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FROM LAB TO TABLE: FOOD SAFETY REGULATIONS FOR CELL-CULTURED MEAT IN THE EUROPEAN UNION AND SINGAPORE - IMPLICATIONS FOR VIETNAM

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Abstract

Confronting the challenges of food safety, environmental impact, and ethical issues in conventional meat production, scientists have pioneered "cell-cultured meat" as an innovative alternative. However, this novel approach brings its own food safety concerns. Globally, there is a varied response to the manufacturing and marketing of "cell-cultured meat", mirrored in differing legislative measures to assure its hygiene and safety. Within this context, the article will analyze three primary concerns: (i) defining the legal concept of "cell-cultured meat"; (ii) examining the food safety regulations for "cell-cultured meat" within the legislative frameworks of the European Union and Singapore; and (iii) providing recommendations for Vietnam to regulate "cell-cultured meat" products to ensure food safety.

Keywords: *cell-cultured meat, EU, food safety standards, novel food, Singapore.*
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Meat has historically been an essential source of nutrition in human diets. However, in the 21st century, objective factors, like climate change, and subjective perceptions of traditional meat production have undergone significant shifts. Humans are starting to consider using new types of "food" that have never been consumed before in history. This change is due to the risks and severe damage from epidemics; concerns about hormonal residues and antibiotics in food; and a growing trend towards a greener and more environmentally sustainable lifestyle. With the global population predicted to increase to 10 billion people by 2050, the demand for meat is expected to double[1] and potentially leading to a global food crisis. At the 4th Summit of the United Nations on Global Food Security, three nutritional burdens[2] were pointed out, which are: hunger, micronutrient deficiency, and obesity.[3] Traditional agriculture and livestock are predicted to be unable to meet the increasing demand for meat consumption, while facing the consequences of climate change and serious meat production decline.

1 FAO (2019), 'Meat and meat products'. Retrieved from: http://www.fao.org/ag/againfo/themes/en/meat/home.html [accessed 06 March 2024].
2 FAO (2020), '4th International Conference on Global Food Security'. Retrieved from: https://www.fao.org/in-action/kore/news-and-events/events-details/en/c/1249950/ [accessed 06 March 2024].
3 FAO (2022), 'The state of food security and nutrition in the world 2022: Repurposing food and agricultural policies to make healthy diets more affordable'. Retrieved from: https://www.fao.org/3/cc0639en/online/cc0639en.html [accessed 06 March 2024].

Scientists have leveraged advanced technology to create a new "superfood" entirely technique-based. Since the 19th century, the concept of using animal tissue has been realized through research and grafting. The lab-grown meat (cell-cultured meat, CCM) revolution accelerated rapidly over the past decade. In 2013, Mosa Meat introduced the first CCM hamburger, costing $330,000, marking a turning point in the global meat industry. CCM offers significant benefits, reducing greenhouse gas emissions by 96%, freeing 82-96% of agricultural land, and saving 7-45% of fresh water.[4] Major corporations are investing in CCM, and in 2020, Singapore approved the sale of lab-grown chicken meat.

Conceptually, CCM products are often compared to traditional meats, with the conclusion that they are "identical" or "indiscernible." Thus, the question is whether CCM products can be defined as traditional meat products. Moreover, in the realm of new food products like CCM, food safety must be considered. It raised the question of whether CCM is considered food and whether current regulations and food safety standards can be applied to this product. In what ways are these challenges being addressed in different countries? The European Union has dramatically enhanced the regulatory framework and processes governing novel food products. Simultaneously, Singapore has taken the groundbreaking step of enacting legislation that officially acknowledges CCM as a novel food, paving the way for a fresh approach to governing.

Within the scope of this article, the authors will focus on discussing some legal issues related to food safety for CCM products. Specifically, the research is presented according to the following structure: (i) ddefinition of CCM, (ii) food safety regulations for CCM products under EU and Singapore laws, and (iii) assessing the applicability of current Vietnamese food safety regulations in the context of CCM products and offering recommendations for Vietnam.

