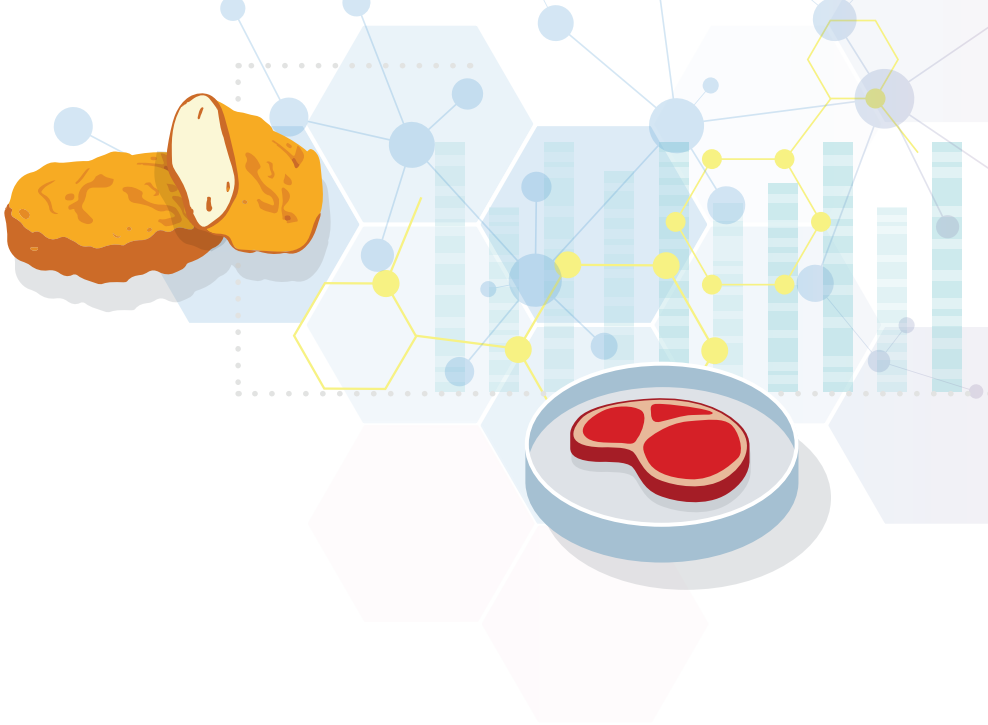
Food and Agriculture Organization of the United Nations

World Health Organization

Food safety aspects of cell-based food

Report of the publication launch webinar, 7 April 2023



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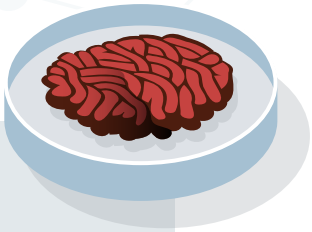
Abbreviations



FAO
Food and Agriculture Organization of the United Nations

FDA
Food and Drug Administration

FRESH
Future Ready Food Safety Hub

FSANZ
Food Standards Australia New Zealand

SFA
Singapore Food Agency

LMIC
low- and middle-income country

USDA
United States Department of Agriculture

WHO
World Health Organization

Executive summary

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) held a webinar to launch the publication entitled "Food safety aspects of cell-based food" published in April 2023. The webinar was attended by a total of 1 015 participants from more than 75 countries.

Cell-based food production involves culturing animal cells in a controlled environment to produce various types of food products. As this technology is constantly evolving, it is important for food safety authorities to keep up with science in order to understand how the products are developed and what food safety considerations are relevant when taking regulatory actions. The webinar included a lecture on the subject by the chairperson of the FAO-led expert consultation, who introduced the contents of the FAO/WHO publication and presented the results of the first global food safety hazard identification of cell-based food. Experts reported that most of the hazards identified were common to conventional food products and emphasized the importance for food safety competent authorities to focus on the materials, inputs and equipment specific to cell-based food production.

Two regulatory experts from the governments of Singapore and Qatar took part in the webinar to introduce the case studies of their respective countries' regulatory frameworks. These case studies illustrated the commonly held idea that a food safety assessment is one of the first steps within the regulatory frameworks presented in the case studies, despite the fact that other elements within the framework may be different. This was borne out by subsequent panel discussions with six panellists from Argentina, Australia, Qatar, Singapore, the United States of America and Zambia who all concurred that a food safety assessment provides a crucial starting point. As regards the readiness to initiate the food safety assessment, while Singapore and the United States of America already have the technical capacity to review applications, other panellists stated that they are not yet fully ready to start the review process, while preparatory activities have been already started. Some webinar participants stated that they would need further international technical assistance to be in a position to fully conduct a food safety assessment at the national level. All panellists emphasized the importance of the FAO/WHO publication as an invaluable source of technical information in this regard, particularly as it lists potential hazards that regulators can draw on. The publication also contains vital information on nomenclature and useful advice on ways to effectively communicate this topic to the public.

