Food and Agriculture Organization of the United Nations

CELL-BASED FOOD AND PRECISION FERMENTATION

PRODUCTS, SAFETY AND THE FUTURE ROLE

STAKEHOLDER ROUNDTABLE MEETING REPORT

SHANGHAI, CHINA, 6 NOVEMBER 2023

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Rome, 2024

Required citation:
FAO. 2024. *Cell-based food and precision fermentation – Products, safety and the future role. Stakeholder roundtable meeting report, Shanghai, China, 6 November 2023.* Rome. https://doi.org/10.4060/cd0311en

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ACKNOWLEDGEMENTS

The Food and Agriculture Organization of the United Nations (FAO) would like to express its appreciation to the many people who contributed to this initiative. The FAO stakeholder roundtable meeting, held in Shanghai, China in November 2023, was organized by Masami Takeuchi (FAO) in collaboration with her FAO colleagues Maura Di Martino and Markus Lipp (provided oversight) as well as key collaborators from the China National Center for Food Safety Risk Assessment (CFSA), including Wu Yongning, Ding Hao and Fan Yongxiang. Chen Junshi, a special advisor to CFSA, significantly contributed to the meeting by liaising with the relevant stakeholders in China. FAO thanks all the presenters, namely Kodira Appachu, Zohar Barbash, Kris Blanchard, Cao Zhehou, Carrie Chan, Chee-Seng Hee, Lou Cooperhouse, Louis Cheung, Edward Henderson, Hannah Lester, Li Ning, Li Yingying, Hu Haijuan, Fiona Louis, Fei Luo, Jin Muraoka, Haba Noam, Hiraku Shibata, Valeria Teloni and Wang Shouwei, for sharing invaluable information and insights based on first-hand production experiences. The meeting was attended by officials from the National Health Commission of China and the Shanghai Municipal Commission of Economy and Informatization, as well as various researchers from academic institutions/universities, including China Agricultural University, Ocean University of China, Jiangnan University and Zhejiang University. The technical and administrative contributions by Yang Ziliang, who organized a tour of his production facilities are also acknowledged. For this report, technical and editorial inputs were provided by various FAO colleagues including Vittorio Fattori, Mia Rowan, Maura Di Martino and Markus Lipp, while the technical editing was done by Agnieszka Gratza.

ABBREVIATIONS

AMR	antimicrobial resistance
bADSCs	Bovine adipose-derived stem cells
BHK-21	Baby Hamster Kidney Fibroblast
bSCs	bovine satellite cells
CFSA	China National Center for Food Safety Risk Assessment
DNA	deoxyribonucleic acid
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FSANZ	Food Standards Australia New Zealand
GHP	good hygiene practices
GMP	good manufacturing practices
GRAS	generally recognized as safe
HACCP	hazard analysis and critical control point
SBP	supporting bath-assisted printing
SFA	Singapore Food Agency
TIP	tendon integrated printing
USDA	United States Department of Agriculture
WHO	World Health Organization

EXECUTIVE SUMMARY

As the global demand for proteins and specific nutrients grows, many people are looking into opportunities to expand the scope of diverse and sustainable sources of such nutrients. Food safety is one of the prominent key issues to ascertain before such products go into the market, and various competent authorities are working to identify and address potential food safety issues and their implications.

After the first stakeholder meeting on cell-based food organized by the Food and Agriculture Organization of the United Nations (FAO) in collaboration with the Government of Israel, many experts suggested FAO to maintain such dialogues to regularly update the knowledge of this fast-improving technology. This led to the stakeholder meeting organized by FAO jointly with the Government of China in November 2023, which considered precision fermentation besides cell-based food.

The present report summarized the results of the meeting attended by a total of 55 participants in Shanghai, China on 6 November 2023. The meeting provided a snapshot of the state of development of these particular technologies and the industry in 2023. As an increasing number of countries are reviewing the regulatory applications, valid examples of how to assess product safety have become available. All participants recognized that open discussions between stakeholders and regulators are key when it comes to clarifying important aspects of food safety, and that supporting the relevant scientific innovations is vital for achieving the overall food security goals and sustainable food production for the future.

Keywords: food safety, cell-based food, cultured meat, cultivated meat, research and development, food production process, input materials, hazard identification, risk assessment, risk communication, food technology

1. INTRODUCTION

Cell-based food production involves culturing cells isolated from animals, plants or microorganisms, followed by processing to generate food products that are comparable to the corresponding conventional food products, including meat, poultry and aquatic products. The global regulatory landscape for cell-based foods has been changing in the last few years. After the Singapore Food Agency (SFA) approved the first of this type of products in 2020, the United States of America green lit two more products in 2022 and 2023, followed by the Government of Israel approving the first cell-based beef product in 2024. The European Food Safety Authority (EFSA) and the Food Standards Australia New Zealand (FSANZ) have also received the regulatory questions or dossiers for review.

Precision fermentation often refers to a process that utilizes microorganisms to produce specific target products through controlled production systems with growth media and bioreactors. A wide variety of products such as proteins, enzymes, vitamins or other bioactive substances can be produced through precision fermentation. Yet, for foods derived from the so-called "precision fermentation", there is currently no internationally harmonized definition, and various countries and jurisdictions reported that they have been receiving approval requests for a wide range of products.

As the global demand for proteins and specific nutrients grows, many stakeholders in the food sector are looking into opportunities to expand the scope of diverse source of such nutrients, in a way that is both environmentally sustainable and nutritionally sound. Food safety is one of the prominent key issues to assure before such products go into the market, and many food safety competent authorities are working to identify and address potential food safety issues and their implications. The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) published the Food safety aspects of cell-based food document in 2023 (FAO and WHO, 2023), containing the comprehensive results of the food safety hazard identification conducted by a group of global experts. The experts stressed that it is important for regulators to have a good understanding of the production process involved in generating food products that are either already commercially available or in the pipeline. FAO is committed to getting various stakeholders to collaborate together in order to advance our collective knowledge of this technology.

In 2022, FAO, in collaboration with the Ministry of Health of Israel, convened the first stakeholder meeting on cell-based food, at which a group of developers and researchers shared the information regarding the products that they have developed and discussed the relevant food safety issues. The report of the meeting was published (FAO, 2023a), and it was recommended to FAO by its Members to pursue such exchanges with stakeholders to keep abreast of this fast-improving technology. This led to the stakeholder meeting organized by FAO together with the China National Center for Food Safety Risk Assessment (CFSA) in November 2023. On this occasion, the meeting addressed both cell-based food and precision fermentation.

A total of 55 participants, including 21 presenters, 27 observers and 7 secretariat members from FAO and CFSA attended the meeting held in Shanghai, China on 6 November 2023. The list of participants and the meeting agenda are available in Annex 1 and Annex 2, respectively. With the aim of updating the current developments in the areas of cell-based food and precision fermentation, presenters presented their own products and discussed the relevant food safety considerations. A special session of the meeting was dedicated to discussing the experiences that some of the companies had in conducting food safety assessment to meet regulatory requirements. The meeting also provided opportunities for stakeholders to expand their networks and to interact with the Chinese authorities who are likely to manage the regulatory actions for product applications in the future.

2. PROCEEDINGS

2.1 Opening session

The meeting was officially opened by Yongxiang Fan, the Deputy Director of CFSA, welcoming all the participants present at the meeting to discuss the most up-to-date knowledge and information based on their development of cell-based foods and products derived from precision fermentation. In China, as well as in various other international communities, the topic has received considerable attention and interest owing to its potential of making agricultural practices more sustainable. CFSA welcomed the opportunity to hold a technical discussion with the stakeholders about the relevant food safety issues and the current trends for this technology. Yongxiang Fan looked forward to the presentations of many interesting food product at the meeting, which would be an important learning opportunity for various government officials in China, especially those who are tasked with conducting food safety assessments. He expressed his gratitude to FAO officials as well as all the presenters and participants, and hoped there would be some fruitful multisectoral discussions.

Following the opening remarks, Masami Takeuchi, Food Safety Officer of FAO, delivered a presentation on the past and present activities of FAO to do with cell-based food and precision fermentation. Using a timeline, she showed that the relevant FAO initiative started in 2021 with a global regulatory technical working group bringing together some volunteering countries. She welcomed China as a new member of this informal working group, which now counts more than 13 countries and over 16 agencies. In the last few years, FAO has developed a technical literature synthesis on three topics: 1) terminologies, 2) production processes, and 3) regulatory frameworks for cell-based food, and she announced that the same kind of literature review on the topic of precision fermentation will appear in 2024–25. FAO made an educational and an animation video (FAO, 2023b), aiming to raise awareness of food safety issues relevant to these technologies and, based on the food safety risk analysis paradigm, FAO collaborated with WHO to conduct the first stage of the formal risk assessment process – "hazard identification" – with a group of global experts in Singapore in November 2022. The results of the expert consultation, together with the above-mentioned literature synthesis and the three country case studies of regulatory frameworks in Israel, Qatar and Singapore were consolidated into the joint FAO/WHO publication titled Food safety aspects of cell-based food, which came out in 2023 (FAO and WHO, 2023).

The global hazard identification was conducted based on four production phases – cell selection, production, harvesting and food processing – and experts concluded that many hazards are already well-known and present in conventionally produced food. Various existing control measures are there to ensure the food safety of cell-based food; however, food safety plans would need to focus on the materials, inputs, ingredients and equipment that are either new or specific to this type of food production, as they may not have been used in conventional food production processes. For this reason, as Masami Takeuchi pointed out, it is important for regulators to learn from companies and producers about the latest technological developments so that the knowledge of how to ensure food safety can be updated and shared more widely. She concluded that, building on the knowledge gained from the first FAO stakeholder meeting that took place in Israel in 2022, the meeting held in Shanghai would document the state of play in 2023 and make the updated information available around the world.