1. Overview of cell-cultured meat

CCM products are often promoted as an edible protein[5] when it is launched on the market. However, international legal science does not yet have a unified definition for CCM in particular or cellular agriculture in general. These terms are interpreted according to the understanding of the biological sciences. Accordingly, "cellular agriculture" is a term used for products such as meat, eggs, milk, seafood... created by culturing tissue in a laboratory.[6] Essentially, CCM (also known through terms like "clean meat", "lab-grown meat", "animal-based meat", or "cultured meat") is a product

4 Chriki, S., Hocquette, J. F. (2020), 'The myth of cultured meat: A review', *Frontiers in Nutrition*, Vol. 7, https://doi.org/10.3389/fnut.2020.00007; Vlčko, T. et al. (2023), 'Cell-based meat labeling – Current worldwide legislation status – A review', *Annals of Animal Science*, No. 4, pp. 927-938.

5 Stephens, N. et al. (2018), 'Bringing cultured meat to market: Technical, socio-political, and regulatory challenges in cellular agriculture', *Trends in Food Science and Technology*, Vol. 78, pp. 155–166.

6 Ong, K. J. et al. (2021), 'Food safety considerations and research priorities for the cultured meat and seafood industry', *Comprehensive reviews in Food Science and Food Safety*, Vol. 20, pp. 5421–5448.

created by applying science and technology.[7] The process of producing this type of meat usually goes through five main stages: (i) collecting tissue samples (biopsy) from animals such as livestock, poultry, seafood, (ii) storing these cells (cell banking), (iii) growing the cells, (iv) harvesting the developed cells, and (v) processing these cells into edible food products.[8] Thus, an edible CCM product is created from a selected animal tissue and being cultured in-vitro with the help of nutrients and other growth factors. In short, the fundamental of CCM differs from traditional concept and based on tissue technology. Despites that CCM can potentially meet raising meat consumption and environmental issues, there are cross-country differences in acceptance of CCM depending on social-historical background and human perception.

Amid raising concerns relating food crisis and safety while Singapore currently imports over 90% of national food consumption, Singapore has become the first and the only country in the world to enact a law introducing its own concept of CCM and recognizing this product as a novel food realizing the "30 by 30" strategy with ambition to produce 30% of total national nutritional needs by 2030. Singapore has introduced regulatory legal framework for CCM. Accordingly, in November 2019, the Singapore Food Agency (SFA) issued a guideline called "Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients".[9] Regarding the concept of "novel food", Article 1, Clause 1 of this guideline stipulates that novel food comprises food and food ingredients that do not have a history of safe use which is understood as components used in the diet of most people for at least 20 years, during which no adverse effects on consumer health have been documented. Clause 6, Article 4 of this document defines CCM as follows: "Cultured meat is meat developed from culturing animal cells. The process to produce cultured meat involves growing selected cell lines (or stem cells) in a bioreactor. The cells are cultured in a suitable growth environment and can then be stacked on a "scaffold" to create products resembling natural meat fibers." This comprehensive explanation aligns with regulatory definitions and provides a thorough understanding of both terms within the context of the guideline.

Meanwhile, EU law does not have specific regulations or guidelines on CCM products, although EU has created a specializing working group to examine the legal issues surrounding novel food in general and some questions relating CCM products in particular. So far, EU's approval of CCM is still on discussion and no formal regulatory act in these markets has been reached. However, EU has quite well-defined regulatory pathway on CCM.[10] It seems

7 Broucke, K. et al. (2023), 'Cultured meat and challenges ahead: A review on nutritional, techno functional and sensorial properties, safety and legislation', *Meat Science*, Vol. 195.

8 GAO (2020), *FDA and USDA could strengthen existing efforts to prepare for oversight of cell- cultured meat*, GAO-20-325.

