Comparative Analysis of Regulatory Approaches to Cell-Cultured Tonic Food Containing No Living Animal Cells

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ABSTRACT

Advancements in cell culture technologies have made possible the mass production of cell-cultured tonic food. Unlike cell-cultured meat products, regulatory issues arising from the commercialization of engineered tonic food have not been sufficiently addressed in the scholarly literature. Using edible bird's nest produced with cell culture technologies as a case study, we examined relevant pre-market regulations concerning safety assessments and labeling in five selected jurisdictions—the United States, the European Union, China, Singapore, and Hong Kong. Our comparative analysis indicates that a favorable market entry regulatory regime, combined with a post-market product tracing system, constitutes an effective approach towards commercialization of novel tonic foods. We suggest that a tailored regulatory approach should be established towards such novel food that takes into consideration local contexts and mobilizes public support from key stakeholders.

I. INTRODUCTION

A. The Consumption of Tonic Food

For a long time, tonic food[1] has been consumed by people around the world to pursue physical health and vitality. For example, shark fins have been documented in traditional Chinese medicine books, which state that their consumption would bring

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[1] The tonic food we discuss in this Article has a relatively small consumer group and a small consumption volume compared with daily edible foods, such as meat, eggs, cereals, etc., but its unit price is often far more expensive. In addition, this type of food is often percieved by the public as having clear health benefits; however, these benefits are not supported with rigorous scientific evidence.

tonic and aphrodisiac benefits to people.[2] Recent biomedical research has indicated potential benefits of some tonic foods for cardiovascular health and the immune system. For instance, studies have shown that caviar contains abundant long-chain polyunsaturated fatty acids and docosahexaenoic acids (DHA), which are perceived to be helpful in preventing heart disease.[3] The consumption of edible bird's nest (EBN), according to previous studies, may lead to positive health impacts given its anti-inflammatory, immunomodulation, and antiviral properties.[4] Other potential positive effects of EBN consumption include: neurodegenerative disease improvement, learning and memory enhancement, as well as anti-aging and skin lightening.[5]

Tonic food is often scarce, naturally grown, and challenging to harvest. Its high price has made the consumption of a variety of tonic food products a symbol of wealth and high social status in many cultures.[6] For example, shark fins were traditionally used as tributes to the emperors,[7] and their perceived value has contributed to thriving consumption of shark fins in contemporary China.[8] Similarly, caviar consumption, which had originated in Russia, has spread to the Western countries and has made caviar a luxury food. Eating caviar can bring self-gratification to consumers, thereby driving demand and making its production highly profitable.[9] Currently, the European Union, the United States, China, Japan, and Russia are the main regions and countries that contribute to the global consumption of caviar.[10]

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[2] Jason L. Jarvis, *Shark Fin Soup: Collective Imagination in the Transnational Public Sphere*, 11 GLOB. MEDIA J.: CAN. EDITION 49, 54–55 (2019); Michael Fabinyi, *Historical, Cultural and Social Perspectives on Luxury Seafood Consumption in China*, 39 ENV'T CONSERVATION 83, 87–88 (2011).

[3] Allison K. Baker, Beata Vixie, Barbara A. Rasco, Mahmoudreza Ovissipour & Carolyn F. Ross, *Development of a Lexicon for Caviar and Its Usefulness for Determining Consumer Preference*, 79 J. FOOD SCI. S2533, S2533 (2014).

[4] Zhang Yida, Mustapha Umar Imam, Maznah Ismail, Zhiping Hou, Maizaton Atmadini Abdullah, Aini Ideris & Norharina Ismail, *Edible Bird's Nest Attenuates High Fat Diet-Induced Oxidative Stress and Inflammation via Regulation of Hepatic Antioxidant and Inflammatory Genes*, 15 BMC COMPLEMENTARY & ALT. MED., 2015, at 1, 4–6.

[5] Gallant Kar Lun Chan, Zack Chun Fai Wong, Kelly Yin Ching Lam, Lily Kwan Wai Cheng, Laura Minglu Zhang, Huangquan Lin, Tina Tingxia Dong & Karl Wah Keung Tsim, *Edible Bird's Nest, an Asian Health Food Supplement, Possesses Skin Lightening Activities: Identification of N-Acetylneuraminic Acid as Active Ingredient*, 5 J. COSMS. DERMATOLOGICAL SCIS. & APPLICATIONS 262, 262 (2015); Amin Haghani, Parvaneh Mehrbod, Nikoo Safi, Nur Ain Aminuddin, Azadeh Bahadoran, Abdul Rahman Omar & Aini Ideris, *In Vitro and in Vivo Mechanism of Immunomodulatory and Antiviral Activity of Edible Bird's Nest (EBN) Against Influenza A Virus (IAV) Infection*, 185 J. ETHNOPHARMACOLOGY 327, 327–28 (2016); S. Careena, D. Sani, S. N. Tan, C.W. Lim, Shariful Hassan, M. Norhafizah, Brian P. Kirby, A. Ideris , J. Stanslas, Hamidon Bin Basri & Christopher Thiam Seong Lim, *Effect of Edible Bird's Nest Extract on Lipopolysaccharide-Induced Impairment of Learning and Memory in Wistar Rats*, 2018 EVIDENCE-BASED COMPLEMENTARY & ALT. MED., 2018, at 1, 3–6; Kian Chung Chok, Ming Guan Ng, Khuen Yen Ng, Rhun Yian Koh, Yee Lian Tiong & Soi Moi Chye, *Edible Bird's Nest: Recent Updates and Industry Insights Based On Laboratory Findings*, 12 FRONTIERS PHARMACOLOGY, 2021, at 1.

[6] Andrea Dell'Apa, M. Chad Smith & Mahealani Y. Kaneshiro-Pineiro, *The Influence of Culture on the International Management of Shark Finning*, 54 ENV'T MGMT. 151, 153–54 (2014).

[7] Fabinyi, *supra* note 2, at 87.

[8] Dell'Apa et al., *supra* note 6, at 153.

[9] Benedetto Sicuro, *The Future of Caviar Production on the Light of Social Changes: A New Dawn for Caviar?*, 11 REVS. AQUACULTURE 204, 204–05 (2019).

[10] EUROPEAN MARKET OBSERVATORY FOR FISHERIES AND AQUACULTURE PRODUCTS, THE CAVIAR MARKET: PRODUCTION, TRADE, AND CONSUMPTION IN AND OUTSIDE THE EU (2021), https://www.eumofa.

Although consumption of tonic food products may have historically originated in specific regions, many are now internationally traded and consumed. Since the beginning of the COVID-19 pandemic, the trade of tonic food has dramatically increased. According to a report released by Insight & Info Consulting Ltd., China's EBN market size had increased from 3.5 billion RMB in 2010 to 40 billion RMB in 2020.[11] The price of tonic food also has also increased. For example, the average intra-EU trade price of caviar increased from 369 euros per kilogram in 2018 to 383 euros per kilogram in 2020.[12]

B. Food Safety and Other Concerns for Tonic Food Consumption and Trade

Heavy metal contamination is one of the major food safety concerns surrounding tonic food. Studies have shown that mercury and other toxins contained in shark fins may negatively affect neurological health.[13] In mainland China, a casual inspection conducted in 2011 by the Zhejiang Provincial Administration for Market Regulation revealed that the nitrite content of "blood EBN" imported from Malaysia had exceeded the permitted standards, with more than 30,000 products in question and the highest nitrite content reaching up to 11,000 ppm.[14] The discovery led to China's immediate suspension on EBN imports from Malaysia until 2014.[15]

In addition to safety concerns, tonic food often triggers issues such as food fraud, smuggling, animal welfare, and ecosystem disruption concerns due to its lucrative characteristics. In 2020, a Chinese Internet celebrity, Xin Ba, promoted an EBN product on a popular webcast platform, Kuaishou. The quality of the EBN product was later questioned by consumers for the extremely low content of its essential nutrient, sialic acid (0.014%). Moreover, the cost of the product was less than 1 RMB, while it is generally sold at 17.2 RMB.[16] In the United States, smuggling of EBN has been

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eu/documents/20178/449260/2021+-+The+Caviar+Market.pdf (last visited Sept. 7, 2024) [hereinafter EUMOFA].

[11] INSIGHT AND INFO CONSULTING LTD., ZHONGGUO YANWO SHICHANG FAZHAN SHENDU FENXI YU TOUZI QIANJING YANJIU BAOGAO (中国燕窝市场发展深度分析与投资前景研究报告) [IN-DEPTH ANALYSIS OF CHINESE EDIBLE BIRD'S NEST MARKET DEVELOPMENT AND INVESTMENT PROSPECT RESEARCH REPORT], https://www.chinabaogao.com/baogao/202202/575923.html (last visited Sept. 7, 2024).

[12] EUMOFA, *supra* note 10.

[13] Wendee Holtcamp, *Shark Fin Consumption may Expose People to Neurotoxic BMAA*, 120 ENV'T HEALTH PERSPS. A191 (2012).

[14] Gallant K.L. Chan, Kevin Q.Y. Wu, Aster H.Y. Fung, Karmen K.M. Poon, Caroline Y. Wang, Elizaveta Gridneva, Rena R.H. Huang, Sisley Y.Z. Fung, Y.T. Xia, Winnie W.H. Hu, Zack C.F. Wong & Karl W.K. Tsim, *Searching for Active Ingredients in Edible Bird's Nest*, 6 J. COMPLEMENTARY MED. & ALT. HEALTHCARE, 2018, at 2; Bee-Hui Yeo, Teck-Kim Tang, Shew-Fung Wong, Chin-Ping Tan, Yong Wang, Ling-Zhi Cheong & Oi-Ming Lai, *Potential Residual Contaminants in Edible Bird's Nest*, FRONTIERS PHARMACOLOGY, 2021, at 1.

[15] Bee-Hui Yeo et al., *supra* note 14, at 1.

[16] Chen Zepeng (陈泽鹏) & Zhang Yurong (张玉容), *Wangluo Yuqing Tuidong Xia Zhengce Yicheng Shezhi De Duoyuanliu Fenxi: Jiyu Wangluozhibo Jianguan Zhengce De Anli Yanjiu (网络舆情推动下政策议程设置的多源流分析: 基于网络直播营销监管政策的案例研究) [Multi-stream Analysis of Policy Agenda Setting Driven by Network Public Opinion: A Case Study Based on the Regulation Policy of Webcast Marketing]*, RENWEN ZAZHI (人文杂志) J. HUM. 119, 124–27 (2021); Beijing Youth Daily (北京青年报), *Guangzhou Shichangjianguanju: Li'andiaocha "Xinba Daihuo Jiayanwo" (广州市场监管局: 立案调查"辛巴带货假燕窝")[Guangzhou Market Regulator Launching Investigation into Xinba's Fakely*

frequently reported,[17] and the quality of such products cannot be guaranteed. The shark fins trade, on the other hand, has raised concerns about animal welfare rights and ecosystem health. The harvest of shark fins results in slicing off fins from living sharks and throwing them back to the water.[18] The sharks without fins are incapable of swimming and sink to the bottom of the sea, where they end in a painful and gruesome death.[19] The practice is not only inhumane but also destroys the ocean's ecosystem.[20]

C. The Emergence of Cell-Cultured Tonic Food

Cell-cultured tonic food promises to mitigate the afore-mentioned drawbacks of naturally derived products, while satisfying consumer demand for quality and nutrition-assured products. Cell-cultured tonic food is not a new concept for food production. In fact, cell-cultured meat has been under development for years. Relevant cell-cultured meat products have been developed or have already been put on the market.[21] The process of creating cell-cultured meat usually involves using animal cell or tissue engineering techniques *in vitro* to expand stem cells collected, and then differentiate them into muscle cells to finally produce foods similar to traditional

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Advertizing Bird's Nest Products], RENMIN RIBAO (人民日报) [PEOPLE'S DAILY] (Dec. 09, 2020) http://xiaofei.people.com.cn/BIG5/n1/2020/1209/c425315-31960079.html; Guangdong Administration for Market Regulation (广东省市场监督管理局), *Tongbao! "Xinba Zhibodaihuo Jishi Yanwo" Shijian Diaocha Chuli Qingkuang (通报！"辛巴直播带货即食燕窝"事件调查处理情况) [Report! Investigation and Handling of the "Xinba Webcast Platform Instant Bird's Nest Beverage Sale" Incident]* https://mp.weixin.qq.com/s/kdAkT5gc8JXR8RKur5RLVg (last visited Sept. 7, 2024).

