



**Food and Agriculture Organization  
of the United Nations**

# Food safety aspects of cell-based food

Background document **three** – **Regulatory frameworks**



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## Abbreviations and acronyms

AMR	Advanced meat recovery
ANPR	Advance Notice of Proposed Regulation
CEPA	Canadian Environmental Protection Act, 1999
CFIA	Health Canada and the Canadian Food Inspection Agency
DSL	Domestic Substances List
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
FSANZ	Food Standards Australia New Zealand
FSIS	Food Safety and Inspection Service
FSSAI	Food Safety and Standards Authority of India
HACCP	Hazard Analysis and Critical Control Point
LMICs	Low- and middle-Income countries
MSP	Mechanically separated poultry
NSNR	New Substances Notification Regulations
OECD	Organisation for Economic Co-operation and Development
SFA	Singapore Food Agency
SFDA	Saudi Food and Drug Authority
USDA-FSIS	United States Department of Agriculture's Food Safety and Inspection Service
WHO	World Health Organization

## Executive summary

Considering the unique outlook for cell-based food production, many countries may put in place various regulatory requirements for cell-based food products to be sold in the markets. Some may require a pre-market authorization process, which often entails assessment of their safety for human consumption and compliance with national regulations. As of 2022, while there is only a limited number of products authorized in one country only, it is just a matter of time before cell-based food starts being authorized elsewhere and/or transported and traded across borders. It is therefore important to first understand the existing frameworks under which cell-based food products may be regulated. It is also important to identify some specific regulations for food safety purposes, so that some good practices can be recognized and documented. A literature review was conducted to provide the time-bound state of the art on the regulatory frameworks that apply to or would apply to cell-based food products in different countries and jurisdictions. The results of the review serve as a basis for the competent food safety authorities to consider the key elements within their regulatory frameworks for effective national food control systems.

**Keywords:** cultured meat, cultivated meat, cell-based food, alternative proteins, regulatory frameworks, legislation, regulations, requirements, authorization process, food safety, standards



# 1. Introduction

## 1.1. Background

In many countries, the commercialization of food produced using novel innovative technologies requires regulatory authorization before food items enter markets. For this pre-market authorization, various assessments, including a food safety assessment, compliance assessment, environmental assessment and some other socio-economic assessments, are conducted by the relevant competent authorities. Because food safety is one of the key interests for consumers, food safety competent authorities often play an important role in this process to ensure that their regulatory frameworks are sufficient and appropriate to cover the safety assurance of such innovative food products. The majority of the legislative texts and regulations related to food are based on food safety risks, nutrition and consumer concerns; therefore, if newly identified hazards or concerns exist for novel food technologies, adjustments to such legal documents will be necessary.

In recent years, many innovations in food production have focused on the so-called “protein transition”, where more sustainable ways of producing animal proteins and alternative non-animal proteins are sought, in order to accommodate the increasing demand for animal products and ensure global food security (Aiking and de Boer, 2020; Henchion *et al.*, 2021). Cell-based food production that makes use of *in vitro* cultivation of animal cells is one of the main technological developments for this. In addition, the production of analogues of specific animal proteins, such as milk or egg proteins, can be done using microbial production platforms. The first development of such products was presented to the general public in 2013, when researchers from the Netherlands presented the first cell-based beef burger (so called “lab-grown” beef burger) (BBC News, 2013). In December 2020, chicken nuggets containing cell-based chicken became the first commercialized product of the kind, after market approval in Singapore (Carrington, 2020). On a wider scale, the research and development of analogues of animal products, such as meat, poultry, seafood, dairy, and eggs produced through cell-based technologies has been advancing quickly in recent years and a large number of companies are developing similar products in over 22 different countries (Byrne, 2021).

Considering the rapid development in the area of cell-based food, it is important that national competent authorities are prepared for market entry of these products in their jurisdictions and have adequate regulatory frameworks in place. In addition to the core food safety assessments, regulatory considerations may be necessary for other issues such as labelling, consumer preference/acceptance, ethical or religious aspects of cell-based food products.