9 SFA (2023), *Requirements for the safety assessment of novel foods and novel food ingredients*.

10 Baum, C. M. et al. (2021), 'Information, attitudes, and consumer evaluations of cultivated meat', *Food Qual. Prefer.*, Vol. 92, p. 12.

to be capable of applying the procedure and requirements for "novel food" to regulate CMM products. EC Regulation No. 178/2002[11] (also known as the EU's General Food Safety Law) does not directly address CCM, including the definition or licensing of CCM to circulate on the market. Annex I of EC Regulation No. 853/2004, which defines "meat" as "the edible parts of animals, including blood," does not acknowledge CCM as falling within the definition of "meat" in the EU's general legal and practical position.[12] This argument is applied to all other lab-grown products such as milk, eggs, seafood… Although there is no specific concept regulation for CCM products like Singapore's approach, CCM products can be understood as a type of "novel food" according to EU Regulation No. 2015/2283.[13] It follows that novel food means *"*any food that has not been used for human consumption to a significant extent in the Union prior to May 15, 1997, regardless of the date of accession of the Member States to the Union, and it must fall into at least one of the following categories: (…) (vi) food consisting of, isolated from, or produced from cell culture or tissue culture derived from animals, plants, microorganisms, fungi, or algae*"* (Article 3, Clause 2). However, this definition is set without providing detailed criteria or the specific process involved and serves as a hypernym. Yet, it plays a crucial function in establishing the legal framework for CCM and provides a significant requirement for introducing this product to the market. Currently, the EU maintains a list of new foods that has been authorized under EU Regulation No. 2017/2470. Nevertheless, it is noteworthy that, as of the present date, this list does not include any CCM products.

In general, the much-anticipated emergence of CCM as an "alternative protein source in our daily diet"[14] has been challenged by the need for more consensus on its precise definition, especially regarding regulatory issues. In the EU, CCM can be classified as a "novel food" under EU proactive legislation. However, the EU has not provided specific criteria or interpretations for the term, leading to ambiguity. This lack of clarity is partly due to the differing views among EU member states on the commercialization of CCM products, preventing a unified approach. In contrast, Singapore has adopted a pro-CCM stance, facilitating market entry and product commercialization by establishing a clear and distinct definition of CCM. It can be observed that Singapore's approach to defining CCM is more specific and comprehensive compared to the broader and less detailed definition in the EU legislations.

11 EUR- Lex (2002), Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

12 *Ibid*.

13 EUR-Lex (2015), Regulation (EU) No. 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No. 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No. 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No. 1852/2001.

14 Wiesner, E. (2023), 'EU protein strategy'. Retrieved from: https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/751426/EPRS_BRI(2023)751426_EN.pdf [accessed 06 March 2024].

2. European Union and Singapore food safety regulations for cell-cultured meat

2.1. European Union food safety regulations for cell-cultured meat

It is crucial to acknowledge that various EU member states have divergent views on permitting the production and consumption of CCM products in the market. On 16 November 2023, Italy became the first country in the world to issue a ban on CCM, while other countries such as Germany, Spain, and the Netherlands are making progress in CCM research. According to the Italian Minister of Agriculture, this ban aims to "protect health, production, work, culture, and national heritage".[15] As a result, Italy completely bans the production, sale, and import of CCM; and prohibits labelling CCM products with terms used for traditional meat. There are currently no specific regulations directly governing CCM products under EU laws. Consequently, these products would fall into the scope of general food safety regulations under the "farm to fork" approach,[16] including six regulations (EC Regulations No. 178/2002; 852/2004; 853/2002; 854/2004; 882/2004 and 183/2005) and two directives (2002/99/EC and 2004/41/EC). These regulations establish general principles to protect consumers' health and food safety for all types of food, including novel food and CCM products.

As analyzed, CCM products are covered by regulations related to novel food. Hence, the EU Regulation No. 2015/2283 on novel food will be applied to regulate related matters, including food safety regulations and the protection of consumer rights. In order to apply EU Regulation No. 2015/2283 on novel food, CCM products must first comply with registration regulations under Enforcement Regulation (EU) No. 2018/456.[17] Accordingly, "novel food" will have to be licensed through three stages, including: (i) The Food Business Operator (FBO) sends a "consultation request" for the novel food to the member state where the FBO plans to launch the product. Based on the conclusion of the member state, the Commission will publish information on the novel food status on the official website ec.europa.eu; (ii) The FBO submits a request for permission to sell and consume the novel food in the European market to the EC; (iii) After consulting with the European Food Safety Authority (EFSA) on issues related to food safety, the EC will decide to allow the novel food to circulate in the market.

