CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



### JOINT FAO/WHO FOOD STANDARDS PROGRAMME FAO/WHO COORDINATING COMMITTEE FOR LATIN AMERICA AND THE CARIBBEAN Twenty-third Session

Virtual

#### 22-26 July 2024

#### **PROPOSALS ON CELL-BASED FOODS**

Submitted by Singapore

#### BACKGROUND

1 New food sources and production systems (NFPS) is a broad term encompassing various approaches and technologies that have potential to contribute to a more diversified, sustainable food system that can address food security and environmental challenges. NFPS ranges from food that has been historically consumed in specific regions of the world but has recently materialized in the global market space (e.g. certain insect species, seaweeds) to novel pioneering technologies (e.g. cell-based foods<sup>1</sup>, precision fermentation).

2 NFPS was first discussed at CAC44 in response to a FAO-WHO document seeking advice on addressing NFPS related issues. Subsequently, a Circular Letter (CL) was issued on the topic and further discussion held at CAC45. As there was no agreement on whether existing Codex mechanisms were sufficient to address new work proposals on NFPS, a second CL was issued to identify specific topics for more discussion, including identification of topics that the current Codex mechanisms could not address.

3 CAC46 then noted that existing Codex mechanisms were sufficient to address new work proposals on NFPS. It also emphasized the importance of addressing challenges posed by NFPS and the important role that Codex could play. Additionally, member countries were also encouraged to submit discussion papers or new work proposals either to active Codex Committees or to the Executive Committee through the Codex Secretariat.

4 This paper is to update member countries on the proposal proposed by Singapore to support the conclusions of CAC46 to further the work on NFPS.

#### WHY THE FOCUS ON FOOD SAFETY CHALLENGES IN CELL-BASED FOOD PRODUCTION?

5 The range of NFPS is extensive and it is important for Codex to focus and prioritize specific areas within the NFPS for new work. Cell-based foods are truly novel, produced with technologies that the world has never seen before in food production.

6 The FAO and WHO have conducted a comprehensive food safety hazard identification of cell-based food production. While some hazards are already well-known and exist in conventionally produced foods, there are additional **hazards unique to the production of cell-based foods** due to the nature of the materials, inputs, ingredients, and equipment used that may not have been used previously for food production. For instance, the use of unorthodox ingredients (e.g. growth factors, small drug-like molecules) during the production process poses difficulties in assessing food safety risks associated. Furthermore, there is a limited understanding of good manufacturing practices for the production of cell-based foods (i.e. should cell-based

<sup>&</sup>lt;sup>1</sup> In this document, the term "cell-based foods" is used as a working terminology to indicate food produced through the culturing of cells isolated from animals. This includes cells isolated from poultry, bovine, porcine, fish and crustaceans sources.

food production be aligned to manufacturing of pharmaceuticals), which may lead to inconsistent approaches towards the management of food safety during production.

#### WHY SHOULD CODEX BE EVALUATING CELL-BASED FOOD?

7 The mandate of Codex is to protect the health of consumers and to facilitate trade. To achieve this, it is imperative for Codex to be responsive in addressing current and emerging issues in a timely manner.

8 Cell-based foods are already allowed for sale in some member countries such as Singapore and the United States. With the potential to contribute to a global sustainable food system, countries such as Australia, China, Singapore, and United States, are investing in future foods, including cell-based foods. Consequently, the world will likely see more of cell-based foods over time even though there is currently minimal trade in cell-based foods. Through Singapore's engagements, many food agencies have shared similar difficulties in the need to address the safety of cell-based foods, while enabling food innovations and trade.

9 Therefore, even though the cell-based food industry is still in its early stages of development, there is a significant opportunity for Codex to keep in tandem with external drivers and better meet the mandate to protect the health of consumers and facilitate trade.

#### WHAT CAN CODEX DO AND HOW? -TWO CELL-BASED FOODS PROPOSALS

10 Singapore is putting forth the following two proposals to Codex to develop guidance and help countries navigate this new area of safety of cell-based foods. Singapore is not proposing for the development of specific standards but some guidelines and codes of practices. The safety of cell-based foods covers a range of aspects such as cell lines, cell culture media, scaffolding, production, and manufacturing practices. The following two proposals will focus on the two aspects where there are more scientific knowledge and data, namely 1) safety assessment of cell culture media components; and 2) hygiene practices for the manufacture of cell-based foods.

