APAC-SCA
Asia-Pacific Society for Cellular Agriculture

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APAC REGULATORY
COORDINATION FORUM

Cell Line Development

White Paper
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FOREWORD

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The current food system—particularly the meat and dairy livestock sector—has been a source of social and economic growth for developed and emerging economies. The food system is also responsible for about 30 percent of current anthropogenic greenhouse gas emissions, with animal products accounting for more than half of those emissions. [1] Despite calls from international organisations such as the United Nations for consumers to adopt a plant-forward diet to limit their carbon footprint, many are not willing to give up eating meat.

In this new global context, the Intergovernmental Panel on Climate Change (IPCC) identified cultivated meat as a transformative solution to the world's food system that "can promise substantial reductions in direct greenhouse gas emissions from food production". [2]

The cellular agriculture industry has grown tremendously, with more than 170 cultivated food companies established since the first cultivated beef burger was debuted over a decade ago. These companies produce a wide range of cultivated proteins, from beef, chicken, seafood, and pork to more specialised entries such as foie gras and caviar.

Many companies have, or will soon possess, the capacity to transition from small-scale research and development to global market commercialisation. Demonstrating that this process can be executed safely and efficiently is now a primary consideration for the industry and regulators.

Despite more countries granting regulatory approvals for cultivated food products, we recognise that many food safety authorities may have questions on the appropriate controls required to prevent or mitigate potential hazards.

APAC-SCA thus initiated and launched the APAC Regulatory Coordination Forum in October 2023 in collaboration with GFI APAC as a formal mechanism for continuous and systematic cross-border dialogue between companies, industry associations, think tanks, governmental agencies, and food safety regulators in different jurisdictions. Gathering fifteen key organisations across ten APAC countries, the Forum focuses on all aspects of cultivated food products fit for human consumption and is intended to complement the activities carried out by food safety authorities. This includes the mutual recognition of coordinated regulatory frameworks, which in turn minimises trade barriers and costs to consumers.

This white paper on cell line development is a product of the ongoing work developed under the APAC Regulatory Coordination Forum. It aims to increase public awareness of the current gaps where regulatory coordination can support innovation and drive the commercialisation of cultivated food products.

By delineating potential solutions and technical recommendations, we hope that this white paper will be helpful for relevant stakeholders to identify the best approaches to deliver science-based policies and regulations as the world strives to meet the soaring demand for alternative proteins.

EXECUTIVE SUMMARY

The production process for cultivated foods usually starts with isolating cells from animals and adapting them for sustained growth and scalability *ex vivo* through a cell line development phase. Given its importance, cell line development was selected as a key topic of focus by the APAC Regulatory Coordination Forum in 2024.

The APAC Regulatory Coordination Forum White Paper on Cell Line Development identifies four current gaps and offers potential solutions and pathways for collaboration among academia, the industry, and food safety regulators. This document serves as a valuable starting point to inform and empower regional regulators, companies, and researchers to facilitate internationally harmonised standards, guidelines, and recommendations on the food safety aspects of cell lines.

1. **Cell line documentation:** Proper documentation ensures the traceability, safety, and regulatory compliance of cell lines used in cultivated food production. Companies currently face challenges related to inconsistent data and documentation requirements, particularly around sourcing animal cells and their characterisation. This section recommends the creation of a “specifically named" guideline for cultivated food cell lines, inspired by existing guidelines from other sectors, as a means of enabling consensus around documentation requirements. In the short term, the development of toolkits that provide guidance on recommended data and documentation for companies to collate is suggested.

2. **Defining cell line stability:** Establishing appropriate guidelines for cell line stability remains a significant challenge. This section explores various approaches used by the industry to date, and potential best practices in line with practical hazards presented by changes in cell line characteristics during the production of cultivated foods. It recommends the need for coordinated guidelines, including preferred characteristics to monitor with associated cutoffs for allowable variability, that address the potential risks of genetic drift and phenotypic changes only where they could affect the quality and safety of cultivated food products.

3. **Genetic modifications:** Using genetic modifications for the development of high-quality cell lines presents opportunities for improving production efficiency. However, regulatory frameworks in the APAC region lack clarity on assessing the safety of genetically modified cell lines. This white paper recommends developing standardised criteria for assessing genetically modified cell lines. It also encourages the conduct of open-access research by relevant experts to advance understanding of the safety implications of these technologies, particularly for regulatory agencies.

4. **Trade requirements:** The regulatory landscape for cellular agriculture products is fragmented, with no clear international standards. This section outlines the need for coordinated international guidelines, particularly around the classification of cell lines, intellectual property, and trade barriers. This white paper emphasises the importance of APAC countries taking a leadership role in setting global standards, in collaboration with a variety of international standard-setting agencies, to promote the safety and marketability of cultivated food products.

The APAC Regulatory Coordination Forum will continue to work closely with companies, industry associations, think tanks, governmental agencies, and food regulators to support the development of scientific, risk-based frameworks to bring cultivated foods to market in a timely manner. Through this work, we will ensure that the APAC region is well-positioned to lead in this emerging sector and build a more secure and climate-resilient food system for all.

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INTRODUCTION

Cultivated foods have garnered increased attention from policymakers in the APAC region as an emerging field that can deliver a steady supply of protein without the environmental and ethical concerns associated with industrial animal agriculture. Cultivated foods are formulated with cells sourced from animals to create a product with organoleptic qualities and texture with the potential to be comparable to those of their conventional counterparts.

The APAC Society for Cellular Agriculture (APAC-SCA) recognises that few countries have experience processing food safety applications for cultivated foods, with many lacking the time, resources, and infrastructure needed to evaluate their safety. APAC-SCA thus initiated and collaborated with the Good Food Institute APAC (GFI APAC) to launch the APAC Regulatory Coordination Forum in October 2023. The Forum hopes to facilitate knowledge sharing and support cross-border coordination among national food safety authorities in the APAC region to develop clear and effective pathways towards commercialising cultivated foods for human consumption.

Given this context, APAC-SCA and GFI APAC organised a series of one-to-one, closed-door virtual consultations with national industry associations and key players across ten APAC countries. These stakeholders signed a non-binding memorandum of understanding to demonstrate their commitment to establishing the Forum. The aim was to identify five regulatory topics that APAC regulators could be interested in collaborating on and shed light on the barriers and drivers that could impede the implementation of an effective regulatory approval process for cultivated foods. Based on ongoing interactions with local regulatory agencies, the consultations revealed the top five regulatory topics for collaboration:

- Cell line development
- Cell culture media components
- Microbiological hazards
- Allergenicity
- Labelling

Cell line development was selected as a topic of focus in 2024, with four issues outlined as current gaps where regulatory coordination could support innovation and commercialisation of cultivated foods.

1. Cell line documentation
2. Defining cell line stability
3. Genetic modifications
4. Trade requirements

By delineating potential solutions and technical recommendations for the issues identified, this white paper is a valuable starting point to inform and empower regional regulators, companies and researchers to facilitate internationally harmonised standards, guidelines, and recommendations on the food safety aspects of cell lines.

The APAC Regulatory Coordination Forum will continue to work closely with companies, industry associations, think tanks, governmental agencies, and food regulators to facilitate dialogues, share best practices, and work towards a consistent approach to cultivated food regulations within the APAC region.