For novel food like CCM, the consultation process will be conducted carefully to ensure accurate scientific evaluation of food safety, as well as determine CCM's long-term impact on consumer health.

15 Kazmin, A. & Ricozzi, G. (2023), 'Italy bans lab-grown meat', *Financial Times*.

16 The Farm to Fork Strategy is at the heart of the European Green Deal aiming to make food systems fair, healthy and environmentally friendly.

17 EUR-Lex (2018), Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) No. 2015/2283 of the European Parliament and of the Council on novel foods.

In addition, Article 24 of the EU Regulation No. 2015/2283 also recognizes the implementation of post-market monitoring measures (PMM) for certain novel foods. PMM is vital for assessing whether the negative impacts identified during the pre-market evaluation phase remain after the product is sold, as proven by the available evidence. [18] Although these are not mandatory measures, they play an essential role in promptly handling the negative impacts of products on consumers. According to Article 24 of the EU Regulation No. 2015/2283, the Commission may impose post-market monitoring requirements for food safety and consider the Authority's opinion. Such requirements may include, on a case-by-case basis, the identification of the relevant food business operators. In particular, PMM might require further information to reduce the uncertainties that could lead to risk and hazard. This mechanism has been applied to genetically modified organisms (GMOs). Apart from general regulations for novel food, the EU has adopted a specific regulatory document relating to the post-market environmental plan: Directive 2001/18/EC. This document encloses all necessary criteria to examine the impacts on the environment of the proposed GMO product.

However, as mentioned above, there are no precise details or requirements for long-term food safety and risk management in CCM products. Therefore, it could raise uncertainty among consumers of this kind of product. Similar to GMOs, PMM could be applied to CCM products because technological process control is a crucial factor in ensuring this type of product's quality and dietary safety. Nevertheless, the requirements must be designed to meet the characteristics of CCM products to ensure food safety.

Moreover, according to information from the EFSA's workshop on CCM in Brussels on 11-12 May 2023, CCM manufacturing and trading companies are still unclear about what data and information they need to provide on the safety of CCM products to EFSA and the EC. It is because these two agencies themselves have not yet understood the CCM production process to put out the necessary instructions. Typically, some issues of standard for cell acquisition for culture (issues of ensuring hygiene safety, origin of cells), standards of cellular agriculture, in general, have not been clearly defined.[19] Therefore, at present, no CCM products in the EU are registered under EU Regulation No. 2017/2470.

Overall, although there are no specific regulations governing CCM, the EU has a general legal framework to consider CCM as a novel food. However, countries in the EU still have different views on allowing CCM products to be commercialized in the market. Thus, the EU has not yet issued specific guidelines and procedures on the information needed to assess product risks,

18 Hepburn, P. et al. (2008), 'The application of post-market monitoring to novel foods', *Food and Chemical Toxicology*, Vol. 46, No. 1, p. 9.

19 Diaz, J. (2023), 'Regulatory framework for cultured meat in the EU'. Retrieved from: https://library.wur.nl/WebQuery/wurpubs/fulltext/647137 [accessed 06 March 2024].

such as food safety standards for the product approval process. This poses several implications. *First,* the differing views amongst EU countries on allowing CCM products to be commercialized could lead to inconsistent market access, creating barriers for producers and potential confusion for consumers. *Second,* without specific regulatory guidance, companies developing CCM may face uncertainty and increased costs associated with navigating the approval process, potentially stifling innovation and slowing down the market introduction of these products.

2.2. Singapore food safety regulations for cell-cultured meat

Singapore is the first country in the world to allow the circulation of CCM chicken products to be marketed on 3 December 2020. The SFA made an official announcement that CCM chicken product produced by Eat Just Californian company fully meets food safety criteria, even superior in protein content, pure microbiology when compared with traditional meat. This development aligns with Singapore's 30 by 30 strategy, which aims to produce 30% of the country's nutritional needs domestically by 2030.[20] Food Business Operators (FBOs) in Singapore are legally obligated to conduct food safety assessments before introducing the products to the market. The Novel Food Safety Expert Working Group (NFSEWG) under the SFA consists of professionals specializing in food science, epidemiology, toxicology, community health policy, and other relevant fields. This group is responsible for establishing food safety standards for CCM products. A CCM product may only be licensed for commercial use after it has received permission from the SFA and the NFSEWG. Concurrently, NFSEWG evaluates the CCM food's interactions with other dairy products and the safety of the production process.[21]