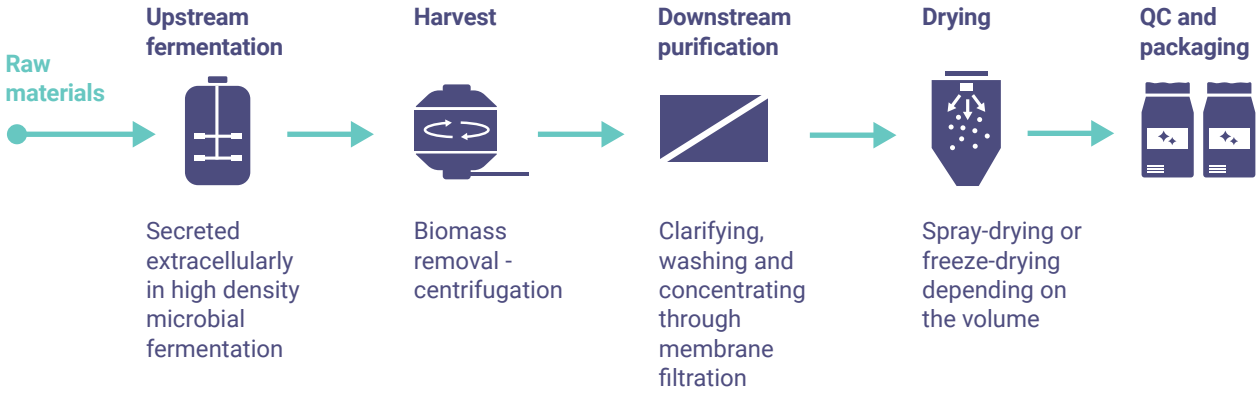
2.2 Presentation sessions

2.2.1 Precision fermentation application to produce collagen products

Fei Luo (Liven Proteins), based in Canada, presented a collagen product derived from precision fermentation. Collagen can be used in the food industry for various purposes, such as improving the nutritional profile, texture, solubility, gelling properties, functional peptides and the bioactivity of a product. According to the presenter, precision fermentation could contribute to minimize the use of animals in collagen production, thus potentially reducing the environmental impact. The presenter stated that this approach would provide option for the 3.3 billion vegan, kosher and halal consumers worldwide.

The manufacturing process consists of five main steps (Figure 1). The process begins with high-density microbial fermentation, during which microorganisms are grown under controlled conditions to produce the desired proteins. Following the fermentation process, the biomass is removed, and the microbial cells are separated from the fermentation broth by centrifugation. The next step is clarification, which involves the removal of remaining solids from the liquid through filtration, resulting in a clear liquid that contains the product of interest. The clarified liquid is then washed to remove residual impurities. The product is then concentrated and dried to remove any remaining water. Depending on the volume of the product, this can be achieved through either spray-drying or freeze-drying. The final product is then packaged.

Figure 1. Collagen manufacturing process using precision fermentation



Source: Adapted from Luo, F. 2023. Animal-free collagen for food and nutrition. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The presenter explained that, in order to ensure product safety, the primary source is a recombinant type I collagen fragment previously employed in the food industry and known to have a history of safe use. The host organism used to produce this synthesized version of collagen is *Komagataella phaffii,* a yeast species with common applications in food biotechnology.

To ensure quality, a thorough characterization is carried out to examine the protein's properties, including its structure, function and interactions with other nutrients and/or materials, at every stage of the manufacturing process. The presenter emphasized the importance of transparent communication with consumers and the company's aim of delivering products with optimal nutrients, taste and texture.

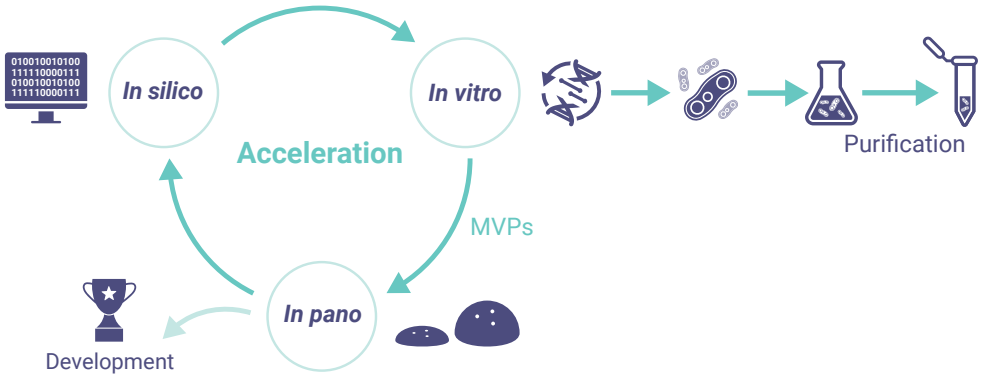
Collagen manufactured by precision fermentation is an example of companies supplying highly sought-after food ingredients that are produced efficiently without harming animals. Ensuring food safety is always important and this applies to all food products, no matter how they are generated. It is therefore important for precision fermentation companies to have an effective food safety plan and to follow good manufacturing practices (GMP) at every step of the production process.

2.2.2 The use of precision fermentation to produce enzymes for the food industry

Ning Li (Puratos), based in China, presented the development of a family 8 xylanase, an enzyme that breaks down arabinoxylan, a key component in wheat flour. Xylanases, together with other enzymes, are used as food ingredients to enhance the texture, appearance and freshness of bakery products since they help to stabilize the quality of wheat. The presenter explained that the patented xylanase produced by precision fermentation can be activated at low temperatures during dough development, which makes them useful in a range of frozen bakery solutions.

The *In silico/In vitro/In pano* enzyme discovery and production cycle is presented in Figure 2. *In silico* uses a computer-based system to discover/identify potentially effective enzymes. After searching on multiple databases, sequence alignments and structural predictions are made. Once potential enzymes have been identified in silico, they are then produced in the pilot lab at the in vitro step. This involves using various genomics techniques such as the recombinant deoxyribonucleic acid (DNA) technology to insert the gene for the enzyme into a suitable host organism, which is then grown in a controlled environment to produce the final product. The final step in the enzyme cycle is the in pano step. It amounts to testing the enzyme in real-life applications, for example in baking processes, to confirm its effectiveness.

Figure 2. Enzyme discovery cycle for xylanase



Source: Adapted from Li, N. 2023. Puratos' view on precision fermentation take enzyme production as examples. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The presenter stated that strain and bioprocess developments were an important way of optimizing the host organism and should be maintained as an effective fermentation mechanism. Innovative and advanced knowledge in modern microbiology, genomics and bioengineering is essential to make enzyme production more efficient and cost-effective. To meet the regulatory requirements for the process of gene modification, whole genome sequencing of the host microorganisms is conducted so that the genetic makeups of the target strain are verified as the qualified presumption of safety status. The purity of the strains is also assessed to ensure that they present no hazards (off-target metabolites, toxicity and allergenicity). Although the final product does not contain genetically modified organisms, final product testing is important to confirm of the no-contamination status.

2.2.3 Myoglobin production through precision fermentation

Kris Blanchard (Luyef), based in Chile, presented a product called TAMEE (an acronym standing for The Authentic Meat-Eating Experience), which is a myoglobin-based ingredient produced through precision fermentation. The presenter explained that the protein in the product has the same amino acid sequence and molecular properties as native bovine myoglobin. It is produced extracellularly by a strain of Pichia pastoris, which is widely used in the food industry. The production process involves five steps, as illustrated in Figure 3. First, genetically modified Pichia pastoris, a species of yeast, goes through a fermentation process to produce bovine myoglobin. Following fermentation, the yeast cells are separated from the media. The media is extracted and undergoes microfiltration to eliminate any yeast cells and other impurities, so that the remaining solution contains the targeted myoglobin. It is then mixed with a buffer to stabilize the protein and spray, which are dried to encapsulate the formulation. The dried product goes through microbiological testing before being stored.

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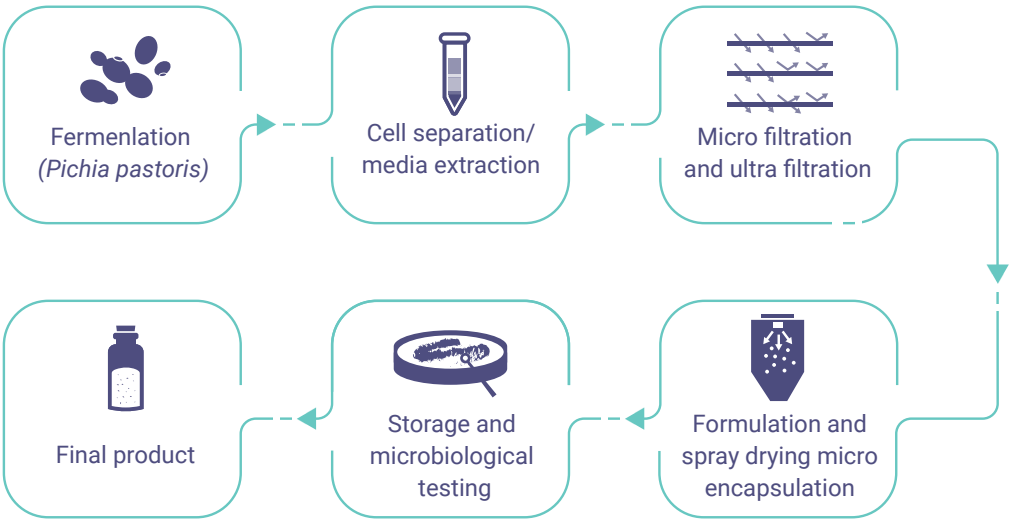
Figure 3. Production overview of the myoglobin products made through precision fermentation



Source: Adapted from Blanchard, K.E. 2023. Safety considerations for precision fermentation-based ingredients. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The presenter stressed that the target myoglobin has a long history of safe consumption, and the amino acid sequence is exactly the same as for the myoglobin found in Bos taurus. Allergenicity and toxicity profiles have been studied in the conventional products and they are considered to be safe. The presenter explained that the production strain, Pichia pastoris, is a staple of the food industry and thus its safety has been recognized. Myoglobin derived from a genetically modified strain of Pichia pastoris, developed by another company, has already been granted the generally recognized as safe (GRAS) status by the US Food and Drug Administration (FDA). Moreover, at the time of the presentation, myoglobin was about to be granted the same status by the Government of Chile, where the regulatory framework is greatly reliant on the FDA approvals, particularly when it comes to protein identity. The presenter said that to market the product in Chile, it is therefore necessary to adhere to both domestic and international regulatory standards. It is also important to ensure proper labelling so as to avoid misleading consumers with respect to the product's nutritional value, allergenic and functional properties.