## 1.2. Scope

One of the key roles of the Food and Agriculture Organization of the United Nations (FAO) is to provide science-based policy advice to its Members, particularly to the Low- and middle-income countries (LMICs) with an expressed need for such technical assistance. The present document provides an overview of the state of the art in various regulatory frameworks for animal cell-based food, and food safety is the core area of interest of this document. The country cases and examples introduced in the document do not mean they have been endorsed by FAO, but they simply mean that such information has been made available. For other countries, this information was not publicly available or not presented in English, and therefore these countries were excluded for the scope of this document. The information provided here was updated until March 2022. It is being published as one of the background document series for the expert consultation in November 2022, thus the contents will be further added to, modified and refined in the final publication in 2023. Therefore, the present document can be considered as valid until that time.

## 2. Methodology

### 2.1. Systematic literature search

A systematic literature search strategy for the collection of data was defined, using search strings related to the regulations/legislation for cell-based food products, in relation to the technologies, products, terminology, food safety and production processes. The strategy covers the collection of data from both English-language scientific literature for the period 2013–2021 and from “grey” information sources without time limits and not only English-language focused. The latter include national/supranational/regional competent authorities, international organizations, private sectors, academia, research institutions, civil societies and non-governmental organizations, amongst others. Information from these grey sources was collected from publicly available websites, white papers, reports, reviews and guidelines. Data from scientific literature were collected from the databases Web of Science, Scopus and Centre for Agriculture and Bioscience International (CAB) Abstracts, and retrieved records from databases were searched through and screened for relevance before retrieval of full references and in-depth screening.

### 3. Results

#### 3.1. Regulatory frameworks and authorization for market entry

Market entry of cell-based food products may require authorization on different levels and the authorization may include a food safety assessment of the cell-based food product, approval of planned and implemented quality controls, assurance protocols for the production process and the use of approved labelling of the products. The essential elements for an effective regulatory framework for cell-based food are still a matter for considerations in many countries. In the following sections, the current status of general and specific regulatory frameworks for cell-based food products is discussed for countries and economic zones where this information is available. These cases are listed in alphabetical order and then summarized in Table 1. Available information on regulatory frameworks for the countries presented here does not always cover the same topics, and certain topics are therefore not discussed in some cases, such as regulations for labelling or the use of genetic modification for food production.

**Table 1.** Developments in different countries relevant for cell-based food products and their safety

Country / economic zone	Competent authority	Legislative/ standard-setting bodies	Cell-based food product on the market? (until 1 March 2022)	Cell-based food-specifically addressed in food safety regulations and/or safety guidelines/instructions? (until 1 March 2022)
<b>Australia and New Zealand</b>	Food Standards Australia New Zealand	Food Standards Australia New Zealand, "Ministry for Primary Industries"	No	No
<b>Canada</b>	Health Canada	Health Canada	No	No
<b>China</b>	National Center for Food Safety Risk Assessment	Food Safety Committee of the State Council	Unknown	No
<b>European Union /European Economic Area /United Kingdom</b>	European Food Safety Authority (European Union) / Federal Food Safety and Veterinary Office (Switzerland) / Mattilsynet (Norway) / Matvælstofnun (Iceland) / Food Standards Agency SA (United Kingdom)	European Parliament, Council, European Commission, national ministries, Food Standards Agency (United Kingdom)	No	Yes
<b>India</b>	Food Safety and Standards Authority of India	Food Safety and Standards Authority of India	No	No
<b>Israel</b>	National Food Service	Ministry of Health	No	No
<b>Japan</b>	Food Safety Committee	Ministry of Health, Labour and Welfare Ministry of Agriculture,	No	No

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Country / economic zone	Competent authority	Legislative/ standard-setting bodies	Cell-based food product on the market? (until 1 March 2022)	Cell-based food-specifically addressed in food safety regulations and/or safety guidelines/instructions? (until 1 March 2022)
		Forestry and Fisheries		
<b>Qatar</b>	Ministry of Public Health	“Qatar General Organization for Standards and Metrology and Gulf Cooperation Council Standardization Organization”	No	No
<b>Singapore</b>	Singapore Food Agency	Singapore Food Agency	Yes Chicken nuggets and processed comminuted poultry products containing cell-based chicken	Yes
<b>USA</b>	Food and Drug Administration / US Department of Agriculture Food Safety Inspection Service	Food and Drug Administration / US Department of Agriculture	No	Yes