CELL LINE DEVELOPMENT

Cultivated foods are produced using animal-derived cells, such as stem cells, harvested from specific tissues to produce desired products.

The production process usually starts with isolating cells from animals, establishing primary cell cultures *in vitro*, and subsequently adapting the cells for sustained growth and scalability through a cell line development phase (see Figure 1). The final goal of this phase is to generate stable and continuous cell lines with desirable functional properties.[3] Robust cell line development is crucial to enable the scaling of cultivated food production while maintaining a focus on quality, safety, cost, and efficiency.

National food safety authorities in the APAC region are at different developmental stages when regulating cell lines for cultivated foods. Singapore and South Korea have publicly accessible frameworks and guidance documents. In Thailand, Japan, India, and China, dedicated working groups have been set up to understand the process of risk assessment and pre-market approvals.

Regulators in Australia/New Zealand and Israel have already undertaken scientific assessments of cultivated foods but have not publicly released their assessment guidelines.

From the industry perspective, a collaborative framework of shared research objectives and information can reduce redundancies and accelerate development of cultivated foods. This would result in better-informed decision-making and the creation of risk- and evidence-based policies across the region that support the growth and acceptance of cultivated foods as sustainable and safe protein sources.

To better understand the current gaps where regulatory coordination could assist in supporting innovation and commercialisation timelines for cultivated foods, a working group under the APAC Regulatory Coordination Forum was formed to identify the priority areas for coordination and collaboration related to cell line development. This white paper will focus on the four issues outlined, as well as potential solutions, technical recommendations, and relevant resources proposed for consideration.

Figure 1: A flow chart of a typical cell line development process for cultivated food

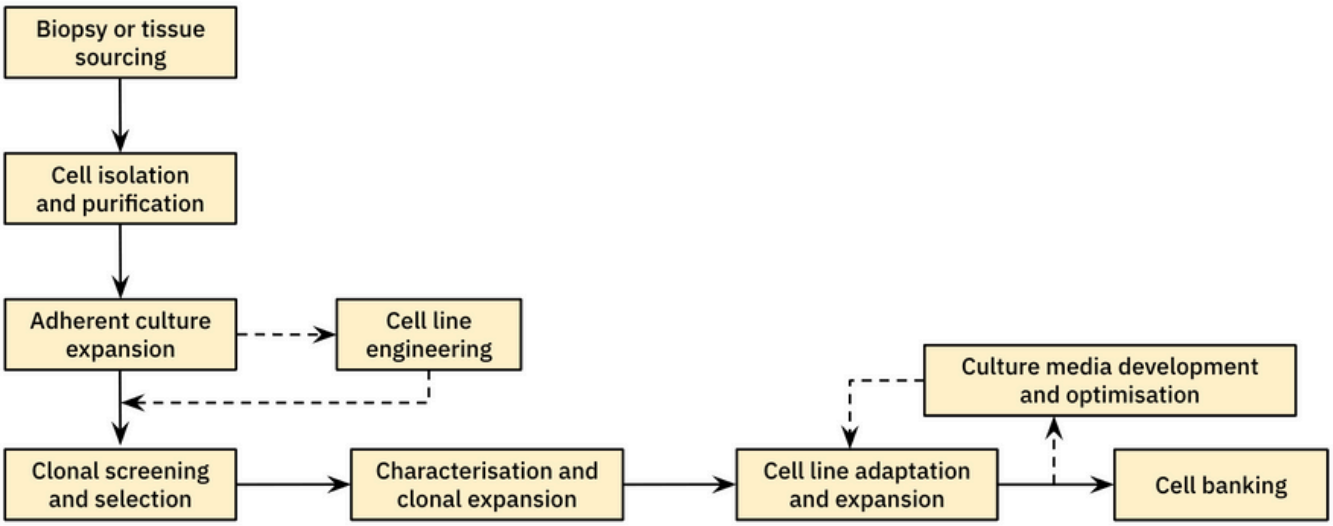

Table 1: Four issues and their recommended areas of coordination and collaboration

Issue identified	Recommended areas of coordination and collaboration
Cell line documentation	• Creating guidelines for cell line documentation that are specifically dedicated to the production of cultivated foods that can facilitate compliance with regulatory submission requirements • Developing toolkits that provide guidance on the data and documentation important for traceability and quality assurance, and methods to obtain them
Defining cell line stability	• Clearly define the parameters to be monitored or tested to demonstrate cell line stability, with an articulated understanding of how these parameters are relevant to the quality assurance of the cell culture during the production process as well as end-product safety • Collaborating to define best practices for end-product characterisation to address regulatory concerns related to cell line stability, such as the potential for increased expression of endogenous allergenic proteins
Genetic modifications	• Encouraging the publication of expert assessments of practical food safety considerations for cultivated foods produced using genetic modification or genetic engineering technology, and proactive information sharing with regulatory agencies on these topics • Establishing critical quality attributes for genetically modified or genetically engineered cell line characterisation and their integration into international guidance documents through bodies such as Codex or ISO
Trade requirements	• Educating policymakers on the development of common standards, guidelines and other regulatory needs to facilitate trade among countries • Streamlining the role of agencies in the creation of international standards, guidelines, and approval processes

Cell line documentation

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Challenges

Cell line documentation can be broken down into two subcategories of information that will be required by food safety authorities to demonstrate the provenance and safety of cell lines used for the production of cultivated foods. One is the sourcing and isolation processes of the primary cells harvested from animal tissues or biopsies, and the second is the characterisation and quality assurance of cell lines developed from the isolated primary cells. These subcategories and their challenges are described below.

Sourcing and isolation processes of the primary cells:

Cells for cultivated food production are typically derived from tissue samples or biopsies sourced from either slaughtered or live animals across a wide range of terrestrial and aquatic species. There is no apparent consensus on a preferred cell type for cultivated meat production. Multiple cell types isolated from a variety of tissues, with unique proliferation and differentiation capacities, are being used according to the needs of each company's production workflow and intended end products (see Table 2).

Table 2: Common cell types used for cultivated food production

Stem cell classification	Stem cell/progenitor sub-type	Proliferation capacity	Differentiation capacity
Adult stem cells	Muscle satellite cells (MuSCs)	Limited	Muscle cells
	Mesenchymal stem cells (MSCs) or fibroblasts	Limited	Fat, bone, cartilage & connective tissue cells
	Fibroadipogenic progenitors (FAPs)	Limited	Fat & connective tissue cells
Pluripotent stem cells	Embryonic stem cells (ESCs)	Indefinite	Any cell type
	Induced pluripotent stem cells (iPSCs)	Indefinite	Any cell type

According to an industry survey on cell line utilisation trends, a majority of companies cited a lack of clarity on documentation requirements related to animal sourcing and cell isolation as a barrier to seeking regulatory approval in their high-priority markets.[4] Most respondents to this survey did not express confidence in their understanding of the data necessary to include in regulatory submission dossiers. Furthermore, there was limited agreement among respondents on the minimum background information deemed necessary to acquire regarding the donor animal as well as details of its farming/breeding environment. This suggests that the types of information that companies are likely to gather are those that are convenient or easily accessible rather than those that would be most important for traceability and regulatory compliance across multiple markets.