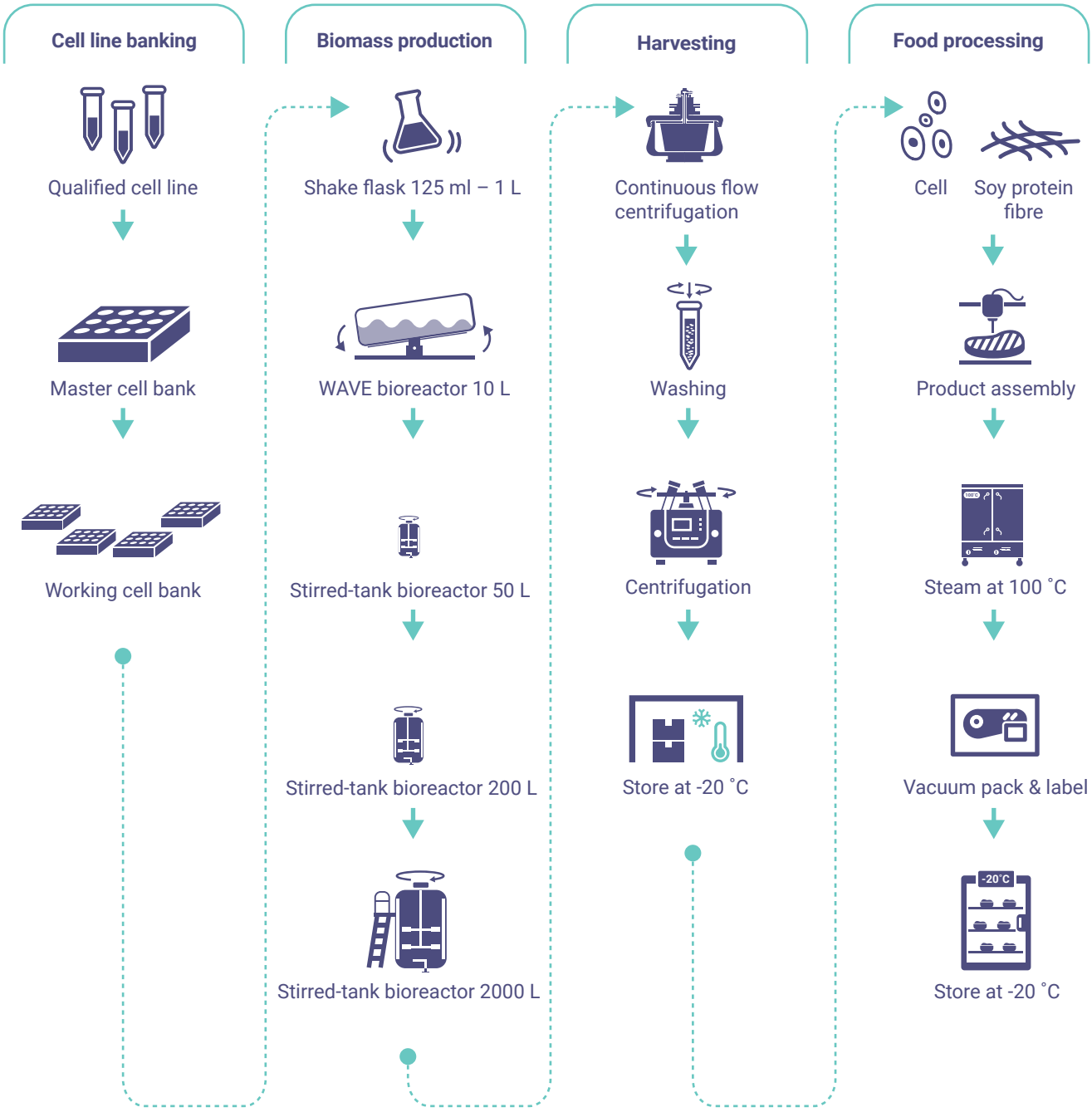
In the future, the presenter hoped to make the production process more cost-effective. Accordingly, future innovations will focus on enhancing the techniques, materials and equipment used in the production process. This includes the design of bioreactors tailored to precision fermentation production. In addition, efforts are being made to develop a second-generation Pichia pastoris strain and bioprocess designs that leverage low-cost and renewable growth media.

2.2.4 Safety and quality of products mixing cell-based food and plant-based ingredients

Chee-Seng Hee (CellX), based in China, presented a hybrid product made from cultivated avian cells and protein fiber. The presenter stated that this product has similar nutritional values, comparable to conventional products, as regards macro nutrients such as protein, fat and carbohydrates.

The production process (Figure 4) consists of four stages: 1) cell banking, 2) biomass production, 3) harvesting, and 4) processing. The process begins with the creation of a master cell bank from a cell line, which is then used to establish a working cell bank. The growth of cells marks the second stage, starting with a 125 ml flask and progressing to a WAVE bioreactor (10 L), a stirred-tank bioreactor (50–200 L) and, finally, a larger 2 000 L stirred-tank bioreactor. Once the cells have grown sufficiently, a harvesting process involving a continuous flow centrifugation separates the cells from the growth media, followed by washing and further centrifugation. The final stage consists of processing the harvested product, which includes heating (with steam at 100 °C), before the products are vacuum packed, labeled and stored at -20 °C.

Figure 4. A schematic overview of the production process of cell-based food products



Source: Adapted from Hee, C.-S. 2023. Regulatory approach for cultivated meat. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The company employs a hazard analysis and critical control point (HACCP) system to ensure food safety. To validate the safety of final products, various testing methods, including sterility tests, virus tests, mycoplasma tests, in silico analysis, genome sequencing and mass spectrometry to confirm that the products do not contain any contaminants such as pathogens and viruses, allergens and toxins.

Acknowledging current trends in cell-based food production, the presenter evoked the need for new food-grade growth media, designed to be safe for human consumption and effective in stimulating proper cell growth, while keeping the costs down. In particular, the industry is moving away from the use of animal-derived substances like fetal bovine serum and exploring animal-free alternatives. Artificial intelligence and machine learning also play a role in improving efficiency, reducing waste and increasing the yield, contributing to optimize the production process.

The company is contributing to various global efforts designed to communicate with the public in a transparent manner so that consumers are well informed about the products and their safety issues. The presenter emphasized the importance of earning consumer trust through effective communication.

2.2.5 Cell-based deer antlers for traditional Chinese medicine/functional food

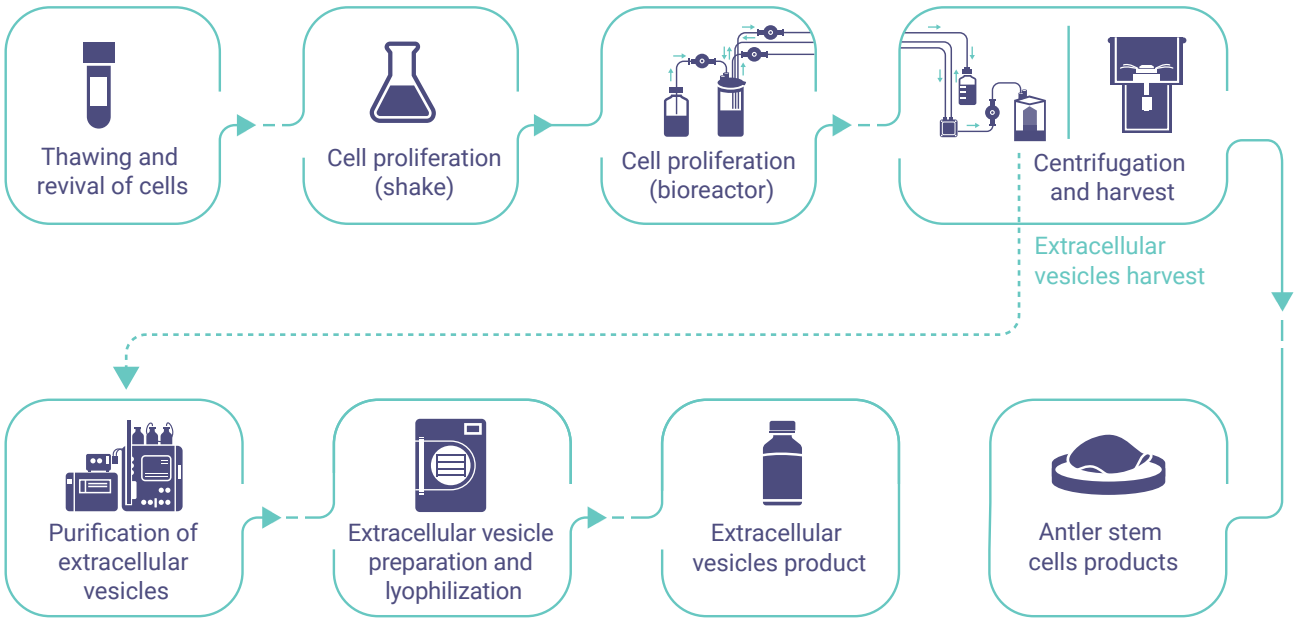
Zhehou Cao (Jimi Biotech), based in China, presented a cell-based deer antlers product. Deer antlers on the heads of deer are covered by a layer of velvety skin, the substance known in popular traditional Chinese medicine/functional food products as “deer antler velvet”, which is rich in blood vessels and nerves.

The presenter stated that conventional methods of harvesting deer antler velvet have been questioned by those who are concerned about ethical and animal welfare issues. The safety of traditional deer-antler velvet products may also have been compromised as a result of suspected pollution and microbiological contamination. The supply of such products is often limited because of the natural growth cycle of deer antlers, resulting in the high price of end products. According to the presenter, cell-based deer antler products can address many of these issues.

Deer antler stem cells can proliferate and differentiate into various cell types. They are behind the rapid and cyclic regeneration of deer antler, which is a unique phenomenon in mammals. Cell-based deer antler products leverage the potential of these multipotent cells for tissue engineering.

The production process, as illustrated in Figure 5, starts by isolating deer antler stem cells. The stem cells are then developed into a specific cell line and stored in the cell bank (frozen). For the purposes of this specific product line development, the cells are revived, proliferated, cultured in bioreactors, and harvested following centrifugation. The deer antler products can then be derived directly from the harvested products; at the same time, extracellular vesicles, cell-derived membrane-surrounded vesicles, can also be harvested and further purified so as to be used to develop deer antler secreted products.