Singapore has engaged Codex member countries in meetings facilitated by the Regional Coordinators regarding the two proposals. During these meetings, there was general recognition from member countries on the benefits and the need for Codex guidance to ensure food safety of cell-based foods. Member countries generally expressed interest to have a better understanding of the importance of the work and how Codex could proceed to carrying out discussions on cell-based foods<sup>2</sup>.

#### <u>Guideline for the conduct of food safety assessment of cell culture media components used in the production</u> of cell-based foods (details in Appendix 1)

12 The development of a guideline for the conduct of food safety assessment of cell culture media components used in the production of cell-based foods will help to facilitate Codex members' assessment of food safety risks associated with components used in cell culture media, many of which have not been previously used for food production. This is achieved by providing guidance on the evidence required for cell culture media components in relation to the potential food safety risks they may pose if present in the final product. This not only assures consumers that cell culture media components in cell-based foods will not cause harm when consumed but also serves as a foundational reference for establishing risk management measures to ensure the safety of cell-based foods.

13 **This proposal will be presented to the Codex Committee on Food Additives (CCFA)** for consideration as new work as cell culture media components may be considered as processing aids given that most media components would either be absent or found only in trace levels in the final product. Although some member countries initially questioned the choice of CCFA, they subsequently agreed with this approach after noting how the use of some culture media components were similar in concept with the use of processing

<sup>&</sup>lt;sup>2</sup> Members consulted also raised the following matters which were outside of the two proposals:

<sup>•</sup> Other food safety issues would also be of importance such as the development of guidelines on the safety of animal cell-lines used in the production of cell-based foods.

<sup>•</sup> Development of Codex guidance on the use of the term "Halal".

<sup>•</sup> Clarity on labelling of these new products would be important, but also acknowledged that some terms were likely to be highly contextualized to local norms within Codex members.

<sup>•</sup> Codex would also benefit from further discussions on guidance for other forms of NFPS, including foods produced from microbial fermentation.

aids. A few member countries also opined that the proposal was more related to risk assessment than Codex's role as a risk manager, but there had been precedents by Codex to develop some risk assessment-related guidelines<sup>3</sup>.

14 While some member countries reflected that certain cell culture media components (e.g. plant and animal derived growth factors) might require expertise in other Codex General Subject Committees, other member countries acknowledged that existing Codex processes allow for consultations between Codex Committees.

#### Code of hygienic practice for manufacture of cell-based foods (details in Appendix 2)

15 The code of hygienic practice for manufacture of cell-based foods aims to provide improved understanding and guidance on the Good Manufacturing Practices (GMP) specific to the production of cellbased foods and consider how Good Cell Culture Practice (GCCP) could be applied. Implementing Good Manufacturing Practices for the production of cell-based foods is crucial to ensure the safety and quality of these foods. The proposed work would help prevent unhygienic practices and conditions in the production, processing, and handling of cell-based food products, leading to public health protection for cell-based foods.

16 This proposal will be **presented to the Codex Committee on Food Hygiene (CCFH)** as for consideration as new work. There was general consensus amongst consulted members that this proposal could indeed be further discussed and developed at CCFH and to consider the following:

- i. Given that the industry is still developing and further improving manufacturing practices, it would be important for the code of hygienic practice to be developed in a modular manner which would not preclude future developments.
- ii. There would already be certain references being used in non-food production, such as the production of pharmaceuticals. Members suggested that Codex could take those existing references into consideration when elucidating a code of hygienic practice that would make sense for food production.

#### RECOMMENDATIONS

- 17 CCEXEC86 noted the two new work proposals on cell-based foods and recommended that:
  - i. The proposed code of hygienic practice be submitted to the CCFH in response to the Circular Letter CL 2024/64-FH Request for proposals for new work and/or revision of existing standards.
  - ii. The proposed guidelines on safety assessment of cell culture media may be submitted to the CCFA.