[17] *CBP JFK Seized Swine Meat & Bird's Nest*, U.S. CUSTOMS & BORDER PROT., https://www.cbp.gov/newsroom/local-media-release/cbp-jfk-seized-swine-meat-bird-s-nest (last visited Sept. 7, 2024); *CBP Finds 63 Bird's Nests in Traveler's Luggage*, U.S. CUSTOMS & BORDER PROT., https://www.cbp.gov/newsroom/local-media-release/cbp-finds-63-birds-nests-travelers-luggage (last visited Sept. 7, 2024).

[18] Mark Carwardine, *What Is Shark Finning and Why Is it a Problem?*, DISCOVER WILDLIFE, https://www.discoverwildlife.com/animal-facts/fish/what-is-shark-finning-and-why-is-it-a-problem/ (last visited Sept. 7, 2024); *Shark Finning and Shark Fin Facts*, SHARK STEWARDS, https://sharkstewards.org/shark-finning/shark-finning-fin-facts/ (last visited Sept. 7, 2024).

[19] Carwardine, *supra* note 18.

[20] Bettina Tran, *Eating Our Way to Their Extinction: What Florida Should Learn From California on Banning Shark Fin Soup and the Shark Fin Trade*, 9 SEATTLE J. ENV'T L. 239, 242–43 (2019).

[21] In 2020, Singapore officially greenlighted the commercial release of cell-cultured chicken in its domestic market, making it the first country in the world to grant such approval. *See* Megan Poinski, *Eat Just Lands First Regulatory Approval for Cell-based Meat*, FOOD DIVE (Dec. 2, 2020), https://www.fooddive.com/news/eat-just-lands-first-regulatory-approval-for-cell-based-meat/589907/; Joe Fassler, *Singapore Just Became the First Nation to Approve Cell-Cultured Meat for Human Consumption*, THE COUNTER (Dec. 3, 2020, 2:04 PM), https://thecounter.org/singapore-first-nation-approve-cell-cultured-meat-human-consumption-eat-just/. In November 2022, the U.S. Food and Drug Administration (FDA) completed the first pre-market consultation project on cell-cultured chicken food developed by UPSIDE Foods company. Only four months later, in March 2023, FDA officially announced their completion of the second pre-market consultation on the cell-cultured chicken food submitted by GOOD Meat Inc. In its announcement, FDA established no specific concerns and problems regarding food safety and expressed optimism about the future of cell-cultured foods. However, FDA also reaffirmed that the consultation does not constitute a formal pre-market approval of novel food, and food developers need to continuously comply with the FDA and USDA regulatory requirements before final market release. *See FDA Completes First Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/news-events/press-announcements/fda-spurs-innovation-human-food-animal-cell-culture-technology (last visited Sept. 7, 2024).

meat.[22] A cell culture engineering process has also been applied to cultivate tonic foods. For example, the Hong Kong-based company Avant Meat in 2019 developed cell-cultured fish maw.[23] The Japanese company IntegriCulture purported to have cultivated the world's first cell-cultured foie gras in 2023 and planned to establish mass production by the end of 2023.[24] And a UK-based company, Caviar Biotec, has succeeded in developing the world's first lab-grown caviar.[25] Similar to cell-cultured meat, the use of cell culture technologies to produce tonic food alternatives may resolve challenges associated with traditional tonic food production such as animal welfare, zoonotic diseases, environmental pollution, energy costs of building infrastructure, and greenhouse gas emissions.[26]

D. Regulatory Issues of Cell-Cultured Tonic Food Containing No Living Animal Cells

Although cell-cultured tonic food is still in the developing stage, advances in cell culture technologies and consumers' consistent preference for tonic food increase the possibilities for its quick commercialization in the coming years. Given this prospect, it is important to examine regulatory pathways towards cell-cultured tonic food and identify potential legal challenges and barriers to commercialization.

Before we continue with the analysis of the regulation of cell-cultured tonic food, it is important to clarify the characteristics of tonic food itself to distinguish it from other daily edible food products (e.g., meat, grain, eggs). One key difference is that the consumer groups for certain tonic foods are relatively small. In addition, the pursuit of physical health and enhancement is often a crucial factor influencing the consumption of tonic foods. Consequently, merchants selling tonic foods tend to advertise the foods' nutritional values and possible functions advancing well-being. This way of marketing tonic food tends to raise more questions about regulation and food labeling than everyday foods, which consumers purchase habitually and are not

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[22] Mark J. Post, Shulamit Levenberg, David L. Kaplan, Nicholas Genovese, Jianan Fu, Christopher J. Bryant, Nicole Negowetti, Karin Verzijden & Panagiota Moutsatsou, *Scientific, Sustainability and Regulatory Challenges of Cultured Meat*, 1 NATURE FOOD 403, 403–10 (2020); Neil Stephens, Lucy Di Silvio, Illtud Dunsford, Marianne Ellis, Abigail Glencross & Alexandra Sexton, *Bringing Cultured Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture*, 78 TRENDS FOOD SCI. & TECH. 155, 158–60 (2018).

[23] *The Journey of Avant Meats*, AVANT MEATS, https://www.avantmeats.com/about-us (last visited Sept. 7, 2024).

[24] *IntegriCulture Produces the World's First Cell-Cultured Foie Gras Without any Serum or Growth Factor*, INTEGRICULTURE (Feb. 21, 2023), https://integriculture.com/en/news/12433/ (last visited Sept. 7, 2024).

[25] Helena Horton, *World's First Lab-Grown Caviar Developed in Britain as Luxury Product Goes Fish-Free*, THE TELEGRAPH (Mar. 20, 2021, 4:00 PM), https://www.telegraph.co.uk/news/2021/03/20/worlds-first-lab-grown-caviar-developed-britain-luxury-product/ (last visited Sept. 7, 2024).

[26] Zuhaib F. Bhat, James D. Morton, Susan L. Mason, Alaa El-Din A. Bekhit & Hina F. Bhat, *Technological, Regulatory, and Ethical Aspects of In Vitro Meat: A Future Slaughter-Free Harvest*, 18 COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY 1192, 1192–98 (2019); Romain Espinosa, Damian Tago & Nicolas Treich, *Infectious Diseases and Meat Production*, 76 ENV'T & RES. ECON. 1019, 1037 (2020); Anmariya Benny, Kathiresan Pandi & Rituja Upadhyay, *Techniques, Challenges and Future Prospects for Cell-Based Meat*, FOOD SCI. & BIOTECHNOLOGY 1225, 1238–39 (2022). Sarah P. F. Bonny, Graham E. Gardner, David W. Pethick & Jean-François Hocquette, *What Is Artificial Meat and What Does It Mean for the Future of the Meat Industry?*, 14 J. INTEGRATIVE AGRIC. 255, 256–60 (2015); Mark J. Post, *Cultured Meat from Stem Cells: Challenges and Prospects*, 92 MEAT SCI. 297, 297–98 (2012).

subject to the same level of scrutiny. The distinct characteristics of tonic food products necessitate a tailored regulatory approach, especially when cell-culture technologies are deployed in their production.

The technical characteristics of cell-culture tonic food raise different regulatory challenges in comparison with their natural counterparts. Foods that contain living animal tissue cells in their end products are comparable to cell-cultured meat products that are mainly compounded by animal cells. There have been previous studies exploring regulatory issues associated with products such as cell-cultured meat.[27] Tonic food that does not contain living animal cells in the final products has different attribution than similar products containing living animal cells. Such products fall under different regulatory regimes and may raise some distinct legal questions. The ensuing legal issues, combined with a continuously advancing food technology, could pose challenges to food regulatory systems and ultimately hinder the commercialization process. The edible bird's nest using cell culture technologies (CCEBN) presents an interesting case study to examine the pre-market regulation of cell-cultured tonic food that contains no living animal tissue cells (NLAC cell-cultured tonic food). Based on our analysis of emerging legal issues, we propose some recommendations for developing a more efficient pre-market regulatory regime for NLAC cell-cultured tonic food. These recommendations could facilitate future regulatory efforts in countries seeking to develop sound regulatory frameworks for novel tonic food products.

E. The Focus of the Study

In this Article, we undertake a comparative legal analysis of the regulatory regimes for novel food in five jurisdictions—the United States, the European Union (EU), China, Singapore, and Hong Kong—and highlight their applicable regulations for CCEBN commercialization. We aim to identify policy gaps and legal challenges and develop recommendations to reshape the regulatory approach to meet future innovation and commercialization challenges of NLAC cell-cultured tonic food. The United States, EU, and China are the jurisdictions most actively promoting the development of novel food, and their regulatory models can provide a blueprint for other countries interested in advancing this innovation. Singapore has traditionally been open to the development and commercialization of novel foods and nutrition alternatives.[28] In particular, Singapore was the first country that approved the market

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[27] *See, e.g.*, Brodie Evans & Hope Johnson, *Contesting and Reinforcing the Future of "Meat" Through Problematization: Analyzing the Discourses in Regulatory Debates Around Animal Cell-Cultured Meat*, 127 GEOFORUM 81 (2021); Hope Johnson, *Regulating Cell-Cultured Animal Material for Food Systems Transformation: Current Approaches and Future Directions*, 13 L. INNOVATION & TECH. 108 (2021); Nicolas Treich, *Cultured Meat: Promises and Challenges*, 79 ENV'T & RES. ECON. 33 (2021); Sarah Kettenmann & Bridget Lamb, *New Regulatory Frameworks for Cell-Cultured Meat*, 34 NAT. RES. & ENV'T 56 (2020); Jaden Atkins, *Regulating the Impending Transformation of the Meat Industry: "Cultured Meat"*, 24 J. TECH. L. & POL'Y 1 (2019); Yujuan Li, Xiongfei Fu & Li Du, *Xibaopeiyangrou De Falü Guifan Yu Jianguan: Waiguo Jingyan Ji Dui Woguo De Qishi (细胞培养肉商业化的法律规范与监管: 外国经验及对我国启示) [Regulating the Commercialization of Cell-cultured Meat: Foreign Experience and Implications for China]*, 3 HECHENG SHENGWUXUE (合成生物学) [SYNTHETIC BIOLOGY J.] 209 (2022).

[28] SMU City Perspectives Team, *Why Singaporeans Have A Taste for Lab-grown Meat*, SINGAPORE MGMT. UNIV. (Apr. 4, 2022), https://cityperspectives.smu.edu.sg/article/why-singaporeans-have-taste-lab-grown-meat; Donna Lu, *All Sizzle, No Steak: How Singapore Became the Centre of the Plant-Based Meat Industry*, THE GUARDIAN (Nov. 5, 2022, 3:00 PM), https://www.theguardian.com/environment/2022/nov/06/all-sizzle-no-steak-how-singapore-became-the-centre-of-the-plant-based-meat-industry.

release of cell-cultured chicken, and it has been committed to continuously improving its regulatory regime on novel food.[29] The last jurisdiction under consideration, Hong Kong, represents another interesting regulatory model, where the general food-related laws also apply to innovative food products, and there are no specific laws or administrative guidelines for emerging food technologies. Similar legal vacuums regarding the regulation of novel food exist in many regions around the world, and our discussion of the Hong Kong law can provide valuable insight. Furthermore, its approach of applying general food law to regulate novel food can also be seen in the United States, with some notable differences that we elaborate on later in this paper.

