumption in Australia and New Zealand; (ii) processing aids – substances used to produce foods but which serve no technological function in the final food for sale; (iii) food additives – substances that serve a technological function in the final food for sale; (iv) foods produced using gene technology; (v) vitamins and minerals; (vi) labelling that indicates the true nature of the food; (vii) definition of cell based meat and (viii) food safety requirements. FSANZ will update its website with further information once the assessment of the current cell-based food is completed in early 2025.

In New Zealand, The Ministry of Primary Industries has published a 'Cell-Cultured Meat Products Policy Statement'. The policy statement signals high level policy expectations for the production, manufacture and sale of novel foods cultured from animal cells. It sits alongside the New Zealand Food Safety regulatory statement for any business proposing to import, manufacture or sell an animal cell-cultured food product for human consumption in the New Zealand market under New Zealand food legislation.

Brazil

The responsibility for food safety in Brazil is shared among governmental entities, including the federal, state, and territorial governments. Brazilian Health Regulatory Agency (Anvisa) is responsible for establishing regulations that apply to all food products sold in Brazil, setting standards to guarantee the safety and quality of food, including beverages, bottled water, ingredients, raw materials, food additives and processing aids, food contact materials, contaminants, residues of veterinary drugs, residues of pesticides, labelling and technological innovations in foods (Novel Foods). The Ministry of Agriculture and Livestock (MAPA) has competencies related to implementation of agricultural policies including promoting agriculture, supporting agribusiness, regulating services related to the agricultural and livestock sectors, plant and animal health, inspection of food products of animal and plant origin. These entities work together to regulate and enforce federal food laws within their respective areas of expertise.

According to the Brazil regulations, a novel food means: foods and ingredients with no history of safe consumption in Brazil obtained from vegetables, animals, minerals, microorganisms, fungi, algae or synthetically, including, but not limited to, those that: a) have a new or intentionally modified molecular structure; b) consist of cell cultures or tissue cultures or have been produced from such cultures; c) have undergone a production process that implies significant modifications; d) have undergone a production process not usually applied in food production; e) are obtained by fermentation, extraction or selective concentration, used for technological purposes in order to modify the physical, chemical, biological or sensory characteristics of food that is not classified as a food additive; f) are made up of nanomaterials obtained through engineering. (Resolution for novel foods ingredients - RDC 839/2023).

Cell-based foods are considered novel foods, since there is no history of safe consumption in Brazil, consist of cell cultures or tissue cultures, and have undergone a production process not usually applied in food production. The procedure for authorizing novel foods involves a pre-market authorization prior its sales. The demonstration of the safety of use of novel foods/ingredients should be conducted based on risk assessment grounded in technical data and scientific studies. Until this date, no cell- based product has passed through the Brazilian novel food procedure yet.

Besides novel foods, also other sectors of legislation may also be applicable in Brazil. For example, genetic modification may have been used to produce improved cell lines for cell-based food production. In that case, the products should comply with Brazilian Biosafety Law 11.105/2005. The risk assessment for approval of genetically modified organisms (GMO), considering the risk to animal and human health and the environment is the competency of the National Technical Commission on Biosafety (CTNBio). According to art. 10 of Law 11.105/2005, CTNBio, coordinated by the Ministry of Science, Technology and Innovation, is a multidisciplinary collegiate body with an advisory and deliberative nature, to provide technical support and advice to the Federal Government in the establishment of technical safety standards and technical opinions regarding the authorization for activities involving research and commercial use of GMOs and their derivatives. The Ministry

of Agriculture and Livestock (MAPA) and the Ministry of Health are among the ministries responsible for inspections in the activities related with GMO use and manipulation to check the compliance with biosafety law and normative requirements.

The biosafety law has some exceptions, some Ingredients obtained from precision fermentation of GMO, that are substances chemically defined according with the law and that does not have neither rDNA nor GMO are regulated under the same Resolution for novel foods ingredients - RDC 839/2023. In addition to these rules on novel and GM foods, generic rules on food hygiene and safety, also within production environments apply, such as good manufacturing practice (GMP) and hazard analysis and critical control point (HACCP) principles.

Canada

Health Canada and the Canadian Food Inspection Agency (CFIA) are the federal authorities responsible for the regulation of foods sold in Canada, including novel foods. Health Canada is responsible for establishing food safety and nutrition quality requirements by setting standards and developing policies to support application of the regulations and standards. The CFIA is responsible for enforcing requirements under the Food and Drugs Act and the Safe Food for Canadians Act.

Health Canada's oversight of novel foods in Canada entails a mandatory pre-market notification requirement, as set out in the Novel Food Regulations (NFR; Division 28 of Part B of Canada's Food and Drug Regulations).

The NFR defines a novel food as: (i) a substance, including a microorganism, that does not have a history of safe use as a food; (ii) a food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and causes the food to undergo a major change; and (iii) a food that is derived from a plant, animal or microorganism that has been genetically modified to alter its characteristics (i.e., adding new characteristics, removing existing characteristics, or altering a characteristic such that it is no longer within the anticipated range for that organism). Most if not all foods made with cultivated animal cells (i.e., cell-based foods) will meet one or more parts of the novel food definition. To date, no cell-based food has been assessed as a novel food in Canada.

Health Canada conducts assessments of novel foods in accordance with their Guidelines for the Safety Assessment of Novel Foods, which set out the criteria for novel food safety assessment that are based on internationally established scientific principles and guidelines developed through work of the Codex Alimentarius Commission, FAO, the World Health Organization (WHO) and the Organisation for Economic Co-operation and Development (OECD). Information that developers provide in their notifications for cell-based foods need to comprehensively address safety and nutrition endpoints, as is required for any novel food. As cell-based foods are a new product class, additional information may be required to support product characterization and safety. Health Canada's regulatory decisions for notified products are made case by case, and on the basis of scientific and technical information reviewed as part of the safety assessment.

In addition to the requirements set out in the NFR, other pre-market regulations may apply to specific products. Further, there are general and post-market provisions that apply to all foods sold in Canada. Examples of regulations and provisions that may apply to cell-based foods include those for: food additives, fortification, nutrition labelling, trade, licenses, preventive controls, traceability, compositional standards, packaging, labelling, environmental and human health impacts of new substances, and animal feed. The mandates for these regulations rest with different government bodies, including Health Canada, the CFIA, and Environment and Climate Change Canada (ECCC). Developers and manufacturers are responsible for meeting the regulatory requirements that apply to their product. Developers can contact Canadian regulators to seek further information and ask any questions about compliance requirements.

Chile

The Ministry of Health (MINSAL) is the Health Authority on Food Safety in the country. The Public Health Sub-Secretariat of the MINSAL houses the Division of Healthy Public Policies and Promotion (DIPOL) where the Department of Food and Nutrition is located, whose purpose is to ensure that foods do not pose a risk to the health of consumers and/or may have a significant impact on the morbidity-mortality profile. The objectives of the DIPOL are to protect public health by reducing the risk of foodborne illnesses, protect consumers from unhealthy, improperly labelled, or adulterated foods, and contribute to economic development by maintaining consumer confidence in the food system and establishing a solid regulatory basis for national and international food trade.

Most of food safety provisions are contained under the regulation known as the food health regulation (RSA in Spanish). This regulation contains clear definition for meat and meat products, as well as labelling provisions, most if which are based on Codex standards.

In 2023, Congress passed a law that emphasizes the correct labelling of meat and meat products. Under the new law, the term "meat" is reserved exclusively for "the edible part of the muscles of animals for slaughter," making it clear that products such as hamburgers, chorizos, and sausages must come from animal sources.

Most of the discussions around labelling, have been in reaction to the growing market of plant-based products. Presently, there is a discussion around the need to legislate tech-food companies involved in the production of novel food products. This is an ongoing discussion that discusses around the growing sector in Chile that is starting to innovate in food production.

China

In China, cell-based food would fall under the definition of “new food raw materials” as defined by the Administrative Measures for the Safety Review of New Food Raw Materials of the National Health Commission of China (NHC, 2017/No. 18) (Liu *et al*., 2024). As stated in Article 2, the term “new food raw materials” refers to the following items which are not of traditional eating habits in China: (1) animals, plants and microorganisms, (2) ingredients extracted from animals, plants and microorganisms, (3) food ingredients the original composition of which has been changed, and (4) other newly developed food raw materials. Therefore, regulatory approvals and subsequent inclusions in the NHC list of authorized new food raw materials will be needed before cell-based foods can be marketed in China (NHC, 2022).