While flexibility in documentation requirements could enable safety assessments to be submitted to multiple regulatory agencies for review, as discussed in Section 3.4.1 of a 2023 food safety report published by the Food and Agriculture Organisation (FAO) of the United Nations and the World Health Organisation (WHO),[5] the broad nature of regulatory guidelines may be precluding stakeholders from adequately acquiring the right data and documentation for dossier submission in the first place. To help bridge this gap and arrive at a middle ground, existing international guidelines pertaining to the origin, source, and history of cell lines, such as those outlined in the International Conference on Harmonisation (ICH) Q5D Guideline on the Derivation and Characterisation of Cell Substrates Used for the Production of Biotechnological/Biological Products,[6] may be considered to develop a version that provides a preliminary outline of animal source documentation considerations relevant to the production of cultivated foods.

Relevant resources:

Cell line development and utilisation trends in the cultivated meat industry: GFI APAC conducted an industry-wide survey to address the lack of publicly available data on cell line developments in the cultivated meat industry. The comprehensive report covers practical measures for meeting future demands for cell lines and characterisation requirements, as well as regulatory concerns.

ICH Q5D guideline on the derivation and characterisation of cell substrates used for the production of biotechnological/ biological products: ICH's guideline on the derivation and characterisation of cell substrates used for the production of biotechnological/biological products provides recommendations on the information that should be presented for pre-market approval.

Food safety aspects of cell-based food: As the commercial viability of cultivated foods expands, FAO and WHO released a publication that examines the technologies used to produce cell-based foods, identifies potential food safety hazards, and explores regulatory frameworks in various countries.

A related challenge is an absence of publicly available guidance that distinguishes the animal source documentation a company should provide if their cells are sourced directly from an animal at a livestock farm/fishery from those of a cell line purchased from a business-to-business (B2B) cell line provider or cell line repository. Increasingly, cultivated food companies are looking to cell line suppliers or cell banks to source high-quality, scalable cell lines rather than solely developing them in-house.

Depending on the source, the availability of information on the origin and identity of the cells can be quite variable. For example, UPSIDE Foods stated in their United States Food and Drug Administration (U.S. FDA) cell culture consultation dossier that their records identified the time and place the cells were obtained from the animal source and inspection details of the animal ante- or post-mortem if it was intended for the human food supply chain. By contrast, GOOD Meat's FDA cell culture consultation dossier detailed that their cell line originated from a commercially available chicken fibroblast cell line (UMNSAH/DF-1) deposited at the American Type Culture Collection (ATCC). They provided a brief description of how the cell line was generated but did not include records related to the animal source itself, likely due to the unavailability of this information from the repository.

In this regard, it would be prudent for regulatory bodies to assess the most necessary and sufficient data for tracing a cell line depending on its source. Collating these as "recommended data to be reported" for a particular sourcing approach would offer a clear direction for companies when preparing cell line documentation for their dossiers.

The species of the animal source is also an important consideration.

In Section 4.3.3.1 of the FAO and WHO food safety report,[5] pathogens from animal-derived cells were identified as potential biological hazards. The potential mitigation control measures considered are (1) access to a health certification of the herd, for terrestrial livestock, or the lot (for aquaculture), and (2) health inspection (pre- or post-slaughter) of the source animals and biopsied tissues by a veterinarian or certified professional. However, it is also noted that health certificates and inspections are rare or non-existent for wild-caught species (e.g., wild fish) and other conventional seafood, and it could be argued that it is more important to check the health status of the subsequent cell line rather than the donor animal since a pathogen-free cell line can be generated even if the health status of a donor animal is unknown.

Therefore, a species-specific approach to determining animal source documentation required for regulatory submission could be considered. Health certifications and veterinarian inspection reports may be recommended for domesticated livestock sources. However, in lieu of health certifications, a list of known pathogens and adventitious agents across different species, both domesticated or wild-caught sources, could be collated to facilitate comprehensive testing of all cell lines and consistent safety data reporting. A useful reference is the FAO's publication titled *Assurance of Seafood Quality* , which lists various disease agents which have been associated with the safety of conventional seafood.[7]

As more B2B cell line developers enter the ecosystem and the cultivated food supply chain grows, clear guidance on the data and documentation requirements for distinct cell sourcing pathways is recommended. This will help ensure consistency and avoid confusion with data reporting in dossiers, especially in cases where companies may be sourcing cell lines via multiple pathways simultaneously.

Characterisation and quality assurance of cell lines:

Ravikumar *et al.* reported that the number one knowledge gap of surveyed cultivated meat companies regarding cell line regulatory documentation was cell line characterisation and testing requirements (n=19/24 respondents).[4] General guidelines from the Singapore Food Agency (SFA),[8] U.S. FDA,[9] European Food Safety Authority (EFSA),[10] and FAO[5] provide initial frameworks from which companies can assess what testing to conduct and documentation to collect; however, ambiguity persists as to which specific information is essential in all, or only, select jurisdictions. This almost certainly results in companies wasting time and resources generating extraneous documentation and/or rendering certain cell lines invalid for use in some, or all, jurisdictions due to a lack of specific documentation required by a regulatory agency. Additionally, inconsistencies in documentation requirements also make dossiers difficult for regulatory agencies to evaluate, further increasing the time and resource burden in the approval process.

An additional challenge is the determination of which analytical protocols will comply with regulatory requirements for documentation development. For example, in their respective U.S. FDA cell culture consultation dossiers, GOOD Meat[11] analysed cell line stability by cytogenetics and RNA sequencing (RNA-seq) based protocols, whereas UPSIDE Foods[12] monitored cell doubling time and protein content to fulfil the same documentation requirement. In this regard, guidance on the most appropriate protocols to employ, flexibility regarding the different options that can be considered, and transparency around protocols that are not recommended will allow companies to adopt experimental approaches best-suited to their capabilities while keeping regulatory compliance at the core of their characterisation efforts.

This guidance may also be extended to describe species-specific cell line safety testing criteria.

According to the U.S. FDA cell culture consultation dossiers of GOOD Meat and UPSIDE Foods, both companies performed plate counts for bacteria, yeasts, and moulds; additional indicator microorganisms (coliform bacteria, and *Enterobacteriacea*, such as *E. coli, Salmonella sp.*) were also enumerated.[10 11] Sensitive polymerase chain reaction (PCR) assays were used to check for mycoplasma contamination. Of note, the two companies tested different panels of avian and mammalian viruses. In this regard, developing a prioritised list of species-specific pathogens and adventitious agents, the presence of which may be assessed easily by companies through standard PCR-based assays, will enable consistency in safety data reported in dossier submissions. These examples highlight the urgency of establishing standardised and publicly available guidelines so that cell line developers can understand what parameters need to be measured and documented during the development process, and companies do not waste resources on following non-compliant protocols or generating extraneous data.

A related hurdle in cell line characterisation is that existing methods were developed for assessing cell lines used in the biopharmaceutical industry. Although this is a useful reference, not all of these standards are applicable to cultivated food. For instance, cell therapy products that involve the transplantation of live human cells are often tested for tumorigenicity before human use,[13] whereas safety concerns over the ingestion of tumorigenic cells are neither pertinent nor unique to cultivated meat (for further details, see section 4.4 of the FAO & WHO 2023 report[5]).