Figure 5. Cell-based deer antler production process



Source: Adapted from Cao, Z. 2023. Cultivated deer antler cell. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The presenter said that cells are cultured in a sterile laboratory that follows strict hygiene standards to prevent the introduction of any contaminants. Moreover, the cells are grown in a custom medium tailored to cell-specific needs and characteristics. The medium is also tested and regularly monitored to ensure its safety. Ensuring the safety of source and input materials is fundamental to ensuring the safety of the final product; at the same time, the final product undergoes rigorous testing and validation to ensure its identity, purity and stability.

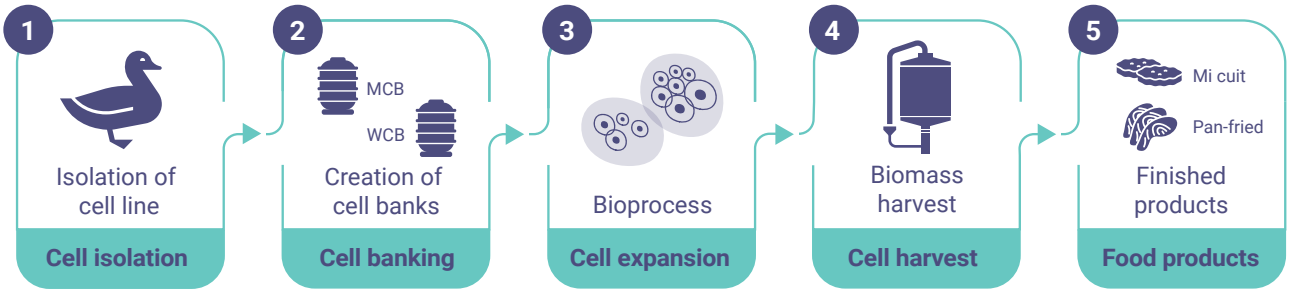
The presenter stressed that deer antlers are an important product in traditional Chinese medicine. A new scientific method of manufacturing the product would contribute to the sustainable development, and impact the future of traditional Chinese medicine as well as functional food.

2.2.6 For the niche market – cell-based alternatives to “foie gras”

Hannah Lester (Gourmey), based in France, presented Gourmey’s cell-based “foie gras” product made from duck cells, unlike conventional foie gras, a delicacy made with duck or geese liver. The marketing of such high-quality products is often targeting high-end consumers. The presenter pointed out that, while the niche market of costly products such as foie gras makes them attractive to many producers, the specific production methods that it entails, which may involve force-feeding and the limited movement of ducks or geese, have raised significant animal welfare concerns. This has prompted countries such as Denmark, India and Italy, among others, to introduce bans on the production of foie gras, a legislation that was pioneered by the US state of California. According to the presenter, a cell-based alternative to foie gras could address many of these concerns.

There are five steps to the cell-based “foie gras” production (Figure 6). Initially, duck stem cells are isolated from fertilized eggs. These cells are then used to develop cell lines that can be further employed for several production cycles. The presenter explained that the cells are cultured in a bioreactor with a growth medium that is animal-free, thus addressing the fundamental concerns of animal welfare. Once the cells have grown, they are harvested and processed into the final products. The final product can be prepared in a variety of ways, grilled, pan-fried or packaged similarly to conventionally-produced “foie gras” (partially cooled).

Figure 6. Overview of cell-based "foie gras" production process



Source: Adapted from Lester, H. 2023. Producing safe and delicious cultivated alternative to "foie gras". Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The presenter explained that prior to production, the cell line is fully characterized to ensure that it is contamination-free and genetically stable over time. The components of the culture media are also outlined in line with food standards. During the production process, GMP and HACCP are set up to have an overall food safety plan. Routine biochemical, microbiological and toxicological testing is performed on the products and ingredients to ensure that the final products are safe for consumption.

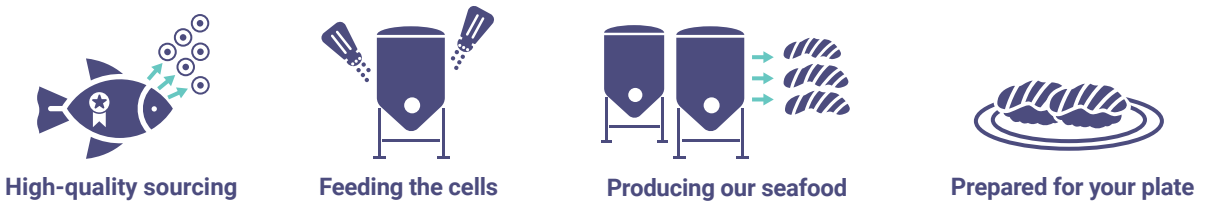
The presenter emphasized the importance of a proactive and transparent approach to food safety communication. Building trust and gaining the confidence of regulatory agencies and consumers is important for the whole industry. Looking ahead, the presenter mentioned that current research is exploring innovative bioreactors that can help to scale up production while reducing the costs. Low-cost food-grade media that can provide excellent nutrients and growth factors for the cells are being developed by various researchers and companies. The presenter felt hopeful that there would soon be a set of technological solutions that could facilitate the effective and simplified safety assessment for scaled-up production.

2.2.7 The commercialization of cell-cultured bluefin tuna in the United States of America

Lou Cooperhouse (BlueNalu), based in the United States of America, shared his experiences of developing a regulatory dossier for the commercialization of cell-cultured tuna. In his opinion, cell-cultured seafood production had the potential to reduce the negative environmental impact of traditional fishing and aquaculture. The presenter highlighted the growing global interest in developing cell-cultured seafood as a strategic approach for ensuring the safe, consistent, accessible and sustainable production of aquatic animals.

The company developed a cell-cultured bluefin tuna toro, in a four-step production process (Figure 7). The first step consists of isolating cells from tuna to develop the target cell line. The cells are grown in a bioreactor, followed by harvesting and food processing. To ensure product safety, good hygiene practice (GHP) is followed to monitor the flows of air, people, materials, product and waste, thereby preventing cross-contamination. A detailed HACCP plan is then developed to prevent any potential hazards from becoming a risk. The standards and consistency of the raw materials used in media and final product formulations are key to ensuring product quality and food safety.

Figure 7. Cell-culturing process fundamentals for cell-cultured seafood



Source: Adapted from Cooperhouse, L. 2023. Food safety dossier development. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

In 2019, the FDA and the United States Department of Agriculture (USDA) have issued an agreement that clarified their respective roles and responsibilities when it came to managing cell-cultured meat and poultry products: the FDA regulates the upstream operation of cell collection, banking, growth and differentiation, whereas the USDA's Food Safety and Inspection Service oversees the harvest through the downstream processing and labelling operations. However, in the case of cell-cultured seafood products, the FDA has the sole oversight of both the upstream and downstream operations.

The presenter said that a regulatory dossier of the product was put together with the FDA requirements in mind. The different sections of the dossier are summarized in Table 1.

Table 1. Regulatory dossier contents for the United States of America

Part	Title	Description
1	Executive summary	High level summary of the safety assessment
2	Manufacturing process description	Overview of the manufacturing process from cell isolation to the final seafood product, including development and manufacturing phases
3	Validation of cell banks	Describes plans for cell line characterization based on BlueNalu's proposed safety decision tree and its application to bluefin tuna cell lines and plans for cell bank integrity testing
4	Microbiological safety	Analysis of microbiological safety concerns and description of steps taken to mitigate risks related to the species, the development phase, cell banking and the manufacturing process
5	Raw Materials Safety	Explains the grouping of chemical inputs into categories based on regulatory status, stage used and anticipated residual with examples and details how residue and exposure levels were estimated and how safety assessments were conducted
6	Potential allergenicity concerns	Identifies allergen concerns, including intrinsic fish allergens, and analyses potential risks related to inputs
7	Characterization of cell-cultured fish fillet compared to conventional fish	Details plans for final product testing and comparative testing for conventional bluefin tuna to establish nutritional equivalence and confirm product safety
8	Summary and conclusions	Contains a complete summary of the assessment as the basis for the conclusion that cell-cultured bluefin tuna is safe for human consumption and nutritionally equivalent to its conventional counterpart

Source: Adapted from Cooperhouse, L. 2023. Food safety dossier development. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

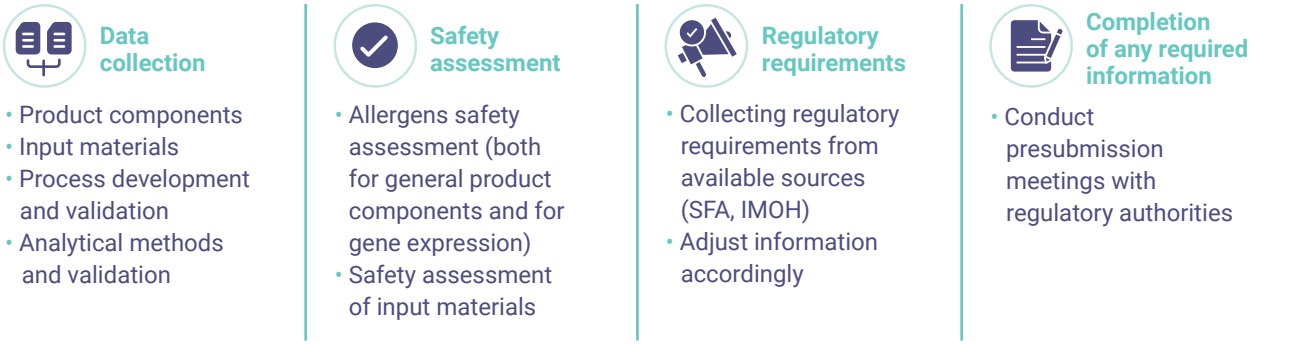
The presenter emphasized that his company considers food safety to be a priority, underscoring the role played by US food safety regulations as essential tools for establishing the current food safety plan for production. At the same time, the company is committed to contributing to a regulatory strategy on a global scale, one which includes a food safety assurance framework.

2.2.8 Experience of preparing a dossier on cell-based beef products

Noam Y. Haba (Aleph Farms), based in Israel, related the company's experience of putting together a comprehensive food safety assessment dossier for obtaining regulatory approval for cell-based beef products.