Further, the NHC procedural regulations established in 2021, and they include the “Provisions on the Application of New Food Materials”, “Procedures for the Safety Evaluation of New Food Materials” and “Application Materials requirement for the Safety Evaluation Opinion of New Food Materials”. These regulations delineate the procedures for the submission, assessment and approval to ensure a thorough evaluation process aligning with national and international food safety standards.

The approval procedure requires that companies wishing to market a new food raw material submit an application dossier containing, amongst other things, a safety dossier to NHC. The safety of these new food raw materials needs to be reviewed by the China National Center for Food Safety Risk Assessment, before approval of their use in food production and trading (CIRS, 2021; Liu *et al*., 2024).

European Union

The novel food Regulation (EU) 2015/2283 (European Union, 2015) definition explicitly includes ‘food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, and microorganisms, fungi or algae’. This aligns with the notion that cell-based foods and the processes for manufacturing them lack a history of substantive and safe consumption within the European Union. Regulatory approval and inclusion in the Union list of authorised novel foods (Commission Implementing Regulation (EU) 2017/2470) will therefore be needed before cell-based foods can be sold within the European Union. The approval procedure requires that companies wishing to market a novel food submit an application dossier containing, amongst other things, a safety dossier (EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) *et al.*, 2024). Besides data from original safety studies, these dossiers may also contain literature and other existing data to support the application. The latter would conceivably apply to product components that are food-grade (e.g. certain natural biopolymers used for scaffolding) or that have a substantial history (25 years) of consumption or traditional use in a country outside the European Union (European Union, 2015; Seehafer and Bartels, 2019).

Moreover, any food should be safe, novel or not, and its labelling should not be misleading, and if it replaces a particular existing product, this replacement should not be nutritionally disadvantageous to the consumer, for which data would need to be provided. The safety of the particular products is then assessed at a centralized European level by experts in a scientific Panel of the European Food Safety Authority (EFSA), which specifically advises the European Commission on matters of food safety, including that of regulated products such as novel foods. The Commission can then take a decision (or propose it to the regulatory European Union bodies) to approve a product for entry into the European Union market.

Besides novel foods, also other sectors of legislation may also be applicable in the European Union. For example, genetic modification may have been used to produce improved cell lines for cell-based food production. In that case, the products should comply with legislation on genetically modified products, such as the GM Food and Feed Regulation (European Union) No. 1829/2003 (European Union, 2003) according to which a pre-market safety assessment will be required. In addition to these rules on novel and GM foods, generic rules on food hygiene and safety, also within production environments apply, such as good manufacturing practice (GMP) and hazard analysis and critical control point (HACCP) principles.

Labelling rules apply, but Seehafer and Bartels (2019) note that in the absence of specific European Union provisions, the national legislation of Member States will have to fill this gap for the time being, and labelling rules are delegated to member states (Seehafer and Bartels, 2019). The European Commissioner has in several instances alluded to the possibility of invoking labelling provisions at the European Union level to ensure that consumers are informed about the nature of these products (EU Parliament, 2018; EU Parliament, 2019).

Indonesia

In Indonesia, several institutions manage food safety, including Indonesian Food and Drug Authority (BPOM), which oversees drugs and food safety to ensure that food and beverages circulating in the country are safe for consumption. BPOM conducts laboratory tests and field inspections and enforces regulations on non-compliant products. The Ministry of Agriculture, through its Directorate General of Livestock and Animal Health and the Directorate General of Food Crops, oversees food products derived from animals and plants, ensuring animal health and the safety of food from the livestock sector. The Ministry of Health also plays a role in food safety, particularly regarding public health, and collaborates with BPOM to ensure that food products pose no health risks. The National Standardization Agency (BSN) sets the Indonesian National Standards (SNI) for food products to maintain quality and safety nationwide. Additionally, through its Research Organization for Agriculture and Food, the National Research and Innovation Agency (BRIN) conducts research and develops innovations related to food safety and quality, helping to advance new technologies and methods for producing safe, high-quality food.

Cell-based food is a relatively new concept in Indonesia, and its regulatory framework is still developing. While no specific, standalone regulations directly address cell-based food, several existing regulatory bodies and frameworks indirectly touch upon the safety and regulation of such innovative food products. These regulations typically fall under general food safety and biotechnology-related guidelines.

India

In India, according to the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations (2016), a novel food is defined as a food that: (a) may not have a history of human consumption; or (b) may have any ingredient used in it which or the source from which it is derived, may not have a history of human consumption; or (c) a food or ingredient obtained by using new technology with innovative engineering processes, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients, which may alter the nutritional value, metabolism or level of undesirable substances (FSSAI, 2016). Cell-based foods would fall under these definitions. For novel foods like cell-based foods to be manufactured and sold in India, approval is required from the Food Safety and Standards Authority of India (FSSAI) for which the procedure is laid out in the Food Safety and Standards (Approval of Non-Specified Food and Food Ingredients) Regulations, 2017 (FSSAI, 2017). Other regulations that are likely to play a role include, amongst others, general quality assurance and hazard management systems and good hygiene and manufacturing practices, as well as e.g. laws against animal cruelty (Kamalapuram *et al.*, 2021).

Iran (Islamic Republic of)

In Iran (Islamic Republic of) , there is no specific regulation or guideline/instruction/ standard exists for Cell-based food products. However, cell-based products can be subject to the “Food and Beverage and Cosmetics Law” but the license to produce, specifications, and safety assessment of novel products including cell-based products is adopted after scientific and technical reviews in the relevant committee under the "Food and Beverage and Cosmetics law".

Biosafety law and related regulations also exist for GMOs. It has been compiled based on the Cartagena protocol and is mostly applied to GM products, their export, import, and safety assessment. The Cell-based products produced using genetic engineering techniques are subject to this law.

Israel

In Israel, the National Food Service of the Ministry of Health is responsible for assuring the safety, quality, and authenticity of food for consumers. The safety assessment standards and laws are to a great extent harmonized with those of the European Union, and Israel’s risk assessors will also take into consideration the assessments of the safety bodies of the European Union, the United States of America, Canada, Japan and the Australian and New Zealand bodies, which can help fast-track the national application (AgroChart, 2016).

Cell-based food is considered to be a novel food under Israeli legislation (Gross, 2021). Novel Food in Israel is defined as food that had not been consumed to a significant degree by humans in Israel before 19 February 2006, when the first Regulation on novel food in Israel came into force. The pre-market authorization process in Israel is outlined in its novel food regulation framework (Israel Ministry of Health, 2015). This framework defines novel food as a food or food ingredient that falls into at least one of the following criteria and which is not classified as a food additive, a food supplement, a processing aid or a food flavouring:

1) Is of a novel primary molecular structure or has undergone an intentional alteration in its primary molecular structure, for which there is insufficient history of safe human consumption before February 2006.

2) It contains a genetically modified organism or a part thereof.

3) It contains a plant, animal, microorganism, fungi or algae, or derived from these, for whom there is insufficient history of safe human consumption.

4) It was manufactured in a process which was not used in Israel for the manufacturing of this specific food or food component, and this process has led to a substantial change in the composition of the food, its structure or components, and has affected its nutritional value, its metabolic qualities or the level of undesired substances in it.

Japan

Cell-based meat marketing in Japan is expected to become operational in late 2022 (Ferrer, 2021), and part of the cell-based meat landscape in Japan has its roots in the do-it-yourself biology (DIY Biology) movement carried out by young scientists, represented in the media wearing futuristic apparel, and guided by "open science" principles (Hanyu, 2021). Japan has not yet communicated any new food regulations or standards that explicitly address a regulatory framework for cell-based meat (Ettinger and Li, 2021).

However, some general basic requirements from the existing food legislation are likely to apply, such as Article 3 of the Japanese Food Sanitation Act that requires that food business operators shall take necessary measures to ensure the safety of the food for sale for human consumption, and Article 7 that states that "when things which have not generally been served for human consumption and have not been proven to be unlikely to cause harm to human health or things including those things have newly come to be sold or are going to be sold as food, the Minister of Health, Labour and Welfare may prohibit the sales of those things as food, by hearing the opinions of the Health Science Council, when the Ministry of Health, Labour and Welfare finds it necessary to prevent food hygienehazards".