Recommended areas for APAC coordination and collaboration

Creating guidelines for cell line documentation that are specifically dedicated to the production of cultivated foods that can facilitate compliance with regulatory submission requirements

Coordination efforts can be channelled towards developing guidance on the cell line-related data and documentation needed for regulatory dossiers. Inspiration may be taken from existing resources from other sectors:

i. ICH Q5D Guideline on the Derivation and Characterisation of Cell Substrates Used for the Production of Biotechnological/Biological Products[6]

ii. U.S. FDA's guidance for industry on the characterisation and qualification of cells used for viral vaccine production[14]

iii. Guidance Document on Good Cell and Tissue Culture Practice 2.0 (GCCP 2.0)[15]

iv. Organisation for Economic Co-operation and Development (OECD)'s Guidance Document on Good In Vitro Method Practices (GIVIMP)[16]

These documents contain guidelines that are useful starting points to enable consensus on cell sourcing, cell culture, and cell banking documentation requirements in the production of cultivated foods. Notably, they are broad and non-binding, which may be advantageous in providing flexibility and opportunity for companies that are employing innovative technologies or techniques to adopt the guidelines that best align with their needs and operations. However, taking into consideration the wide variety of technologies used in the production of cultivated foods and the requirement for case-by-case assessments, the challenge of such broad guidelines is that they can create uncertainties around the documentation practices or data acquisition approaches that may be acceptable for a particular process or input. This could lead to companies being unable to receive regulatory approval or facing significant delays.

Therefore, to arrive at a middle ground, a "specifically named" guideline dedicated to cultivated foods may be adapted from the currently available guidance documents mentioned above and tailored accordingly.

Such a resource presents a significant opportunity to reduce uncertainty amongst companies and promote coordination of regulatory requirements across countries. For example, developed resources could be integrated into the International Organisation for Standardisation (ISO) guideline on the "principles for production of cell cultured food products", for which a working group was recently launched to be collaboratively developed by national standards organisations of member countries. A key consideration for such a document would be the provision of certainty and specificity in appropriate processes, protocols, and data requirements, while maintaining a provision to support and promote innovation in the nascent cultivated food industry. This will require close collaboration between national standard-setting bodies, regulatory agencies, cultivated food product manufacturers, upstream ingredients and raw material suppliers, and ancillary service providers to strike an appropriate balance that will remain fit for purpose.

Developing toolkits that provide guidance on the data and documentation important for traceability and quality assurance, and methods to obtain them

While comprehensive international standards or guidelines relevant to all aspects of cell sourcing and cell line development will likely take years to develop and approve, toolkits could be developed in the short term to facilitate the cross-coordination of information and knowledge amongst food regulators of different countries. These toolkits could contain templates and guidance that would reduce the burden on companies to independently determine what information collection and testing they should complete and reduce the burden on regulators to communicate their requirements and assess dossiers that use a variety of methodologies and rationales.

Topics that may be addressed in the toolkits include:

(A) Information regarding the cell sourcing pathway: A checklist may be created to capture information regarding a company's cell sourcing approach and include details important for traceability, such as:

a. Species in consideration

b. Farm/ranch licences

c. Specifics of the farming/breeding method used at the location

d. Physiological characteristics of the source animal (e.g., age, sex, weight, breed, etc.)

e. Health indicators of the source animal (e.g., vaccination status, disease transmission history within the herd, etc.)

f. Health certifications and veterinarian inspection reports for domesticated livestock sources

g. Anatomical location of the source tissue

h. Cell type and isolation details

i. Cell line generation method

j. Cell line specification sheet (only if purchased from a repository or B2B cell line provider)

(B) Time points for cell line characterisation: The purpose of genotypic, phenotypic, and functional characterisation is to ensure cell line safety and quality. The toolkit may include a description of recommended critical checkpoints when cell line safety and quality testing should be performed along the production stages (Table 3) and indicate a minimum number of samples required for testing.

Table 3. Proposed production stages for cell line characterisation

Stage of production for cell line characterisation	Definition
Initial cell line development	This is the initial point at which an individual cell line with a homogenous phenotype is developed from an initial heterogeneous mix of cells obtained from an animal or egg.
Master cell bank	A preserved master bank of cells provides a characterised common starting source for each production lot.
Working cell bank	A working cell bank, derived from the master cell bank, is usually used to provide cells to initiate the manufacturing process.
Production – cell proliferation	At this stage of production, the aim is to exponentially increase the number of cells in production.
Production – cell differentiation	At this stage of production, the aim is to trigger the maturation of proliferating stem or progenitor cells into a differentiated cellular phenotype, generally muscle or fat cells.

(C) Tools for cell line characterisation: A directory of commonly used resources, characterisation criteria, analytical approaches, and experimental methods may be developed to help companies understand the types of characterisation data and documentation relevant to regulatory approval and how to obtain them. A flowchart or table indicating the parameters that should be documented at various stages of cell line development, together with suggested assays for each parameter, would be helpful.

Considering cell line safety, the toolkit could include:

a. A prioritised list of known pathogens and adventitious agents to test cell lines derived from different species, especially wild-caught species that would not have health certifications. An example of a useful reference that can be used for this is the FAO's publication, titled *Assurance of Seafood Quality*, which lists various disease agents associated with the safety of conventional seafood.[7]

b. Examples of analytical kits that test for common foodborne pathogens, such as PCR kits[17] offered by the biotechnology solution providers, may be adopted as a standardised tool for safety testing against species-specific pathogens.

c. A description of experimental methods that may be employed for species validation, especially during initial passages and cell banking, such as DNA barcoding,[18] isoenzyme analysis,[19] or antibody-based assays.[20] Other options include sequencing for the mitochondrial cytochrome C oxidase I (COI) gene, which UPSIDE Foods performed for species verification of their cultivated chicken cells;[12] a similar method is used by the U.S. FDA to identify different fish species.[21] UPSIDE Foods also conducted enzyme-linked immunosorbent assays (ELISA) for meat species identification in accordance with the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) Microbiology Laboratory Guidebook: Identification of Animal Species in Meat and Poultry Products.[12,22]

Considering cell line quality, the toolkit could include:

a. A description of characterisation criteria and experimental methods that may be used to evaluate cell line quality as discussed further in the **'Defining cell line stability'** section. For example:

   i. It is important to monitor the population doubling time and cell yields during the proliferation and differentiation phases. Both parameters were measured by UPSIDE Foods[11] and GOOD Meat,[12] as deviations away from the acceptable range may indicate issues with cell line safety and/or quality. A low cell yield can indicate microbial contamination, cell line instability, or a change in cellular phenotype (e.g., differentiation). Measuring the protein content per cell serves a similar purpose, though this may be difficult to quantify for cell lines grown on scaffolds and microcarriers.

   ii. To ensure that cell identity is maintained during proliferation and cells differentiate into desired target cell types during differentiation, the expression of cell type-specific genes, proteins, or cell surface markers is important to evaluate. For example, differentiated muscle cells should express muscle cell-specific genes encoding for proteins, such as myosin heavy chain.[23] A combination of methods like quantitative PCR,[24] ELISA-based assays,[25] western blot analyses,[26] and flow cytometry[27] may be used to confirm this.

   iii. To evaluate whether cell functionality is maintained during proliferation or suitably acquired during differentiation, phenotypic assessments may be carried out. For example, differentiated fat cells should be positive for lipid droplets.[23] Staining, using a histochemical dye like Oil Red-O or fluorescence-based dyes like BODIPY, may be used to confirm the presence of lipid droplets.[28]

b. Information of service providers with offerings relevant to cell line characterisation:

   i. Isoenzyme analysis services are available from a number of providers, including Creative Bioarray [29] and Molecular Diagnostics Services. [30]

   ii. Organisations such as SGS, [31] Eurofin Scientific, [32] and QIMA [33] offer testing services for food microbiology, food allergens, and food nutritional analysis, though the testing procedures may need to be adjusted and validated for cultivated foods.