There were four main phases to the dossier preparation process (Figure 8). The first step consisted in collecting data regarding product components, input materials, process development/validation, and analytical methods and validation. All the components had to be listed along with the relevant food safety information to make it clear to regulators what was used in the production process. The data thus acquired was used to carry out analyses as part of the product's safety assessment. This involved evaluating product allergens and ensuring the safety of all input materials. Once the draft dossier had been completed, the criteria specified by particular regulatory bodies were examined and incorporated into the product file. Specific requirements, forms and detailed information were sourced from the governments of Singapore and Israel, for example, so as to tailor the dossier to their respective regulatory agencies. Lastly, presubmission meetings were held with the relevant agencies/authorities to address any questions or uncertainties concerning the information needed to finalize the dossier.

Figure 8. Dossier development process for cell-based beef products



Source: Adapted from Haba, N.Y. 2023. Novel food regulatory dossier building. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The final dossier will eventually include:

- comprehensive information about the product;
- the safety assessment of the input materials used in the production process;
- the analysis of product allergenicity that should include an assessment of the input materials and the allergenicity of the proteins expressed by the cells; and
- information on the environmental hygiene conditions in order to minimize the related risks, given the susceptibility of the process to microbiological contamination.

The presenter stressed that planning and designing studies for food safety assessment needed to be well aligned with regulatory requirements. Hence the importance of early and frequent consultations with the target regulatory agencies/authorities for developing a successful dossier. To lend credibility to the dossier, it can be useful to have an in-depth literature review detailing the results of the studies conducted as part of safety assessments. In the interest of readability, if there should be any guidelines or examples to follow, it is recommended to align the structure and terminology of the dossier with those adopted in the guidelines. Besides a thorough food safety assessment, clear labelling is considered to be a key regulatory step by many governments; thus, the applicants must understand the relevant governments' labelling requirements to ensure that there is no confusion on the regulators' part during the dossier submission process.

2.2.9 Regulatory and food safety dossier development for a cell-based product

Ed Henderson (Vow), based in Australia, gave a presentation about preparing the regulatory dossier on their cultured quail parfait, made from Japanese quail cells. The company is currently targeting three markets (Singapore, Australia–New Zealand and the United States of America) for the product.

For the company, preparing a regulatory dossier involves five key activities, which are common to all the target markets (Figure 9):

1. Discovery and scoping: This phase consists of identifying potential markets, their respective regulatory pathways and key regulatory agencies, of assessing market appeal and reviewing potential requirements for approval.

2. Planning: In this phase, a dossier template can be created. Based on the relevant regulatory requirements, various analyses and testing are scheduled for safety assessment. Once the resources for assessment have been allocated, a project team can be formed.

3. Safety testing: This involves collecting samples, identifying a suitable analysis, dispatching samples to the labs, and reviewing the results to ensure product safety and regulatory compliance.

4. Documentation and research: A comprehensive review of scientific literature is conducted to develop the dossier, explaining data and analysis results, before the draft is reviewed with legal compliance and confidential commercial information (CCI) in mind, and finalized.

5. Regulator engagement: The relevant regulators are regularly consulted throughout the whole process, including at the presubmission stage, in order to ensure transparency.

Figure 9. Schematic time frame for the development of a dossier on cell-based quail

Source: Adapted from Henderson, E. 2023. Regulating the roost: Vow cultured quail and three dossiers. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The presenter singled out three key areas to consider when preparing a food safety dossier: 1) microbiological specifications, which include information about the measures taken to prevent, control and reduce microbiological risks associated with the product, ensuring its safety for consumption; 2) the safety of the culture medium/growth factors (e.g. the reconstituted components required for cell growth), as well as the types of inputs used, their sources and roles in the production process; and 3) genetic stability, that is to say the consistency of the genetic composition of cultured cells over time. The dossier should provide an adequate explanation of how the genetic stability is maintained.

The presenter gave some tips on how to prepare a dossier, insisting that early and regular engagement with regulators was the most useful of them all. Presubmission consultations with regulators are there to give applicants the opportunity to make informal enquiries on the dossier in preparation. Such consultations benefit not only for the applicants but also the regulators, since the product-specific technical information that they gain in the process can be useful in making case-by-case assessments. Setting out specific points to be discussed throughout the regulatory consultation sessions is good practice.

It is worth noting that conducting safety assessments at the same scale as the intended production can provide more accurate and representative data while helping to demonstrate that the product will remain safe and consistent during the full-scale production. Consulting scientific experts is essential when dealing with any potentially novel materials or complex scientific methodologies.

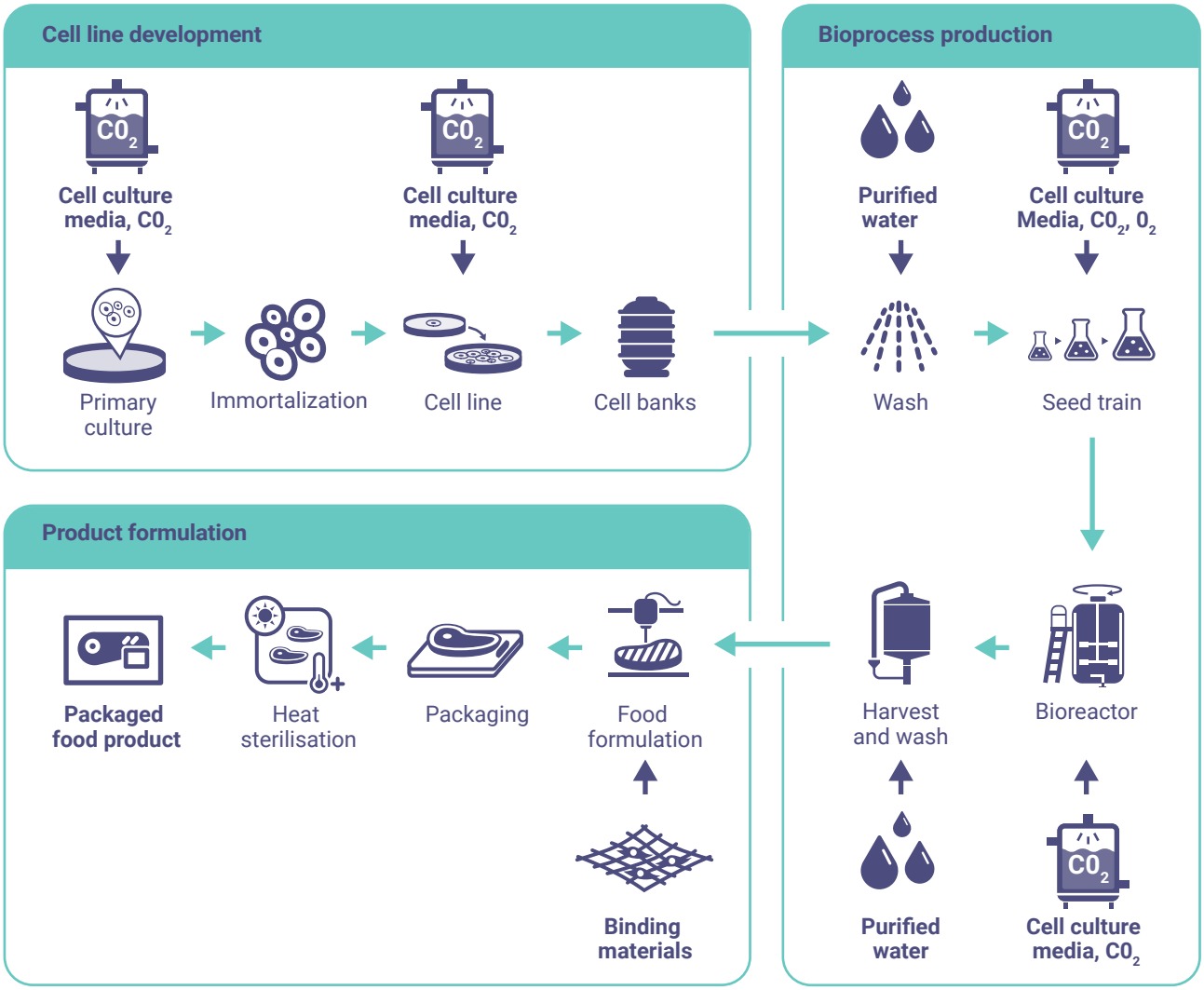
In addition, it has been a good practice for the company to establish a robust communication strategy to engage with various stakeholders, including the public, media, industry, the government and the scientific community. This strategy encompasses several strands, including an open-door policy designed to foster trust and collaboration by maintaining transparency with all stakeholders; the publication of peer-reviewed articles disseminating research findings in reputable scientific journals aimed at the broader scientific community; and government engagement to raise awareness of the technology used in developing the product.

2.2.10 A cell-based fish product and its food safety assurance process

Carrie Chan (Avant), based in Singapore, presented a cell-based fish product, claiming that it can address some conventional fishery and aquaculture challenges. For fishery, these include the problems with marine pollutants, bycatch, dwindling harvest, and fishing quota. For aquaculture, these include water pollution affecting aquaculture fish, antibiotic misuse or overuse in aquaculture impacting on the food safety issues of residues, as well as the overall antimicrobial resistance (AMR) development in the environment and the contamination of pathogens, including AMR pathogens.

The production process follows three main stages (Figure 10): 1) cell-line development, 2) bioprocess production, and 3) product formulation. The process starts by isolating cells from a fish specimen, passaging the primary culture until it is spontaneously immortalized, characterizing them and establishing a cell bank. The cells are then proliferated in a bioreactor. In the final phase, the cultured fish cells are harvested and mixed with other food-grade plant-based ingredients to make the final formulation. The product is then processed to take various forms, such as fillets, nuggets or patties, and packaged for sale.

Figure 10. A production process overview for cell-based fish



Source: Adapted from Chan, C. 2023. Cultivated marine proteins. Cultivating sustainable and safe cell-based fish. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The safety assessment of the product is conducted in line with the regulatory approval requirements set out in the SFA's guidelines, evaluating the cell lines, the culture media, the scaffolding structures, the genetic stability of the cell culture, and the presence of heavy metals and microbiological contaminants in the input, inline and output materials. In addition, a food safety plan is set up to ensure that the final product is free from all potential risks for human consumption.