North Macedonia

Cell based food in North Macedonia is regulated by the Food Safety Law's articles referring to novel foods as it is recognized as one of the novel foods categories. The definition of cell-based food refers to all cell-based food derived from cultures of cells or tissues from animals, plants, and microorganisms, fungi or algae. The competent authority for placing on the market of cell-based food as well as all novel foods is the national Food and Veterinary Agency (FVA).

According to the legal requirements stipulated in article 55 of the Food Safety Law all novel foods must be authorized by the FVA prior being placed on the market. All novel foods must be safe, their labelling must not mislead the consumer, and they must not be nutritionally disadvantageous when replacing a particular existing product. Further safety requirements are provided in the Rulebook on the specific safety requirements for novel foods (OG of RNM 173/2020), which is aligned to the EU Regulation 2283/2015.

The authorization procedure and the necessary documentation is defined by the Rulebook on the form and content of the application, method and procedure for issuing approval, its duration, the required documentation and the amount of expenses in the procedure for issuing approval for placing on the market a product from the group of novel foods (OG of RNM 47/2021). A company that intends to place a novel food on the market in North Macedonia must submit to the FVA a technical dossier including data on the production process, composition and safety studies for the novel food. The FVA decides on the validity, completeness and relevance of the data and issues an approval or rejects the application for placing on the market of that novel food. All novel foods must also comply with other horizontal legislation on safety and labelling applicable to conventional food. So far, there has been no request for placing on the market of a cell-based food in North Macedonia.

Qatar

According to the 2021 news reports, Qatar would host a cultured chicken meat production facility which is to become operational shortly, a first of its kind for the Middle East and North African region. Whilst an export licence may have been granted, Qatar's Free Zone Authority and Ministry of Public Health also intend to grant regulatory approval for the new product (Business Wire, 2021). For the regulatory risk assessment of novel foods, the Gulf Standardization Organization, of which Qatar is a member, developed a guideline for novel food products.

Republic of Korea

In the Republic of Korea, the Ministry of Food and Drug Safety (MFDS) is responsible for establishing the law and regulation on the safety of food ingredients and novel foods. MFDS amended the law - 'Enforcement Rules of the Food Sanitation Act' to include the cell-based food ingredient in the scope of novel foods (MFDS, 2023) and the related regulation - "Standards for recognition of Temporary Standards and Specifications for Foods (MFDS, 2024)". MFDS also provide the guidance on preparing an application and safety evaluation considerations for applicants of the cell-based food ingredient (MFDS, 2024).

Under the regulation, the applicants of cell-based food ingredients should submit a dossier demonstrating its safety to the MFDS. The MFDS is in charge of recognizing of cell-based food ingredients through review of the safety evaluation data. At the moment, no cell-based food ingredient has been approved for sale in Korea.

Saudi Arabia

The Kingdom of Saudi Arabia, represented by the Saudi Food & Drug Authority (SFDA) is responsible for protecting the community through science-based regulations and implementing effective controls to ensure food safety. The regulations cover food safety, quality and labelling requirements. SFDA also oversees Halal certification to ensure that all food products comply with SFDA Halal food requirements. As part of its commitment to advancing food safety and innovation, SFDA is also guided by its Fourth Strategic Plan. This plan emphasizes support for biotechnology and the development of novel food technologies. It aims to enhance the regulatory framework for biotech products, foster innovation in food production, strengthen collaboration with stakeholders in the biotech industry and ensure that new technologies are effectively integrated into the regulatory system. Through these efforts, SFDA seeks to ensure that the benefits of biotechnological advancements are realized while maintaining the highest standards of safety and quality.

Cell-based food is regulated within the Saudi Technical Regulation “General Requirements for Novel Foods” No. (SFDA FD 5013:2020) and there is a procedure for the scientific evaluation process. The steps of this procedure are also summarized in the "Guideline to Apply for the Approval of Novel Foods" published on the Authority's website. This guideline includes the requirements that must be met for scientific evaluation when requesting approval to register a product as a novel food. The applicant must attach a file containing documents that contribute to the process of scientific evaluation of the novel food. The most prominent of these documents is a description of the newly created food, which includes a detailed description of the food source, the production process, and synthetic data using approved methods.

Singapore

In Singapore, processed comminuted poultry products containing cultivated chicken or quail cells have been granted regulatory approval and marketed since 2020 and a novel food regulatory framework was established by the Singapore Food Agency (SFA) in 2019. Cultivated meat are considered to be a novel food as they do not have a history of safe use (SFA, 2020). Under Singapore’s regulatory framework for novel foods, companies producing novel food products are required to conduct and submit safety assessments of their products for the SFA’s review before they are allowed to be put on sale. To facilitate this process, SFA has released a guidance document on the food safety information that would be required for novel food safety assessment (SFA, 2021a). The information should cover potential food safety risks, such as toxicity, allergenicity, the safety of its production method, and dietary exposure arising from consumption. Companies must also provide detailed information on all the inputs used in their manufacturing processes and how these manufacturing processes are controlled to prevent food safety risks.

In particular, SFA notes that the science for producing cultivated meat is still at an early stage. The specific requirements for information that should be submitted for the safety assessment of cultivated meat are included in the SFA guidance document (SFA, 2021), but the SFA notes that information required may change based on the developments on the science of producing cultivated meat. For example, since the release of SFA’s novel food guidance document in 2019, additional guidance has been included to provide further clarity on the necessary information required for safety assessments. This includes how applicants can demonstrate that genome instability and genetic drift would not result in the production of undesirable substances in cultivated meat at levels that can pose a food safety hazard, as well as the safety assessment approach that can be applied for biological substances used in culture media in cultivated meat/seafood production. SFA has also articulated the application of good cell culture practices (GCCP) to ensure reproducibility and consistency of cellular products.

To ensure that the safety assessments provided by applicants are rigorously reviewed, SFA has established a Novel Food Safety Expert Working Group to provide scientific advice. The expert working group comprises experts specializing in food science, food toxicology, bioinformatics, nutrition, epidemiology, public health, genetics, carcinogenicity, metabolomics, fermentation technology, microbiology and pharmacology. The composition of this expert working group is refreshed periodically, to ensure that SFA continues to have access to the necessary scientific advice as new novel foods emerge.

SFA also emphasises the importance of engaging companies to share about the novel food regulatory framework even when the companies are in the early stages of their research by conducting Novel Food Virtual Clinics since September 2021. This will help companies prioritize resources towards productive research directions and will minimize compliance costs and time. Regarding labelling, SFA requires that cell-based meat products be labelled such that their nature can be clearly conveyed to consumers, with terms such as “cultivated meat”, “cell-based meat” or “cultured meat” (SFA, 2021).

SFA is also actively pursuing international discussion and alignment of approaches for the safety of cultivated meat, by proposing new work to address food safety challenges of regulating cultivated meat at Codex. These proposals focus on the safety assessment of cell culture media components and the development of guidelines for the hygienic manufacture of cultivated meat. SFA also organises an annual Roundtable on Novel Food Regulations, which provides an opportunity for regulators, industry and academia to jointly discuss, and address issues and challenges related to the regulation of novel foods.

Thailand

At present, there is no specific regulation for cell-based food in Thailand. However, any food manufactured with the novel process such as, precision fermentation may or may not fall under the Notification of Ministry of Public Health No. 376 issued in 2016 depending on the output or finished products of the process. The novel food registration is enforced by the Notification Number 376, which defined Novel food as a substance (both finished product or a single ingredient) or an innovative process to produce food.

For cell-based and precision fermentation, safety assessment of the product shall be evaluated prior to product registration and the label shall be submitted to Food and Drug Administration for approval before use. There is no specific regulations or guidance on labelling for cell-based and precision fermentation.

Labelling of novel food shall follow the Notification of the Ministry of Public Health No. 450 regarding labelling of pre-packaged foods packaged for both imported and domestically produced food products. Indication of ingredient source shall be expressed on its label to help consumer in making informed decision. Information on food labels shall not be false or misleading to consumers.

The growing interest of novel food, especially cell-based and precision fermentation, influences Thailand to develop more innovative food products. There is an ongoing process to establish a guideline for cell-based food safety assessment and additional requirements for critical control points in the facilities manufactured these innovative foods to ensure the safety and suitability of the product.

United Arab Emirates

Through its National Food Safety Committee, the Ministry of Climate Change & Environment (MOCCAE) is working with its partners on implementing Federal Law No. 10 of 2015 on Food Safety and its executive regulations, which includes strict controls and standards to ensure food safety throughout the food chain. The law aims at establishing and developing systems to monitor and inspect food, its facilities and at entry ports, creating a national food accreditation and registration system, establishing of a rapid food and feed alert system throughout the food chain, developing mechanisms for the exchange of information at the national and global levels, as well as raising community awareness of best food practices.