The webinar included an interactive discussion session with the participants, during which basic food safety and regulatory questions were raised. FAO and WHO concluded the webinar with the offer to provide technical assistance to those countries in need of it.

Keywords: webinar, food safety, cell-based food, production process, regulatory framework, risk analysis, risk assessment, hazard identification, expert consultation, food standards

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1. Introduction

1.1. Background

After the Singapore Food Agency (SFA) approved a cell-based food product in 2020, the global regulatory approval status of cell-based food products did not change for a few years. Since the Food and Drug Administration (FDA) of the United States of America and the United States Department of Agriculture (USDA) gave the green light to two cell-based food products in 2022 and 2023, the overall regulatory landscape has gradually been changing around the world.

Cell-based food production involves culturing cells to develop a variety of food products, including various types of animal products. As this technology is constantly evolving, it is important for food safety authorities to keep up with science in order to understand how the products are developed and what food safety considerations are relevant for taking regulatory actions.

While the authorities with sufficient technical capacities and financial as well as human resources were able to initiate the preparatory process of reviewing the food safety assessment dossiers of cell-based food products, many of the authorities in low- and middle-income countries (LMICs) reported having a limited ability to do the same. To address this gap, the Food and Agriculture Organization of the United Nations (FAO), in collaboration with the World Health Organization (WHO), held an expert consultation with the aim of conducting a food safety hazard identification, the first step in a formal risk assessment process. Detailed results of hazard identification, together with introductory information on the subject, were consolidated into a publication designed to provide competent food safety authorities with vital information about food safety aspects of cell-based food.

In order to help LMICs increase their awareness on the topics introduced by the publication, FAO and WHO jointly organized a global publication launch webinar with the specific aims of 1) making an electronic copy of the publication available to better understand various technologies/techniques currently being used in cell-based food production; 2) presenting key results of food safety hazard identification conducted by FAO experts; 3) sharing examples of national regulatory frameworks for food safety assurance in a small number of selected countries; and 4) providing opportunities for participants to join in an interactive session to discuss country-specific issues and regulatory needs.

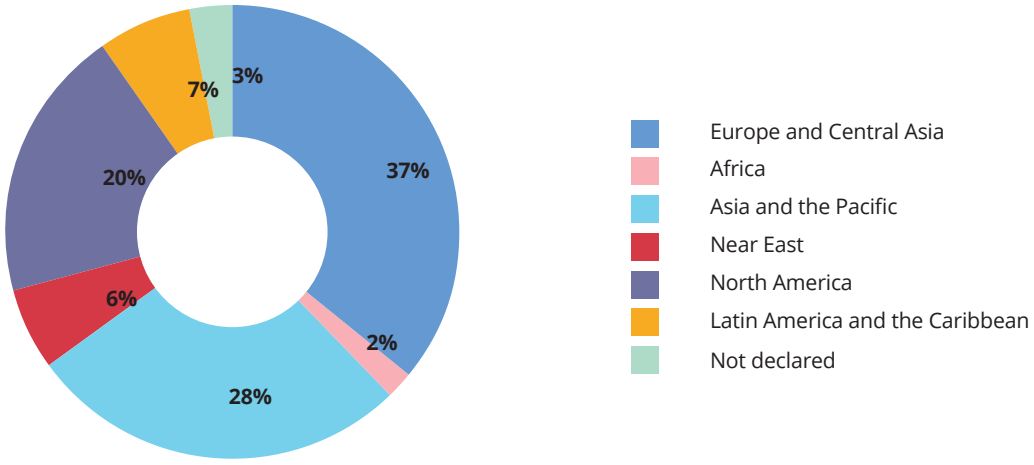
1.2. FAO/WHO publication

The FAO/WHO publication entitled *Food safety aspects of cell-based food* was officially launched during the webinar. The publication contains the first global food safety hazard identification of cell-based food, as the critical first step in the risk assessment process. In addition, the publication contains the literature synthesis of three important topics: 1) relevant terminology issues, 2) an overview of the generic production process of cell-based food and 3) current regulatory frameworks complemented by three country case studies (Israel, Qatar and Singapore). The hazards identified during the expert consultation are listed in tables reflecting four different production phases: cell-sourcing, cell-production, harvesting and food processing. The causal chains for each identified hazard are explained to allow for a more detailed characterization of the hazards in question. A section of the publication addresses additional concerns voiced in some mainstream media or on social media, and explains why experts do not consider them to be hazards.