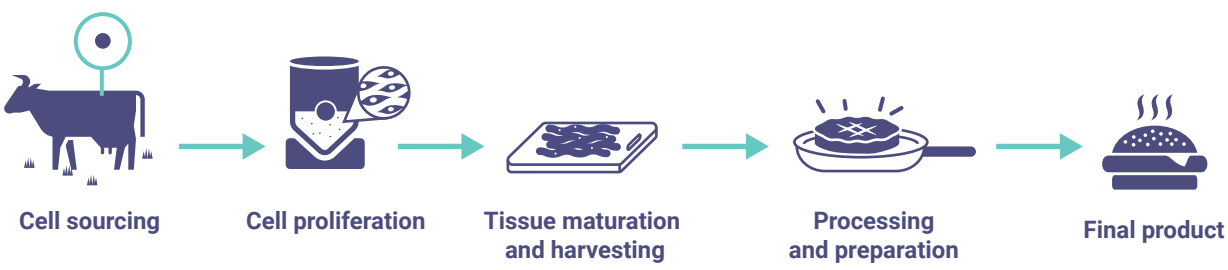
The presenter said that she expected the product would obtain the regulatory approval soon. She pointed out that advancements in scaffolding materials and culture media are important for reducing production costs and enhancing the texture of the final product. The company is looking to overcome the challenge of finding suitable and scalable sources of scaffolding materials and culture media so as to achieve price parity with conventional products.

2.2.11 From myosatellite cells to beef burgers

Valeria Teloni (Mosa Meat), based in the Kingdom of the Netherlands, presented the company's cell-based beef burger, which has been claimed as the world's first cultured beef burger in 2013. Because the project was initiated within a government-funded research framework, the presenter stressed that the burger was developed with the aim of fundamentally reshaping the global food system by the reducing adverse impacts that livestock production has on the environment.

The production process comprises five stages, as illustrated by Figure 11. First, a small sample of cells is obtained from a live cow through a biopsy under local anesthesia. This small sample can potentially yield up to 80 000 burgers. Those cells are isolated and then cultured in a bioreactor with a serum-free growth media. All the conditions, such as temperature, oxygen levels, pH levels and levels of required nutrients are controlled for cell proliferation. As a result, trillions of cells can be produced, and subsequently differentiated into muscle and fat tissues in the process. After maturation, muscle tissue is mixed with fat tissue, forming a composition similar to conventionally produced beef products.

Figure 11. Cell-based beef burger production process overview



Source: Adapted from Teloni, V. 2023. Same beef, new process: The Mosa Meat journey. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

Ensuring food safety, as the presenter explained, hinges on evaluating whether the raw materials are safe. To achieve this, a comprehensive list of potential hazards is drawn up to each, thus ensuring the effective implementation of safety monitoring measures. All the production processes, including cell selection, cell culturing, harvesting and food processing, are important when it comes to devising safety plans. End-product testing is also routinely conducted, with the primary aim of making sure that there are no contaminants in the final product.

The presenter made it known that the company hoped to complete the regulatory dossier development soon, and to secure regulatory approvals from various authorities, including the SFA and the EFSA. Once approved, the primary focus will shift to scaling up production, bringing the ultimate goal of reshaping the food system within view.

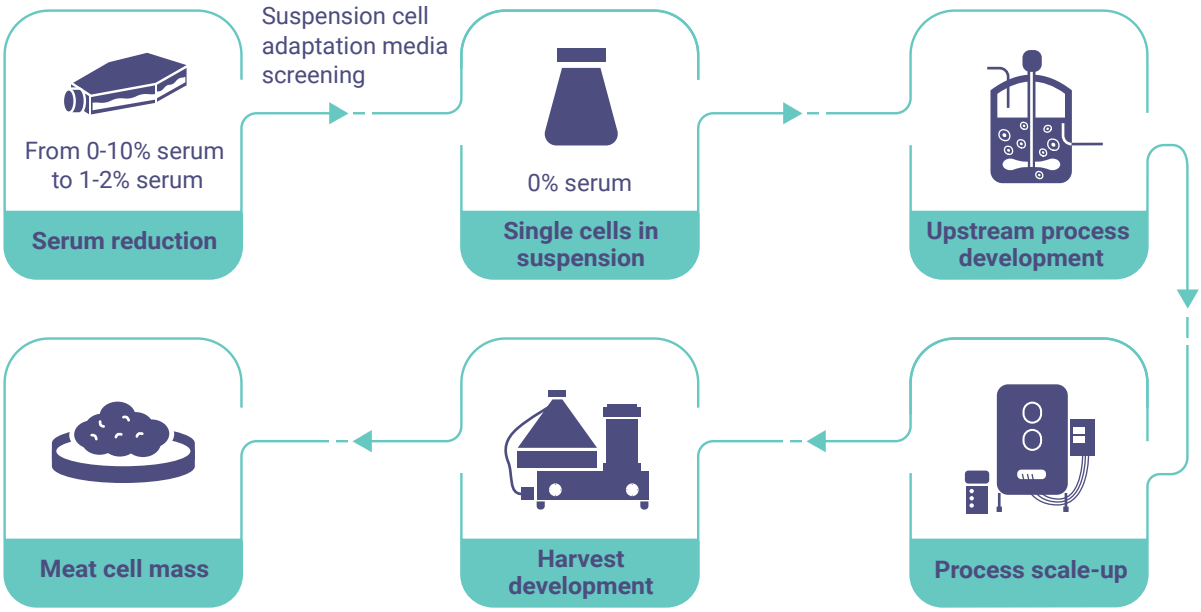
2.2.12 Customizing growth media: No one-size-fits-all solution

Louis Cheung (JS Biosciences), based in China, was tasked with presenting the development of cell culture media intended for precision fermentation and cell-based food applications. Cell culture media is a critical element of the production process, containing essential nutrients for cell proliferation and requiring custom optimization for different cell lines and applications. Each cell line has specific needs and preferences when it comes to nutrient levels and ratios. Given that there is no universal formula that can address all needs, it is necessary to tailor media to each specific cell line.

A case study on the adaptation of adherent Baby Hamster Kidney Fibroblast (BHK21) cells to suspension was presented, as an example of the growth media development process. BHK21 cells, which are normally attached to a surface to grow, are adapted to grow in suspension while freely floating in the culture medium. The presenter explained that this adaptation process was crucial for scaling up production, as suspension cultures are easier to manage in a large bioreactor and tend to be more cost effective compared to cells cultivated in the adherent mode.

As part of the adaptation process (Figure 12), the serum concentration is gradually reduced so that adhered cells are slowly acclimated to a low-serum and then a serum-free medium. Once the cells are fully adapted and growing in suspension, they can be transferred to a conventional stirred-tank bioreactor for cultivation on a large scale.

Figure 12. The adaptation of adherent BHK21 cells to suspension



Source: Adapted from Cheung, L. 2023. Scalable cell media and upstream technologies for commercializing cultivated meat at large scale. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

While developing cell culture media, a thorough analysis and characterization of raw materials are essential to identify any impurities and/or heavy metals in the media, since this will eventually be required for the safety assurance of the end product. These impurities could also negatively impact on cell growth, thus compromising the quality and safety of the final product.

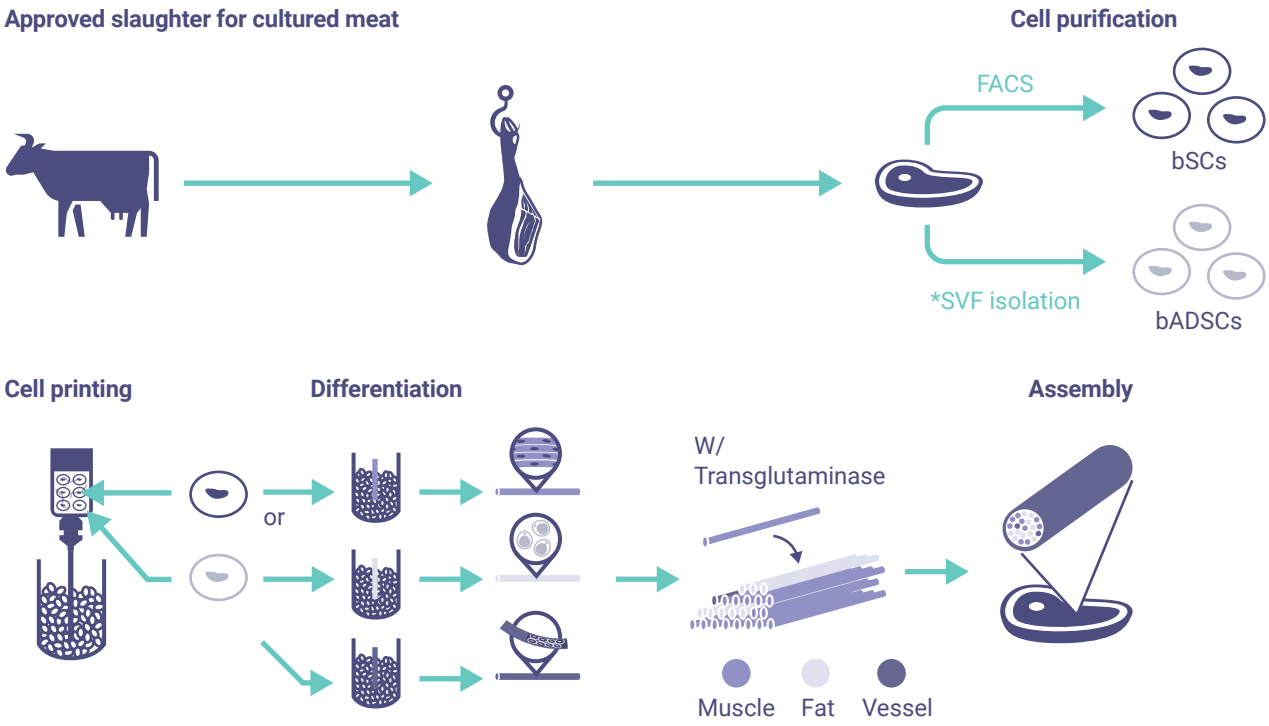
Louis Cheung noted that in the cell-based food production and precision fermentation area, new techniques, such as cultivating cells in concentration, fed-batch or perfusion mode, are being explored to achieve high productivity and increase the yield of proteins and cell masses. He stressed that sourcing food-grade raw materials and identifying the cost drivers of a media formula can also reduce the costs incurred when additional food safety assessment are required and potentially enhance the scalability of the production.