Our analysis is organized into four sections. First, Part II clarifies the attributes of CCEBN and the emerging legal issues. Specifically, we examine whether CCEBN constitutes a novel food product and whether it is defined as genetically modified (GM) food in the jurisdictions under consideration. Parts III and IV discuss two pre-market regulatory issues—safety assessment and labeling. Part V outlines recommendations based on the analysis of legal challenges concerning pre-market regulation, which aim to facilitate a tailored and appropriate pre-market regulation of novel tonic food.

II. ATTRIBUTES OF CCEBN

CCEBN, produced by cell-culture technologies, is compositionally identical to its natural counterpart—EBN. Before discussing its pre-market regulation, the legal nature of CCEBN must first be identified to determine specific applicable laws and agencies that have regulatory authority. In this Part, we first briefly introduce the technical characteristics of CCEBN. Next, we discuss whether CCEBN can be defined as food and explore its detailed subcategories under food attribution. We look at whether CCEBN could be recognized as novel food or conventional food,[30] since the application of cell-culture technologies differentiates CCEBN from other food produced by conventional methods, while the adoption of cell-removal technology can render a CCEBN product not substantially different from traditional EBN. In addition, we consider whether CCEBN constitutes a genetically modified food type due to the frequent involvement of GM elements in CCEBN culturing and manufacturing. Furthermore, as EBN is traditionally consumed for nourishing effects, defining CCEBN as a healthcare supplement (i.e., as a dietary supplement) will also be explored to position CCEBN in the context of the respective legal frameworks.

A. Context of CCEBN

Producing EBN with cell-culture and 3D-manufacturing facilities in a biological laboratory has emerged as a novel approach.[31] Although there is a long way to go before fully replacing wild harvesting of natural EBN, a "tissue engineering" (TE)-inspired method provides one promising alternative. TE refers to the medical technology of fabricating human tissue or organ substitutes *in vitro*, by culturing living cells in 3D matrices (scaffolds) that support the cells to grow and function, before

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[29] Poinski, *supra* note 21; Fassler, *supra* note 21.

[30] In this Article, "conventional food" refers to the food produced using traditional animal agriculture. Conventional food is the natural counterpart to the novel food produced by cell-culture technology.

[31] Yu Liu, Yangyang Liu, Jiayue Liu, Yuwei Li, Jian-Bo Wan, Yiming Niu, Lei Dong, Li Du & Chunming Wang, *Tissue-Engineered Edible Bird's Nests (TeeBN)*, 9 INT'L J. BIOPRINTING, 2023, at 1.

transplanting them *in vivo* to replace the diseased or degenerated tissue.[32] Along with its rapid progress in medical applications over the past few decades, TE has also enabled the construction of engineered EBN. Because the way swiftlets produce EBN is also a function of live tissue (saliva gland), researchers proposed to culture the cells of the gland, such as epithelial cells, in a 3D matrix to mimic the formation of natural EBN.[33] A prototype comprises two layers: 1) a feeding layer optimized with 3D printing to provide a suitable condition for epithelial cell growth, and 2) a receiving layer comprised of food-grade polysaccharides similar in composition to the ones of natural EBN.[34] The most important factor is that the optimal 3D-culture conditions in the feeding layer allow the encapsulated epithelial cells to secrete key ingredients, most notably sialic acid and epidermal growth factor, the major nutritional factors of natural EBN. These ingredients can be collected through biological binding and physical entrapment by the receiving layer.[35]

EBN engineered in this manner has at least three advantages. First, all the processes and resource materials are controllable, and the products contain no toxic substances commonly detected in natural EBN such as heavy metals and nitrous acids. Particularly, the existence of the latter has long (and intentionally) been portrayed as "more precious" blood EBN. Second, if CCEBN can provide the same nutritional benefits as does natural EBN, as the inventors showed with metabolic data from mice, traditional harvesting of birds from the caves of Southeast Asia will only exist in documentary records stored in nature and history museums.[36] Modern biotechnology makes possible a "one stone, no birds" approach that prevents ecological harms. Third, the receiving layer can be customized with multiple essential (e.g., releasing kinetics) and non-essential (e.g., combination with other nutritional substances or even condiments) factors.

B. CCEBN as a Type of Food

Legislative documents in the five jurisdictions under consideration offer definitions of food, and CCEBN seems to fit into four of these legal definitions. In the United States, a definition of food is provided in the Federal Food, Drug, and Cosmetic Act (FDCA), which refers to an article used for food or drinking by human or animal, or articles used for components of any such article.[37] In the EU, Regulation (EC) No. 178/2002 introduced in 2002 defines food (foodstuff) as any substance, including water, that has a reasonable expectation of being ingested by humans, whether or not it is unprocessed, partially processed, or processed.[38] Hence, CCEBN, due to its clear use for human consumption, falls within the food classification in both the United

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[32] *Id.* at 1, 3; François Berthiaume, Timothy J. Maguire & Martin L. Yarmush, *Tissue Engineering and Regenerative Medicine: History, Progress, and Challenges*, 2 ANN. REV. CHEM. & BIOMOLECULAR ENG'G 403, 404 (2011).

[33] Liu et al., *supra* note 31, at 1–2.

[34] *Id.* at 3.

[35] *Id.* at 2–3.

[36] *Id.* at 12.

[37] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(f) (2018).

[38] Regulation 178/2002, of the European Parliament and of the Council, 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, art. 2, 2002 O.J. (L 31).

States and the European Union. In China, CCEBN could also be classified as food since it conforms to the Food Safety Law of China (FSL), in which food is identified as "all kinds of finished products and raw materials intended for human consumption or drinking, as well as items that are traditionally used as both food and traditional Chinese medicine (TCM), but do not include items intended for therapeutic purposes."[39] In Singapore, CCEBN aligns with the definition of food as what is "capable of being used, or represented as being for use, for human consumption."[40] Hong Kong, by contrast, has not defined "food" in its law. Instead, it adopts the legislative model of enumerating specific food types and stipulating requirements to exclude some stuff from the food category such as the exclusion of live animals or live birds, medicine, Chinese herbal medicine, and proprietary Chinese medicine, among others.[41] Hence, the attribution of CCEBN in Hong Kong is rather different, which we discuss in greater detail below.

1. CCEBN: Conventional Food or Novel Food?

Under the food classification, it is important to consider under which category CCEBN falls, i.e., as a conventional food or as a novel food. The method of bio scaffold-assisted cell culture adopted in CCEBN production differentiates it from conventional food in terms of cultivation path, while the use of techniques to remove animal cells from the CCEBN final product makes it compositionally equivalent to traditional EBN. Therefore, the key is to determine whether the lack of animal tissue cells in the CCEBN final product will eliminate the novelty of its producing method (cell-culture), which would enable the categorization of the product as conventional food. If deemed novel food, CCEBN should undergo relevant safety assessments and receive special regulation. By contrast, its categorization as conventional food would require more conventional regulation.

The U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have developed the "Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species" (Formal Agreement), which purports to oversee human food made from cultured cells of livestock and poultry by employing "animal cell culture technology" and to ensure that "any such products brought to market are safe, unadulterated and truthfully labeled."[42] In determining what is subject to regulation, the Formal Agreement emphasizes the characteristics of parent cell sources, cell culture technology adopted, and intended use of final product (food consumption). Even though this legal definition may not be appropriately

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[39] Zhonghua Renmin Gongheguo Shipin Anquan Fa (中华人民共和国食品安全法) [Food Safety Law of the People's Republic of China] (promulgated by Standing Comm. Nat'l People's Cong., Feb. 28, 2009, effective June 1, 2009; rev'd by Standing Comm. Nat'l People's Cong., Apr. 29, 2021), art. 150 (China).

[40] Sale of Food Act 1973 §§ 1, 2A (Sing.).

[41] Food Safety Ordinance, (2022) Cap. 612 §§ 1, 2 (H.K.).

[42] *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell (last visited Sept. 7, 2024); *Human Food Made with Cultured Animal Cells*, U.S. DEP'T OF AGRIC., https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/human-food-made-cultured-animal-cells (last visited Sept. 7, 2024).

applicable to CCEBN, it highlights the importance of "cell culture technology" in categorizing food products into the "novel food" category. In 2018, the EU Regulation (EU) 2015/2283 entered into force, which provides a definition of novel food and outlines its related marketing issues. According to the Regulation (EU) 2015/2283, novel food refers to any food that has not been consumed by human to "a significant degree" within the EU before 15 May 1997.[43] Upon this general description, the EU has enumerated some cases that could fall under the novel food category, such as food "isolated or produced from cell culture or tissue culture of an animal, plant or micro-organisms."[44] In this way, even if the use of cell-removal technology does not comply with the requirement that CCEBN is produced by cell culture of an animal, the EU provides another possibility of a legal rationale by holding that CCEBN is isolated by cell culture of an animal. Therefore, the condition for using cell culture technology has been lifted in deciding the novelty of food. In Singapore, the Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients (Singapore Novel Food Requirements), published by the Singapore Food Agency (SFA), defines the novel food as substances that have not been consumed with a proven safety consumption history of at least twenty years.[45] In particular, "compounds that are chemically identical to naturally occurring substances but produced through advances in technology" shall be deemed novel foods.[46] In this regard, CCEBN is likely to be considered a novel food due to the novelty of its producing methods.

In mainland China, according to the FSL and the Administrative Measures for the Safety Review of New Food Raw Materials of China (SR-NFRM), the novel food raw material refers to the following substances that have not been traditionally consumed: 1) animals, plants, and microorganisms; 2) ingredients isolated from animals, plants, and microorganisms; 3) ingredients in conventional food have their original composition changed; and 4) other newly researched and developed novel food.[47] The notion of "food with traditional consumption" is understood as comprising at least thirty years of food production and commercialization history in any local or provincial area, and it cannot be incorporated into the Pharmacopoeia of China as a medicinal product.[48] In the second and third situations, SR-NFRM has not specified any producing method that will render the food novel, but rather has focused on ingredients that are not traditionally consumed to determine the novelty of food. These ingredients can be acquired either by isolating from animals, plants, and microorganisms or altering the original composition of ingredients in conventional food. Hence, irrespective of what producing methods are used, since the ingredients (salivary secretions) and related compositions of CCEBN (the final product) present

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[43] Regulation 2015/2283, of the European Parliament and of the Council on Novel Foods, art. 3, 2015 O.J. (L 327).

[44] *Id.*

[45] *Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients*, SING. FOOD AGENCY (Jul. 20, 2023), https://www.sfa.gov.sg/docs/default-source/food-information/requirements-for-the-safety-assessment-of-novel-foods-and-novel-food-ingredients.pdf.

[46] *Id.*

[47] Xin Shipinyuanliao Anquanxing Shencha Guanli Banfa (新食品原料安全性审查管理办法) [Administrative Measures for the Safety Review of New Food Raw Materials] (promulgated by Nat'l Health & Fam. Plan. Comm'n, May 31, 2013, effective Oct. 1, 2013; rev'd by Nat'l Health & Fam. Plan. Comm'n, Dec. 26, 2017), art. 2, CLI.4.309372 (China).

[48] *Id.* at art. 23.

no difference from that of traditional EBN, CCEBN is less likely to be legally deemed as novel food under these two conditions. The fourth situation provides flexibility, allowing this provision to cope with unforeseeable regulatory challenges. The stress on "newly researched and developing" attributes in recognizing products as novel food appears consistent with the application of cell culturing technology for producing CCEBN, but even so, the generality of such a characterization requires additional clarification from the oversight authority.