### 3.1.1 Australia and New Zealand

Food Standards Australia New Zealand (FSANZ) is the agency that draws up the standards for the regulation of the use of food ingredients, additives and processing aids in Australia and New Zealand. Its Food Standards Code also covers the composition of dairy, meat and beverages as well as foods developed by new technologies, such as genetic modification. FSANZ is responsible for some labelling requirements for packaged and unpackaged food, including specific mandatory warnings or advisory labels.

FSANZ also develops Australia-only primary production and processing standards. FSANZ deals with new types of foods, including foods produced by new technologies, but its Food Standards Code does not contain permissions or requirements for cell-based meats (FSANZ, 2021). The Food Standards Code defines a novel food as a non-traditional food that requires an assessment of the public health and safety considerations, whereby 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 indicates that cell-based meats 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 meats, 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.

### 3.1.2 Canada

Health Canada and the Canadian Food Inspection Agency (CFIA) are the federal authorities responsible for the regulations dealing with foods sold in Canada, including novel foods. Health Canada is responsible for establishing the standards and policies governing the safety and nutritional quality of foods and developing labelling policies related to health and nutrition. CFIA develops standards related to the packaging, labelling and advertising of foods, and handles all inspection and enforcement duties. Health Canada controls the sale of novel foods in Canada via a mandatory pre-market notification requirement, as set out in Division 28 of Part B of Canada's Food and Drug Regulations (Canada, 2021). Health Canada's guidelines for the assessment of novel foods are grounded in the internationally harmonized principles for the comparative safety assessment of foods derived from recombinant DNA organisms as outlined by the Codex Alimentarius Commission, FAO, the World Health Organization (WHO) and the Organisation for Economic Co-operation and Development (OECD) (Health Canada, 2021).

According to the Canadian regulations, a novel food means: (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 such that the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. To our knowledge, no cultured meat product has passed through the Canadian novel food procedure yet, whilst these products appear to fall within three domains of novel food classification: no history of use, novel process, and possibly genetically engineered (Suresh, 2018).

The procedure for authorizing a novel food involves a pre-market notification in writing to the government which should include (amongst other things) the following information regarding the novel food: (i) the common name under which the novel food will be sold; (ii) a description of the novel food, together with details of the methods for manufacturing, preparation, preservation, packaging and storage, details of the major change (if any), information on its intended use and directions for its preparation, information demonstrating its history of use as a food in a country other than Canada (if applicable), and information that establishes that the novel food is safe for consumption; (iii) information on the estimated levels of consumption by consumers of the novel food; and (iv) the text of all labels to be used in connection with the novel food.

In addition, along with Health Canada oversight, Environment and Climate Change Canada (ECCC) and Fisheries and Oceans Canada (FOC) also have responsibilities for ensuring that novel products respect all environmental responsibilities. Other regulations that could apply to cell-based food products are the New Substances Notification Regulations (NSNR) under the Canadian Environmental Protection Act, 1999 (CEPA) (Cellular Agriculture Canada, 2021). The CEPA sets toxicity criteria to ensure that no new substances are introduced into Canadian commerce before their potential risk to human health and the environment has been assessed. 'Substance' is defined by the CEPA as any distinguishable kind of organic or inorganic matter, whether animate or inanimate, and includes chemicals, biochemicals, polymers, biopolymers, and living organisms. The NSNR is divided into two separate sets

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of new substances provisions: new living organisms (e.g. bacteria, viruses, cells) are subject to the NSNR (Organisms), while new chemicals and polymers are subject to the NSNR (Chemicals and Polymers). Substances that are not listed on the Domestic Substances List (DSL) are considered new substances and may require notification under the NSNR prior to being imported into or manufactured in Canada. For the cell-based meat industry this means that cultured cells, if not already on the DSL, would most likely be subject to the NSNR (Organisms). Tissues that are generated through cell culture, as well as substances used in the cellular agriculture process, would likely be subject to NSNR (Chemicals and Polymers).