18 Member countries are invited to consider the two proposals, provide comments and support the initiation of new work at the respective subsidiary Codex Committees:

- i. The guideline for the conduct of food safety assessment of cell culture media components used in the production of cell-based foods at CCFA; and
- ii. A code of hygienic practice for manufacture of cell-based foods at CCFH.

<sup>&</sup>lt;sup>3</sup> For instance:

<sup>•</sup> The Guidelines for the Simple Evaluation of Dietary Exposure to Food Additives (under CCFA) provides brief guidance on the evaluation of dietary exposure to food additives. It is still in use.

<sup>•</sup> The Principles for the Risk Analysis of Foods Derived from Modern Biotechnology was developed in 2003. Though this is no longer in the list of Codex standards.

#### Appendix 1

# NEW WORK PROPOSAL FOR DEVELOPMENT OF A GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF CELL CULTURE MEDIA COMPONENTS USED IN PRODUCTION OF CELL-BASED FOODS

#### 1. Introduction

Cell culture media is a critical component in the production of cell-based foods<sup>4</sup>. During the production process of cell-based foods, animal cells are cultured in cell culture media which contains a complex mixture of salts, sugars (glucose), vitamins, amino acids, organic acids, growth factors, hormones and small molecules for the cells to grow. Some of these components are utilised as the cells proliferate, whilst others may remain in the cultivated cells as residues which have no further technological function and could be considered as processing aids. However, there are currently no internationally harmonized guidelines defining which cell culture media components are deemed acceptable for use in cell culture media.

#### 2. Purposes and scope of the standard

The purpose of the proposed new work is to develop guidelines for the conduct of food safety assessment of cell culture media components used in the production of cell-based foods.

The scope of the guideline would include a framework on the general considerations and the associated studies/ evidence required to assess the safety of different types of cell culture media components, an advisory list of commonly used cell culture media components and its minimum purity requirements and a glossary of terms that would be used in this document.

#### 3. Relevance and Timeliness

At CAC44, the FAO and WHO called for Codex to recognise food system innovations that seek to address challenges related to feeding a growing global population, and at the same time produce food more sustainably. CAC46 extensively discussed and underscored the importance of addressing the challenges related to new food sources and production systems (NFPS) and encouraged the submission of new work proposals pertaining to NFPS. These developments reflect the growing recognition of the need for Codex to establish international frameworks and guidelines to ensure the safety and regulation of NFPS on a global scale.

As a form of NPFS, cell-based foods offer a potential solution to global food challenges, addressing issues such as the limited availability of arable land and the unpredictable threats posed by climate change. Additionally, cell-based foods have the potential to complement the conventional livestock agricultural system by offering a more resource-efficient alternative. The feed conversion ratio for cell-based foods is lower compared to conventional farmed animals like beef, pork, and chicken, resulting in reduced resource usage<sup>5</sup>. The production of cell-based foods has the potential to significantly reduce the environmental impact of food production by reducing carbon emissions and minimizing water and land use<sup>6</sup>. Moreover, the sustainable production of cell-based foods aligns with the global shift towards environmentally friendly and ethical food sources, thereby contributing to a more sustainable and resilient food system for the future.

An increasing number of countries are granting approval for the commercial sale of cell-based foods with more approvals anticipated in the near future. As of early 2024, cell-based foods have been allowed for commercial sale in Singapore, the United States of America and Israel, while other Codex members such as Australia, New Zealand, Switzerland, the Republic of Korea, and the European Union are in the process of reviewing safety assessments or have made modifications to safety assessment criteria in order to ensure the safety of cell-based foods.

The safety assessment of cell culture media components is crucial as it would provide guidance on the evidence required for cell culture media components in relation to the food safety risk that it would pose if present in the final product. This provides assurance to consumers that cell culture media components that may be present in cell-based foods will not cause harm when consumed, especially when considering

<sup>&</sup>lt;sup>4</sup> In this document, the term "cell-based foods" is used as a working terminology to indicate food produced through the culturing of cells isolated from animals.

<sup>&</sup>lt;sup>5</sup> Swartz, E. (2021). Anticipatory life cycle assessment and techno-economic assessment of commercial cultivated meat production. *The Good Food Institute*.