1.3. Webinar overview

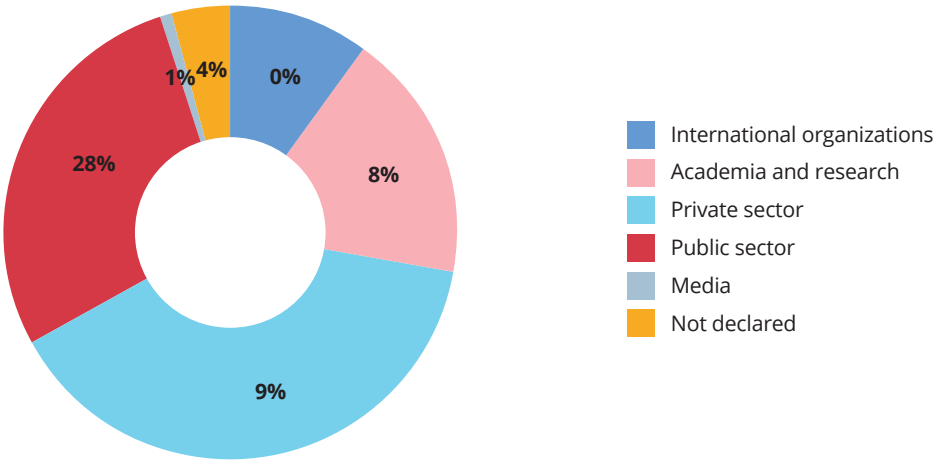
Consisting of two 90-minute sessions, the webinar took place on 5 April 2023. The number of registrations reached the maximum limit of 2 000 participants, of which a total of 1 015 people from over 75 countries participated in the webinar. Thirty-seven percent were from Europe and Central Asia, 28 percent from Asia and the Pacific, 20 percent from North America, 7 percent from Latin America and the Caribbean, 6 percent from the Near East and 2 percent were from Africa (Figure 1; 3 percent did not declare where they were connecting from). As regards sector representations, 28 percent were from the public (government) sector, 18 percent from academia and research institutes, 10 percent from international organizations, 40 percent from the private sector (Figure 2; 4 percent did not declare their affiliations).

FIGURE 1 Regional distribution of the participants



(FAO&WHO, 2023)