### 3.1.3 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 (NHFP, 2013). 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. The safety of these new food raw materials needs to be reviewed by the National Center for Food Safety Risk Assessment, before approval of their use in food production and trading (CIRS, 2021).

### 3.1.4 The European Union, the European Economic Area and the United Kingdom of Great Britain and Northern Ireland

The preamble to the Novel Food Regulation (European Union) No. 2015/2283 (European Union, 2015) explicitly mentions that its scope includes food from the culture of cells or tissues 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 Catalogue of approved novel foods 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 Dietetic Products *et al.*, 2016). 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 also 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) rules.

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 (Parliament, 2018, Parliament, 2019). As for the United Kingdom of Great Britain and Northern Ireland, it has retained European Union legislation on novel foods, including its risk assessment and decision-making procedures, although these take place at the national level as of May 2021 (except for Northern Ireland, which continues to abide by European Union rules and procedures for authorization) (FSA, 2020).

### 3.1.5 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, Handral and Choudhury, 2021).

### 3.1.6 Israel

In Israel, the National Food Service at 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, 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.



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- 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.

### 3.1.7 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 Pharmaceutical Affairs and Food Sanitation Council, when the Ministry of Health, Labour and Welfare finds it necessary to prevent food sanitation hazards” (Japanese Law Translation, 2022).

A technical working group within the Japanese Ministry of Agriculture, Fisheries and Food has recently started developing strategies for various types of alternative protein sources (replacing animal products), such as plant- and insect-based substitutes but also cell-based meat. Besides regulations, these strategies also consider other aspects, such as research policy, public-private partnerships, consumer acceptance, and food security. The establishment of the Food Tech Research Group in April 2020 has been instrumental in gathering the perspectives from government agencies, research institutions, and industrial players.

### 3.1.8 Qatar

According to recent news reports, Qatar hosts 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 Coast Countries Standardization Organization, of which Qatar is a member, is currently developing guidelines (Bayrakhdar, 2020). These are likely to follow the model crafted by the Saudi Food and Drug Authority (SFDA), which issued general requirements and a guide for applicants in 2020 (Wojcicka-Swiderska, 2021).

The SFDA documents feature animal-cell-based foods as a novel food category (SFDA, 2020a). As regards the safety data to be provided, the guidelines for applicants briefly outlines data requirements. These include, for example, completed risk assessments and authorized uses elsewhere, intended uses and estimated consumer intake, nutritional value, and toxicological and human consumption data (SFDA, 2020b). More information on the regulatory developments for cell-based foods can be found in Qatar’s case study.



### 3.1.9 Singapore

In Singapore, chicken nuggets containing cell-based chicken 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. The SFA states that alternative proteins generally refer to proteins derived from sources other than animal protein. Some forms of alternative proteins, such as “cultured meat”, are considered to be a novel food as they do not have a history of being consumed by humans as food (SFA, 2020). Cultured meat refers to “meat developed from animal cell culture, where the process to produce cultured meat involves growing the selected cell lines (or stem cells) in a bioreactor. These cells are grown in a suitable growth media, and subsequently onto a ‘scaffold’ to produce products resembling meat muscle”.

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. In order to facilitate this process, SFA has released a document on the food safety information that would be required for novel food safety assessment. 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 the materials used in their manufacturing processes and how these manufacturing processes are controlled to prevent food safety risks.

In particular, the SFA notes that the science for producing cultured meat is still at an early stage. The specific requirements for information that should be submitted for the safety assessment of cultured meat are shown in Box 1, but the SFA notes that information required may change based on the developments on the science of producing cultured meat. The SFA may also accept, for its own review, safety assessment reports conducted by food safety authorities in other countries, such as Australia, Canada, New Zealand, Japan, the European Union and the United States of America, provided these assessments have been conducted in conformity with reference documents from the authorities in the United States of America, EFSA or FAO/WHO.