<sup>&</sup>lt;sup>6</sup> Tuomisto, H. L., & Teixeira de Mattos, M. J. (2011). Environmental impacts of cultured meat production. *Environmental science & technology*, *45*(14), 6117-6123.

components that have not been previously used for food production. This assessment requires the gathering of various types of evidence to demonstrate that these components do not pose any unacceptable food safety risk. The guidelines will serve as a foundational reference for establishing risk management measures to ensure the safety of cell-based foods. By promoting a consistent approach to safety assessment, these guidelines also pave the way for harmonization among regulators in their evaluation of the safety of cell-based foods. This harmonization, in turn, facilitates trade by ensuring a unified standard that can streamline international market access for such products.

An advisory list of cell culture media components deemed acceptable for use based on the guidelines would be added as an appendix, to offer guidance on the components that have been deemed acceptable based on the safety assessment developed. To provide clarity, a glossary of terms that would be used would also be included to improve understanding and comprehension of the guideline.

#### 4. Main aspects to be covered

The guidance document will encompass a framework outlining the necessary evidence for various types of culture media components. It will provide regulators and industry stakeholders with a reference for general considerations and the associated studies and evidence needed to assess the safety of these components.

### 5. Assessment against Section 2: Criteria for establishment of work priorities General Criterion

# Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work will significantly support regulators in developing their framework for assessing cellbased foods by providing a reliable reference on the necessary information to assess the safety of cell culture media components with no consumption history. This is crucial in enhancing safety as it allows regulators to establish comprehensive safety assessments for components that have not been traditionally consumed in food products.

By having clear guidelines and reference points, regulators can effectively evaluate the potential risks associated with these novel components, thereby ensuring the safety of cell-based foods for consumers.

#### Criteria applicable to general subjects

a) Diversification of national legislations and apparent resultant or potential impediments to international trade.

The lack of international guidance on safety assessments for cell-based foods will not only lead to diverging approaches and confusion on the requirements but also impede trade by creating barriers due to differing regulations and standards across countries. The harmonization efforts by Codex can play a crucial role in assisting countries in the development of a unified framework for the regulation of cell-based foods, thereby facilitating smoother trade and market access for these products.

- b) Scope of work and establishment of priorities between the various sections of the work. Please refer to section one which includes the scope of work to be undertaken.
- c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

FAO/WHO published a document on the food safety aspects of cell-based food which includes a section on hazard identification of cell-based foods. Separately, FAO has been organising a few conferences on the topic of cell-based foods, such as an expert consultation to identify food safety hazard in cell-based foods in 2022 and the yearly stakeholder roundtable meeting on cell-based food production and precision fermentation.

#### d) Amenability of the subject of the proposal to standardization.

The subject of the proposal is amenable to standardization as the guideline would be developed using science-based risk assessment approach.

#### e) Consideration of the global magnitude of the problem or issue

The nascent field of cell-based food presents an exciting frontier in the food industry, with numerous companies actively developing innovative products in this space. However, before these cell-based

foods can enter the market, they would require regulatory approval. This lack of regulatory clarity has the potential to impede the growth and development of the cell-based food industry. The Codex guidance would represent the first step towards international harmonisation of safety assessments for cell-based foods. It would also offer regulators a foundational reference upon which they can develop their own risk management measures to evaluate the safety of cell-based foods.

The Codex Procedural Manual also includes references to the volume of production, consumption, and trade, which help Codex determine its work priorities. Currently, over 160 cell-based food companies are keen to obtain approval to market their cell-based food products but are unable to do so due to differences in regulatory processes. The establishment of international standards would facilitate the approval process for companies across various countries, thereby driving industry growth and facilitating trade of the product. This advancement holds the potential to address global food challenges by contributing to the development of a sustainable and resilient food system through the production of meat.

#### 6. Relevance to Codex Strategic Objectives

The proposed work directly relates to several Codex strategic goals from the Codex Strategic Plan: 2020 2020-2025.

• Strategic Goal 1: Address current, emerging and critical issues in a timely manner

The production of cell-based foods offers a more sustainable alternative to conventional meat production. Cell-based foods are a more sustainable option as it requires less land and water and have a lower global warming potential<sup>7</sup>. Prioritizing sustainably produced food is crucial for ensuring the long-term availability of food while minimizing adverse environmental impact. Sustainable food production plays a pivotal role in addressing food security challenges by ensuring stable and resilient food supplies. It also contributes to equitable access to affordable and nutritious food, thereby bolstering food security for future generations.