In scenarios where companies may be unable to provide some data due to technical limitations, regulatory agencies should retain the flexibility to assess submissions on a case-by-case basis and offer room for alternatives. Finally, while cell line safety and quality data can be collected in-house, some claims should be independently validated by a certified third party to provide extra assurance. This can include verifying cell line identity and sterility and confirming the biochemical and nutritional profiles of the produced cell mass. For example, GOOD Meat indicated in its U.S. FDA cell culture consultation dossier that master and working cell banks were checked for cell purity/identity both in-house and at a third-party laboratory. [11] As the industry continues to expand, we believe there will be an increasing demand for certified third-party service providers to help cell line developers conduct standardised assays for cell line safety and quality.

Defining cell line stability

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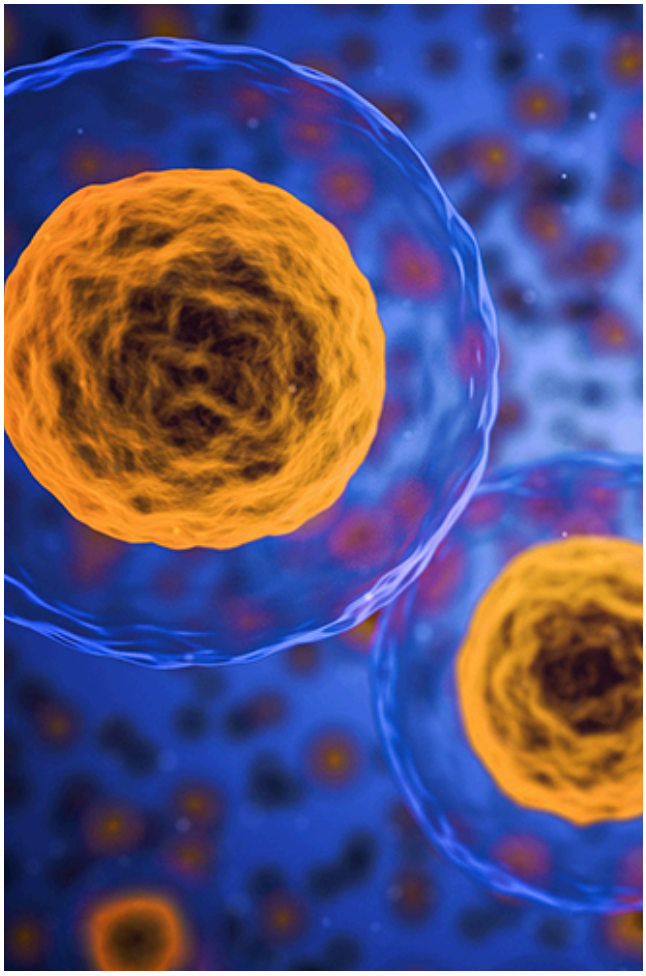
Challenges

Currently, there is a lack of international consensus and guidance on whether demonstrating cell line stability is fundamentally required for food safety, and if so, what type of data or best practices are sufficient to demonstrate it. This is illustrated by the fact that demonstration of genetic stability is not a food safety consideration for conventional food production. The gene expression profiles of cells for cultivated food production are expected to change as the cells transition from a primary state to homogeneous two-dimensional cultures and eventually for some, suspension cultures over time. In practice, stability can be inferred if there is no alteration in phenotype, doubling time, and the expression of specific markers that define their identity as stem, muscle, or fat cells.

One option raised by stakeholders as a more practical alternative to the demonstration of genetic stability is that end-product characterisation can be relied upon for all relevant food safety considerations. An assessment of known metabolites, toxins, and allergens may be sufficient to demonstrate the safety for consumption of the end product. However, an international consensus on the suitability of this approach and appropriate markers and acceptable variability thresholds of end-product characterisation would need to be generated.



Specific challenges related to cell line stability and its effects on food safety include:

- The potential for genetic and phenotypic drift, which can lead to changes in cellular morphology and behaviour over time.[34] Monitoring these changes is essential, and setting up guidelines for quality control (QC) parameters during production such as the number of passages and doubling time could help manage this risk. However, establishing such guidelines can be challenging due to the variability in how different cell lines behave.
    - For example, genome instability resulting from prolonged passaging could theoretically lead to dysregulation in gene expression, potentially increasing the expression of endogenous allergenic proteins. Monitoring these proteins, either at the transcription level or through targeted protein-level assays, could be useful to identify any increased allergenicity risk.[35] Coupling this with allergenicity assessments of the end product may be a prudent approach towards evaluating food safety more comprehensively. This could involve targeted analysis and characterisation to determine if any known allergen is present in the final product.
- Unintended effects, such as pleiotropy or off-target effects, which can arise during the genetic modification process. Currently, there is no coordinated guidance on how such effects can be monitored. There needs to be a clearer understanding of the potential food safety risk that could actually arise. Characterising the end product by doing ribonucleic acid sequencing (RNA seq) and karyotype analysis could be one way to address these concerns.

Based on publicly available regulatory dossier information, we can understand which approaches and considerations of cell line stability have been deemed acceptable by regulatory authorities to date. This has variably included cytogenetic, genomic, transcriptomic, proteomic, and cell activity phenotype quantification across the three dossiers, resulting in partial public disclosures from GOOD Meat, UPSIDE Foods, and Vow Foods. The wide array of techniques used to demonstrate and justify cell line stability from these initial approvals demonstrates the lack of consensus on this topic in the sector.

A brief outline of the approaches used by these companies is included below:

GOOD Meat conducted characterisation of cell line stability of cultivated chicken cells for manufacturing by both cytogenetic analysis and RNA sequencing at the parental cell bank stage and from one representative end-of-production harvest of cultivated chicken.

- Their overarching justification of stability was that: “A cell line is considered stable if modal chromosome number does not change significantly and there is no accumulation of cytogenetic aberrations (chromatid-type, chromosome-type, and severely damaged) during the process.[36] If such characteristics are not stable, then it should be demonstrated that the instability does not adversely impact manufacturing or product consistency.”
- In the cell culture consultation dossier, it was stated that RNA sequencing was performed in addition to cytogenetic analysis, due to the fact that bird species present a high number of chromosomes and many cytologically indistinguishable micro-chromosomes. This highlights that some species-dependent considerations may need to be incorporated into future guidance development.
    - RNA sequencing data was also used to demonstrate that no upregulation of allergenic proteins occurred in end-of-production cells.

- GOOD Meat did not state what their acceptable threshold for chromosomal stability was, but indicated that 76 percent of cells at the parental cell bank stage contained 72-78 chromosomes, while 67 percent of cells contained between 68-74 chromosomes (noting that the normal number of chicken chromosomes is 78).