Unlike the EU, Singapore provides regulations related to information on safety assessment criteria for CCM products (Clause 6, Clause 7 of Article 4) and safety assessment methods for biological substances used in the production of CCM and CCM seafood (Clause 1 of Article 5) in the document "Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients". Clause 7, Article 4 of the SFA recognizes that the field of CCM manufacturing is still in the early stages of development. Consequently, this organization mandates that FBOs provide detailed information in their CCM Food Safety Assessment Reports. It also noted that these criteria are subject to modification as science and technology advance.[22] The relevant requirements pertaining to GMO, including nutritional content, comparison of antibiotic residues, growth stimulants, and other parameters identified through research, can be found in Sections 3.6 and 3.11.

20 Singapore food agency, '30 by 30'. Retrieved from: https://www.ourfoodfuture.gov.sg/30by30/ [accessed 06 March 2024].

21 Singapore Food Agency (2024), 'Novel food'. Retrieved from: https://www.sfa.gov.sg/food-information/novel-food/novel-food [accessed 06 March 2024].

22 Clause 7, Article 4 of the SFA.

In addition, Section 4.7.5, 4.7.6, 4.7.7, and 4.7.8 of the documents require information related to cell lines, culture media, genome instability, or genetic drift that does not produce toxic substances in the final product. Furthermore, as CCM is susceptible to contamination with chemicals and biological substances during the production process, FBOs need to provide additional information proving that they have practiced good cell culture practices (GCCP) and evaluated food safety according to strict microbiological requirements regulated in Good Manufacturing Practice (GMP) and Hazard Analysis Critical Control (HACCP). Risk assessment also needs to be carried out from controlling the quality of raw materials used in the product to the final product.[23]

Under the comparative view of EU and Singapore's legal frameworkds on CCM products, Singapore has taken a more proactive approach than the EU in regulating these products by adopting specific regulatory approvals, definitions, and procedures for their commercial sale. Despite Singapore's advanced regulatory framework, there are still two concerns related to the food safety of CCM during the manufacturing process that remain unaddressed by Singaporean law. *First*, there is a food safety risk from genetic modification in CCM products. During manufacturing, cells must duplicate multiple times in an extracorporeal environment, leading to genetic instability and variation. It can cause differences in the morphology and properties of CCM products. Therefore, ensuring the stability of CCM-producing cells is crucial. Additionally, food safety concerns related to proteins or unwanted metabolites must be considered, as they can be produced uncontrollably due to genetic instability and modification. *Second*, the safety assessment of biological products used in cell culture poses a significant issue. Cell culture requires glucose, amino acids, salts, vitamins, and water to maintain cell health. Typically, fetal bovine serum (FBS) is added to promote animal cell growth, but many companies now prefer plasma-free solutions for cost, environmental protection, and food safety. These solutions often include insulin, transferrin, and other growth substances that have never been used in food and lack specific health indicators. Thus, assessing the safety of these substances is crucial, as they may remain in the final CCM food product.[24]

3. Implications for Vietnamese food safety regulations in governing cell-cultured meat

3.1. Current Vietnamese legislative landscape

At present, Vietnamese legislation has no regulations addressing the concept of novel foods in general or CCM in particular. Instead, Vietnam has decided to regulate GMO in the 2010 Food Safety Law and guiding documents, while

23 Singapore Food Agency (2024), 'Novel food'. Retrieved from: https://www.sfa.gov.sg/food-information/novel-food/novel-food, [accessed 06 March 2024].

24 *Ibid*.

leaving other novel foods unregulated.[25] The concept considered to have the most similarities with CCM is "fresh meat", recorded in subsection 3.1, Section 3 of National Standard Document 7046:2019. "Fresh meat" is "meat of livestock, poultry, birds and pets in the form of whole carcasses, half carcasses, pieces or minced meat, produced at ambient temperature and stored at a temperature not lower than 0°C." This concept does not reflect the nature of CCM, as it is made from animal cells and in-vitro culture, not produced at ambient temperature. Therefore, legal regulations for "fresh meat" do not directly apply to CCM.