Ministry of Industries and Advanced Technologies (MoIAT) is responsible for issuing national standard (such as UAE.S 5048:2021: general Requirements for Novel Foods) through technical committees and specialized working groups that include representatives of relevant entities in the industrial, commercial, and service sectors, research and educational institutions, and government authorities. MoIAT oversees the UAE National Enquiry Point for the Technical Barriers to Trade (TBT) Agreement, its responds to inquiries on standards and notifies WTO of standards projects. Also, MoIAT is the contact point of codex.

Cell based food falls under UAE.S 5048:2021: general Requirements for Novel Foods. UAE.S 5048:2021 stated the general requirement for importing manufacturing and marketing a novel Food. novel Food undergoes a pre-marketing evaluation regarding risk analysis and health and safety considerations, including carrying out the necessary laboratory tests prior to handling and marketing. No novel food should be traded or marketed unless the requirements of this standard have been met and the approval of the competent authorities (permit to put a novel food in the market) has been obtained.

United Kingdom of Great Britain and Northern Ireland

The regulatory requirements mirror the EU legislation on a range of various regulatory topics including and not limited to labelling issues. Relevant risk assessment and decision-making procedures take place at the national level, except for Northern Ireland, which continues to abide by European Union rules and procedures for authorization (FSA, 2020). Relevant information on preparation of cell cultivated protein applications can be found on line: Cell-cultivated products, the Food Standards Agency.

Uruguay

In accordance with the provisions of Law 19.924 and its modification through Law 20.212 of 6th November 2023, in its articles 292, 292BIS, and 292TER, a five-year ban is established on the import, manufacture, and commercialization in the country of products intended for human consumption that are substitutes for meat and artificially produced in a laboratory through the cultivation of animal-origin cells. This prohibition does not apply to cases where these products are imported or manufactured for scientific or academic research purposes.

According to the same regulation, a Monitoring Commission is created within the Ministry of Industry, Energy, and Mining to monitor the development and evolution of food production technology through the cultivation of animal cells in laboratories. This commission consists of representatives from the Ministries of Industry, Energy, and Mining (MIEM, chair); Public Health (MSP); Livestock, Agriculture, and Fisheries (MGAP); Foreign Affairs (MRREE); Environment (MA); and the National Council for Innovation, Science, and Technology (CONICYT).

The Commission's main responsibilities are to advise the Executive Authority on studies related to the production of these foods, assess human health aspects, evaluate their impact on the environment and on the competitiveness of the export sector, as well as monitor the evolution of the international market and the regulations governing these products in relevant markets. Before the expiration of the ban, the Commission must submit a final report to the Executive Authority on the state of the art regarding the production, consumption, commercialization, and import of these foods.

Finally, the law provides that if individuals or legal entities were already engaged in the activities banned by the law at the time it came into effect, for at least two years, they will be granted an additional two-year period to adjust their products or services without incurring liability for infringement, as long as they comply with certain conditions.

United States of America

In the United States of America, jurisdiction over cell-based human food products is dependent on the animal from which developers derive the cultured cells. HHS-FDA has sole responsibility for the oversight of human foods derived from animals other than livestock, poultry, or Siluriformes fish. This includes all foods derived from the cells of seafood (except Siluriformes fish). HHS-FDA also has sole jurisdiction over the production of all cell-based foods for animals, such as pet foods and other animal feeds, regardless of the source of the cells.

In 2019, HHS-FDA and USDA-FSIS established a joint regulatory framework for the oversight of animal cell cultured human food products derived from livestock, poultry, and Siluriformes fish. Under this agreement, the HHS-FDA oversees the initial stages of production, including the collection, banking, growth and differentiation of cells for livestock, poultry, and Siluriformes fish. A transition from HHS-FDA to USDA-FSIS oversight occurs during harvest. The USDA-FSIS then oversees the processing, packaging, and labelling of the resulting meat and poultry food products. For foods comprising cultured cells from non-amenable species (e.g., seafood (other than Siluriformes fish), game meat), HHS-FDA will oversee processing, packaging and labelling in addition to the culture process.

Developers of cell-based human food products complete a pre-market consultation with HHS-FDA, which will typically address the production process employed, including material inputs, and the safety of the resulting cell-based product (i.e., the harvested cell material). If these consultations on the safety of the cell-based product are successful and once commercialization has begun, the HHS-FDA will initiate inspections for the production process of products under its exclusive jurisdiction. HHS-FDA will conduct premarket inspections or other assessments to cover the establishment of preharvest manufacturing controls (e.g., cell collection, cell banking, and proliferation and differentiation through harvest) and post-market inspections covering the implementation of the preharvest controls.[9] To date, FDA has completed two pre-market consultations. FDA maintains an inventory of completed consultations where stakeholders can view the disclosable portion of a firm's safety narrative, any applicable amendments submitted by a firm, FDA's scientific memorandum, which documents FDA's evaluation of safety data and information submitted by a firm, as well as FDA's response letter.

Upon completion of a pre-market consultation with FDA, developers of cell-based food products derived from livestock, poultry, and Siluriformes fish must take the additional step of applying for a grant of inspection from USDA-FSIS. They must also undergo FSIS' new technology review process to assess suitability of any new ingredients or new applications of previously approved ingredients, including processing aids. USDA-FSIS also needs to review and approve any labels for cell-based meat and poultry food products before labels can be used on products in commerce. USDA-FSIS will, at the time of harvest, initiate inspections of the establishment's harvest or processing operations. USDA-FSIS also conducts product and environmental sampling in such establishments as part of inspection. Developers must ensure that sanitation and quality control procedures (e.g., HACCP) are in place for the production, harvest, and processing of such products.

The labelling of cell-based meat and poultry food products is within the USDA-FSIS' jurisdiction, whilst that of other cell-based foods is within that of the HHS-FDA. Both agencies coordinate on labelling policy for animal food products derived from cultured cells and both agencies have announced their intention to address the labelling of these products. HHS-FDA published a "Request for Information" in October 2020 in which it requested comments for "the labelling of foods comprising or containing cultured seafood cells." HHS-FDA

[9] For products under sole FDA jurisdiction (e.g., products that are not derived from livestock, poultry, and Siluriformes fish), FDA will conduct inspections of the entire production process.

intends to use the information and data resulting from this notice to determine what type(s) of actions, if any, the agency should take to ensure that these foods are properly labelled. Likewise, USDA-FSIS issued an "Advance Notice of Proposed Regulation (ANPR)" in 2021 to solicit public comments and information on the labelling of cell-based products under its jurisdiction. Specifically, USDA-FSIS' ANPR solicited input as to whether terms are needed to discern cell-based products from conventionally produced products, which terms should be in the product name of a food containing cultured livestock or poultry cells, which terms could be potentially misleading if names refer to the shape, form, parts, or cuts of meat or poultry food products (e.g., fillet, steak, wing), and which names could have a negative impact on consumers and industry. It also sought input on the labelling of blended products (those containing both cell-based and conventionally produced meat or poultry) and if the legal definitions of meat and poultry products should be amended so as to include or exclude foods derived from cultured animal cells.

Later this year, USDA-FSIS intends to issue labelling guidance to provide information to establishments on how to label cell-based meat and poultry food products and intends to publish a proposed rule to establish regulatory requirements for the labelling of such products. The proposed rule will include a summary of the input FSIS received in response to its ANPR. As noted in the ANPR and above, the labels of all products subject to USDA-FSIS jurisdiction, including cell-based meat and poultry food products, must be approved by USDA-FSIS prior to use in commerce.

Regulatory snapshot of 2024: precision fermentation

Similar to the regulatory snapshot on cell-based food, the TWG members have also shared the relevant information about the regulatory status, activities and considerations on the topic of **precision fermentation** derived food products (Table 2).

Table 2. Summary of the regulatory snapshot on precision fermentation (PF) in the country contexts (as of July 2024). The original full table is available in the Annex.