UPSIDE Foods demonstrated phenotypic stability of their cell lines over long term passaging to "ensure that analytical data from finished product testing is reliable and representative of long-term commercial production." UPSIDE Foods quantified cell doubling time and tissue production over time. They quantified the stability of these phenotypic traits by a cutoff of <30 percent change in their average value based on triplicate samples cultured for more than 90 days. Development of consensus on appropriate cutoff points for acceptable cell variability is an important consideration for any future guidelines developed on this topic.

- As UPSIDE Foods also included an assessment of a cell line that employed gene engineering technology, they provided the following safety justification related to the potential effects of pleiotropy and off-target effects: "Findings over the last 20 years of research, however, have demonstrated that unintended compositional effects that could be caused by genetic amendments have not materialised.[37] This conclusion is consistent with observations by UPSIDE Foods that naturally occurring transgenic events routinely occur in poultry without evidence of significant deleterious effects to the animal or its lineage of descendants. For example, in nature, the integration of DNA from retroviruses (known as endogenous retroviral fragments) into the chicken's genome in a manner that is passed vertically from one generation to the next is endemic within poultry consumed as food without known pleiotropic or other deleterious effects; many of these integrations are even translated into protein."[38]

Vow Foods investigated both genotypic and phenotypic stability of its quail embryonic fibroblasts from initial cell line development through to final harvest from the bioreactor. Vow Foods conducted whole genome sequencing, which found the greatest number of genomic variants occurred when the quail cells were adapted to culture conditions during the immortalisation process. They claimed these variants remain stable up to the harvest stage, with only a very small proportion of new variants occurring during the production process.

- Vow Foods also determined that genomic variants observed did not alter biological components or processes based on a gene ontology analysis. This included additional studies investigating the effect of longer cell culture cycles and altered culture media formulations, which did not impact their conclusions.

- To investigate phenotypic stability, Vow Foods conducted a targeted proteomic analysis focused on proteins that are relevant to the safety of food or could impact the whole diet of consumers (because of anti-nutrient or allergenic properties).

Recommended areas for APAC coordination and collaboration

Clearly define the parameters to be monitored or tested to demonstrate cell line stability, with an articulated understanding of how these parameters are relevant to the quality assurance of the cell culture during the production process as well as end-product safety

The overarching aim for coordination and collaboration should include defining the genetic, transcriptomic, proteomic, metabolomic, and/or phenotypic parameters that are suitable for characterisation and monitoring for cell line stability, and building an international consensus on this topic. This should also include clarification of relevant species or cell type specific considerations, such as the unique chromosomal considerations for bird species as highlighted by GOOD Meat. Of particular interest to stakeholders is collaboration to define best practices for end-product characterisation as a preferred approach to address regulatory concerns related to cell line stability, such as the potential for increased expression of endogenous allergenic proteins.

Existing resources such as the ICH Q5D guideline on cell-substrate stability provide a framework that is relevant in certain aspects of cultivated food production, though not all elements may apply. Therefore, there is a need for international coordination to define the appropriate elements of this guideline to adopt, modify, or discount.

A specific area that requires research support is the development of a scientific understanding of genetic components that are relevant to food safety due to a link to toxin production that could be impacted as a result of genomic instability, as highlighted in Section 4.3.3.3 of the FAO & WHO 2023 report. [5] This research would need to consider different species and cell types. However, as highlighted by the FAO & WHO, this hazard is not unique to cultivated foods, as a similar hazard is present in the cellular therapeutics and biosimilars industries, where best practices could be referred to and possibly adopted for cultivated foods guideline development.

Collaborating to define best practices for end-product characterisation to address regulatory concerns related to cell line stability, such as the potential for increased expression of endogenous allergenic proteins

Progress to this end will require greater information sharing from companies relating to internal quality assurance practices employed and justifications for preferred approaches that would satisfy food safety and other regulatory considerations.

Scientific open-access reviews by independent experts of relevant cell line stability considerations for food safety would be important to underpin future guideline developments and inform regulatory and industry best practices. Additionally, this could uncover areas where open-access research may be required.

An important question to address will be the development and justification of cutoff points for acceptable variability of any specific characteristic to be monitored. These efforts will have to incorporate risk management and food safety considerations, as well as manufacturing practicalities and acceptable QC limits.

Genetic modifications

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Challenges

Genetic modification in cell line development offers significant advantages for cultivated food production, particularly through the creation of immortalised cell lines and the genetic reprogramming of cells into specific lineages, such as muscle or fat, using induced pluripotent stem cells (iPSCs). Manipulating specific genes can reduce proliferation time, immortalise cells, and enable adaptation to diverse conditions, such as non-adherent culturing and various media compositions.[39]

While the use of genetic tools for inducing desired functional traits in cell lines for cultivated foods is most beneficial, there are certain safety risks that need to be addressed. For instance, gene editing or modification tools used on cell lines could result in unintended off-target effects on the cellular genome leading to altered genetic/phenotypic characteristics and cell line instability. Such genetically altered cell lines would have similar safety concerns as expressed under the **'Defining cell line stability'** section.

Overall, the major challenge lies in the lack of standardised criteria for characterising the safety of these modified cell lines from a consumption perspective.

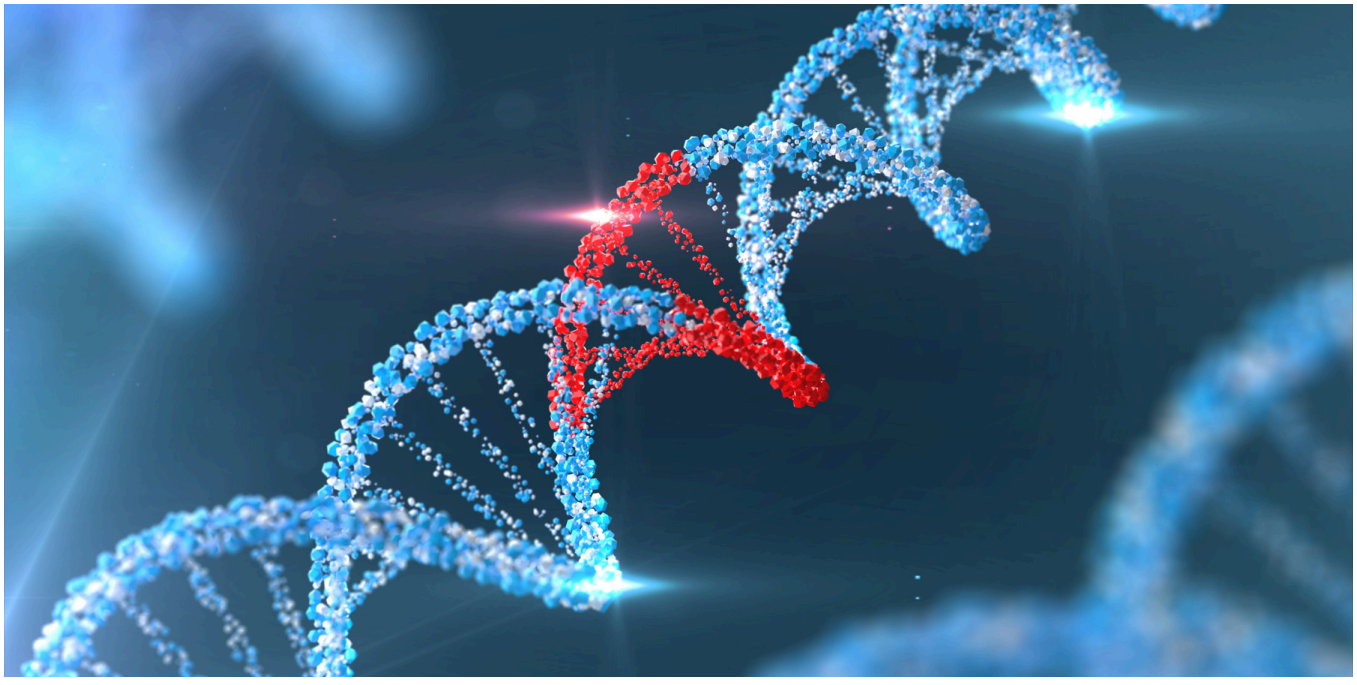
There is also a lack of international coordination on the definition of "genetic modification" and which technologies would be treated as genetic modification, in particular as related to gene editing. Gene editing is an emerging technology that does not involve introducing a gene from a different organism and therefore should be differentiated from genetic modification. In some jurisdictions, gene editing is not considered genetic modification as it does not introduce foreign DNA sequences to genomes of the host organisms. However, in some other jurisdictions, gene editing is still considered genetic modification but may be entitled to some sort of simplified regulatory process.