2. CCEBN Using GM Techniques: Is It a GM Food?

Although the final product of CCEBN does not have living animal tissue cells, it is not uncommon that the parental cells, ingredients, or additives utilized to culture EBN may be involved with the application of GM techniques. The key issue is whether such involvement is sufficient to move CCEBN to the GM food classification. GM technologies deployed to produce CCEBN mainly include: 1) transgenic manipulation in relation to "inserting novel genetic sequences into recipient genomes," and 2) precise gene-editing that causes "genomic change . . . in a target genomic site."[49] GM regulations in the United States and the European Union were initially developed to address transgenic technology. However, with the rapid development of gene editing, these jurisdictions have incorporated gene editing into the original transgenic-based regulations by updating original legal documents and through court decisions.[50]

When cell culture and GM converge in product development, the EU, China, and Singapore have designated specific procedures to address technological convergence in their novel food regulations. For instance, the EU excludes GM food from the purview of novel food regulation, instead regulating such products under the current GM laws, rendering authorization of novel food unnecessary in such cases.[51] Likewise, China does not regulate GM technology use in food under the purview of novel food regulations, but rather under the existing GM rules.[52] Singapore has opted for a different regulatory pathway. The government requires additional GM-related information to be submitted for novel food safety assessment if "GM organisms are used for novel food production."[53] In the United States, the Formal Agreement has not resolved the "jurisdictional confusion" that arises once cell-cultured meat

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[49] Ziyao Fan, Yulian Mu, Kui Li & Perry B. Hackett, *Safety Evaluation of Transgenic and Genome-Edited Food Animals*, 40 TRENDS BIOTECHNOLOGY 371, 371–72 (2022).

[50] *Modernizing the Regulatory System for Biotechnology Products: The 2017 Update to the Coordinated Framework for the Regulation of Biotechnology & the National Strategy for Modernizing the Regulatory System for Biotechnology Products*, U.S. DEP'T OF AGRIC., https://usbiotechnology regulation.mrp.usda.gov/biotechnologygov/home/modernizing/modernizing_biotechnology_framework (last visited Sept. 7, 2024) [hereinafter *Modernizing the Regulatory System for Biotechnology Products*]; Hans-Georg Dederer, *Confédération Paysanne and Others v. Premier Ministre and Ministre De L'Agriculture, De L'Agroalimentaire Et De La Forêt (C.J.E.U.) [Peasant Confederation and Others v. Prime Minister and Minister of Agriculture, Agri-Food and Forestry]*, 58 INT'L LEGAL MATERIALS 1281 (2019); Alberto Asquer & Inna Krachkovskaya, *Uncertainty, Institutions and Regulatory Responses to Emerging Technologies: CRISPR Gene Editing in the US and the EU (2012–2019)*, 15 REGUL. & GOVERNANCE 1111 (2021).

[51] Regulation 2015/2283, *supra* note 43, at art. 2.

[52] Xin Shipinyuanliao Anquanxing Shencha Guanli Banfa, *supra* note 47, at art. 24.

[53] SING. FOOD AGENCY, *supra* note 45, at 3.9–3.10

"converge[s] with other emerging biotechnologies, including genome editing."[54] Therefore, a close review of specific GM regulations in these jurisdictions is necessary to further clarify the legal status of CCEBN.

Countries around the world have strived to accommodate GM food development with specific regulatory measures. Such measures can either be product-based or process-based, the two most common regulatory approaches. The product-based approach emphasizes regulation of the final product, regardless of the biotechnology methods used to produce it.[55] The process-based approach prioritizes the process to manufacture the final product and rests on the assumption that it is the biotechnology used that makes products fundamentally different and more risky than their counterparts developed through conventional methods.[56] From this perspective, whether CCEBN will be categorized and regulated as GM food hinges upon the regulatory approach employed by the country under consideration. Specifically, the adoption of a product-based approach is less likely to differentiate CCEBN from its natural counterpart EBN since they share essentially identical composition in final products, regardless of the GM elements involves in culturing process, while the adoption of a process-based categorization will have the opposite effect.

In the United States, the "Coordinated Framework for Regulation of Biotechnology" published in 1986 (the 1986 Framework) establishes a product-based regulatory approach in principle under its "production regulation" section, clarifying that "the manufacture by the newer technologies of food . . . will be reviewed by FDA . . . in essentially the same manner for safety and efficacy as products obtained by other techniques."[57] This regulatory approach has been reaffirmed in updates to the 1986 Framework made in 1992 and 2017, which specified that oversight from the federal authority should be product-based and would apply only when "risk posed by the introduction [of a new product] is unreasonable."[58] Therefore, FDA has not developed a "particular statutory provision or regulation [that] deals expressly with food produced by new biotechnology."[59] When "confronted by an issue concerning the regulation of food produced by new biotechnology," FDA urges foods to be made safe for human consumption in accordance with the FDCA and other applicable laws that comprise the pre-existing general statutory frameworks for all food.[60] Nevertheless, some regulatory deviations by FDA hamper the adherence to the product-based approach and slightly steer towards a process-based orientation.[61] This was well demonstrated by the plant-derived food consultation scheme and the GM

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[54] Walter G. Johnson, *Conflict Over Cell-Based Meat: Who Should Coordinate Agencies in U.S. Biotechnology Regulation*, 74 FOOD & DRUG L.J. 478, 486 (2019).

[55] Gary E. Marchant & Yvonne A. Stevens, *A New Window of Opportunity to Reject Process-Based Biotechnology Regulation*, 6 GM CROPS & FOOD 233 (2015); Adrian Ely, Beate Friedrich, Dominic Glover, Klara Fischer, Glenn Davis Stone, Ann Kingiri & Matthew A. Schnurr, *Governing Agricultural Biotechnologies in the United States, the United Kingdom, and Germany: A Trans-Decadal Study of Regulatory Cultures*, 48 SCI., TECH., & HUM. VALUES 1293, 1301–04 (2023).

[56] Ely et al., *supra* note 55, at 1304–08.

[57] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23304 (June 26, 1986).

[58] *Modernizing the Regulatory System for Biotechnology Products*, *supra* note 50.

[59] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23312.

[60] *Id.* at 23312–13.

[61] Marchant & Stevens, *supra* note 55, at 235.

animal pre-market approval. Once food products are plant-derived, although no compulsory authorization is required, FDA still encourages food developers' participation in a voluntary pre-market consultation scheme to ensure food safety and regulatory compliance.[62] FDA will not conduct comprehensive food safety assessments but will consider whether there are outstanding safety issues requiring further legal action.[63] Even if the consultation process is voluntary and will not demonstrate FDA's endorsement of the product's safety for consumption, companies are generally inclined to initiate such consultations.[64]

In situations where animals undergo intentional genomic alterations (IGAs) using advanced molecular technologies, FDA has adopted a risk-based approach for their regulation.[65] Under this regulatory model, FDA evaluates the product's risks and the effectiveness of proposed risk mitigation measures to determine whether pre-market approval should be applied to certain food products.[66] Specifically, FDA categorizes products into three risk-based groups: 1) Category 1 includes products with the least risk, and developers are not expected to consult with the FDA prior to marketing; 2) Category 2 comprises products for which FDA has no further questions that would require additional supportive data, and developers are excused from submitting a pre-market application; 3) Category 3 includes products deemed highly risky, which are subjected to FDA's rigorous pre-market safety assessment and approval process.[67] FDA encourages food developers to engage with them early in the process to determine whether the food product under consideration falls into Category 1 or 2. This early interaction enables FDA to exercise enforcement discretion, potentially exempting the product from pre-market approval.[68] In May 2024, FDA released draft guidance seeking public comments on the approval process for IGAs in animals.[69] Once finalized, this guidance will be used to assess technical issues, and to determine the food safety of Category 3 products or those Category 2 products where the FDA

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[62] *Consultation Programs on Food from New Plant Varieties*, U.S. FOOD & DRUG ADMIN. (Mar. 30, 2022), https://www.fda.gov/food/food-new-plant-varieties/consultation-programs-food-new-plant-varieties (last visited Sept. 7, 2024).

[63] *Guidance for Industry: Consultation Procedures under FDA's 1992 Statement of Policy for Foods Derived from New Plant Varieties*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-consultation-procedures-under-fdas-1992-statement-policy-foods-derived-new-plant (last visited Sept. 7, 2024).

[64] Alice Yuen-Ting Wong & Albert Wai-Kit Chan, *Genetically Modified Foods in China and the United States: A Primer of Regulation and Intellectual Property Protection*, 5 FOOD SCI. & HUM. WELLNESS 124, 133 (2016).

[65] U.S. FOOD & DRUG ADMIN., HERITABLE INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS: RISK-BASED APPROACH: GUIDANCE FOR INDUSTRY (2024), https://www.fda.gov/media/74614/download [hereinafter HERITABLE INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS GUIDANCE].

[66] HERITABLE INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS GUIDANCE, *supra* note 65, at 1–3.

[67] *Id.* at 3–10. The FDA has specified two conditions that meet requirements of Category 1, including "(1) IGAs in animals of nonfood-producing species that are regulated by other Federal government agencies or entities, such as insects with intentionally altered genomes that are regulated by Animal and Plant Health Inspection Service; and (2) animals of nonfood-producing species that are raised and used in contained and controlled laboratory conditions for research (e.g., mice and rats)." *Id.* at 5.

[68] *Id.* at 7–9.

[69] U.S. FOOD & DRUG ADMIN., U.S. FOOD & DRUG ADMIN., HERITABLE INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS: RISK-BASED APPROACH: DRAFT GUIDANCE FOR INDUSTRY (2024), https://www.fda.gov/media/150658/download.

has decided not to use its enforcement discretion over the approval requirement.[70] The process for approving GM animals is stricter when compared to the voluntary consultations for GM plants. To date, only two GM animals for food consumption have gained approvals in the United States, through a lengthy assessment process that extended over a nearly twenty-year period.[71] In consideration of the deviations, GM elements used in developing CCEBN may be subject to different regulation requirements based on whether the elements are plant-derived or animal-derived. Even so, the regulation on CCEBN may not be accurately predicted and shaped due to the voluntary nature of the consultation process used in GM plant-based food and the approval exemption in low-risk GM animal use.[72] It is, therefore, imperative for CCEBN developers to consult with FDA to determine the appropriate regulatory pathway for their products.[73]

The EU follows a strict process-based regulatory approach.[74] Specifically, any food "produced from or containing ingredients produced from GMOs" should undergo rigorous scientific assessment, and only when food safety is clearly demonstrated can market authorization be obtained.[75] General safety rules in the Regulation require that GM food shall neither adversely affect human health, animal health, or the environment, nor mislead consumers. Furthermore, if the GM food is intended to replace another food, it must not result in a nutritional disadvantage to the consumer under normal ingestion.[76] Although this general requirement seems to be quite similar to that of novel food regulation, as we will discuss later, the assessment and approval of GM foods constitute a more stringent process requiring more materials, analyses, and samples exhibited.[77] Subsequently, this makes it more burdensome and time consuming for the applicant.[78] While the EU has adhered strictly to a process-based approach, some flexibility was shown in recognizing a GM-based vegetarian cheese product as non-GMO, with a discretion that the GM elements serve as "processing aid" rather than "processing ingredients" and thus such cheese was produced "*with*" rather than "*from*" GM elements.[79] In this regard, there are ways to avoid undergoing the strict process of GM authorization if the use of certain GM elements is too minimal

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[70] *Id.*

[71] GMO Crops, Animal Food, and Beyond, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/agricultural-biotechnology/gmo-crops-animal-food-and-beyond (Mar. 5, 2024).

[72] HERITABLE INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS GUIDANCE, *supra* note 65.

[73] *Q&A on FDA Regulation of Intentional Genomic Alterations in Animals*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/animal-veterinary/intentional-genomic-alterations-igas-animals/qa-fda-regulation-intentional-genomic-alterations-animals (last visited Sept. 7, 2024).