Country / jurisdiction	PF definition	PF-specific regulations	Other applicable regulations	Pre-market food safety assessment	Food safety assessment guidelines	Pre-submission consultation	Categorization of PF products (e.g. additives, ingredients)	Labelling requirements specific to PF	PF derived products on the market
Argentina	No	No	Yes	Required	Not mentioned	Available	Depends on the intended use	Not specific to PF	Yes
Australia	No	No	Yes	Required	Yes	Available	Depends on the intended use	Not specific to PF	Yes
Brazil	No	No	Yes	Required	Yes	Available	Depends on the intended use	Not specific to PF	Yes
Canada	No	No	Yes	Required	Yes	Available	Depends on the intended use	Yes	Yes
Chile	No	No	Not mentioned	Required	Internal guidelines exist	No	Depends on the intended use	Not specific to PF	No
China	No	No	Yes	Required	Yes	No	Depends on the intended use	Not specific to PF	Yes
European Union	No, but a working definition exists	No	Yes	Required	Yes	Available	Depends on the intended use	Not specific to PF	Yes
Guatemala	No	No	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned
Indonesia	No	No	Yes	No	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned
Iran (Islamic Republic of)	No	No	Yes	Required	Yes, but not specific to PF	No	Depends on the intended use	Not specific to PF	Yes
Israel	No	No	Not mentioned	Required	Yes	Available	Depends on the intended use	Not specific to PF	Yes
Japan	No	No	Yes	Required if GMO is used	Yes but for GMO only	Available	Depends on the intended use	Not specific to PF	Yes

New Zealand	No	No	Yes	Required	Yes, but not specific to PF	Strongly advised	Depends on the intended use	Not specific to PF	Yes
North Macedonia	No	No	Yes	Not mentioned	No	Available	Depends on the intended use	Not specific to PF	Yes
Qatar	No	No	Yes	Required	Yes	No	Depends on the intended use	Not specific to PF	No
Republic of Korea	No	No	Yes	Required	Yes	Available	Depends on the intended use	Not specific to PF	Yes
Saudi Arabia	No	No	Yes	Required	Not mentioned	Not mentioned	Not mentioned	Not specific to PF	No
Singapore	No, but a working definition exists	No	Yes	Required	Yes	Encouraged	Depends on the intended use	Not specific to PF	Yes
Switzerland	No	No	Yes	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned	Not mentioned
Thailand	No	No	Yes	Required	Not mentioned	Not mentioned	Not mentioned	Not specific to PF	Not mentioned
United Arab Emirates	No	No	Yes	Required	Yes	No	Depends on the intended use	Not specific to PF	Yes
United Kingdom of Great Britain & Northern Ireland	No	No	Yes	Required	Yes	Encouraged	Depends on the intended use	Not specific to PF	Yes
United States of America	No	No	Yes	Voluntary but strongly encouraged	Yes	Strongly encouraged	Depends on the intended use	Not specific to PF	Yes

Ongoing initiatives by FAO and WHO

Precision fermentation with a focus on food safety: Together with the information shared by TWG, FAO is currently conducting a literature synthesis on food safety aspects of precision fermentation, and the in-depth analysis will be published in late 2024 or early 2025 on the nomenclature / definition issues, production processes and regulatory frameworks.

Report on the legal issues related to cell-based food and precision fermentation-derived products: FAO is in parallel working on a report that provides an overview of the regulatory frameworks concerning these food technologies. The objective of this report is to examine the legislative considerations and challenges that national regulators and policymakers face regarding cell-based and precision fermentation-derived food products and to identify existing legislative trends in key jurisdictions, providing a non-exhaustive landscape of current regulations. The report will cover existing areas of international and national law to focus on areas where legal uncertainty and complexities arise. By analysing these areas, the study seeks to offer insights into the evolving regulatory landscape and highlight potential areas for future governance and regulatory developments around cell-based food and precision fermentation-derived products.

At the international level, the report highlights the relevance of existing legal instruments – such as the Codex Alimentarius standards, WTO agreements, which impact food safety, international trade, and labelling, as well as the Cartagena Protocol on Biosafety – in relation to the production of cell-based food and precision fermentation-derived products. Also, the intellectual property and human rights implications of cell-based food and precision fermentation are explored.

On the national level, regulatory frameworks for cell-based and precision fermentation-derived products are varied, with different approaches taken by countries. Food safety, -pre-marketing authorisation, and coordination among regulatory bodies are key areas where different countries have often adopted distinct regulatory pathways. Additionally, the report explores how product-specific or vertical food regulations, such as those related to animal-derived foods, are being adapted to accommodate cell-based products. The report also looks at how legislation deals with the import/export of these food products and their production materials, and to a lesser extent with health and nutrition claims and labelling.

Overall, the report underscores the diversity of regulating cell-based and precision fermentation-derived products across multiple legal domains, highlighting areas where further legislative developments may arise on the national and international levels. The report will be accompanied by a comparative section that explores current modes of regulating cell-based and precision fermentation food products on the national level. Publication is planned for 2025.

Conclusions and next steps

While the 2023 FAO/WHO publication on food safety aspects of cell-based food has extensive results of hazard identification for food safety risk assessment, it is only the first step of the formal risk assessment process within the food safety risk analysis paradigm. To conduct a proper risk assessment, it is essential to collect a sufficient amount of scientific data and information that is required for exposure assessment and risk characterization. To this aim, competent authorities may wish to collaborate with other countries and jurisdictions to share the regulatory approaches and experiences so that data and insights required for safety assessment can be complemented.

Safety assessment of cell-based foods and the one of precision fermentation-derived food products may have some similarities, but can be fundamentally and completely different, depending on the exact production processes of each product. Therefore, active engagement of stakeholders is useful to maintain the transparency for the overall regulatory actions, as well as informed decision making that are based on science.

In order to safeguard the health of consumers and to facilitate global discussions on the topic of cell-based food, FAO and WHO will continue to develop the scientific advice for their Members. FAO and WHO remain available for further technical support and engagement for effective knowledge transfer and dialogue facilitation.

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Annex

Original regulatory snapshot table on Precision Fermentation (PF) filled by the countries participating in the informal Technical Working Group (As of July 2024)

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
Argentina	No official definition for precision fermentation	No specific regulation for precision fermentation, regulation for microorganisms is present	Not specific for precision fermentation	Required, but not specific for precision fermentation	Several enzymes are on the market, purified products	Either, depending on the products	No specific requirements for labelling	
Australia	No official definition for precision fermentation	No specific regulations for precision fermentation products. Precision fermentation products derived from GM microorganisms are regulated as food produced using gene technology under Standard 1.5.2 in the *Australia New Zealand Food Standards* Code which is developed and maintained by Food Standards Australia New Zealand (FSANZ). Other food standards may also apply, for example if the PF product is intended for use	Pre-market approval is required for food produced using gene technology, food additives, nutritive substances and processing aids. Pre-application assistance is available by contacting FSANZ directly. Further information available from: https://www.foodstandards.gov.au/food-standards-code/changing-the-code/pre-application-assistance	Guidelines and data requirements for food safety assessment of various substances and food ingredients are set out in the FSANZ Application Handbook: https://www.foodstandards.gov.au/sites/default/files/2023-11/Application%20Handbook%20at%201%20July%202019.pdf	A number of approved food additives, enzyme processing aids and nutritive substances derived using precision fermentation are likely in foods for sale in Australia, for example various steviol glycoside sweeteners, food enzymes and a number of human identical milk oligosaccharide substances. FSANZ has also approved soy leghemoglobin as a nutritive substance in meat analogue	See previous answers – most of the precision fermentation products approved to date are food additives, enzyme processing aids or nutritive substances.	There are no labelling requirements specifically related to precision fermentation. Standard ingredient labelling requirements apply such as for food additives or nutritive substances. GM labelling may also apply if novel DNA or novel protein is present in the food for sale. The FSANZ assessment will also consider whether additional labelling will also apply, e.g. allergen labelling.	Through pre-application discussions FSANZ is aware of a number of other precision fermentation products that are in the pipeline for submission to FSANZ over the next 12 months.

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		as a food additive, a nutritive substance or a processing aid. The relevant food standards are joint food standards with New Zealand.			products such as the Impossible burger.			
Brazil	No official definition	There is no specific legislation for precision fermentation. Food ingredients obtained from GMO are regulated under the same resolution for novel foods ingredients - RDC 839/2023 (https://antigo.anvisa.gov.br/documents/10181/6582266/RDC_839_2023_.pdf/a064b871-55dd-44b9-ab40-16ca7672497d) In case of additives, the legal requirement to be met is RDC 778/23 (https://antigo.anvisa.gov.br/documents/10181/656	A pre-market approval is necessary for any novel food ingredients or additives. For novel foods a consultation is possible (https://consultas.anvisa.gov.br/#/consultadeassuntos/detalhe/4144?codigosAssunto=4144).	Yes, the applicant must follow Guide 23/2019 (https://antigo.anvisa.gov.br/documents/10181/5355698/Guia+23_2019_vers%C3%A3o+1_de+23+07+19.pdf/96bc484d-2bde-4c99-9296-65c9325a033a).	Yes. 2'fucosyllactose, glucosamine, 6'-sialyllactose sodium salt	Food ingredients produced from GMO can be novel foods (nutritive purpose) or additives/processing aids. (technological function)	No specific labelling as precision fermentation derived product.	