However, CCM can potentially be considered "food" under Clause 20, Article 2 of the 2010 Food Safety Law. This regulation defines food as "a product that people can eat in fresh form or that has been pre-processed, processed, and preserved, except cosmetics, tobacco, and other substances used as medicine." Additionally, Clause 21, Article 2 defines fresh food as "unprocessed food including meat, eggs, fish, seafood, fresh vegetables, fruits, and other unprocessed foods." Thus, it can be inferred from the above concept that other fresh foods may include genetically modified food, or other plant or animal foods studied in the laboratory such as CCM. This interpretation suggests that the existing legal definitions do not explicitly exclude CCM products. However, Vietnam has yet to promulgate specific technical regulations governing CCM products.

Similar to traditional food, first of all, CCM will have to comply with general food safety standards specified in Article 10 of the Food Safety Law. This provision provides that food products shall conform to relevant technical standards and abide by regulations concerning the limits of pathogenic microorganisms, pesticide residues, veterinary drug residues, heavy metals, pollutants, and other potentially harmful substances. The specific compliance requirements for CCM will vary depending on whether it is categorized as fresh or processed food, as additional stipulations are outlined Articles 11 and 12 of the 2010 Food Safety Law.

To ensure safety, fresh foods must be traceable according to the law. In the case of fresh foods originating from animals, a veterinary hygiene certificate from a competent veterinary agency is required. Processed foods must be composed of safe ingredients that maintain their natural properties and do not produce harmful substances when combined. Furthermore, processed and prepackaged foods need to register a declaration of conformity with a competent state agency before being distributed on the market.

25 Decree No. 69/2010/ND-CP of the Government: On biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms; Decree 15/2018 Detailed regulations implementing a number of articles of the Food Safety Law; Decree No. 118/2020/ND-CP amending and supplementing a number of articles of Decree No. 69/2010/ND-CP dated 21 June 2010 of the Government on biosafety for genetically modified organisms, genetic specimens and products of genetically modified organisms; Circular No. 2/2014/TT-BNNPTNT dated 24 January 2014 of the Ministry of Agriculture and Rural Development stipulating the order and procedures for issuance and revocation of Certificates of genetically modified plants eligible for use as food, animal feed.

Likewise, according to Article 19.1 of the 2010 Food Safety Law, food production and trading establishments must meet general conditions to ensure food safety, including maintaining an appropriate production site, which must be spacious and separate from toxins, pollution, and other harmful effects. In addition, these establishments must have a water source that meets technical standards for food production and have adequate equipment to handle raw materials, process, package, preserve, and transport food products. It is essential for CCM products that the water used in bioreactors must meet stringent purity standards to avoid contamination of cultured cells. Furthermore, these establishments must have adequate facilities for washing and sterilizing food, measures to prevent insects and pests, an effective waste treatment system, and be compliant with environmental protection regulations. Moreover, they must continuously maintain food safety conditions, keep accurate records of the origin of raw materials, and keep documents on the entire production and business process. Accordingly, maintaining food safety conditions and keeping detailed records of the origin and provenance of cell lines, culture media, and other inputs are essential for traceability and safety authentication. Additionally, they must comply with health, knowledge, and practices regulations of individuals directly involved in food production and business.

However, there needs to be more clarity regarding the authority and specific regulations for CCM production facilities. This uncertainty arises from the absence of explicit regulations concerning this type of food in the existing legal framework. To be more specific, current Food Safety Law regulations do not adequately address the specific risks of CCM, such as bacterial contamination, genetic instability, and potential genetic mutations. These issues arise due to the complex cell culture procedures and lack of transparency in the production process.[26]

Due to the lack of specific technical regulations for CCM products in Vietnam, organizations and individuals involved in their production and sale must ensure their products meet food safety standards and be prepared to assume legal liability for these claims. Therefore, food production and trading establishments must meet food safety and consumer protection standards through self-declaration before sale.[27] It is considered a compulsory step before bringing products to the market.[28] Within this regulatory framework, the principal method by which competent authorities monitor goods is via post-market inspection, which takes place after the things have been available to consumers. Therefore, from the author's perspective, this approach places

26 Sylvester, B. P. et al. (2019), 'From petri dish to main dish: The legal pathway for cell-based meat', *Kentucky Journal of Equine, Agriculture and Natural Resource Law*, Vol. 12, pp. 274–276.