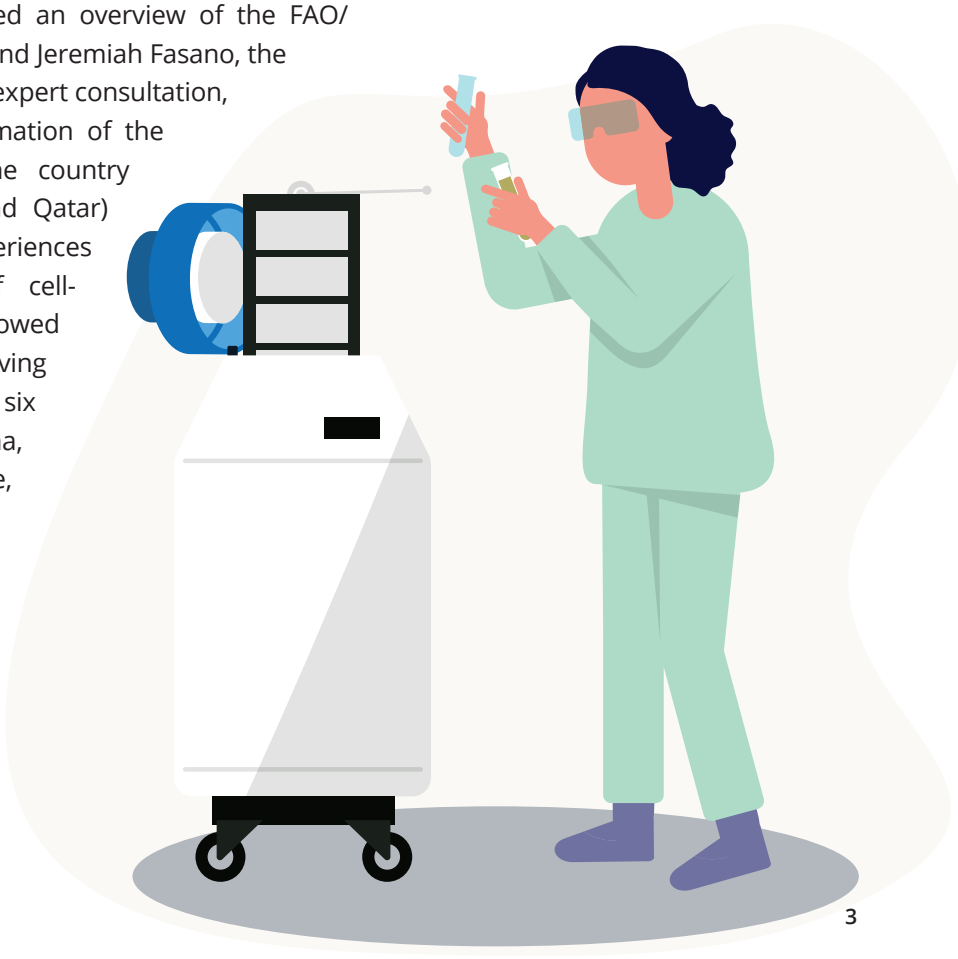
FIGURE 2 Participants by sector



The recordings of the two 90-minute sessions are available at the following links: Session 1 (https://youtu.be/ZONU85ZDGkg) and Session 2 (https://youtu.be/e52T-N5LY_o).

1.4. Webinar proceedings

The webinar was officially opened by Corinna Hawkes, Director of the Food Systems and Food Safety Division, FAO, and Francesco Branca, Director of the Department of Nutrition and Food Safety, WHO. Following the opening, Masami Takeuchi, Food Safety Officer, FAO, provided an overview of the FAO/WHO activities in this area, and Jeremiah Fasano, the Chairperson of the FAO-led expert consultation, presented a detailed information of the consultation outcomes. The country case studies (Singapore and Qatar) were presented to share experiences on regulatory aspects of cell-based food. This was followed by a panel discussion involving panel members from six countries, namely Argentina, Australia, Qatar, Singapore, the United States of America and Zambia. An open discussion session led to an interactive discussion with the participants, and Juliana De Oliveira Mota, Technical Officer, WHO, brought the webinar to a close.



2. Opening sessions

During her opening remarks, the FAO Director stated that technically sound regulatory guidance is vital to achieving sustainable and healthy agrifood systems and that the FAO/WHO publication *Food safety aspects of cell-based food* plays a key role in this respect. FAO's Strategic Framework is geared towards achieving the 2030 Sustainable Development Goals which can be realized by making agrifood systems more efficient, inclusive, resilient and sustainable. Food safety serves as a critical enabler for nearly all the activities within this framework. As new technologies emerge, the question of whether the food resulting from such technologies can be as safe as that produced by more conventional processes always comes to the fore, and cell-based food production is no exception.

The WHO Director acknowledged the importance of food safety in his own opening remarks and stated that the webinar explored the potential of cell-based foods as a means of boosting the supply of animal proteins, in the pursuit of a healthy diet for all. The FAO/WHO publication serves as a scientific foundation that Members can consult to prepare any necessary regulatory actions to ensure the safety of these products. While three billion people worldwide cannot afford a healthy diet, access to high quality animal source proteins, such as meats, dairy products, fish and eggs, is becoming a significant challenge. At the same time, the production of animal proteins is reported as having possibly significant environmental impacts, which can also be influenced by consumer choices and production patterns, such as the use of intensive animal farming practices to meet the increased demand for animal proteins. In this context, the WHO Director emphasized that FAO and WHO have the responsibility to gather and assess the current knowledge on new food-related technologies.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3. Relevant activities at the global level

Following the opening remarks, FAO Food Safety Officer Masami Takeuchi explained the relevant activities led by FAO/WHO. In early 2021, an informal technical working group brought together interested regulators to discuss the needs of their respective countries. This informal group is still active, and currently boasts more than 35 regulatory experts from over 13 countries and members who meet to discuss their needs and challenges as far as regulatory activities of cell-based food are concerned. A call for experts and available data was issued in early 2022 to prepare for an expert consultation. In the meantime, three surveys have been produced of technical literature dealing with terminologies, production processes and regulatory frameworks. In September 2022, a stakeholder roundtable meeting was held in Israel to understand the current status of the cell-based food development in the private sector. In November 2022, the first expert consultation was conducted in Singapore to identify in a comprehensive way potential food safety hazards in cell-based food production. All the outputs were compiled into the final FAO/WHO publication that was officially launched at the webinar.