2.2.13 Experience of developing designed cell-based Wagyu beef

Fiona Louis (Osaka University), based in Japan, presented a cell-based Wagyu beef product developed using a 3D bioprinting technology designed to have a controllable pattern of muscle, fat and vascular fibers that mimics the structure and taste of conventional Wagyu beef. The group developed the tendon integrated printing (TIP) method, a novel bioprinting technology used to produce cell fibres, making it possible for the construction of muscle, fat, and blood vessels to be predesigned. Formed without a scaffolding structure, the resulting steak-shaped beef is 10 mm long with a diameter of 5 mm, and it comprises 42 muscle fibres, 28 adipose fibres and 2 blood capillary fibres.

The manufacturing process involves three main stages (Figure 13). The first one consists in the isolation of bovine satellite cells (bSCs) and bovine adipose-derived stem cells (bADSCs). These cells serve as the building blocks for the creation of the meat-like tissue. The cell growth is supported by the ZACROS cell-culturing system, developed by the Fujimori Kogyo Co., Ltd., which enables a large-scale culture of stem cells using a tank shaking method. Supporting bath-assisted printing (SBP) of bSCs and bADSCs to fabricate the muscle, fat and vascular tissue with a fibrous structure is the second stage. These cell fibers are then assembled in a way that mimics the structure of a steak, which determines the texture and mouthfeel of the final product.

Figure 13. Flow charts showing the production stages of the tailor-made, cell-based Wagyu beef



Source: Adapted from Louis, F. 2023. Cell-based Wagyu meat. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The presenter reported that their cell-based Wagyu beef steak has taste, aroma and texture that closely resemble those of conventional Wagyu beef. A total of 59 aroma compounds were identified in the product, including γ-Nonalactone, an aromatic compound possibly linked to the unique flavour of conventional Wagyu beef. At the processing phase, a fatty acid composition similar to that of the conventional Wagyu beef fat is confirmed in the cell-based wagyu fat fibers. The composition can be altered by adjusting the fatty acid content of the culture medium, resulting in organoleptic features that mirror those of the conventional product.

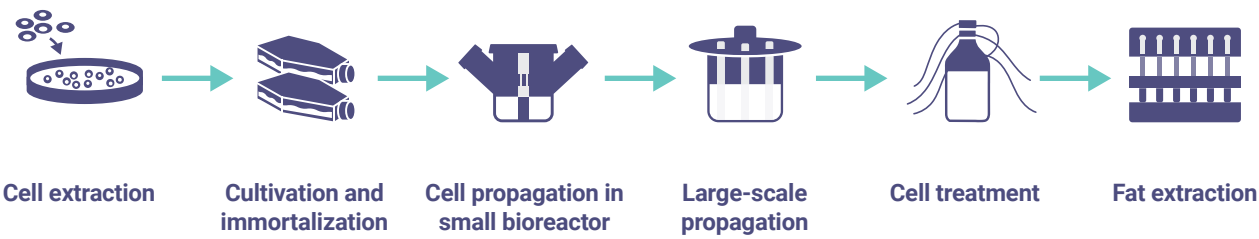
The automation of the entire production process is envisioned for the near future, in a collaboration with the Shimazu corporation aiming to mass produce cell-based Wagyu beef. While the group uses only food-grade materials and ingredients as a first step of food safety assurance, the industry in Japan is currently waiting for the Japanese government to set up a regulatory framework to start approving cell-based food. This is just one of the products made thanks to the efforts of various groups of researchers in companies and labs in Japan with the aim of developing safe and advanced cell-based food technologies.

2.2.14 A cell-based approach to producing milk lipids

Zohar Barbash (Wilk), based in Israel, discussed how cell-based milk lipids derived from immortalized milk-producing cells are used to develop yogurt and other dairy products. The presenter noted that, while the global demand for milk and milk ingredients is on rise, conventional dairy production practices face various difficulties due to the global climate crisis. The company aims to address these challenges by producing customized infant formula, milk or milk ingredients with desired nutritional and functional properties, tastes and preferences.

As shown in Figure 14, the production process can be explained in six steps. The process begins with the extraction of cells from samples taken from women, milk cells or animal mammary tissue. Extracted cells undergo an immortalization process which modifies them so that they can continue to grow and divide in a controlled culturing process. Once a sufficient cell mass is achieved through cell propagation in a small bioreactor, they are moved into a large-scale propagation system. Cells are then treated to stimulate a higher yield of fatty acid. Finally, the fat/lipid is extracted to make the final product.

Figure 14. Overview of the milk lipid production process using the cell-based approach



Source: Adapted from Barbash, Z. 2023. Wilk: Challenges in producing cell based cultured milk components. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

According to the presenter, the product's lipid profile indicates a close similarity with those found naturally in human and bovine milk. A lipidomic analysis reveals that most of the lipids developed in the cell-based product are present in natural milk. From the perspective of a history of safe consumption, it is important to maintain or even improve on this by constantly monitoring and refining protocols and treatment methodologies.

The presenter emphasized the importance of enhancing cell yield in each propagation cycle as a way of facilitating large-scale production and optimizing the manufacturing process. To achieve this aim, one of the important steps is the adaptation of the growth media to allow for a higher proliferation of cells, which in turn increases the overall cell mass. Cost reduction is another aspect that needs to be tackled with a view to scaling up.

The company recognizes the importance of forging strong partnerships with key players in the global dairy market. Leveraging their scientific and food-tech expertise can lead to advances in terms of product development and manufacturing techniques, as well as safety assessment methodologies. These partnerships would create additional market opportunities, while enabling the products to reach a wider audience that stands to benefit from them.

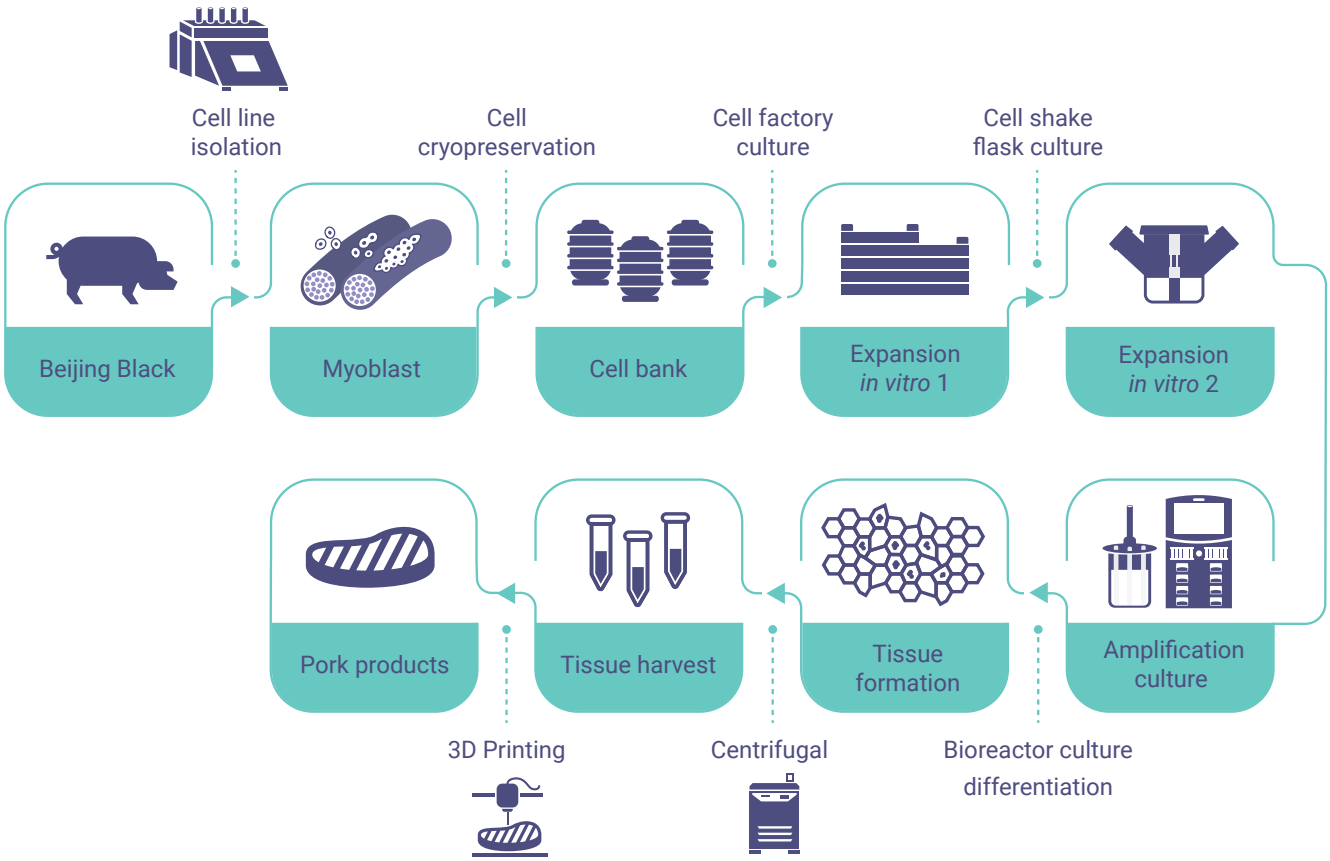
2.2.15 Cell-based pork products developed from Beijing Black

Beijing-based Yingying Li (Future Food Science and Engineering Research Department at the China Meat Research Center) presented three cell-based pork products: 1) a fried pork chop, derived from White Duroc swine cells; 2) a pork burger, developed from Beijing Black swine cells; and 3) grilled pork, also made from Beijing Black swine cells. All these products are processed using 3D printing.

© China Meat Research Centre / Liu Wenting

The production process for Beijing Black-derived products comprises eight steps, as illustrated in Figure 15. First, cells targeted for culturing and proliferating with myoblast are isolated from the animal (Beijing Black) through cell cryopreservation, and the resulting cell line is stored in a cell bank. The cells from the bank undergo two rounds of expansion in vitro, prior to being amplified and cultured in a bioreactor where they are differentiated so as to form a muscle tissue. The formed tissue is harvested using a centrifuge and then processed in a 3D printer to arrive at the final product.