To ensure that the safety assessments provided by applicants are rigorously reviewed, the 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 SFA also emphasises the importance of engaging companies in the novel food regulatory framework even when the companies are in the early stages of their research, as this will help companies prioritize resources towards productive research directions which will minimize compliance costs and time. To this end, the SFA introduced Novel Food Virtual Clinics in September 2021.

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).

Box 1. The Singapore Food Agency requires that the following data are provided for the pre-market safety assessment of cultured meat

- Safety data required for novel foods in general
  - Identity and source.
  - Purity, including any metabolites, contaminants, toxins, residues of solvents, by-products etc. that are expected to be present.
  - Information on tests conducted.
  - Information on the inputs used for the production of the novel food, including their specifications, purity, and safety, and whether these comply with specifications in the Singapore Food Regulations, British Pharmacopoeia, European Pharmacopoeia, JECFA or Food Chemical Codex. This also covers food processing and contact substances used but not intended to be an ingredient of the final product.
  - Intended uses, proposed use levels and anticipated intake.
  - Demonstration that the hazards potentially originating from the inputs, production process and side reactions will not pose safety risks. This may include proof that the hazard is present at levels not raising concern, risk assessments following hazard characterization, or an exposure comparable to those in any foods that are replaced by the novel food. Exposure assessments should be conducted using consumption data on novel food analogues already consumed in Singapore, for which further data requirements will be developed.
  - Demonstration of absence of toxicity according to a weight-of-evidence based toxicological assessment of the whole novel food or its key constituents:
    - *In vitro* and *in vivo* toxicity tests covering genotoxicity, general systemic toxicity, chronic toxicity and carcinogenicity, and reproductive and developmental toxicity.
    - Metabolism or toxicokinetic studies, if relevant.
    - Potential allergenicity studies according to a weight-of-evidence approach including *in silico* and *in vitro* methods, and specific serum screening for purified proteins, and phylogenetic relationships for production organisms.
  - Description of the manufacturing process.
  - Training of staff in food safety, food handling, food hygiene and hygienic operation of facilities.
- Safety data for the genetic modifications involved (if any)
- Safety data specific to cultured meat
  - Product characterization, e.g. composition, residual antibiotics, growth factors and other modulators, and their comparison with levels reported in the literature.
  - Description of inputs, e.g. cell lines or stem cells used, culture media, growth factors, antibiotics, materials used as scaffolds, solvents, enzymes and processing aids.
  - Information on cell lines: background information, identity, source, preparation and banking, chemicals used for induction, freedom from infectious agents, any modifications made to the cell lines, compliance of biopsy collection with food safety and animal health requirements.
  - Information on culture media, e.g. composition (also including added substances, impurities), removal of the media from the product (if applicable), risk assessments of non-food-grade substances and unintended metabolites in the culture media and in the final product (comparison with levels in conventionally produced meat), and the potential for antimicrobials to cause antimicrobial resistance.
  - The purity and genetic stability of the cell lines, e.g. the whole-genome sequencing of the cell lines (WGS) before and after passages, assessment of the possible food safety risks linked to the observed genetic differences, safety assessment of potential food safety risks based on the cell line's nature (e.g. marine biotoxins in shellfish) and their mitigation measures.

### 3.1.10 The 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. The FDA will have 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). The 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.

The FDA and the United States Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) have established a joint regulatory framework for the oversight of human food products derived from livestock, poultry, and Siluriformes fish. (FDA, 2019). Under this agreement, the FDA will oversee the initial stages of production, including the collection, banking, growth and differentiation of cells for livestock, poultry, and Siluriformes fish. A transition from FDA to USDA-FSIS oversight will occur at the time of harvest. The USDA-FSIS will then oversee the processing, packaging, and labelling of the resulting meat and poultry products. For foods comprising cultured seafood (other than siluriform fish) or game meat cells, the FDA will oversee processing, packaging and labelling in addition to the culture process.