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4. The results of the expert consultation

The Chairperson of the expert consultation, Jeremiah Fasano from the United States of America, presented the results of the first global food safety hazard identification of cell-based food. He explained that the consultation focused on the scientific aspects of the matter. The experts agreed that a food safety risk analysis paradigm is applicable but, given that consumers have not been exposed to the products yet, the formal risk assessment which includes an exposure assessment cannot be carried out at present. Therefore, it was agreed that identifying potential food safety hazards in a comprehensive way was a critical first step.

The Technical Panel considered all the potential hazards and put together an exhaustive list based on the four stages of the cell-based food production, namely: 1) cell sourcing; 2) cell growth and production; 3) cell harvesting; and 4) food processing and formulation. A number of considerations were identified for each hazard, including the potential consequences for human health, the type of hazard, potential control measures, relevant or comparable prior experiences, and the causal chain that connects the hazard to a potential food safety risk. The causal chains illustrated the sequence of events required for a hazard to become a risk. The experts found that, for cell-based food, the majority of such hazards are already well known, and they apply to conventionally produced food. For example, microbiological contamination can occur at any stage of the food production process, including those stages involved in producing cell-based food. However, it is important for food safety plans to focus on the materials, inputs, ingredients and equipment that are unique to cell -based food production.

The Technical Panel also noted alleged food safety concerns surrounding cell-based foods flagged up by mainstream press and on social media. Developing the causal chains for these supposed issues was not possible in the light of current scientific knowledge, even as a hypothetical consideration. That is why they were not included in the list of potential hazards, although a separate section was put together with a view to explaining why the experts did not consider them to be hazards.

During the expert consultation, four Technical Panel members with expertise in social science teamed up to develop a practical guide for competent food safety authorities to engage stakeholders in communication regarding the food safety aspects of cell-based food.

5. Country cases on regulatory frameworks

5.1. Qatar's experience

The first country case study was presented by Mehdi Triki, Food Safety Analyst at the Ministry of Public Health in Qatar, who stated that the country is exploring the potential of cell-based food production. The establishment of a cell-based food production factory was allowed in the Qatar Free Zone in 2021, but the sales of cell-based food products for domestic consumption have not yet been approved. Two conditions need to be met for cell-based food to be approved in Qatar, namely: 1) pre-market evaluation as a novel food, which includes a food safety assessment; and 2) compliance with Halal standards, if the developed products are of animal origin (apart from aquatic animals). The latter is assessed by several governmental entities, including a Halal-specific regulatory body (Ministry of Awqaf and Islamic Affairs). In this regard, the first step for the Ministry of Public Health is to conduct a pre-market evaluation, a process that involves the evaluation of the safety and suitability of the cell-based products for the local consumers by a designated multidisciplinary scientific committee. It is important to note that Qatar has already made considerable advances in this respect. With this in mind, the government agency is using the FAO/WHO publication as a major point of reference for the evaluation and assessment of the safety and suitability of cell-based food products.

5.2. Singapore's experience

The second case study, drawing on Singapore's experience, was presented by Teng Yong Low, Branch Head of Risk Assessment and Communications at SFA. Singapore is the first country to have approved a cell-based food and their experience of reviewing the food safety assessment dossier has proved invaluable for various regulatory bodies in the world. Teng Yong Low explained that the SFA discusses with the applicants the exact use of cell lines, all the inputs, including growth media/factors, scaffolding materials and nutrients to consider potential hazards that could pose food safety risks to consumers. Since the SFA's template/guidelines for the food safety assessment of cell-based food are made available online and included in the FAO/WHO publication, other regulators can consult their checklist and go over key food safety considerations when preparing their guidelines. Mr Low highlighted the importance of early discussions with the applicants. An informal consultation prior to submission is advantageous for regulators and applicants alike: it gives regulators more lead time to prepare and gain the necessary scientific knowledge to assess new innovations, and enables applicants to understand what information is useful with respect to regulatory compliance considerations.

6. Panel discussion

6.1. The current regulatory framework in various countries

6.1.1. Food Standards Australia New Zealand (FSANZ)

Food Standards Australia New Zealand (FSANZ) categorizes cell-based food as a novel food. FSANZ has recently received the first application. The agency gives applicants the opportunity for a pre-submission consultation so that their questions can be addressed in confidence. This practice has also been considered useful in Singapore and in the United States of America, and FSANZ confirmed that the approach has helped to get a full picture of the application. FSANZ has been involved in FAO's informal technical working group since the beginning, contributing to the international efforts to collect good practices.