With cell-based food production being a growing industry, the establishment of the advisory list, would provide guidance on information required from certain cell culture media components to member countries who are in the midst of establishing regulations for cell-based food approvals.

- <u>Strategic Goal 2: Develop standards based on science and Codex risk-analysis principle</u> Development of standards is expected to leverage on expertise from various FAO expert committees/meetings. This would ensure that scientific advice is used consistently in line with Codex risk analysis principles.
- <u>Strategic Goal 3: Increase impact through the recognition and use of Codex standards</u> As there is currently no international guidance for cell-based foods, member countries would refer to Codex standards for cell-based foods, which would increase awareness and utilisation of Codex standards.

# 7. Information on the relationship between the proposal and other existing Codex documents, as well as other ongoing work

The proposed work would take guidance from several Codex documents that aids in risk assessment, such as Guidelines on the Application of Risk Assessment for Feed (CXG 80-2013), Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CXG 30-1999), Working Principles for Risk Analysis for Food Safety for Application by Governments (CXG 62-2007), Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CXG 44-2003), and Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CXG 46-2003).

#### 8. Identification of any requirement for and availability of expert scientific advice

There might be a need to seek scientific advice from FAO/WHO's expert body JECFA for inputs on risk assessment required for cell culture media components.

# 9. Identification of any need for technical input to the standard from external bodies, for planning purposes

<sup>&</sup>lt;sup>7</sup> Sinke, P., Swartz, E., Sanctorum, H., van der Giesen, C., & Odegard, I. (2023). Ex-ante life cycle assessment of commercial scale cultivated meat production in 2030. *The International Journal of Life Cycle Assessment*, 28(3), 234-254.

None identified so far.

10. Proposed timeline for completion of new work, including the start date, proposed date for adoption at Step 5, proposed date for adoption by the Commission

A five-year timeline is proposed for the completion of the proposed work as listed below:

- 2024: Preliminary consultations with Codex members
- 2025: Table intention to submit new work at CCFA as AOB item
- 2026: Consideration of the proposed new work at CCFA
- 2026: Formation of EWG to discuss project document for new work
- 2027: Consideration of draft project document for new work at CCFA
- 2027: Approval of new work by CAC50
- 2028: Discuss new work and circulate draft text at CCFA for comments
- 2028: Adoption of draft text at Step 5 at CAC51
- 2029: Circulate draft text at CCFA for comments
- 2029: Adoption at Step 8 at CAC52

# NEW WORK PROPOSAL FOR DEVELOPMENT OF A CODE OF HYGIENIC PRACTICE FOR THE MANUFACTURE OF CELL-BASED FOODS

#### 1. Purposes and scope of the standard

The purpose of the proposed new work is to develop a code of hygienic practice for the manufacturing of cellbased foods<sup>8</sup>.

The scope of the code of hygienic practice will cover key elements of a cell-based food production facility, including plant facilities, operating requirements, guidance on storage, temperature control, personal hygiene of staff, cross contamination control and waste management.

#### 2. Relevance and Timeliness

At CAC44, the FAO and WHO called for Codex to recognise food system innovations that seek to address challenges related to feeding a growing global population, and at the same time produce food more sustainably. CAC46 extensively discussed and underscored the importance of addressing the challenges related to new food sources and production systems (NFPS) and encouraged the submission of new work proposals pertaining to NFPS. These developments reflect the growing recognition of the need for Codex to establish international frameworks and guidelines to ensure the safety and regulation of NFPS on a global scale.

As a form of NPFS, cell-based foods offer a potential solution to global food challenges, addressing issues such as the limited availability of arable land and the unpredictable threats posed by climate change. Additionally, cell-based foods have the potential to complement the conventional livestock agricultural system by offering a more resource-efficient alternative. The feed conversion ratio for cell-based foods is lower compared to conventional farmed animals like beef, pork, and chicken, resulting in reduced resource usage<sup>9</sup>. The production of cell-based foods has the potential to significantly reduce the environmental impact of food production by reducing carbon emissions and minimizing water and land use<sup>10</sup>. Moreover, the sustainable production of cell-based foods aligns with the global shift towards environmentally friendly and ethical food sources, thereby contributing to a more sustainable and resilient food system for the future.