[74] Tetsuya Ishii, *Crop Gene-Editing: Should We Bypass or Apply Existing GMO Policy?*, 23 TRENDS PLANT SCI. 947, 947 (2018); Stuart J. Smyth, *Regulatory Barriers to Improving Global Food Security*, 26 GLOB. FOOD SEC., 2020, at 1–2.

[75] Regulation 1829/2003, of the European Parliament and of the Council on Genetically Modified Food and Feed, art. 3, O. J. (L 268).

[76] *Id.* at art. 4.

[77] Astrid Seehafer & Marvin Bartels, *Meat 2.0–The Regulatory Environment of Plant-Based and Cultured Meat*, 14 EUR. FOOD & FEED L. REV. 323, 324–28 (2019).

[78] *Id.*

[79] Alan McHughen, *A Critical Assessment of Regulatory Triggers for Products of Biotechnology: Product vs. Process*, 7 GM CROPS & FOOD 125, 135–37 (2016).

for them to be considered "processing ingredients."[80] Based on our analysis, CCEBN produced with assistance of GM elements will likely be treated and regulated as a GM food in the EU. Even though it can be argued that the minimal use of GM elements in its production does not clearly render CCEBN suitable for GM food classification, it still requires developers' engagement with the regulatory authority to establish whether GM involvement is "remote" enough. Similarly, CCEBN can be exempted from mandatory labeling requirements in the EU under the following conditions: 1) that it does not contain or consist of any GM elements, or "is not produced from or does not contain ingredients produced from GM elements"; and 2) that it includes material which "contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient" due to inadvertence or technical requirements.[81]

China has also adopted a process-based regulatory approach for GM organisms, which are defined as "the animals, plants, microorganisms and their products being genetically modified for the use in agricultural production or processing."[82] China's process-based regulation applies to almost every stage in developing a GM organism, ranging from the initial research and experimentation to the later activities of production, processing, marketing, import, and export.[83] Accordingly, relevant GM research and testing should be supervised and subject to safety evaluation.[84] Any subsequent engagements in the production and processing of GM organisms in agriculture shall obtain approval from competent authorities.[85] Some detailed regulations and guidelines on safety evaluation have been put in place, mandating case-by-case evaluation in order to prevent dangers or potential risks to humans, animals, plants, microorganisms, and the ecological environment.[86] China has a mandatory labeling requirement for GM products included in the Catalogue of Genetically Modified Organisms in Agriculture, and a "zero tolerance" policy is adopted for the presence of GM substances. This means that if included in the

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[80] Giovanni Tagliabue & Klaus Ammann, *Some Basis for a Renewed Regulation of Agri-food Biotechnology in the EU*, 31 J. AGRIC. ENV'T ETHICS 39, 40 (2018).

[81] Regulation 1829/2003, *supra* note 75, at art. 12.

[82] Nongye Zhuanjiyin Shengwu Anquan Guanli Tioali (农业转基因生物安全管理条例) [Regulation on Administration of Safety of Agricultural Genetically Modified Organisms] (promulgated by St. Council, May 23, 2001, effective May 23, 2001; lastly rev'd by St. Council, Oct. 7, 2017), art. 3 (China).

[83] *Id.* at art. 2; Jingang Liang, Xiaowei Yang, Yue Jiao, Danxia Wang, Qiang Zhao, Yu Sun, Yunhe Li & Kongming Wu, *The Evolution of China's Regulation of Agricultural Biotechnology*, 3 ABIOTECH 237, 237–39 (2022).

[84] Nongye Zhuanjiyin Shengwu Anquan Guanli Tioali, *supra* note 82, at art. 9–10.

[85] *Id.* at art. 21.

[86] Nongye Zhuanjiyin Shengwu Anquan Pingjia Guanli Banfa (农业转基因生物安全评价管理办法) [Administrative Regulations for the Safety of Genetically Modified Organisms in Agriculture] (promulgated by the Ministry of Agric. and Rural Affs. of the People's Repub. of China, Jan. 5, 2002, effective Mar. 20, 2002; rev'd by the Ministry of Agric. and Rural Affs., Jan. 21, 2022), art. 4 (China); *Nongyeyong Jiyin Bianji Zhiwu Anquan Pingjia Zhinan (农业用基因编辑植物安全评价指南) [Guidelines for Safety Assessment of Gene-edited Plants for Agricultural Use]*, THE MINISTRY OF AGRIC. AND RURAL AFFS. OF THE PEOPLE'S REPUB. OF CHINA, http://www.moa.gov.cn/ztzl/zjyqwgz/sbzn/202201/t20220124_6387561.htm (last visited Sept. 7, 2024); Gao Feiyu (高飞雨), *Zhuanjiyin Jishu Shengwu Anqaun Guanli Jizhi Fazhan De Duice Yu Jianyi (转基因技术生物安全管理机制发展的对策与建议) [The Development of Biosafety Management Mechanism of Genetically Modified Technology: Countermeasures and Suggestions]*, 12 NONGXUE XUEBAO (农学学报) [J. AGRIC.] 89 (2022).

Catalogue, CCEBN will be labeled as a GM product even if no GM presence can be detected.[87]

In Singapore, pre-market safety assessment of GM foods is jointly conducted by the SFA and Singapore Genetic Modification Advisory Committee (GMAC), and approval is based on the result of that assessment.[88] However, Singapore Novel Food Requirements mandate that a developer who uses GM technology to produce novel food should submit the GM information for a comprehensive safety assessment of novel food. Accordingly, the GM information should include detailed procedures for the gene editing process, safety assessment, risk assessment and risk management measures, safety information regarding the host/recipient strain, and so on.[89] Besides the comprehensive assessment conducted by the novel food authority, it remains unclear whether any additional approval from GMAC or involvement of GMAC into the collective assessment is needed. Singapore does not require any mandatory labeling for GM organisms, meaning that producers can freely opt to label their food as "GM" or "non-GM" as long as the characterization is factual and not misleading.[90]

In Hong Kong, the Center for Food Safety has stated on its website that there are no specific laws regulating GM foods, and a non-compulsory labeling requirement is adopted; however, any GM food sold must satisfy the standards of fitness for human consumption set out in the Public Health and Municipal Services Ordinance, and the labeling should not "falsely describe their food products," as urged by the Public Health and Municipal Services Ordinance.[91] The Center also declares the availability of some foods containing GM ingredients in Hong Kong market that are under approval by competent trade and regulating agencies in their places of origin.[92] From the current practice, the following concerns may arise: 1) whether the verification and approval granted by authorities and institutions in other regions can sufficiently demonstrate the fulfillment of safety standards in Hong Kong, and 2) whether this practice will substantially replace and even make obsolete pre-market authorization by the Hong Kong government, and if so, how much pressure will be transferred to post-market oversight. At least for now, Hong Kong seems to have adopted a product-based regulation approach or has been tolerant to the GM food market entry. In the

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[87] Nongye Zhuanjiyin Shengwu Anquan Guanli Tioali, *supra* note 82, at art. 27–28; Yaohui Huang, Dianfeng Fan, Yue Jiao, Xiaozhi Wu & Jiming Ye, *Qiantan Duoguo Zhuanjiyin Chanpin Biaoshi Zhidu Dui Woguo De Qishi (浅谈多国转基因产品标识制度对我国的启示) [Enlightenment of GMO Labeling System in Other Countries to China]*, 12 CURRENT BIOTECH. 516, 519–21 (2022).

[88] *Singapore Guidelines on the Release of Agriculture-Related GMOs*, GENETIC MODIFICATION ADVISORY COMM., https://www.gmac.sg/singapore-guidelines-on-the-release-of-agricuture-related-gmos/ (last visited Sept. 7, 2024).

[89] *Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients*, *supra* note 45, at 3.9–3.10.

[90] *Labelling on Genetically Modified Food*, SING. FOOD AGENCY, https://www.sfa.gov.sg/food-information/labelling-packaging-information/labelling-on-genetically-modified-food (last visited Sept. 7, 2024).

[91] *Genetically Modified Food*, CTR. FOR FOOD SAFETY OF HKSAR, https://www.cfs.gov.hk/english/programme/programme_gmf/programme_gmf_gi_info6.html (last visited Sept. 7, 2024); *Guidelines on Voluntary Labelling of Genetically Modified (GM) Food*, CTR. FOR FOOD SAFETY OF HKSAR, https://www.cfs.gov.hk/english/programme/programme_gmf/programme_gmf_gi_label_index.html (last visited Sept. 7, 2024).

[92] *Genetically Modified Food*, *supra* note 91.

current regulatory environment, it may be possible that CCEBN will be not regulated as a GM food in Hong Kong.

3. Healthcare Supplement

Based on a food classification distinguishing between novel foods and GM foods, a question arises about whether CCEBN can be considered a healthcare supplement for its long-recognized nutrition value to human health. The definition of healthcare supplement (HCS) varies from country to country. For example, it has been designated as "dietary supplement" in the United States, "food supplement" in the EU, and "health food" in China. To avoid ambiguity, here we adopt the term HCS as representative for all these designations. In the United States, the Dietary Supplement Health and Education Act of 1994 stipulates that a dietary supplement constitutes only a supplement to diet and cannot be consumed as a traditional food or as a sole item in a meal.[93] CCEBN fails to meet the dietary supplement criteria under this definition, since it can be used separately as a meal or dietary food.

In the European Union, the Directive 2002/46/EC treats the HCS as a subcategory of food, requiring that it serves as a supplement to the normal diet, and be a concentrated source of nutrients or a substance with a nutritional or physiological effect.[94] It should be presented in the form of dosage, such as a capsule, tablet, or powder, and it should be "designed to be taken in measured small unit quantities."[95] Hence, CCEBN does not fit into the EU's HCS classification either, as it is neither a concentrated source of nutrients nor can it be sold in the form of dosage being designated to be taken.

In Singapore, the administration of HCS is under the purview of the Health Singapore Authority (HSA). HCS is specially defined in reference to its use to support, maintain, or improve the human physical health function and shall not be used as a sterile injectable or preparation.[96] Any substances satisfying these two conditions can be commercialized without the pre-market approval and registration by HSA, leaving HCS dealers to voluntarily choose whether to notify the HSA.[97] The first condition is that they must contain certain health ingredients, and the second one is that they "must be administered in small unit doses in dosage forms," rather than in the form of food and beverage.[98] Hence, CCEBN does not fit into the HCS classification used in Singapore.

In China, the legal definition of HCS as a subcategory of food is predicated on the presence of a health function, which is scientifically demonstrated and "can not cause any acute, subacute or chronic harm to human body."[99] The FSL articulates a strict

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93 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(ff).

94 Directive 2002/46/EC, of the European Parliament and of the Council on the Approximation of the Laws of the Member States Relating to Food Supplements, art. 2, O. J. (L 183).

95 *Id.*

96 *Regulatory Overview of Health Supplements: Understand the Requirements to Import, Manufacture or Sell Health Supplements in Singapore*, HEALTH SCIS. AUTH., https://www.hsa.gov.sg/health-supplements/overview (last visited Sept. 7, 2024).

97 *Id.*

98 *Id.*

99 Zhonghua Renmin Gongheguo Shipin Anquan Fa, *supra* note 39, at art. 75.

supervision and management of HCS so as to maintain such a standard.[100] China has formulated an HCS ingredient list and has urged that HCS can only be produced and commercialized if they involve the use of listed ingredients.[101] Any intention to include novel substances into the ingredient list should undergo a pre-market technical review and registration procedure.[102] CCEBN thus falls outside the legal category of HCS in China and may only be recognized as a highly nutritious food.