6.1.2. United States of America

The United States of America has an agreement in place between the USDA and FAO to share oversight of the cell-based food production technology. The agreement, which came into effect in 2019, defines the responsibilities of each agency in the oversight process. The FDA is responsible for the oversight of cell collection, cell banking and cell culture, and for conducting premarket consultations to evaluate production materials, processes and manufacturing controls associated with the cell culture phase. For cells from poultry and livestock used for human food, the USDA assumes oversight at harvest and is responsible for the subsequent oversight of processing, formulation, packaging and labelling. For cells from fish and seafood species and for game animal species, the FDA remains responsible for the oversight of processing, formulation, packaging and labelling. Like other food agencies, the FDA has a policy of being open to engaging with industry at an early stage in the development, as this stands to benefit the industry and the government alike

6.1.3. Zambia

Zambia has recently initiated a discussion on food safety regulatory actions concerning cell-based food. It is likely that it will be classified as a novel food, and that the biosafety authority will handle the regulatory actions. The awareness of cell-based food among consumers is currently low, therefore it may be necessary for the regulatory authorities to help consumers understand how the safety of cell-based food products can be ensured. The FAO/WHO publication will be useful in this respect, particularly the sections on hazard identification and the advice regarding scientific communication. The country-specific case studies included in the publication present lessons learned and key food safety issues for consideration.

6.1.4. Argentina

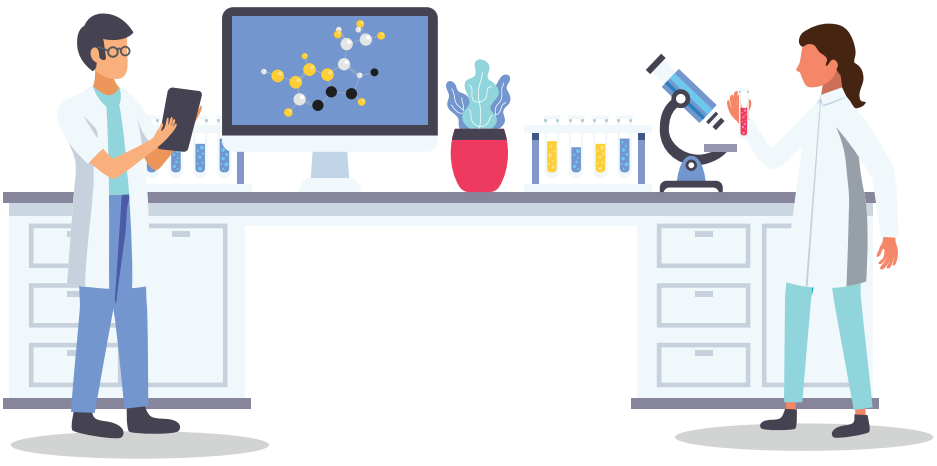
In Argentina, a review of the existing regulatory framework considering the possible applicability of cell-based food can be a first step in the process. Argentina is known to have a robust livestock industry, but there is enough room for healthy competition between meat companies and other protein-based food producers. Some biotechnology entrepreneurs may consider this an opportunity to develop high-value input materials for the cell-based food industry; for example, there can be a new market for development of cell lines, growth media, growth factors, scaffolding materials and microcarriers. For the time being, no specific regulatory framework for cell-based food is in place; however, Argentina can benefit from early engagement with the general public to discuss key issues including food safety, in order to gain consumer trust. Creating an environment enabling people to learn about various cell-based food products and the processes involved in their production would help to initiate constructive discussions between consumers and producers on how cell-based food products can potentially supplement the livestock industry, for example and the coexistence (e.g. use of terms) with the livestock-derived meat industry. The FAO/WHO publication provides first-hand information to assist the relevant regulators in their preparations.

6.2. The need for international collaboration and knowledge sharing

The panel discussed the gaps that need to be filled to ensure the regulatory readiness of competent food safety authorities around the world. Some industrialized countries have already initiated the relevant actions to set the food safety assessment process in motion. However, many regulators, particularly those in low- and middle-income countries, are faced with limited human and technical resources and would significantly benefit from collaboration and information sharing by countries with experience in this domain. For example, in Singapore, the SFA has published a guidance manual outlining data requirements for the food safety assessment, which is publicly available. In the United States of America, the food safety assessment dossiers that have been granted the "no further questions" status from the FDA are published and available online. These resources make sound scientific knowledge accessible to those who need to learn about food safety related considerations of cell-based foods.