There is a lack of convergence on this topic and a need to build globally coordinated definitions and regulatory policies.[40] Furthermore, there is a lack of consensus on the preferred methodology and criteria for evaluating consumer safety of such technologies when applied in cultivated foods. The currently available methodology for evaluating genetic modification in most jurisdictions is designed for field crops, farm animals, and industrial fermentation of microorganisms.

This absence of consensus complicates the assessment of their performance and safety, potentially impeding the broader adoption of these methods. For example, the recently enacted Genetic Technology (Precision Breeding) bill in the United Kingdom only applies to precision bred plants and vertebrate animals.[42]

Regulatory frameworks need to address these gaps to ensure consistency and safety across various species and cell types. Furthermore, the regulatory environment in the APAC region presents additional challenges. There is considerable uncertainty about the acceptability of genetic modification for cell line development across different countries in this region. The lack of clear regulatory guidelines poses a significant risk for companies seeking approval for genetically modified organisms (GMOs), creating a barrier to market entry and potentially delaying the commercialisation of genetically modified cell lines.

In addition to regulatory hurdles, public perception poses a challenge. The association of genetic modification with cultivated foods could influence consumer attitudes, as public views on GMOs are often mixed. This perception risk may impact the acceptance and marketability of cultivated food products, making it vital for companies to engage transparently with the public and effectively communicate the benefits and safety of these technologies. To overcome these challenges, collaboration between regulatory bodies, industry stakeholders, and the scientific community is essential to establish clear guidelines and promote public understanding.



Recommended areas for APAC coordination and collaboration

Encouraging the publication of expert assessments of practical food safety considerations for cultivated foods produced using genetic modification or genetic engineering technology, and proactive information sharing with regulatory agencies on these topics

Effective communication with regulators, as well as through regulatory bodies and scientific and industry associations to the public, is crucial in advancing the safe and accepted use of genetic modification and genetic engineering in cell line development for cultivated foods.

To facilitate a better regulatory understanding of food safety risks associated with genetically modified or gene-edited cells in cultivated foods, a promising approach is to encourage scientific research studies that can generate technical safety data investigating the safety and stability of such cell lines for cultivated foods. These collaborative research activities could focus on addressing key technical questions in the safety assessment of genetically modified or gene-edited cell lines in cultivated foods. For instance, expert-driven data-gathering exercises could help establish the best models for demonstrating the safety of non-spontaneously immortalised cell lines, including their long-term genetic stability and the ideal timing and frequency of testing during the cultivated food production process as linked back to the **'Cell line documentation'** section of this paper. Relatedly, these data would also be insightful in understanding the safety implications of genetic engineering technologies (such as CRISPR-Cas) in relation to genetic modification tools, in order to support regulators in formulating a more lenient framework for gene-edited cell lines.

Overall, conducting rigorous studies resulting in peer-reviewed publications that address key knowledge gaps surrounding the safety of genetically modified or gene-edited cell lines would generate wider consensus among the scientific and regulatory community on the most adequate/conducive regulatory approach for complete food safety risk assessment of end products generated from such cell lines.

UPSIDE Foods achieved immortalisation through the introduction of a cisgene expressing chicken telomerase reverse transcriptase (TERT). While scrutinising their dossier, the U.S. FDA observed that it did not identify any properties of the cells that would render them different from other animal cells with respect to safety for food use. [41] The FAO & WHO 2023 report titled *Food safety aspects of cell-based food* also noted that there is no risk of immortalised cell lines proliferating post-harvesting. [5]

Recommended areas for APAC coordination and collaboration

Establishing critical quality attributes for genetically modified or genetically engineered cell line characterisation and their integration into international guidance documents through bodies such as Codex or ISO

To further support these efforts, making a case for coordinated international guidance is essential. There is potential in advocating for the development of Codex guidance on food safety specifically for genetically modified or gene-edited cell lines used in cultivated food, or more broadly, on establishing the safety of such cell lines for this purpose. This topic could also be addressed in the newly established process to develop an ISO document on the "principles for production of cell cultured food products". Additionally, building regional consensus among regulatory scientists on best practices or Hazard Analysis and Critical Control Point (HACCP) and Good Manufacturing Practice (GMP) models could enhance the establishment of safety protocols for cultivated foods derived from genetically modified or gene-edited cell lines. An important consideration in this process could be the establishment of cell line banks that include genetically modified or gene-edited cell lines with demonstrated safety, providing a reliable resource for the industry and regulators alike.

Consideration for the industry and food safety regulators:

The rapidly changing nature of the cultivated food industry highlights the need to have a regulatory system that responds to new technologies in a timely manner. Increasingly, jurisdictions are moving towards an approach based on the characteristics of the product and not the means of development.

By allowing for risk-appropriate decision-making and focusing on outcomes, regulatory systems can thus accommodate new developments in biotechnology techniques.

Trade requirements

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Challenges

The regulatory landscape for cultivated foods is currently characterised by a lack of clarity and a high degree of unfamiliarity among regulatory agencies with the products, associated risks, and appropriate risk assessment processes. This uncertainty is compounded by the vastly different regulatory environments and approaches towards cultivated foods across various countries. These differences make it challenging for companies to operate internationally, as they must navigate a patchwork of regulations that can be heavily influenced by the interests of existing market players or consumer skepticism towards novel products.

Furthermore, there is often confusion about which regulatory bodies should take the lead in overseeing the safety assessment for cultivated foods. This ambiguity stems from the absence of established international standards specifically addressing the unique aspects of these novel products, particularly concerning sanitary and phytosanitary (SPS) measures and technical barriers to trade (TBT). It is further complicated by the different agency and geographic responsibilities in different jurisdictions. As a result, companies face additional hurdles when attempting to bring their products to market, as it is unclear which regulatory frameworks apply or how to comply with them effectively.

Another complicating factor is the uncertainty regarding the classification of cell lines under the Harmonised System (HS) when crossing international borders. This lack of clarity can create logistical challenges and regulatory compliance issues for companies looking to operate across national boundaries. To address these challenges, there is a need for clearer, more harmonised international standards, as well as better-defined regulatory frameworks that can accommodate the unique nature of cultivated foods.