27 Circular No. 19/2012/TT-BYT on Guiding the declaration of conformity and declaration of compliance with food safety regulations.

28 Food safety regulations declaration. Retrieved from: https://congbosanpham.vfa.gov.vn/HomePage.do# [accessed 10 February 2024].

food safety risks on consumers, unlike the EU system, which includes pre- and post-market inspections. The absence of specific pre-market regulations in Vietnam, instead relying on self-declaration by food producers, may pose more significant risks to consumer safety than benefits. It could lead to inconsistencies in safety standards between producers, which could create uneven levels of protection, and the slow detection of problems through post-market inspections, which means that problems may only be identified after harm has been caused. This lack of rigorous pre-market inspections could pose health risks to consumers when harmful contaminants or improperly manufactured CCM products could cause foodborne illness. Addressing these risks through rigorous regulations and pre-sale testing would better protect consumers and promote greater confidence in CCM products.

Moreover, although CCM is not included in the import ban list as per Decree 69/2018/ND-CP, any such imported product is still required to conform to the food safety requirements delineated in Articles 38, 39, and 40 of the Food Safety Regulation. However, because Vietnam has not yet established technical regulations for this type of food, import will depend on international agreements and treaties to which Vietnam is a member. Presently, these treaties do not explicitly address the importation of CCM, and products are only permitted to pass through customs if they meet the established import inspection standards. Consequently, the issue of whether the importation of CCM into Vietnam is permissible has not yet been definitively determined within the existing framework of official regulatory guidelines.

Such lack of specific legal regulations for CCM hinders commercial development, technological innovation, and environmental sustainability, while also posing potential consumer health risks. Therefore, updating food safety regulations is crucial to protect consumers and facilitate market access for innovative food products. The lack of clear and comprehensive regulations and the uncertainty in scientific research on food safety and health effects creates challenges for regulating novel foods like CCM. This ambiguity makes governments hesitant to make significant changes, preferring a "wait-and-see" approach as authorities need more rigorous scientific data before formally authorizing CCM's production and use.

3.2. Recommendations for regulatory improvements on cell-cultured meat products in Vietnam

With rising food demand and climate change posing significant challenges, the authors argue that Vietnam needs to prepare a legal framework to recognize CCM products and ensure food safety, thereby protecting consumer health. Starting with appropriate food safety standards and regulations is critical since the CCM manufacturing business is still nascent. This approach ensures that future developments align with consumer health concerns and sets the stage

for the long-term success of this sector. Therefore, the authors propose two suggestion for regulatory improvements on CCM products in Vietnam:

(i) Defining CCM within food safety regulations

Vietnam may stipulate a subclause in Article 20 of the Food Safety Law, drawing on Singapore's experience introducing the CCM concept outlined in Article 4.6 for assessing the safety of novel foods and food ingredients: "Cultured meat refers to meat developed from animal cell culture. The process to produce cultured meat involves growing the selected cell lines (or stem cells) in a bioreactor. The cells are grown in a suitable growth media and may subsequently be assembled on a "scaffold" to produce products resembling meat muscle".

Adopting Singapore's definition of cultured meat has demonstrated clarity and comprehensiveness, describing the essential technical characteristics relevant to defining CCM. This clarity ensures that all stakeholders, including regulators, manufacturers, and consumers, consistently understand what constitutes CCM, facilitating effective regulation and oversight. Therefore, leveraging Singapore's definition and regulatory framework provides Vietnam with a solid foundation to ensure the safety of novel foods, promote innovation, and enhance public confidence in these products.

(ii) Researching the current Vietnamese Genetically Modified Food Guidelines with a focus on CCM-related issues

Since Vietnamese law does not yet have regulations on food safety standards for CCM, as presented in section 3.1, similar to traditional food, CCM must comply with the general food safety standards specified in Article 10 of the 2010 Food Safety Law. The requirements vary based on whether CCM is categorized as fresh or processed food, as outlined in Articles 11, 12, and 19 of the 2010 Food Safety Law. However, the existing legal framework lacks explicit regulations to address the unique risks associated with CCM adequately.