An increasing number of countries are granting approval for the commercial sale of cell-based foods with more approvals anticipated in the near future. As of early 2024, cell-based foods have been allowed for commercial sale in Singapore, the United States of America and Israel, while other Codex members such as Australia, New Zealand, Switzerland, the Republic of Korea, and the European Union are in the process of reviewing safety assessments or have made modifications to safety assessment criteria in order to ensure the safety of cell-based foods. Some cell-based food companies are also looking to the establishment of cell-based food production facilities in other Codex members such as Malaysia and Thailand.

However, the establishment of commercial production facilities for cell-based foods is hindered by the absence of international guidance on acceptable good manufacturing practices specific for such facilities, which poses a significant challenge for the industry.

While the general guidance covered in the Codex General Principles of Food Hygiene (CXC 1-1969) is useful, the current document does not comprehensively cover the specific requirements for the production of cellbased foods. Areas such as air cleanliness levels, segregation of rooms for different purposes (e.g., cell culture room, media preparation room), and the management of general and biological waste are crucial considerations unique to the production of cell-based foods. Implementing Good Manufacturing Practices and taking Good Cell Culture Practice into consideration during the production of cell-based food products is essential to ensure the safety and quality of these food products.

The proposed work would build on the existing General Principles of Food Hygiene (CXC 1-1969) to provide regulators and industry members with clear and comprehensive guidance tailored to the specific requirements

<sup>&</sup>lt;sup>8</sup> In this document, the term "cell-based foods" is used as a working terminology to indicate food produced through the culturing of cells isolated from animals.

<sup>&</sup>lt;sup>9</sup> Swartz, E. (2021). Anticipatory life cycle assessment and techno-economic assessment of commercial cultivated meat production. *The Good Food Institute* 

<sup>&</sup>lt;sup>10</sup> Tuomisto, H. L., & Teixeira de Mattos, M. J. (2011). Environmental impacts of cultured meat production. *Environmental science & technology*, *45*(14), 6117-6123

of a cell-based food production facility. The proposed work would prevent unhygienic practices and conditions in the production, processing, and handling of cell-based food products, leading to public health protection for cell-based foods.

### 3. Main aspects to be covered

The project format will follow the General Principles of Food Hygiene (CXC 1-1969). The proposed structure would be a general guidance document on key elements of production facilities of cell-based foods including plant facilities, operating requirements, guidance on storage, temperature control, personal hygiene of staff, cross contamination control and waste management.

# 4. Assessment against Section 2: Criteria for establishment of work priorities General Criterion

# Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries

The proposed new initiative will offer comprehensive guidance on the specific requirements for a cell-based food production facility, ensuring food safety and thereby strengthening consumer protection. Additionally, the development of this initiative aims to facilitate a better understanding of hygienic practices for the production of cell-based foods. Ultimately, this effort will play a pivotal role in enhancing the overall food safety standards for cell-based foods.

### Criteria applicable to general subjects

a) Diversification of national legislations and apparent resultant or potential impediments to international trade.

The absence of international guidance on good manufacturing practices tailored to cell-based food production facilities has led to confusion regarding the necessary requirements. The proposed work aims to address this gap by providing clear and comprehensive guidance on the specific requirements of such facilities. This guidance will serve as a valuable point of reference for countries seeking to establish or enhance their regulations in this domain.

- b) Scope of work and establishment of priorities between the various sections of the work. Please refer to section one which includes the scope of work to be undertaken.
- c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

The Good Food Institute (GFI) Brazil has previously published a book in 2023 titled "HACCP plan development and application to a cultivated meat target-product" which aims to provide guidance for production of cell-based food products.

d) Amenability of the subject of the proposal to standardization.

Although the processes used by industry may be subject to further development and refinement, the subject of the proposal is amenable to standardization by developing it in a modular nature of different elements in a cell-based food production facility, with the capacity for further additions based on developments of technologies in the future.