Recommended areas for APAC coordination and collaboration

Educating policymakers on the development of common standards, guidelines and other regulatory needs to facilitate trade among countries

There is a pressing need for greater education of relevant government actors to facilitate the development of both domestic and international standards for the treatment of cultivated foods. This education is crucial for ensuring that policymakers understand the unique aspects of these products and the associated regulatory needs. Additionally, there must be clarity on the specific inputs required from various domestic agencies during the creation of standards and approval processes. This clarity will help streamline the regulatory framework and ensure that all necessary considerations are addressed.

Streamlining the role of agencies in the creation of international standards, guidelines, and approval processes

The APAC region has a unique opportunity to take a leadership role in this space. By proactively developing common standards, APAC countries could position themselves as rule-makers rather than rule-takers.

Such standards could serve as a blueprint or significantly influence international standards established by global bodies like the Codex Alimentarius Commission, the World Customs Organisation (WCO), and other relevant standard-setting organisations such as the ISO. Ideally, the APAC region as a whole—instead of individual countries—could provide a blueprint in these international standard-setting bodies and organisations.

The Codex Alimentarius Commission, formed under the auspices of FAO and WHO, has the dual mandate to protect consumer health and ensure fair food-trade practices.[43] Codex standards are the result of intensive and multi-round discussions, with considerable input from industry representatives; most of its decisions are adopted by consensus.[44] While Codex standards are not de jure binding, they have significant legal relevance through their reference in the law of the World Trade Organisation (WTO).

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) operates on the assumption that domestic SPS measures shall be based on international standards, guidelines, or recommendations (Article 3.1 SPS Agreement), and that SPS measures that "conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent" with relevant WTO law (Article 3.2 SPS Agreement, emphasis not in original). WTO members that "introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations" need to justify that deviation on the basis of a scientific justification.

The WCO, officially titled the Customs Co-operation Council (CCC), is an international organisation with responsibility for "[enhancing] the effectiveness and efficiency of customs administration." [45] Among its mandates, based on the 1983 International Convention on the Harmonised Commodity Description and Coding System, is the maintenance of the Harmonised Commodity Description and Coding System (Harmonised System or HS), a nomenclature used for the uniform classification and determination of applicable tariffs of internationally traded goods. The Harmonised System Committee (HSC) has considered amendments to the nomenclature and is considering whether cultivated foods should "be classified as meat, fish, milk, and so on" or whether "these products [should] be classified separately" during the HS 2028 review cycle. [46] The uncertainty surrounding this classification, which the WCO attributes to "the political sensitivities with these products," provides an opportunity for APAC countries to meaningfully contribute to the development of international standards.

The ISO is in the preparatory stage of developing a standard for "Principles for production of cell cultured food products." [47] ISO is a non-governmental organisation with the goal of developing international standards and is composed of representatives from the national standards organisations of member countries. The goal for the ISO standard on cultivated food products is to develop a benchmark for the evaluation of the "design, operation and performance of cell cultured food products practices and systems." [47] It thus only applies to the production process of cultivated foods rather than the safety of the product itself. This is an important distinguishing feature of the non-binding standards set by ISO compared to the standards set by Codex (an intergovernmental organisation). While Codex standards are technically not binding as such, they acquire a quasi-binding nature by way of Article 3 of the SPS Agreement.

As a next step, the APAC region could pursue a coordinated approach through the development of common positions among APAC countries in these standard-setting bodies. By aiming for a higher degree of regulatory alignment, APAC countries can not only ensure the safety and quality of cellular agriculture products, but also guide global regulatory practices in this rapidly evolving industry and benefit from a first-mover advantage.

CONCLUSION

Incorporating insights from national industry associations and key players across ten APAC countries, the White Paper on Cell Line Development serves as a crucial stepping stone in shaping the future of cultivated food production within the APAC region. As the global food system grapples with climate change, population growth, and increasing demands for sustainable protein sources, the need for regulatory coordination has never been more urgent. The white paper identifies key challenges in cell line documentation, defining cell line stability, genetic modifications, and trade requirements, all of which present significant barriers to the commercial viability of cultivated foods.

This document lays the groundwork for the questions and research that need to be addressed to facilitate the development of a collaborative regulatory framework that can streamline approval processes, foster innovation, and ensure the safety and traceability of cell lines used in cultivated food production. By leveraging international organisations, such as the Codex Alimentarius and ISO, as well as developing APAC-specific guidelines, the APAC Regulatory Coordination Forum aims to bridge existing gaps and reduce redundancies in the regulatory landscape. Additionally, addressing the potential risks and opportunities posed by cell lines and techniques for their optimisation will be crucial in gaining public trust and ensuring regulatory clarity.

Moving forward, the APAC region has a unique opportunity to lead the global conversation on cellular agriculture. By fostering cross-border coordination and aligning regulatory efforts, APAC countries can position themselves at the forefront of the cultivated food industry. Continued collaboration between industry stakeholders, regulatory agencies, and academia will be instrumental in building a sustainable, resilient, and food-secure future. The proposed initiatives in this white paper offer a blueprint for not only addressing the current regulatory challenges but also setting global standards for the future of cultivated food products.

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ABOUT THE APAC REGULATORY COORDINATION FORUM

The APAC Regulatory Coordination Forum was launched in October 2023 by the APAC-SCA, in collaboration with GFI APAC.

Gathering fifteen key organisations across ten APAC countries, the Forum focuses on all aspects of cultivated food products fit for human consumption and is a formal mechanism for continuous and systematic cross-border dialogue between companies, industry associations, think tanks, governmental agencies, and food safety regulators in different jurisdictions. These stakeholders signed a non-binding memorandum of understanding to demonstrate their commitment to establishing the Forum.

From an industry perspective, mutual recognition of coordinated regulatory frameworks would streamline review processes for companies that want to simultaneously enter multiple markets, thereby reducing trade barriers and costs to consumers. By facilitating knowledge sharing and supporting cross-border coordination among national food safety authorities in the APAC region, the Forum intends to complement the activities carried out by food safety authorities in developing clear and effective pathways towards the commercialisation of cultivated foods for human consumption.

Top Five Regulatory Topics for Collaboration

APAC-SCA and GFI APAC organised a series of one-to-one, closed-door virtual consultations with forum members to identify the top five regulatory topics that APAC regulators could be interested to collaborate on. Based on their ongoing interactions with local regulatory agencies, the top five regulatory topics include cell line development, cell culture media components, microbiological hazards, allergenicity, and labelling.

Published White Papers in 2024

In 2024, cell line development and cell culture media components were selected as the topics of focus, with white papers developed to outline the current gaps where regulatory coordination could assist in supporting innovation and commercialisation of cultivated foods.

By delineating potential solutions and technical recommendations for the issues identified, these resources serve as a valuable starting point to inform and empower regional regulators, companies and researchers to facilitate internationally harmonised standards, guidelines, and recommendations on the food safety aspects of cell lines and culture media inputs.

The APAC Regulatory Coordination Forum will continue to work closely with companies, industry associations, think tanks, governmental agencies, and food regulators to facilitate dialogues, share best practices, and work towards a consistent approach to cultivated food regulations within the APAC region.

Want to know more? Contact us at info@apac-sca.org

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