Figure 15. Steps involved in producing cell-based Beijing Black pork products



Source: Adapted from Li, Y. 2023. Cell cultivated pork – Key technologies for cell cultivated pork steak production. Presented at the Stakeholder roundtable meeting on cell-based food and precision fermentation, 6 November 2023. Shanghai, China.

The presenter emphasized that identifying potential food safety hazards throughout the entire production process is important for monitoring and ensuring product safety. Potential hazards include pathogen contamination, chemical contamination/residues and changes in cell characteristics. As far as the regulatory framework is concerned, the presenter underscored the importance of implementing effective traceability systems in the case of all food items, including cell-based food products. Where cell-based food is concerned, it is necessary to cover raw materials, input materials, growth media, growth factors, nutrients used, materials, additives and ingredients used in the final food processing in the traceability scope so that, in the event of something going wrong, the system can identify the potential cause of a given food safety issue. The presenter added that having a sound traceability system would also boost consumer confidence.

The presenter considers that more research is needed on materials for scaffolding and microcarriers, which are small adherent beads that can support the growth of cells in suspension culture. They are widely used in the biotechnology and biopharmaceutical industries, but have not been extensively explored for use in food production. Scaling-up equally poses a challenge for all cell-based food developers, many of whom are focused on the immediate goal of achieving stability and sustainability for large-scale productions.

2.3 Special discussion session on food safety regulatory dossier development

FAO facilitated a special discussion session on food safety assessment designed to help with the preparation of regulatory dossiers. Three participants who went through the process of the dossier development came forward to discuss their experiences. According to them, in the most likely scenario, the vast majority of regulatory frameworks around the world would require a premarket approval for cell-based food products, and many of them were also likely to put in place a similar requirement for foods derived from precision fermentation. Since a food safety assessment would be one of the core elements in such approval schemes, if companies plan to commercialize a given product, they need to be able to prepare an extensive dossier, containing a comprehensive food safety assessment.

As of November 2023, only a handful of companies have completed food safety assessments for approval, but their number is growing. Some presenters thought that they were close to obtaining the regulatory approval (for example, Aleph Farms obtained the regulatory approval for one of their products soon after the meeting, in January 2024), and the experiences they shared were valued by all the participants. In some countries, including the United States of America, government agencies publish the food safety dossiers online for transparency. Experienced participants urged all the developers to carefully review those publicly available resources, including dossiers, regulatory guidelines (such as those published by the Singapore Food Agency), and the hazard identification section of the FAO/WHO publication to initiate the process of food safety dossier development.

The experienced participants recommended paying attention to six main categories of food safety issues: 1) the genetic stability of cells/cell lines; 2) microbiological hazards to do with cell lines; 3) exposure to the substances used in the production process; 4) toxicity and allergenicity for the general population; 5) post-harvest microbiological contamination risks; 6) chemical contamination/ residue levels. In addition, some countries/jurisdictions may request information about nutritional risks. The same participants added that regulators found narratives based on scientific facts to be most convincing when it came to demonstrating the safety of the products, using evidence- and risk-based studies.

It was highlighted that allergenicity is a challenging topic for all types of food products. The last few decades have seen a significant rise in allergies, and food allergies and increased food-related sensitivities are becoming a problem everywhere. While most reactions can be considered mild, life-threatening reactions do occur. It can safely be said that for any given food item, someone out there can be either allergic to it or have a sensitivity reaction. Therefore, the aim of the safety assessment as far as allergenicity is concerned is not so much to prove the absence of allergens but to conclude that a particular component presents a low risk to the general population or to ensure that the labelling is appropriate. With that in mind, conducting a scientific analysis and cross-referencing products and compositions with allergen databases to identify and declare a known allergenicity is essential.

There was a fruitful discussion concerning the potential usefulness of having international standards for input materials and ingredients used in the production process. For example, the United States of America has a list of generally recognized as safe (GRAS) food ingredients and packaging materials. This type of material “food grade” list, no matter what it is called, can be found in different countries and jurisdictions; if it is linked to regulations, it often means that those materials can come into direct contact with food. However, it usually does not guarantee the complete safety of the materials, including scaffoldings and microcarriers, because the level of safety may change based on the conditions and types of material being used. Many participants initially felt that a universal list could be useful, but as the discussion went on, everyone agreed that achieving an international harmonization of the list may not be realistic, given the complexity of the issue. Experienced participants recommended a more realistic solution: to look for such lists (either a black list or a white list) in the targeted market’s regulatory framework(s) and use them as a starting point for evaluating the safety of materials/ingredients used in the production process.

Throughout the session, experienced participants stressed the importance of early engagement with regulators. This stands to benefit not only applicants but also regulators. Many government agencies are open to being contacted for such informal consultations at the presubmission stage. As most of the products will likely need to be evaluated on a case-by-case basis, such consultations give regulators a good understanding of the products and the production processes involved. At the same time, they are an opportunity for the applicants to ask questions regarding requirements and guidelines. All the competent food safety authorities who are ready to review dossiers recognize that the mechanism of informal presubmission consultations amounts to good practice.

2.4 Closing remarks

In his closing remarks, FAO Senior Food Safety Officer Markus Lipp congratulated all the presenters on their excellent and well-informed presentations, highlighting the fact that the meeting covered a wide variety of food products derived from cell-based food production and precision fermentation. He pointed that this field was still new and that, owing to its novelty, it was crucial to initiate and pursue open discussions, both at the policy level and at the technical level. When a technology is being rapidly developed and adopted, it is not reasonable to expect regulators to be aware of all the details concerning the latest developments of this particular technology right from the start. Thus, exchanges such as those that took place at this meeting can help stakeholders and regulators to learn from each other. The topic of bioidentical substances between conventional products and products derived from precision fermentation, in particular the debate on whether or not having the identical primary, secondary and/or tertiary structures suffices for claims of bioidentity, was a good example of how the input provided by stakeholders can provide valuable information and contribute to making regulatory frameworks effective. In conclusion, Markus Lipp emphasized FAO's ongoing commitment to providing a forum for multisectoral discussions on a global scale. He thanked all the participants for actively engaging in the animated discussions, which contribute to achieving global food safety by fostering international collaborations.


@Ambi Realfood/ Kamila Santos

3. CONCLUSIONS

The meeting, bringing together 21 speakers who presented the most up-to-date products showcasing cell-based food production and precision fermentation, provided an overview of the current state of development of these technologies and the industry in 2023. As more countries are reviewing the regulatory applications, a set of helpful examples illustrating the approach and methodologies for assessing product safety have become available. The presenters shared their insights on the latest trends in product development, and the audience, including government officials in the host country, was able to identify key food safety considerations that could be unique to cell-based food and precision fermentation. All the participants agreed that continuing to hold open discussions with different stakeholders was a crucial way of clarifying important issues in the area of food safety for consumer protection, as well as supporting relevant scientific research and innovation aimed at achieving the food security goals – sufficient, safe, nutritious and sustainable food production for the future.

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FAO. 2023b. Ensuring the safety of cell-based food (20 min), English: https://youtu.be/Vn7OCVV_o4Y, and Cell-based food production and food safety (1min 43 sec), English: https://youtu.be/YyUoP2d3Zos, Arabic: https://youtu.be/gDeo4ptglyg; Spanish: https://youtu.be/ZsBJQV8iNY0; French: https://youtu.be/7yttqKP-n9E; Russian: https://youtu.be/E9kcKadp5Bo; and Chinese: https://youtu.be/dZFknqkctoI

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- Masami Takeuchi, Food Safety Officer
- Maura Di Martino, Food Safety Specialist
- Markus Lipp, Senior Food Safety Officer

ANNEX 2. MEETING AGENDA

Time	Items	Speaker
08.00 – 09.00	Registration and networking coffee	
09.00 – 09.15	Opening	Yongxiang Fan, Deputy Director (CFSA)
09.15 – 09.30	Objectives and FAO activities	Masami Takeuchi (FAO)
09.30 – 09.45	Animal-free collagen for food and nutrition (Liven Proteins)	Fei Luo
09.45 – 10.00	The Puratos view on precision fermentation (Puratos)	Li Ning
10.00 – 10.15	Safety considerations for precision fermentation-based ingredients (Luyef Biotechnologies)	Kris Elliot Blanchard
10.15 – 10.30	Q&A	
10.30 – 11.00	Coffee/tea break	
11.00 – 11.15	Regulatory approach for cultivated meat (CellX)	Chee-Seng Hee
11.15 – 11.30	Cultivated deer antler cell (Jimi Biotechnology)	Cao Zhehou
11.30 – 11.45	Producing safe and delicious cultivated foie gras (Gourmey)	Hannah Lester
11.45 – 12.00	Q&A	
12.00 – 13.00	Lunch	
13.00 – 14.30	1. Special discussion session – food safety dossier development; 2. Food safety dossier development (BlueNalu); 3. Novel food regulatory dossier building (Aleph Farms); Regulating the roost: Vow cultured quail and three dossiers (Vow)	Facilitator: Masami Takeuchi
14.15 – 14.30	Cultivated marine proteins (Avant Meats)	Carrie Chan
14.30 – 14.45	Same beef, new process: The Mosa Meat journey (Mosa Meat)	Valeria Teloni
14.45 – 15.00	Q&A	
15.00 – 15.30	Coffee/tea break	
15.30 – 15.45	Scalable cell media and upstream technologies for commercializing cultivated meat at a large scale (JS Biosciences)	Louis Cheung, Appachu Kodira
15.45 – 16.00	Cell-based Wagyu meat (Osaka University)	Fiona Louis, Hikaru Shibata, Jin Muraoka
16.00 – 16.15	Wilk: Challenges in producing cell based cultured milk components (Wilk)	Zohar Barbash
16.15 – 16.30	Cell cultivated pork (China Meat Research Center)	Li Yingying, Wang Shouwei, Hu Haijuan
16.30 – 16.45	Q&A	
16.45 – 17.00	Wrap-up and closing remarks	Markus Lipp (FAO)

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CD0311EN/1/04.24