Developers of cell-based products should complete a pre-market consultation with the FDA, which will typically address the processes used and the resulting products, including the biological materials used. If these consultations on the safety of the cell-based product are successful and once commercialization has begun, the FDA will initiate inspections for the production process of products under its exclusive jurisdiction. However, developers of cell-based food derived from livestock, poultry, and siluriformes fish must take the additional step of applying for a USDA-FSIS grant of inspection. Upon issuance of a USDA-FSIS grant of inspection, FDA will initiate inspections for the production process of cell-based meat or poultry products and the USDA will, at the time of harvest, initiate inspections at a frequency similar to those for traditional meat and poultry. Developers must also ensure that sanitation and quality control (HACCP) procedures are in place for the production.

The labelling of poultry and meat is within the USDA's remit, whilst that of seafood (siluriformes species not included) is within that of the FDA. Both agencies are jointly pursuing a consistent labelling policy for animal food products derived from cultured cells and both agencies have announced their intention to address the labelling of these products. The FDA published a "Request for Information" in October 2020 in which it requests comments for "the labelling of foods comprising or containing cultured seafood cells." The FDA 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 (FDA, 2020). The FSIS did so through an "Advance Notice of Proposed Regulation (ANPR)", while noting that the proposed labels for cell-based products comprising livestock or poultry cells will be subject to a pre-market review (FDA, 2020, USDA, 2021). Notably, the FSIS ANPR draws a parallel with two historic cases of advanced meat separation techniques applied to poultry for the production of boneless "separator" meat. In a first case for Mechanically Separated Poultry (MSP), a new standard of identity was established by the USDA-FSIS as physical form, texture, and ingredients (e.g. bone content) of these MSP products were considered materially different from those of other boneless poultry products produced by hand deboning techniques. In a second case for new meat products derived from advanced meat recovery (AMR), the USDA-FSIS did not impose a new labelling requirement, as AMR meat was considered comparable to meat derived by hand deboning in terms of its composition, appearance, and texture, so long as it was produced in accordance with the regulations. Instead, compositional requirements were set and the legal definition of meat modified so as to clarify that boneless meat products (such as AMR meat) were not allowed to contain significant portions of bone or bone components.

The USDA used its ANPR to solicit comments on questions as to whether terms are needed to discern cell-cultured products from others, which terms should be in the product name of a food containing animal cells, which terms could be potentially misleading if names refer to the form of a meat or poultry product (e.g. fillet, steak), and which names might have a negative impact on consumers and industry. It also asked if the legal definitions of meat and poultry products should be amended so as

to include or exclude foods derived from cultured animal cells. These issues of regulation and safety in the ANPR thereby also addressed the various aspects identified by the scientific investigations into the impact of naming of these products on acceptance and on interpretation accuracy.

### 3.2. Legislation in relation to religious laws and regulations

As mentioned by Bhat *et al.* [2019], cell-based meat does not involve slaughtering a large number of animals, and could therefore be considered to be free of any ritual link such as Halal, Kosher or Jhatka. However, the initial source of the cells and biopsies for starting cell cultures will certainly have an impact on the perception and decision of consumers (Bhat *et al.*, 2019). If the culture medium and initial cells were halal (i.e. myoblasts and media taken from animals considered halal or animal-free media), the developed cell-based meat may be allowed by Islamic law, according to some Muslim scholars (Billinghurst, 2013). Likewise, if the initial cells were taken from a kosher animal slaughtered according to Jewish law, the developed product may be considered kosher (foods considered permissible by Jewish dietary laws), according to several rabbis. A recent decision on the kosher status by some rabbis declared that “cultured meat” products derived from embryonic stem cells (ESCs) taken from a bovine blastomere/blastula is considered “Kosher Parve” – i.e. not meat per se – and as such can be eaten together with dairy (Greenwood, 2022). A consensus on these issues does not yet exist, due to the different nature of the religious certifying bodies (JTA., 2018, Kenigsberg and Zivotofsky, 2020, Shurpin, 2018).

### 3.3. Other potentially relevant legislation and regulations

Besides food safety-related legislation and regulations, there may be other regulatory elements that could be of concern for cell-based food production. For cell sourcing and isolation, there may be relevant legislation related to taking biopsies from live or dead animals, and this could involve animal welfare issues. In addition, isolated cells might be stored in cell banks for which regulations exist in several countries (EMA, 1998; FDA, 2010). Cell-based food production might also produce new types of biological or chemical by-products and waste, for which specific regulations apply, such as environmental legislation. Furthermore, by-products might also be used in feed applications if they meet the feed safety requirements.