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		1857/RDC_778_2023_COMP.pdf/1d50d56f-3aa1-4a62-8e19-f56068cc7337) Also, genetically modified organisms (GMOs) are regulated by Brazilian Biosecurity Law 11.105/2005.						
Canada	No official definition	Any food ingredient for nutritive purposes produced from an organism genetically modified to change the organism's characteristics meets the definition of Novel Food and is subject to the pre-market provisions under the *Food and Drug Regulations* B.28 (*Novel Food Regulations*)	Petitioners preparing a Novel Food pre-market submission are encouraged to request a pre-submission consultation by contacting the Submission Management Information Unit (smiu-ugdi@hc-sc.gc.ca). The consultation meeting is a voluntary service allows petitioners to ask questions about the pre-market process their intended approach for meeting safety end-points.	Yes. See Guidelines for the Safety Assessment of Novel Foods - Canada.ca section 4.2.3 for GM microbes. For products produced using cultured cells other than microbes, please consult SMIU.	Yes. 2'fucosyllactose, soy leghemoglobin, beta-lactoglobulin	Food ingredients produced from GM organism and are for nutritive purposes are Novel Foods. Products for other food uses could be classified as food additives or processing aids. Consultation with Food Directorate is recommended for any questions regarding classification.	Under federal law, all foods sold in Canada, including any approved product of cellular agriculture such as precision fermentation derived products, must be labelled so that they will not be mistaken for another food. The label must have the food's common name that is specific and accurately identifies or describes the food in clear terms to allow a person to make an informed purchasing decision. All label information must be truthful and not	n/a

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
							misleading, including any health- or environment-related claims. Other food labelling rules may also apply, such as labelling for health and safety (i.e., allergen labelling) and compositional standards of identity. They would apply on a case-by-case basis.	
Chile	No.	No. Chile does not have any specific legislation for precision fermentation.	No relevant legislation.	For any food product that the Chilean health authority does not have history record of safe consumption, the health authority asks food businesses for some additional tests to have the production process approved. These tests depend on the nature of the food products, for example, toxicological tests. There are internal guides established by the central level of the Ministry of	No, but there are some enterprises in the country that are innovating in this area (and the government is expecting to set up regulatory frameworks accordingly)	No specific regulations.	No specific regulations.	There is a definition of “new food” in the Chilean legislation. ACHIPIA is assisting the Ministry of Health to make a specific regulator framework for new foods with relevant definitions, an approval process and criteria for approval. The current definition is: “New food, ingredient and food material: that food, ingredient and

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
				Health, so that the local health authority applies these criteria, but there is no specific regulations. Usually these processes take a long time and there are no homologous criteria regarding the requirements to approve the products for consumption.				food material obtained through physical-chemical synthesis process or through processes that occur in nature that do not correspond to molecule or compound typical of known human nutrition."
China	No. At present, there is no definition of "precision fermentation" in China's relevant national food safety standards, but for some products of precision fermentation, China is allowed to use. For example, some food additives and nutritional fortifiers produced by genetically modified microorganisms have been approved for use.	No specific one. However, China Food Safety Law asked National Health Commission (NHC) to carry our pre-market approval of following three new food products, novel foods/new food ingredients, new food additives, new food related products. NHC allow to use new technologies, such as precision fermentation to produce the enzymes and ingredient with genetically modified	Yes. In China, three new food products (novel foods/New Food Ingredients, new food additives, new food related products) using new technologies, such as precision fermentation, need the pre-market approvals.	Yes. At present, for food additives and nutritional fortifiers produced by genetically modified microorganisms, the safety of the strains produced is mainly based on the relevant management documents of genetically modified microorganisms of the Ministry of Agriculture and Rural Affairs. Now CFSA is studying the classification and management measures for novel foods, novel foods and new food-related products	Yes. Some food additives and nutritional fortifiers produced by genetically modified microorganisms have been approved for use. For example: HOMs produced by microbial fermentation. Up to now, China has approved 2-FL and 1 LNnT produced by 4 different strains, which can be used as nutritional fortifiers for children's milk	They are usually food additives and nutritional fortifiers. New food ingredients will come soon.	Such substances are managed in accordance with food additives in China, and their labeling should comply with the GB29924 National Food Safety Standards General Principles for the Labeling of Food Additives". If new food ingredients, GB7718 should be comply with National Food safety standards for food labelling.	

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		microorganisms. However, at present, for food additives and nutritional fortifiers produced by GMO and synth-biology technology , the safety of the producing strains is first evaluated by the Ministry of Agriculture, mainly based on the relevant management documents of GMO. After issuing the GMO biosafety certificate, NHC take the pre-market approval after the CFSA risk assessment.		produced by genetically modified microorganisms or precision fermentation, and establishing the related guideline based on classification.	powder, infant formula, etc.			
European Union	No legal definition. In the absence of a legal definition and for the purpose of the 27th EFSA's Scientific Colloquium on "Cell culture-derived foods and food ingredients", EFSA defined	No specific regulation for PF-derived foods. In the EU, food ingredients derived from PF require pre-market authorisation under different regulatory frameworks and are subject to risk	For novel foods a consultation is possible in the case that food business operators would be unsure on whether or not a food which they intend to place on the market within the EU falls within the scope of the Novel Foods	Yes, EFSA guidance documents for: Novel foods (https://www.efsa.europa.eu/en/applications/novel-food-traditional-food/regulationsandguidance) GMMs: https://www.efsa.e	Yes. This counts e.g. for common food additives (vitamins, colorants) and enzymes from precision fermentation, that are already on the market for a long time.	This This depends on nature and use of the product, see column C.	No specific labelling as precision fermentation derived product. If a PF product falls under the GMO legislation (See column C), the GMO labelling provisions apply.	

Country / jurisdiction	Definition	Specific regulations	Pre-market food safety assessment	Safety assessment guidelines	Products on the market	Categorization of the products (additives or ingredients)	Labelling requirements	Additional information
	precision fermentation (PF) as the use of engineered microbial cell factories in the production of food ingredients.	assessment by EFSA. • Food additives and flavourings fall under the scope of Regulations (EC) No 1331/2008, 1333/2008 and 1334/2008, • Food enzymes under Regulation (EU) 1332/2008, • Novel foods under Regulation (EU) 2015/2283, • Genetically modified organisms (GMOs) under Regulation (EC) No 1829/2003.	Regulation. But it is not specific to precision fermentation products., https://food.ec.europa.eu/safety/novel-food/consultation-process-novel-food-status_en In addition, general pre-submission advice by EFSA is available, together with other dedicated services for potential applicants. https://www.efsa.europa.eu/en/applications/about/services	uropa.eu/en/efsajournal/pub/2193 Food additives: https://www.efsa.europa.eu/en/efsajournal/pub/2760 Food enzymes: https://www.efsa.europa.eu/en/efsajournal/pub/6851 FYI, EFSA is currently developing a horizontal guidance on the risk assessment of microorganism intentionally added to the food chain, in order to harmonise the scientific requirements for the risk assessment across regulatory sectors. This guidance is relevant for precision fermentation derived products.	With regards to Novel foods i) Ice-structuring protein (ISP) type III (originally isolated from *Macrozoarces americanus*), produced by precision fermentation, was authorised in 2009. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009D0344 ii) Several human-identical milk oligosaccharides (HiMOs) produced by precision fermentation are already authorised as novel foods (2'-fucosyllactose, 3-fucosyllactose, 2'-fucosyllactose / difucosyllactose mixture, lacto-N-tetraose, lacto-N-neotetraose, 3'-		Note: general labelling requirements or restrictions may exist. E.g. food additives need to be mentioned as ingredient on a label. Precision fermentation derived dairy products cannot be named as e.g. milk or cheese.	