### e) Consideration of the global magnitude of the problem or issue

The nascent field of cell-based food presents an exciting frontier in the food industry, with numerous companies actively developing innovative products in this space. However, before these cell-based foods can enter the market, they would require regulatory approval. This lack of regulatory clarity has the potential to impede the growth and development of the cell-based food industry. The Codex guidance would serve as the initial step towards the international harmonization of cell-based foods.

The Codex Procedural Manual also includes references to the volume of production, consumption, and trade, which help Codex determine its work priorities. Currently, over 160 cell-based food companies are keen to obtain approval to market their cell-based food products but are unable to do so differences in regulatory process. The establishment of international standards would facilitate the approval process for companies across various countries, thereby driving industry growth and facilitating trade of the product. This advancement holds the potential to address global food challenges by contributing to the development of a sustainable and resilient food system through the production of meat.

#### 5. Relevance to Codex Strategic Objectives

The proposed work directly relates to several Codex strategic goals from the Codex Strategic Plan: 2020-2025.

• Strategic Goal 1: Address current, emerging and critical issues in a timely manner

Cell-based food production is a growing industry, with the establishment of the Code, it would provide practical guidance on good manufacturing practices for cell-based food production facilities for member countries. CAC45 had also recognised that setting international standards on NFPS is in line with this goal.

The production of cell-based foods offers a more sustainable alternative to conventional meat production. Cell-based foods are a more sustainable option as it requires less land and water and have a lower global warming potential<sup>11</sup>. Prioritizing sustainably produced food is crucial for ensuring the long-term availability of food while minimizing adverse environmental impact. Sustainable food production plays a pivotal role in addressing food security challenges by ensuring stable and resilient food supplies. It also contributes to equitable access to affordable and nutritious food, thereby bolstering food security for future generations.

- <u>Strategic Goal 2: Develop standards based on science and Codex risk-analysis principle</u> Development of standards is expected to leverage on expertise from various FAO expert committees/meetings. This would ensure that scientific advice is used consistently in line with Codex risk analysis principles.
- <u>Strategic Goal 3: Increase impact through the recognition and use of Codex standards</u> As there is currently no international guidance for cell-based foods, countries would refer to Codex standards for cell-based foods, which would increase awareness and utilisation of Codex standards. The Codex Code of Hygienic Practice is already widely recognised and used by many countries. Member countries can look towards this Code for further guidance on the production of cell-based foods.
- 6. Information on the relationship between the proposal and other existing Codex documents, as well as other ongoing work

The Code of Hygienic Practice will build on the General Principles of Food Hygiene (CXC 1-1969).

#### 7. Identification of any requirement for and availability of expert scientific advice

FAO/WHO published a document on the food safety aspects of cell-based food. There may be a need to seek scientific advice from these relevant experts who were involved in producing this document.

Additionally, there may be a need for additional scientific advice from FAO/WHO's expert body JEMRA for inputs related to microbial standard in the manufacture of cell-based foods.

# 8. Identification of any need for technical input to the standard from external bodies, for planning purposes

The Good Food Institute is a non-profit organization that promotes development of alternative proteins including, cell-based foods, products derived from precision fermentation or biomass fermentation. They may be consulted due to their extensive work in NFPS related topics.

# 9. Proposed timeline for completion of new work, including the start date, proposed date for adoption at Step 5, proposed date for adoption by the Commission

A five-year timeline is proposed for the completion of the proposed work as listed below:

- 2024: Preliminary consultations with Codex members
- 2025: Consideration of the proposed new work at CCFH
- 2025: Formation of EWG to discuss project document for new work

2026: Consideration of draft project document for new work at CCFH

<sup>&</sup>lt;sup>11</sup> Sinke, P., Swartz, E., Sanctorum, H., van der Giesen, C., & Odegard, I. (2023). Ex-ante life cycle assessment of commercial scale cultivated meat production in 2030. *The International Journal of Life Cycle Assessment*, 28(3), 234-254.

2026: Approval of new work by CAC49

2027: Discuss new work and circulate draft text at CCFH for comments

2027: Adoption of draft text at Step 5 at CAC50

2028: Circulate draft text at CCFH for comments

2028: Adoption at Step 8 at CAC51