6.3. Stakeholder engagement

Ideally, food safety regulators should have a sufficient knowledge and a good grasp of how cell-based foods are produced but, given that each product can be completely different, it is normal that the developers – and not the regulators – should be the most knowledgeable ones. For this reason, it is critical that cell-based food developers/producers share relevant information with regulators in a transparent and timely manner, so that the necessary food safety assessments can be conducted in the most efficient way. Panel members from FSANZ, the SFA and the FDA were confident to have very good communication channels with industry groups that facilitate the discussion of technical issues related to food safety with stakeholders. All these agencies have a system in place to encourage early engagement by assisting applicants in asking regulatory questions prior to submission. For example, Singapore is hosting a platform called Future Ready Food Safety Hub (FRESH), which brings together regulators, academia/researchers and private sector scientists/developers in a bid to strengthen their technical capacity to achieve food safety.



7. Interactive session

7.1. Initial public reactions

The audience enquired about public reactions to cell-based foods and, based on the experience in Singapore, it was explained that to have various reactions from consumers is to be expected. Some are very curious about the products, and the tasting restaurant in Singapore is usually fully booked. Some, particularly the younger generations, are keen to learn about the potential benefits when it comes to sustainability. And there are also others who do not like the idea that products should be man-made as opposed to of animal origin. Most people, in the case of Singapore, seem not to be fully aware of the products and thus potentially undecided. For the latter group, the SFA can help by making relevant information available on their website. In addition, the SFA provided journalists and media outlets with technical information about the technologies involved and the products, as well as the approaches and methods used to ensure food safety.

7.2. Nutritional equivalency

Consumers who are not familiar with the production process of cell-based food may not be aware that muscle tissues and fat tissues often need to be produced separately and, in that sense, the product's nutritional composition is fundamentally different from "whole" animal products. They may wonder if the nutrients derived from cell-based food are the same (kind and amount) as those more conventional products contain. However, a distinct feature of cell-based food is that nutrient contents can be designed, in that one can develop a super lean meat or a very fatty tender meat, and various micronutrients can potentially be added to mimic or even improve the taste, flavour or health benefits. For this reason, it is important for regulators to provide consumers with accurate information related to nutrition. The bioavailability of nutrients is another topic that needs further research and investigations. For these reasons, most experts advise not to seek "equivalence" of cell-based foods with the conventionally produced food items, but rather to ensure information that consumers receive on the products they are purchasing is clear.