Therefore, Vietnam could improve its CCM regulations by drawing inspiration from the European Union and Singapore's guidelines for genetically modified foods, given the similarities in biotechnological processes and genetic intervention. This assessment process in Vietnam, which already exists for genetically modified foods as outlined in Article 9 of Decree No. 15/2018, could be adapted to include specific provisions for CCM. Such decree, which details the implementation of specific articles of the 2010 Food Safety Law, includes regulations on the procedure for granting and revoking the Certificate of eligibility for GMO intended for use as food, along with a list of such organisms. Based on this foundation, Vietnam can enhance its current regulations by creating more detailed guidelines for CCM products. It could involve creating comprehensive reports on specific food safety concerns related to CCM, incorporating the Singapore regulations related to information on safety assessment criteria for CCM products and safety assessment methods for

biological substances used in the production of CCM. However, it is essential to conduct further research to address the unique aspects and challenges of CCM that Singapore and EU's legislation may need to cover adequately. ●

References

[1] Baum, C. M. et al. (2021), 'Information, attitudes, and consumer evaluations of cultivated meat', *Food Quality and Preference*, Vol. 92

[2] Broucke, K. et al. (2023), 'Cultured meat and challenges ahead: A review on nutritional, techno functional and sensorial properties, safety and legislation', *Meat Science*, Vol. 195

[3] Chriki, S., Hocquette, J. F. (2020), 'The myth of cultured meat: A review', *Frontiers in Nutrition*, Vol. 7, https://doi.org/10.3389/fnut.2020.00007

[4] Diaz, J. (2023), 'Regulatory framework for cultured meat in the EU'. Retrieved from: https://library.wur.nl/WebQuery/wurpubs/fulltext/647137 [accessed 06 March 2024]

[5] FAO (2019), 'Meat and meat products'. Retrieved from: http://www.fao.org/ag/againfo/themes/en/meat/home.html [accessed 06 March 2024]

[6] FAO (2020), '4th International Conference on Global Food Security'. Retrieved from: https://www.fao.org/in-action/kore/news-and-events/events-details/en/c/1249950/ [accessed 06 March 2024]

[7] FAO (2022), 'The state of food security and nutrition in the world 2022: Repurposing food and agricultural policies to make healthy diets more affordable'. Retrieved from: https://www.fao.org/3/cc0639en/online/cc0639en.html [accessed 06 March 2024]

[8] GAO (2020), *FDA and USDA could strengthen existing efforts to prepare for oversight of cell-cultured meat*, GAO-20-325

[9] Hepburn, P. et al. (2008), 'The application of post-market monitoring to novel foods', *Food and Chemical Toxicology*, Vol. 46, No. 1

[10] Kazmin, A. & Ricozzi, G. (2023), 'Italy bans lab-grown meat', *Financial Times*

[11] Ong, K. J. et al. (2021), 'Food safety considerations and research priorities for the cultured meat and seafood industry', *Comprehensive reviews in Food Science and Food Safety*, Vol. 20

[12] Stephens, N. et al. (2018), 'Bringing cultured meat to market: Technical, socio-political, and regulatory challenges in cellular agriculture', *Trends in Food Science & Technology*, Vol. 78

[13] Sylvester, B. P. et al. (2019), 'From petri dish to main dish: The legal pathway for cell-based meat', *Kentucky Journal of Equine, Agriculture and Natural Resource Law* Vol. 12

[14] Vlčko, T. et al. (2023), 'Cell-based meat labeling – Current worldwide legislation status – A review', *Annals of Animal Science*, No. 4

[15] Wiesner, E. (2023), 'EU protein strategy'. Retrieved from: https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/751426/EPRS_BRI(2023)751426_EN.pdf [accessed 6 March 2024]

Author Contribution

All authors contributed to the study conception and design. All authors read and approved the final manuscript.

Declarations

Conflict of Interest: The authors declare no competing interests.

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