4. Hong Kong's Ambiguous Classification

Hong Kong's law includes a general enumeration to main food categories and food classifications, without conceptualizing the definition of "food." However, it is difficult to find a proper juncture between food and CCEBN under main food categories and food classifications provided by this law. Speculations about designating CCEBN as a drug (Proprietary Chinese Medicine or PTM) have also received limited support from the Chinese Medicine Ordinance of Hong Kong. PTM could be a product:

> composed by an animal-origin active ingredients habitually consumed by the Chinese people, prepared in the form of a finished dose form, and known or claimed to be capable of diagnosing, treating, preventing or alleviating any human disease or the symptoms of any disease, or regulating the functional state of the human body.[103]

Hence, the positioning of CCEBN in Hong Kong as a legal category is uncertain and needs a further clarification.

C. Summary

Based on our examination of food laws in the European Union, the United States, China, and Singapore, CCEBN is likely to be categorized as food in all four jurisdictions. Regulations of novel food in the European Union, the United States, and Singapore all highlight the use of novel methods of cell culture as a precondition for recognizing novel foods. Being designated as a novel food, a particular regulatory path, different from that of conventional food, will be followed to receive a pre-market review. Although Chinese law has not explicitly specified cell culturing as a criterion to distinguish novel food from conventional food, the catch-all provision makes it possible for CCEBN to be recognized as a type of novel food in China. When the use of GM is involved in a cell culture process, the EU and China are likely to identify CCEBN as a GM food, and relevant GM laws apply to pre-market reviews. By contrast, as the United States follows a product-based regulatory approach to food safety evaluation, it is very likely that it will recognize CCEBN as a non-GM food product. Singapore regards CCEBN as novel food even when the GM technology is involved in the process of culturing and manufacturing CCEBN. On this basis,

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[100] *Id.* at art. 74.

[101] *Weishengbu Guanyu Jinyibu Guifan Baojian Shipinyuanliao Guanli De Tongzhi (卫生部关于进一步规范保健食品原料管理的通知) [Notice of the Ministry of Health on Further Regulating the Management of Raw Materials of Health Food]*, NAT'L HEALTH COMM'N OF THE PEOPLE'S REPUB. OF CHINA, http://www.nhc.gov.cn/sps/s3593/200810/bc239ea3d226449b86379f645dfd881d.shtml (last visited Sept. 7, 2024).

[102] Zhonghua Renmin Gongheguo Shipin Anquan Fa, *supra* note 39, at art. 76–79.

[103] Chinese Medicine Ordinance, (2022) Cap. 549, § I (2) (H.K.).

Singapore requires the submission of information and materials related to the respective GM technology to conduct pre-market assessment.

In contrast to the aforementioned jurisdictions, Hong Kong's current law is not clear about whether CCEBN constitutes a food or drug, and there is no certainty as to whether CCEBN should be considered novel food or GM food when GM techniques are used during the production. Hence, CCEBN seems to fall into a grey area in terms of its legal regulation in Hong Kong. Considering that traditional EBN is often considered tonic food, we also explore the possibility of including CCEBN in the category of HCS. All jurisdictions under consideration have their own regulations that primarily apply to HCS, which distinguishes HCS from the way tonic food is publicly perceived, and CCEBN can hardly meet these legal requirements.

III. PRE-MARKET REGULATION: SAFETY ASSESSMENT OF CCEBN

Based on the preceding analysis, CCEBN is very likely to be considered novel food, and, hence, any undertaking to commercialize CCEBN products would need to meet relevant pre-market regulation requirements. Food safety assessment is an indispensable aspect of pre-market regulation as it allows for identification and mitigation of possible risks to human health and the environment.[104] In this part, we will first identify potential legal challenges by reviewing how CCEBN would be regulated under the different regulatory regimes of the five jurisdictions. Although these challenges may not apply to the same degree in all jurisdictions, it is important to consider their impacts and develop specific recommendations for improvement. Our analysis of regulatory practices across jurisdictions highlights both valuable legal practices and gaps in regulatory oversight of CCEBN. It further aims to support the development of a more appropriate regulatory framework for CCEBN and other NLAC cell-cultured tonic food.

A. Pre-Market Safety Assessment Approaches and Challenges

1. The U.S. Joint Regulatory Approach

In the United States, FDA and USDA jointly oversee the production of cell-cultured meat under the Formal Agreement, which is a non-legally binding arrangement and exerts no obligations on FDA and USDA. However, it serves as a mutual regulatory collaboration alleging to pursue harmonized and effective oversight of novel food within the existing legal framework.[105] The existing legal frameworks grant statutory authorities to FDA and USDA, in which FDA's administrative enforcement is premised on the FDCA, the Public Health Service Act, and the Fair Packaging and Labeling Act, while the legal basis for USDA to regulate cell-culture meat comes from the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA).[106] Three working groups have been established to facilitate the implementation of this Formal Agreement, namely, the

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[104] Antonio Fernandez & Claudia Paoletti, *What is Unsafe Food? Change of Perspective*, 109 TRENDS FOOD SCI. & TECH. 725 (2021).

[105] *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, *supra* note 42.

[106] *Id.*

FDA's pre-market reviews group, the product labeling group (led by USDA), and the group for transferring inspections between agencies.[107] The Formal Agreement divides the regulatory responsibilities of FDA and USDA by treating cell harvesting as the key node. Specifically, FDA has been tasked with conducting pre-market safety consultation to include oversight of tissue collection, cell lines and banks, manufacturing controls, all components and inputs, and proliferation and differentiation of cells through the time of harvest.[108] FDA has recently indicated that it intends to issue relevant guidance for pre-market consultation and has encouraged companies to negotiate with FDA at the early development phase regarding getting relevant cell-cultured food prepared for market placement.[109] When the cells are ready for harvesting, FDA and USDA will assist each other in accomplishing the regulation "handover."[110] Later, when the cells are harvested, the establishment has to bear a USDA mark of inspection in accordance with the FMIA and the PPIA, thus indicating its legal compliance in producing human food.[111] Further, USDA urges the establishment that intends to process, package, or label those harvested cells into human food to obtain a grant of inspection in order for the product to enter the market.[112]

Strictly speaking, the United States has not developed a coherent legal framework, but rather an arrangement intended to address overlapping regulatory powers on cultured meat, with no legally binding responsibilities allocated to relevant authorities such as FDA and USDA.[113] The Formal Arrangement is de facto a coordination of the cell-cultured meat regulatory "turf battle" between FDA and USDA, which reflects the differences in food safety regulation principles and pathways upheld between them.[114] Under these differences, stakeholders are pursuing their own interests by lobbying single authorization from either FDA or USDA. Some actors intending to preserve traditional meat consumption, e.g., meat lobbyists, such as the U.S. Cattlemen's Association, opt for the USDA oversight, which places its regulatory focus on the processes used in the creation of cultured meat, as well as on clear product labeling.[115] Others promoting cell-cultured food (e.g., environmentalists and animal

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[107] *Food Safety: FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat*, U.S. GOV'T ACCOUNTABILITY OFF. (Apr. 7, 2020), https://www.gao.gov/products/gao-20-325 (last visited Sept. 7, 2024).

[108] *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, *supra* note 42.

[109] *FDA Completes Second Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology*, *supra* note 21.

[110] *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, *supra* note 42.

[111] *Id.*

[112] *Id.*

[113] *Id.*

[114] Helena Bottemiller Evich, *Welcome to the Turf Battle over Lab-Grown Meat*, POLITICO (June 15, 2018, 6:12 PM), https://www.politico.com/story/2018/06/15/lab-grown-meat-feds-turf-battle-629774.

[115] Leanna Garfield, *There's a Growing Battle Between Fake Meat Startups and Big Beef, and Neither Side Is Backing Down*, BUS. INSIDER (June 10, 2018, 10:06 AM), https://www.businessinsider.com/beef-companies-file-petition-against-lab-grown-meat-startups-2018-2; Ryan Johnson, *Cell-Cultured Protein: A Letter to Trump From US Meat and Poultry Groups*, THE PIG SITE (July 27, 2018), https://www.thepigsite.com/news/2018/07/cellcultured-protein-a-letter-to-trump-of-us-meat-and-poultry-groups-1; *Petition for the Imposition of Beef Labeling Requirements to Address "Made in USA" Claims*, U.S. DEP'T OF AGRIC. (Oct.

rights activists) embrace FDA's regulation, which emphasizes the safety of the end products, rather than the methods used to cultivate such products.[116] In the absence of a unified federal legal action, and with the administrative power of FDA and USDA intertwined, the current arrangement may be fairly appropriate, or, at least, expedient, because FDA has experience in regulating the use of advanced biotechnology for food production, such as genetic modified technologies, and USDA has developed expertise in post-market oversight of meat and poultry products.[117]

The Formal Agreement is deployed mainly for cell-cultured meat, and whether this approach can also be applied to the pre-market safety assessment of CCEBN needs further clarification. CCEBN is quite different from cell-cultured meat in many respects. For example, the Formal Agreement is designed to regulate production of human food products derived from the cells of livestock and poultry, while the swiftlet (and its cells) used to produce CCEBN does not fall under livestock and poultry classification in the traditional sense. Moreover, even if we assumed that CCEBN can be regulated under the Formal Agreement, it may still be tricky to apply such level of oversight. This is because there is no swiftlet cell present in CCEBN end products due to the cell removal technique, which means that FDA and USDA's oversight agreement is no longer needed to regulate the final product for sale. In addition, EBN, as a tonic product, is distinguished from those routinely consumed food products, such as meat and grains, in terms of consumption quantity, dietary habits, and food acceptability. As a result, a regulatory approach for CCEBN should take into consideration these attributional differences.

Given that the regulatory model for cell-cultured meat does not appear applicable to CCEBN, two regulatory pathways may be envisioned as more appropriate approaches. First, FDA may assume responsibility for pre-market review for CCEBN. In the current regulatory landscape, swiftlets are not regulated under the FMIA and PPIA, so CCEBN cultured from swiftlets does not fall under the purview of the Formal Agreement and is not subject to administration by USDA. Accordingly, FDA, under the FDCA and Public Health Service Act, should lead the oversight of the entire course of CCEBN production, from cell collection to final product for marketing. FDA has taken on this role in the case of cell-cultured seafood with the understanding that such products shall be solely regulated by FDA.[118] Nevertheless, further clarification will still be required for FDA to enable its exclusive authority over CCEBN regulation and differentiate it from the regulation of conventional foods. The second possible solution is to expand the Formal Agreement or its legal basis (FMIA, PPIA), including products like CCEBN into its scope. Under the latter scenario, it would take a rather lengthy and rigorous process. Expansion of the Formal Agreement would be hard to achieve,

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23, 2019), https://www.fsis.usda.gov/federal-register/petitions/petition-imposition-beef-labeling-requirements-address-made-usa-claims (last visited Sept. 7, 2024).

[116] Tammi S Etheridge, *What's the Beef? The FDA, USDA, and Cell-Cultured Meat*, 78 WASH. & LEE L. REV. 1729, 1785–94 (2022); Kelly Servick, *As Lab-Grown Meat Advances, U.S. Lawmakers Call for Regulation*, SCIENCE (May 10, 2018), https://www.science.org/content/article/lab-grown-meat-advances-us-lawmakers-call-regulation.

[117] Atkins, *supra* note 27; Johnson, *supra* note 54.

[118] *Human Food Made with Cultured Animal Cells*, U.S. FOOD & DRUG ADMIN. (Mar. 21, 2023), https://www.fda.gov/food/food-ingredients-packaging/human-food-made-cultured-animal-cells (last visited Sept. 7, 2024); *Foods Made with Cultured Animal Cells*, U.S. DEP'T OF AGRIC., https://www.fsis.usda.gov/inspection/compliance-guidance/labeling/labeling-policies/foods-made-cultured-animal-cells (last visited Sept. 7, 2024).

at least within a short timeframe since its initial development involved considerable negotiations and coordination between two agencies. Furthermore, to initiate and pass a legislative proposal to expand the use of the FMIA or PPIA would be an even more daunting task.