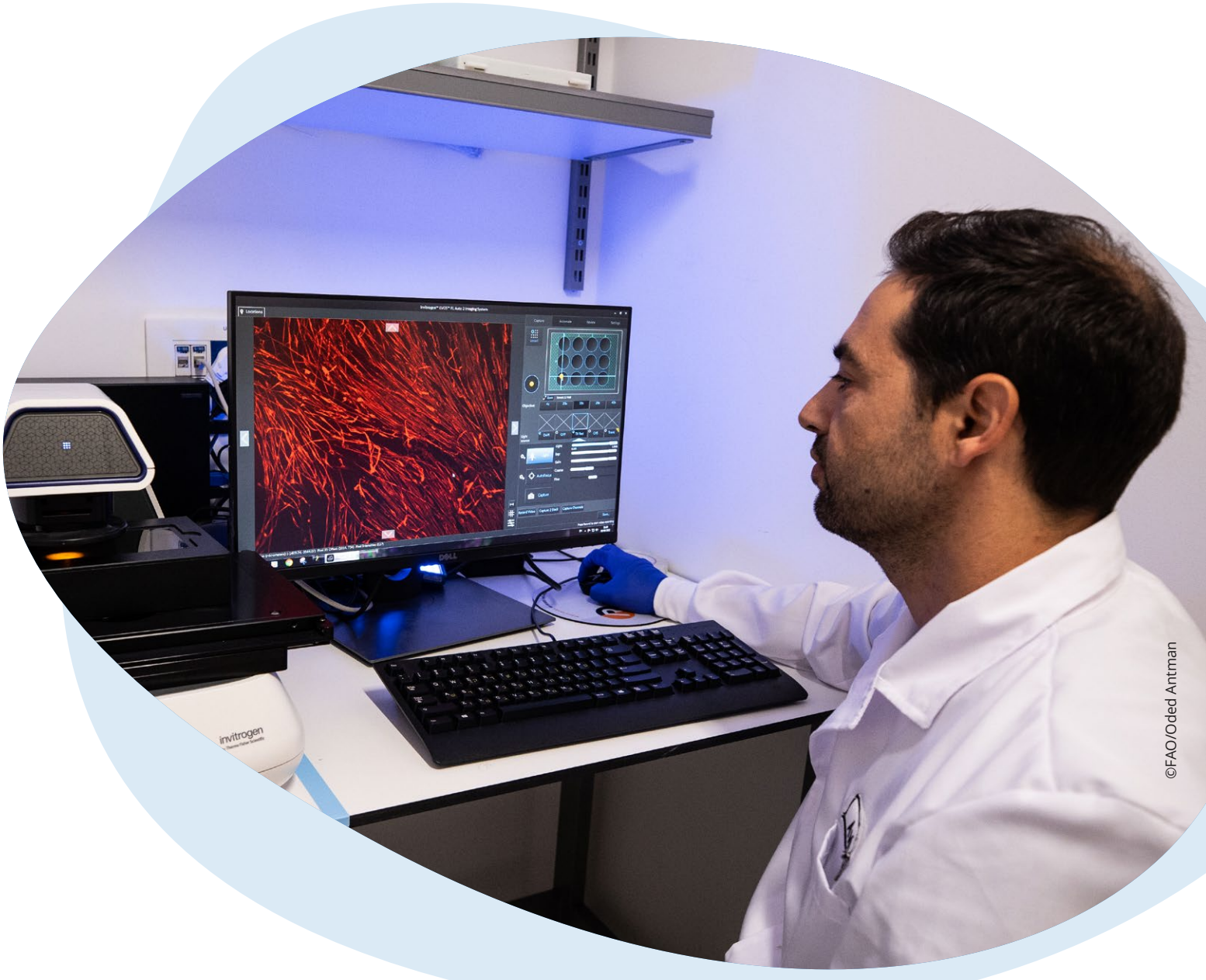
7.3. Approval timelines

An audience member from the industry asked about the expected timelines for the regulatory approval processes. Currently there are no fixed timelines for regulatory approval processes in many countries. The panellist from the United States of America

provided an indicative timeline of 12 months based on the first two applications, but it is not yet a standardized timeline. It may be advisable for regulators to set up a time frame so that it is clear to the applicants.

7.4. Allergens

Allergens might be present in cell-based food products, just as in any other conventionally produced food. For known allergens, panellists said that most countries have effective analytical tools to identify them. For novel proteins, there are various methods to assess potential allergenicity so that the attendant risks can be evaluated.



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8. Conclusion and a way forward

The webinar, attended by over 1 000 participants from various regions, gave an overview of the current regulatory situation as regards the food safety aspects of cell-based food by having speakers from two leading countries where regulatory approval systems are in place. The participants also obtained basic information on what is cell-based food, how it is generally produced and what hazards may be involved when considering food safety.

Prior to and during the webinar, all the registered participants received a link to download the FAO/WHO publication which included detailed results of the expert consultation, including all the identified potential hazards. The chairperson of the expert consultation presented each section of the publication and reported that most of the hazards identified were also common in conventional food production processes. It is therefore important for competent food safety authorities and the industry to have a focus on novelty, if any.

The regulatory country cases, as exemplified by Singapore and Qatar, provided useful insights for many countries looking to take the first steps in regulatory preparations, particularly as regards the food safety assessment processes. While the two countries have significantly different regulatory environments, all the panellists from different countries concurred that 1) a food safety assessment is the first step in the regulatory approval process, and that 2) the existing regulatory framework is likely to be sufficient to manage cell-based foods and there is therefore no need to develop any new laws/regulations. Panel discussions highlighted the differences between countries with greater resources and capacities, and countries where these are quite limited. For the latter, panel members stressed that reading and understanding the FAO/WHO publication is the most useful way to start the process, as the publication contains the results of hazard identification, the very first step of risk assessment proper.

Overall, participants have learned from the speakers and panellists' insights as to various practical issues, such as how regulators set up communication channels between regulators and applicants, regulatory good practices, scientific issues concerning potential hazards, and the development of communication strategies for consumers. On this last point, panellists yet again suggested referring to the FAO/WHO publication, which has a section on effective communication, as well as evidence-based resources for managing and ensuring food safety. By and large, the webinar was well received, and the presentations of the expert consultation and country case studies, the panel discussion and the interactive open discussion sessions all met with a positive response from the participants.

Reference

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