## 4. Discussion

Cell-based food production technologies have matured over the years and commercialization of these products has been initiated in a limited number of countries, while market introduction is expected in other countries in the coming years. Considering the fast global developments in cell-based food production, countries may wish to be well prepared in order to have the necessary regulatory frameworks, bodies and infrastructure in place for assessing the safety of cell-based food products and production processes, as well as legislation developed for accepted terminologies and labelling requirements for marketing these products.

Analysis of the global developments in the regulation and risk assessment of cell-based food products indicates that, in most countries, cell-based foods can be assessed within existing novel food regulations. Singapore has already made amendments to its novel food regulations to specifically include cell-based foods (cultured meat), while the United States of America has drawn up a formal agreement for food made from cultured cells of livestock (including siluriformes fish) and poultry that addresses safety and labelling requirements. In addition, the USDA has stated its intent to draw up regulations on the labelling of meat and poultry products derived from animal cells. This new labelling regulation is being prepared via a public process consistent with US agency practices for rulemaking. Consistent with the USDA/FDA formal agreement, the FDA has also requested information on labelling of foods comprising or containing cultured seafood cells to determine what type(s) of actions, if any, the agency should take to ensure that these foods are properly labelled.

The labelling of cell-based food products in most countries is expected to be clear, understandable and not misleading for consumers and to be distinguishable from related products, such as conventional meat or fish or plant-based meat replacers. No regulations seem to exist worldwide for the designation of the modifier part of “cultured meat”, but there are restrictions in many countries for the “meat” part. In some countries, terms related to conventional meat or meat products will not be allowed, such as in Germany and France, while Singapore has indicated that meat terms will be allowed with suitable qualifying terms, and in the United States of America and other countries this is still a matter of debate.

Other legislative acts that may be of importance include religious food laws, legislation on biopsies, animal welfare legislation, and environmental regulations for the removal of “cultured” meat production waste (Stephens *et al.*, 2018). Opinions from Muslim and Jewish religious scholars indicate that cell-based meat products might be labelled as Halal or Kosher respectively, and therefore these products adhere to some of the existing religious laws, which is an important factor for manufacturing and marketing cell-based foods in certain countries. However, some others are also stating that such labelling depends on exactly what cells and materials have been used during the entire process of the production; thus a case-by-case approach may be appropriate or the establishment of some standards that could guide regulators.

These developments can serve as examples for other countries to decide whether assessment of cell-based food products is possible within their existing and relevant food regulations, or if specific regulations need to be developed for cell-based food products for which they can provide information on what elements might be important to include in novel food legislation. To set up the regulatory frameworks, it is also important for the competent authorities to do so in a transparent dialogue with various stakeholders, including consumers, the private sector, civil society, partner agencies and policy makers (FAO/WHO, 2016).

At its 44th session in November 2021, the Codex Alimentarius Commission discussed this important topic with the paper prepared by FAO and WHO, entitled “New food sources and production systems: need for Codex attention and guidance?” (Codex Alimentarius, 2021) During the session, while a number of emerging issues relevant to food safety, such as seaweed, microalgae, edible insects, protein alternatives and 3-D printed foods were highlighted, cell-based food was also included as an option to be included in the scope of future discussion. The Codex Executive Commission is currently analysing the submitted information from the Members and observers on the issues so that the future direction of the potential work by the Codex can be determined (Codex Alimentarius, 2022).

There is currently a limited amount of information and data on the food safety aspects of cell-based foods to support regulators in making informed decisions, and therefore active and global data-sharing is desired to employ an evidence-based approach to prepare any necessary regulatory actions. For LMICs, it may be of benefit to start dialogues with other countries and international organizations to learn from their experiences and to obtain technical advice and assistance, in order to develop a significant capacity for the safety assurance of cell-based food products. It is also important to discuss these matters on a global scale and to share experiences and good practices, as this can contribute to strengthening appropriate and effective regulatory frameworks with no duplication of efforts.

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