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					sialyllactose sodium salt and 6'-sialyllactose sodium salt). In addition, a lacto-N-fucopentaose I / 2'-fucosyllactose mixture has already been assessed by EFSA with positive outcome.			
Guatemala	No specific definition	No specific regulation for precision fermentation						
Indonesia	No	No specific regulation, but Food Law 86 of 2019, of the Indonesian Food Authority.	No specific pre-market assessment for these products.	General Food safety assessment is required for new food products entering the market, as well as halal evaluation				
Iran (Islamic Republic of)	No official definition	Fermented food products have its own regulation in Iran (Islamic Republic of), no specific regulation for precision fermentation	Pre-market approval is necessary for fermented products	Assessment conform Biosafety Law and regulations for GMOs	Yes. Fermentation derived enzymes and food products		Labelling requirements for fermented products, not specific to precision fermentation	
Israel	No legal definition.	No specific regulation for - precision	pre-market approval is needed in case of novel food but not	general guidelines for novel food are available in	yes. Food additives and HMO that are derived from	it depend on the intendent use, there are food	no specific labelling.	

Country / jurisdiction	Definition	Specific regulations	Pre-market food safety assessment	Safety assessment guidelines	Products on the market	Categorization of the products (additives or ingredients)	Labelling requirements	Additional information
		fermentation derived foods.	specific to precision fermentation. For novel food consultation is possible but it is not set in the regulation.	Hebrew on the NFS website.	precision fermentation are on the market for quite some time.	additives but also ingredients.		
Japan	No official definition for precision fermentation.	No specific regulations for precision fermentation products. The safety assessment of foods and food additives produced by recombinant DNA techniques (hereafter GM foods) is mandatory under the Food Sanitation Act. Further information available from: https://www.caa.go.jp/en/policy/standards_evaluation/dna_techniques	No specific regulations for precision fermentation products. In the case of GM Foods, pre-market approval is required, and the applicant can request a prior consultation in order to confirm whether such foods, etc. fall under a target of notification or safety assessment.	In the case of GM foods, the following guidelines would apply. See Guideline; https://www.fsc.go.jp/senmon/idensi/gm_kijun_english.pdf https://www.fsc.go.jp/senmon/idensi/index.data/Standards_GM_microorganism.pdf https://www.fsc.go.jp/senmon/idensi/gm_tenkabutukijun_english.pdf https://www.fsc.go.jp/senmon/idensi/gm_hitanpakutenkabutu_kijyun_english.pdf	No official definition for precision fermentation. The GM foods and food additives which completed safety assessment are available to use and distribute on the market.	Depending on the final use of the product, it may be considered as food additive or ingredients.	No official definition for precision fermentation.	
New Zealand	No legal definition for precision fermentation.	No specific regulations have been identified for precision fermentation in NZ, but the food safety framework	The use and sale of food/substances derived from precision fermentation requires pre-	Guidelines on the pre-market approval process as well as data requirements for different product categories (e.g.	The FSANZ process has approved: soy-based 'heme' (Soy	To date: Soy Leghemoglobin) approved as a nutritive substance (iron in the form of soy leghemoglobin)	No specific labelling currently for precision fermentation-derived products. In New Zealand, food labelling	

Country / jurisdiction	Definition	Specific regulations	Pre-market food safety assessment	Safety assessment guidelines	Products on the market	Categorization of the products (additives or ingredients)	Labelling requirements	Additional information
		allows for additional regulation to be developed as identified and needed to address new risks introduced by food processing. Precision processing is seen as a food production process that is subject to regulation. Food safety requirements are risk-based and a processor would need to prove their method produced a safe and suitable/fit for purpose product. Once permission for a novel food has been granted, and a processor applies to make it in New Zealand, the processor needs to meet food/product processing requirements; including validating product safety	market approval by Food Standards Australia and New Zealand (FSANZ). Depending on the nature and intended use, the final product may be approved as food produced using gene technology, food additives, processing aids and/or nutritive substances. Most PF products are regulated in the Australia and New Zealand Food Standards Code (the Code) as foods produced using gene technology . Other regulations relating to food additives and processing aids may also apply. FSANZ strongly advise applicants to arrange a meeting with FSANZ to discuss their application prior to submission.	food additives, nutritive substances, food produced using gene technology) are available in the 'FSANZ Application handbook': https://www.foodstandards.gov.au/food-standards-code/consultation/applicationshandbook	Leghemoglobin); Lacto-N-neotetraose (LNnT); 2'-Fucosyllactose (2'FL) - produced by microbial fermentation using a genetically modified (GM) strain of Escherichia coli K-12; Rebaudioside M as a steviol glycoside; Precision fermentation-derived enzymes	for use in meat analogue products; Lacto-N-neotetraose (LNnT) is approved as nutritive substance added to infant formula products; 2'-FL as a nutritive substance for use in infant formula products; Rebaudioside M as a steviol glycoside food additive; Enzymes as processing aids. Precision fermentation products meet the definition of 'food' in NZ legislation, and the system enables them to be categorised according to the food sector they are developed by.	requirements are set through the Code. A FSANZ assessment would identify any changes needed to the Code for product labelling. Where there is a GM component to substances produced using precision fermentation, and novel DNA or novel protein is present in the food for sale, there is a requirement to label the ingredient as 'genetically modified'	

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		and suitable or fitness for purpose. MPI provides guidance: https://www.mpi.govt.nz/food-business/running-a-food-business/risk-management-programmes-rmps/develop-a-risk-management-programme/ And https://www.mpi.govt.nz/food-business/running-a-food-business/food-control-plans/custom-food-control-plans/						
North Macedonia	No legal definition.	Foods derived by precision fermentation are generally considered novel foods in North Macedonia. Thus, they need to comply with the requirements concerning novel foods provided in the Law on food safety and the	Pre-submission consultation is available for all novel foods in case food business operators are unsure on whether or not a food which they intend to place on the market in North Macedonia falls within the	No guidelines are currently available.	Yes, precision fermentation – derived food ingredients considered as novel foods which are authorized by the EU and included in the Union list of novel foods can be placed on the market in	Depending on the proposed use of the product and in line with the adopted EU authorizations. Generally, they are considered novel foods, but may also be considered food improvement agents (additives, enzymes).	No specific labelling requirements for precision fermentation ingredients other than those specified in the Union list of novel foods (EU Regulation 2470/2017) which is transposed in the	

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		Rulebook of specific requirements for safety of novel foods (OG of RNM 173/2020) which is aligned with EU Regulation 2283/2015. Novel foods require pre-market authorization in North Macedonia.	scope of the novel foods. Rulebook on the consultation process for novel foods is planned to be adopted by the end of 2026 but it is not specific to precision fermentation-derived novel foods.		North Macedonia as well. These mostly fall in the category of HIMOs, such as 2'-fucosyllactose, 3'-fucosyllactose, 3'-sialyllactose sodium salt etc.		national legislation.	
Qatar	No	Novel food standard GSO 2696:2022	Yes, it must be evaluated by SC regarding its safety and suitability	There is a procedure that must be followed according to the relevant GSO standard 2696:2022	No, any food or ingredients issued from Genetically modified bacteria or microbes are not yet allowed in Qatar	We do not have any official definition for precision fermentation products	Yes, all ingredients should be presented clearly to the consumer	There are some precision fermentation products that are in the process of being evaluated from a food safety perspective
Republic of Korea	No official definition	New food ingredient derived from precision fermentation is subject to 'Standards for Approval of Temporary Standards and Specifications for Foods, etc.' under Food Sanitation Act (Article 7.2) for	Yes. There is a division called the Pre-submission Consultation Division in MFDS and applicants can receive consultation when applying to that division.	Yes. 'Guideline for safety assessment of new food ingredients' and 'Explanation of safety assessment regulations for genetically modified foods' for in Korean is on the Ministry of Food and Drug Safety website. https://www.mfds.go.kr/brd/m_1060/li	Yes. 2-fucosyl lactose	Usually considered as food ingredients	No specific labelling as precision fermentation derived product. Basically, the name of ingredient used in foods shall be labelled under Act on Labelling and Advertising of Foods.	