2. The EU Regulatory Approach

In 2020, the "Farm to Fork Strategy" of the EU Commission proposed the development of alternative proteins as a key research area that contributes to fair, healthy, and environmentally friendly food systems.[119] The EU regulation mandates that the CCEBN needs to be authorized and then listed into the "Union List of Authorized Novel Food" (the Union List) before being placed on the market.[120] The process can be started either through the European Commission's initiative or following an application made to the Commission by an applicant.[121] When applicants cannot accurately self-determine whether the product in their application is a novel food, they have the option to consult with the competent authority.[122] Upon an application receipt, the Commission summarizes the relevant information from the application and releases it to the public.[123] After that, the Commission may decide solely or reach out for assistance with the safety assessment to the European Food Safety Authority (EFSA).[124] Upon request by the Commission, the EFSA conducts assessment and renders an opinion within nine months from the time the Commission receives the application.[125]

Assessments conducted by EFSA focus on three aspects related to novel food safety: 1) whether the novel food under review is equivalently safe to other comparable food types that have already been put on the market within the EU, 2) whether the composition of the novel food and its consumption brings safety risks to human health, and 3) whether the novel food intended to replace another food will have nutritional disadvantages in normal consumption.[126] The assessment of novel food should be completed based on clear scientific evidence, or, alternatively, the precautionary principle will be applied should scientific evidence not be sufficient to support safe consumption.[127] Moreover, in 2021, for the purpose of clarifying the application process for authorization, the Commission requested that EFSA formulate scientific and technical guidelines.[128] These guidelines standardize the documentation in order

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[119] *Farm to Fork Strategy: For a Fair, Healthy and Environmentally-Friendly Food System*, EUR. COMM'N, https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en#Strategy (last visited Sept. 7, 2024).

[120] Regulation 2015/2283, *supra* note 43, at art. 6.

[121] *Id.* at art. 10.

[122] *Id.* at art. 4.

[123] *Id.* at art 10.

[124] *Id.*

[125] *Id.* at art. 11.

[126] *Id.* at art. 7.

[127] Stephens et al., *supra* note 22, at 162.

[128] Eur. Food Safety Auth. Panel on Dietetic Prods., Nutrition & Allergies, *Guidance on the Preparation and Submission of An Application for Authorisation of A Novel Food in the Context of Regulation (EU) 2015/2283 (Revision 1)*, 19 EFSA J., 2021, at 1.

to help applicants prepare well-structured applications that demonstrate the safety of novel food and facilitate the assessment process.

After conducting the assessment, the EFSA forwards its opinion to the Commission, and then the Commission decides whether to grant authorization within seven months after receiving the opinion. The decision is made by considering general conditions, any relevant provisions of the EU law, the opinion from the EFSA, and other legitimate considerations.[129] In determining whether to authorize, the Commission submits the draft implementing act to the Standing Committee on Plants, Animals, Food and Feed, and the Standing Committee delivers an opinion regarding authorization.[130]

CCEBN, as we already discussed, would need to comply with the EU's novel food regulations and undergo the required pre-market authorization process, even if the final product contains no cell-cultured animal cells. According to the current pre-market evaluation process, the agencies that would be charged with the approval of CCEBN are centralized and operate at the EU-level, rather than in the member states. Moreover, the agencies' authorization is separated in dealing with the novel food's approval process, as the European Commission is tasked with reviewing novel food (the EFSA may charge the responsibilities of scientific and technical review, upon request by the Commission), while the Standing Committee on Plants, Animals, Food and Feed determines whether to grant approval. In this regard, either agency would be able to determine the fate of CCEBN, which increases the uncertainty about whether marketing approval for the CCEBN products can be obtained. In addition, given the strong emphasis on food safety and nutrition value, the review process for novel food in the EU is long. Normally, an eighteen to twenty-four-month process for novel food in the EU is needed.[131] In particular, the EU has not yet approved any cell-cultured food products for marketing.[132] Given the stringent and time-consuming process for novel food approval, CCEBN developers are likely to encounter significant barriers and uncertainties if they decide to proceed with CCEBN commercialization in any EU jurisdiction.

3. China's Regulation on Novel Food

As examined above, CCEBN is likely to be considered novel food under the catch-all clause of China's novel food regulation, and it will require pre-market assessment for commercialization. The SR-NFRM's regulatory focus on the novel food safety issues mandates that any novel food needs to satisfy the "necessary nutritional requirements, be also non-toxic, and does not cause any acute, subacute, chronic or other potential harm to human health."[133] On this basis, the commercialization of CCEBN is subject to administrative approval by the National Health Commission (formerly known as National Health and Family Planning Commission).[134] The

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[129] Regulation 2015/2283, *supra* note 43, at art. 12.

[130] *Id.* at art. 12, 30; Regulation 182/2011, of the European Parliament and of the Council Laying Down the Rules and General Principles Concerning Mechanisms for Control by Member States of the Commission's Exercise of Implementing Powers, art. 5, O. J. (L 55).

[131] Seehafer & Bartels, *supra* note 77, at 325.

[132] *The Safety of Cell Culture-Derived Food – Ready for Scientific Evaluation*, EUR. FOOD SAFETY AUTH., https://www.efsa.europa.eu/en/news/safety-cell-culture-derived-food-ready-scientific-evaluation (last visited Sept. 7, 2024).

[133] Xin Shipinyuanliao Anquanxing Shencha Guanli Banfa, *supra* note 47, at art. 3.

[134] *Id.* at art. 4.

National Health Commission is responsible for safety review, and the specific technical review is implemented by the Health Supervision Centre of the Commission.[135] In terms of processing times, under the Chinese law, a safety review for a novel food product should be completed within sixty days upon receiving an application.[136]

There are several issues concerning the regulatory process that need to be considered. For instance, the current law lacks detailed classification on different kinds of novel food. In addition, the authorities have not established domestic standards for evaluating the safety consumption of novel food, let alone developing specific standards targeting diverse novel food kinds. Furthermore, the current regulation only generally stipulates the types of materials that need to be submitted for safety review, with no specific guiding documents.[137] Given all these uncertainties, novel food developers are left to use their self-prescribed standards or adhere to safety standards developed in foreign jurisdictions. To date, the Chinese government has not approved any cell-cultured meat, and it is unclear how CCEBN would be evaluated under the existing administrative approval process.

4. Singapore's Approach to Regulating Cell-Cultured Meat

Singapore is a frontrunner in promoting cell-culture meat advancement.[138] The SFA is responsible for safety evaluation of novel food. SFA adopts a relaxed approach towards regulatory approval of novel food and has developed specific pre-market safety assessment guidelines for different products such as cell-cultured meat and foods produced through precision fermentation. The guidelines have been continuously updated, and there have been six versions since the initial publishing in 2019.[139] The updates have made possible the assessment of novel foods produced by using the emerging biotechnologies. According to Singapore Novel Food Requirements, food producers seeking to commercialize CCEBN must obtain a pre-market approval, which is based on SFA's review and assessment of the results from food safety self-testing conducted by applicants.[140]

For CCEBN producers, safety testing conducted internally should be based on their estimate of the potential safety risks associated with CCEBN products. Moreover, they are encouraged to follow some internationally recognized testing methods and standards recommended in Singapore Novel Food Requirements to demonstrate the food safety of CCEBN.[141] The Singapore Novel Food Requirements have not specified any format for documents submitted for safety assessment, and SFA recognizes submission materials endorsed by the United States, European Union, and WHO.[142] Upon the submission of a complete application, the review and assessment by SFA are

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[135] *Id.* at art. 5.

[136] *Id.* at art. 11.

[137] *Id.* at art. 6.

[138] Poinski, *supra* note 21; Fassler, *supra* note 21.

[139] *Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients*, *supra* note 45.

[140] *Id.*

[141] *Id.*

[142] *Id.*

completed within nine to twelve months, without charging any fee.[143] Applicants that have passed the safety assessment receive an approval that is not publicly released.[144] Although Singapore's loose legal regulations seem to provide more possibilities for CCEBN's commercial releasement, their requirements about the self-estimated risk-testing methods also mean that the safety assessment process is difficult to predict accurately. Hence, CCEBN developers' constant engagement with oversight agencies will be indispensable, and even compulsory in a sense, or they may fail to follow and comprehend the latest regulatory directions. In addition, the heavy reliance on self-testing may ignite concerns about accuracy and scientific validity of the testing results. This is especially the case with non-Singapore-based enterprises, which are allowed by the Singapore Novel Food Requirements to have their novel food applications processed by SFA without conducting inspections on their manufacturing sites.[145]

5. The Lack of Regulation in Hong Kong

Hong Kong does not have any laws or guidelines for regulating novel food. It is worth noting that in the absence of such rules, the Centre for Food Safety of Hong Kong has published a statement regarding cell-cultured meat on the Hong Kong government's official website, noting that the Public Health and Municipal Services Ordinance of Hong Kong generally requires that all food sold in Hong Kong be "wholesome and fit for human consumption," including cultured meat.[146] It also states that cell-cultured meat is not yet commercially available in Hong Kong, and that its production technology is still expensive, so it is necessary to reduce cost and streamline mass production to increase its economic benefits.[147] The Centre's statement seems to indicate that the prospective regulatory approach to novel food will likely focus on evaluating the final product, rather than the producing method. In this regard, once CCEBN is classified as food, as we discussed earlier, Hong Kong may embrace CCEBN products since they are compositionally identical to traditional EBN.

The regulatory status quo in Hong Kong resembles that of the United States as there is no special legal regulation targeting novel food and general food laws apply. Nevertheless, the United States has actively responded to the newly emerging biotechnologies by making regulatory arrangements among existing agencies and strengthening their collaborations on addressing unprecedented issues and safety risks. By contrast, Hong Kong has not established similar arrangements to handle regulatory challenges presented by novel foods. It is unclear whether its regulatory framework can sufficiently address the challenges of novel biotechnologies in food production.

B. Common Regulatory Practice on Novel Food Safety Assessment

Our examination of the regulatory frameworks of the five jurisdictions has highlighted some common regulatory practices and principles. Apart from Hong Kong, regulations on novel food in the United States, EU, China, and Singapore have

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[143] *Id.*

[144] *Id.*

[145] *Id.*

[146] *Food Safety Topics: Cultured Meat*, CTR. FOR FOOD SAFETY OF HKSAR, https://www.cfs.gov.hk/english/whatsnew/whatsnew_fst/whatsnew_fst_Cultured_Meat.html (last visited Sept. 7, 2024).

[147] *Id.*

not deviated from the underlying principles of their traditional food law systems. Rather, the established regulatory pathways have served as pillars for the regulation of novel food, with some additional steps to strengthen the process of pre-market review and approval. For example, the EU regulations regarding novel food clearly maintain the focus on the precautionary principle already enshrined in general food regulations (Regulation (EC) No 178/2002).[148] China has used their general food law—the Food Safety Law—as a baseline to formulate relevant regulation, making the food law systems comprehensive in the oversight of novel food.[149] Moreover, pre-market review and approval are usually accomplished by the established administrative authority tasked with overseeing food safety issues. At the same time, regulatory agencies rely on opinions by professional institutions that have expertise in conducting testing and evaluation of food safety. The EU regulation on novel food provides an example of this approach, in which the safety assessment follows the fundamental tenets of the established food policy, namely, sufficient scientific evidence and thorough risk analysis.[150] Risk analysis incorporates three interconnected processes: risk assessment, risk management, and risk communication.[151] Risk assessment is managed by the "EFSA and its scientific panels," while the latter two components are under the purview of the European Commission.[152]

Furthermore, authorities in all jurisdictions under consideration have stipulated the necessary documents and information that applicants need to prepare for safety review, as well as additional materials that should be presented in case of insufficient support for safety consumption. However, except for the EU, which issued a guidance in 2021 with detailed requirements about food safety that applicants should comply with prior to receiving authorization for novel food,[153] other jurisdictions only set out general principles related to novel food safety. Governments in these jurisdictions have all adopted a case-by-case approach to authorization. For example, Singapore in its guidelines indicates that there is "no one-size-fits-all approach to the testing of novel foods and companies should adopt effective testing strategies based on their understanding of the hazards that may be present in their novel foods."[154] The use of a case-by-case approach seems justified given the emerging status of cell-cultured food products, the limited scientific evidence about safety and risks, and the few novel types of products ready for commercialization. Nonetheless, clear standards and detailed guidelines for safety assessment should be established, as they play an important role in guiding research, development, and commercialization of cell-

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148 Regulation (EU) 2015/2283, *supra* note 43, at art. 12.