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		safety assessment.		st.do?multi_itm_seq=0&board_id=data0011&seq=&data_stts_gubun=C9999&srchTp=0&srchWord=%EC%8B%9D%ED%92%88%EC%9B%90%EB%A3%8C				
Saudi Arabia	No	There are general technical regulations, standards and guidelines of food product safety, labelling, and additives and others that apply to all food products marketed or sold in Saudi Arabia. In addition, there is a specific technical regulation for Novel Foods: • SFDA.FD 5013 : General Requirements for Novel Foods. and Technical regulations for Genetically Modified Organisms:	Generally, food products that are considered novel, such as those containing new ingredients or innovative production techniques, may require pre-market approval from the Saudi Food and Drug Authority before they can be imported, manufactured, or sold in Saudi Arabia. In many jurisdictions, including Saudi Arabia, the regulatory framework for novel food products, including those derived from precision fermentation, depends on factors such as	Novel foods are subject to scientific evaluation process to ensure their safety and effectiveness in producing a product suitable for human consumption. This procedure takes place before authorizing the marketing of the novel food product	No		No, but there are general requirements for labelling of prepacked foodstuffs and it depends on the product requirements. SFDA.FD/GSO 9: Labelling Of Prepackaged Food Stuffs.	When it comes to cell-based food products, Saudi Arabia is not only concerned about ensuring the safety of these products for the consumer, but we're also keen to study the religious aspect of such products. Therefore, currently Saudi Arabia is leading the Islamic view file on 2 levels: 1. Islamic member countries under Standards and Metrology Institute for Islamic Countries (SMIIC). 2. Gulf member countries under GCC

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		• SFDA.FD/GSO 2141: General Requirements for Genetically Modified Unprocessed Agricultural Products. • SFDA.FD/GSO 2142: General Requirements for Genetically Modified Processed Food and Feed. • SFDA.FD/GSO 2143: General requirements for risk assessment and traceability for genetically modified products. • SFDA.FD/GSO 2371: General requirements for risk assessment and traceability for	their safety, composition, intended use, and similarity to existing food products. Guide to The Approval of Novel Foods – link.					Standardization Organization (GSO).

Country / jurisdiction	Definition	Specific regulations	Pre-market food safety assessment	Safety assessment guidelines	Products on the market	Categorization of the products (additives or ingredients)	Labelling requirements	Additional information
		genetically modified products.						
Singapore	No official definition. Working definition of precision fermentation is ingredients that are chemically identical to naturally occurring substances but produced by unconventional processes.	Product of precision fermentation could be evaluated as novel foods. Novel foods are required to undergo pre-market safety assessment before being allowed for sale. Requirements for safety assessment are detailed in SFA's novel food guidance document. SFA is currently in process of public consultation for the Food Safety and Security Bill (FSSB), which amongst other matters, will seek to formalize the need for companies to seek pre-market approval for novel foods. Where substances	SFA will direct companies intending to sell novel foods to attend the SFA Novel Food Clinic to better understand SFA's requirements. For companies that are intending to sell food additives produced with precision fermentation, SFA encourages these companies to review SFA's guidance document on food additives and engage with SFA early on their plans.	Novel food companies applying for application of precision fermentation products can refer to the SFA Novel Food guidance document (specifically Section 4.2-4.3) and also fill up the self-assessment checklist for precision/biomass fermentation processes.	Yes, in the area of food additives, various food enzymes that are derived from precision fermentation have been listed as permitted food additives in the Singapore Food Regulations. In the area of novel foods, Beta-lactoglobulin is an example of a novel food produced by precision fermentation that has been previously assessed and allowed for sale as a novel food ingredient.	This is dependent on the intended use proposed by the developer.	There is currently no specific labelling requirement for a precision fermentation derived product. Labels should be truthful and not misleading, e.g., beverage containing whey protein made using precision fermentation should not be labelled as milk from cows. Allergen labelling is still required for substances that are chemically equivalent to existing allergens.	

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		derived from precision fermentation are intended to be used as food additives (i.e. their addition is intended to fulfill a specific technological function), companies are required to apply for the inclusion of their food additive into the Singapore Food Regulations.						
Switzerland	No official definition	No specific regulation, if host is genetically modified then follows GMO regulation, otherwise Novel Foods regulation, which are based on EU regulations and guidance by EFSA						
Thailand	No official definition	There is no specific regulation for cell-based food in Thailand. However, any food manufactured with the novel	-	For cell-based and precision fermentation, safety assessment of the product shall be evaluated prior to product registration and submission of the	-	-	No specific labelling as precision fermentation derived product. Labeling of novel food shall follow the Notification of the Ministry of	Thailand is on the process to develop the guideline for cell-based food safety assessment and additional requirements for

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		process such as, in this case, precision fermentation may or may not fall under the Notification Number 376 depending on the output or finished products of the process. Novel Food Registration is enforced by the Notification of Ministry of Public Health No. 376 issued in 2016, which defined Novel food as a substance (both finished product or a single ingredient) or an innovative process to produce food.		label to Food and Drug Administration for approval before use. There is no specific regulations or guidance on labelling for cell-based and precision fermentation.			Public Health No. 367 regarding labeling of prepackaged foods packaged for both imported and domestically produced food products. Indication of ingredient source shall be expressed on its label to help with the consumer's choice. Information on food labels shall not be false or misleading to consumers.	critical control points in the facilities manufactured these innovative foods to ensure the safety and suitability of the product.
United Arab Emirates	No official definition	No specific regulation for precision fermentation derived foods. Any food ingredient derived from precision fermentation is considered as a Novel Food. Therefore, it falls	YES, Novel Foods undergo a pre-marketing evaluation from the competent authorities with regard to risk analysis and health and safety considerations, including carrying out the necessary	YES, There is a general framework for risk assessment and requirements for the novel food are stated in UAE.S 5048:2021: General Requirements for Novel Foods	YES, Several types of Genetically Modified foods are available in UAE markets.	Depending on the final use of the product it may be considered as ingredient or food additive, other.	YES All food labelling in UAE falls under the regulation UAE.S 9: Labelling of Pre-Packed Foods	NA

Country / jurisdiction	*Definition*	*Specific regulations*	*Pre-market food safety assessment*	*Safety assessment guidelines*	*Products on the market*	*Categorization of the products (additives or ingredients)*	*Labelling requirements*	*Additional information*
		under UAE.S 5048:2021: General Requirements for Novel Foods	laboratory tests prior to handling and marketing.					
United Kingdom of Great Britain and Northern Ireland	No official definition	No specific regulation for PF-derived foods. Food ingredients derived from PF likely to require pre-market authorisation where they meet the definition of a novel food , GM or other regulated product. They would be subject to our regulated products service and risk assessment	There is no requirement for pre-submission consultation. Those interested in applying for precision fermentation products are encouraged to engage with the pre-application team to support the development of their application.	For precision fermentation products that are subject to regulated products premarket authorization we continue to use the EFSA guidance. We have also developed a hazard identification for cultured meat which may be useful for informing the development of applications.	Yes, there are a number of products of precision fermentation that were authorized before the UK's exit from the EU. Under the respective regulated products frameworks. We have also authorized a number of products, in particular HMOs for use in the UK market.	The classification of the precision fermented product would depend on the regulatory framework that applied – some are foods, some are additives, and some are GMOs depending on their characteristics, how they are produced and function.	No specific labelling is required for precision fermentation products. Products would be labelled as a GMO or additive where they meet the definition of that regulated product regime. There is the potential to label if there is a risk management need.	
United States of America	No official definition.	Substances produced from precision fermentation are regulated using the same legal provisions to used to regulate the use of other food ingredients. We have tools available to help developers determine the	Yes. We strongly encourage firms wishing to engage in our premarket processes to meet with us prior to making a submission. Pre-submission meetings are typically available upon request and	Yes. We have a wide range of tools available to help developers. We have tools available to help developers determine the regulatory status of a food ingredient and guidance that can be used to inform safety assessment and	Yes. Such products have arguably been on the market since the 1990's when chymosin was produced in a genetically engineered microbe.	Ordinarily substances derived from precision fermentation (purified substances intended to be added to food for a specific intended use) would be considered ingredients and	Whether labeling indicating that a food contains an ingredient that is "bioengineered" may depend on specific aspects of the product and how it is intended to be used. This program is administered by the Department	

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		regulatory status of a food ingredient and guidance that can be used to inform safety assessment and how to make a submission to our programs.	are operated virtually.	how to make a submission to our programs. We also recognized that the Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombiant-DNA Microorganisms may have useful information. Because precision fermentation can be used to produce a wide range of products, we strong suggest that developers meet with us before making a premarket submission to our programs. During such meetings we can point developers to the guidance most relevant to their product.		would be regulated as food additives unless their use is generally recognized as safe. Importantly, however, the fact that a product was or was not produced through precision fermentation is not determinative of its regulatory status.	of Agriculture's Agricultural Marketing Service. Resources for complying with bioengineered labeling requirements can be found here.	