149 Xin Shipinyuanliao Anquanxing Shencha Guanli Banfa, *supra* note 47, at art. 1, 21.

150 *Communication from the Commission on the Precautionary Principle*, COMM'N OF THE EUR. COMMUNITIES (Feb. 2, 2000), https://op.europa.eu/en/publication-detail/-/publication/21676661-a79f-4153-b984-aeb28f07c80a/language-en; Annalisa Volpato, *Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective*, *in* NOVEL FOODS AND EDIBLE INSECTS IN THE EUROPEAN UNION 15, 22–26 (Lucia Scaffardi & Giulia Formici eds., 2022).

151 Regulation 178/2002, *supra* note 38, at art. 3.

152 Volpato, *supra* note 150, at 23.

153 Regulation 2015/2283, *supra* note 43, at art. 6.

154 *Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients*, *supra* note 45.

cultured food products.[155] In this regard, transparency regarding the processes and results of applications and the disclosure of evaluation methods are crucial for responsible development of cell-cultured food products.

IV. PRE-MARKET REGULATION: LABELING REQUIREMENTS FOR CCEBN

Except for safety assessment, labeling issues are also important for CCEBN commercialization, as labeling would enable consumers to make informed choices about CCEBN products.[156] In regards to cell-cultured meat, there has not been a consensus as to whether it should be labeled as "meat" or "non-meat" and to what extent these labels reflect the nature of that food.[157] Labeling issues are more complex in the context of CCEBN, because these products are in nature different from the cell-cultured meat. In the United States, in order to prevent adulterated or misbranded sale, USDA is tasked by FMIA, PPIA, and EPIA to preapprove the labeling of meat, poultry, and egg products, and then verify them through inspections before they can be introduced into the market.[158] On this basis, the Formal Agreement mandates USDA's preapproval authority in the cell-cultured meat context.[159] USDA has therefore been engaged in rulemaking pertaining to the labeling of cell-cultured meat and poultry products and has sought public comments for the proposed rules in September 2021.[160] In addition, the labeling guidelines issued by USDA mandate that any label containing a special statement is subject to USDA's special evaluation, so in the context of cell-cultured meat products, labels containing or not containing statements about cell culture foreseeably come under USDA's scrutiny.[161] Hence, it may be anticipated that CCEBN products will be subject to preapproval before the formal market entry. However, when considering the attributes of CCEBN, the exact labeling requirements may not be easy to predict. The advent of CCEBN, due to its non-meat or poultry characteristics, inevitably encounters the legal lacuna created by the narrow applicability of FMIA and PPIA, which are limited to regulating the misbranding of meat and poultry products.[162] This legal gap is not surprising since the

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[155] Kimberly J. Ong, Jeremiah Johnston, Isha Datar, Vincent Sewalt, Dwayne Holmes & Jo Anne Shatkin, *Food Safety Considerations and Research Priorities for the Cultured Meat and Seafood Industry*, 20 COMPREHENSIVE REVS. FOOD SCI. & FOOD SAFETY 5421, 5422–23 (2021); Sivasubramanian Ramani, Deunsol Ko, Bosung Kim, Changjun Cho, Woosang Kim, Cheorun Jo, Chang-Kyu Lee, Jungsun Kang, Sunjin Hur & Sungkwon Park, *Technical Requirements for Cultured Meat Production: A Review*, 63 J. ANIMAL SCI. & TECH. 681, 684 (2021).

[156] Michael Siegrist & Christina Hartmann, *Consumer Acceptance of Novel Food Technologies*, 1 NATURE FOOD 343, 347 (2020).

[157] Benjamin DeMuth, Trey Malone, Brandon R. McFadden & Christopher A. Wolf, *Choice Effects Associated with Banning the Word "Meat" on Alternative Protein Labels*, 45 APPLIED ECON. PERSPS. & POL'Y 128, 129–31 (2022).

[158] *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, *supra* note 42.

[159] *Id.*

[160] Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells, 86 Fed. Reg. 49491 (proposed Sept. 3, 2021) (advance notice of proposed rulemaking).

[161] *FSIS Guideline for Label Approval*, U.S. DEP'T OF AGRIC., https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-GD-2024-0001.pdf (last visited Sept. 7, 2024).

[162] 21 U.S.C. § 601(j) (2018); 21 U.S.C. §§ 453(e), (f) (2018).

use of FMIA on cell-cultured meat products has already required additional considerations given the absence of meat definition in it.[163]

The FDCA entitles FDA to regulate all foods except meat, poultry, and some egg products and oversee the labeling of food products.[164] However, the agency has little power to fill the aforementioned legal gap, since "[u]nder FDA's laws and regulations, FDA does not pre-approve labels for food products," but mainly monitors whether the commercialized products remain consistent with the information contained in their labeling.[165] In October 2020, FDA started a Request for Information about labeling of foods produced from cell-cultured seafood cells, asking the public to comment on three aspects: 1) names or statements of identity for foods derived from cultured seafood, 2) consumer understanding of such names or statements, and 3) how to distinguish cultured seafood from those conventionally produced ones.[166] However, it did not specify whether it would conduct pre-market approval for product labeling. Hence, it remains unclear how the labeling of foods falling under the sole jurisdiction of FDA (such as seafood) will be regulated before their market placement.

In rare cases, FDA may also extend the pre-market approval authority to the labeling, provided that such labeling contains certain claims. These claims include three categories: health claims, nutrient content claims, and structure/function claims.[167] Health claims portray food as having a "reduced risk of a disease or health-related condition," and this characterization must be based on scientific evidence or "authoritative statement" from an official scientific agency or the U.S. government agencies responsible for "public health protection or nutrition research."[168] For the former scenario, FDA will review the scientific evidence to decide whether to render the authorization, while in the latter case, FDA would not ask for scientific evidence exhibition but only urge food producers to provide prior notification, and the labeling can be claimed only when FDA does not raise objections to the content of notification.[169] In addition, there is another kind of health claim that can be made under FDA's discretionary authority, in which FDA finds the intended claims still credible and non-misleading, even if "scientific evidence falls below that required for FDA to issue an authorizing regulation."[170] The nutrient content claims should also undergo

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[163] Zoe A. Bernstein, *The Fight over Frankenmeat: The FDA as the Proper Agency to Regulate Cell-Based "Clean Meat"*, 86 BROOK. L. REV. 593, 612–25 (2021); Da Young Lee, Seung Yun Lee, Jae Won Jung, Jae Hyun Kim, Dong Hun Oh, Hyun Woo Kim, Ji Hyeop Kang, Jung Seok Choi, Gap-Don Kim, Seon-Tea Joo & Sun Jin Hur, *Review of Technology and Materials for the Development of Cultured Meat*, CRITICAL REVS. IN FOOD SCI. & NUTRITION 8591, 8608 (2023).

[164] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 341–350; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE (2013).

[165] GUIDANCE FOR INDUSTRY: A FOOD LABELING GUIDE, *supra* note 164.

[166] *FDA Seeks Input on Labeling of Food Made with Cultured Seafood Cells*, U.S. FOOD & DRUG ADMIN. (Oct. 6, 2020), https://www.fda.gov/food/cfsan-constituent-updates/fda-seeks-input-labeling-food-made-cultured-seafood-cells.

[167] *Label Claims for Conventional Foods and Dietary Supplements*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements (last visited Sept. 7, 2024).

[168] *Id.*

[169] *Id.*; *Questions and Answers on Health Claims in Food Labeling*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2017), https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-health-claims-food-labeling (last visited Sept. 7, 2024).

[170] *Label Claims for Conventional Foods and Dietary Supplements*, *supra* note 167.

FDA's authorization process, which refer to the description of "level of nutrients" other than simply listing what nutrients are contained in food, or the comparison of the levels of nutrients in different foods.[171] Regulation of the remaining category—structure/function claims can be the most tolerant without resorting to FDA's pre-approval, as it may only tell the general "role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body."[172] However, the issue of pre-market approval of the labeling of CCEBN still fails to be ascertained from these regulations, because it will depend on whether the food producers make claims, which category of claim they choose to make, and what degree of clarity such claims can bring.

In recognizing the significance of labeling, the Formal Agreement has also expressed an expectation that FDA and USDA will work together to develop a common principle for cell-cultured food labeling and claims to ensure that the relevant product is "labeled consistently and transparently."[173] These joint labeling principles may be developed from the labeling requirements that are applied by the agencies for cell-cultured products subject to their jurisdiction.[174] Whether the common principle can be used or can serve as a reference in the context of CCEBN is unclear. The absence of uniform labeling laws can further limit the federal authority, which is indicated by the prospect of USDA's approval of labels using the term "meat" conflicting with some state laws.[175] For example, Missouri passed an amendment to the Meat Advertising Law in 2018, which strictly prohibited the description of products not derived from livestock or poultry as meat and imposed measures, such as imprisonment and fines, for infringements.[176] The State of Mississippi, after being lobbied by the Mississippi Cattlemen's Association, has employed its meat labeling legislation that prohibits any plant-grown or cell-cultured meat from being labeled "meat."[177] This legal requirement was fiercely criticized by plant-based meat advocates, and subsequently a vegan food company together with the Plant Based Foods Association filed a lawsuit challenging the constitutionality of the prohibition on plant-grown meat.[178] Faced with a resolute opposition, Mississippi amended the rule to allow plant-grown meat to be excluded from the law, provided that its plant

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[171] *Id.*

[172] *Id.*; *Structure/Function Claims*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/food/food-labeling-nutrition/structurefunction-claims (last visited Sept. 7, 2024).

[173] *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species*, *supra* note 42.

[174] *Human Food Made with Cultured Animal Cells*, *supra* note 118.

[175] Margaret Rosso Grossman, *USDA and FDA Formal Agreement on Regulation of Cultured Meat*, 14 EUR. FOOD & FEED L. REV. 385, 388 (2019).

[176] MO. REV. STAT. § 265.494(7) (2018).

[177] Katherine Sievert, Mark Lawrence, Christine Parker & Phillip Baker, *Understanding the Political Challenge of Red and Processed Meat Reduction for Healthy and Sustainable Food Systems: A Narrative Review of the Literature*, INT'L J. HEALTH POL'Y & MGMT. 1, 6 (2020); *Mississippi Food Labeling Law: Mississippi Makes Selling "Veggie Burgers" A Crime*, INST. FOR JUST., https://ij.org/case/mississippis-unconstitutional-food-labeling-law/ (last visited Sept. 7, 2024).

[178] MISS. CODE ANN. § 75-35-15(4) (2019); Shareefah Taylor, *Meat Wars: The Unsettled Intersection of Federal and State Food Labeling Regulations for Plant-Based Meat Alternatives*, 15 UNIV. MASS. L. REV. 269, 283 (2020).

cultivation attribute is clarified.[179] Nonetheless, this compromise decision has not impacted the overall prohibition on cell-cultured meat.[180] Uncertainties regarding cell-cultured food labeling currently exist at both the federal and state levels. Even if there is a possibility that federal guidelines for the labeling of cell-cultured meat and poultry will be adopted in the near future, their applicability to CCEBN is still under question.

In the European Union, Singapore, and China, labeling information is required to be submitted to complete the pre-market safety review and obtain approval for the novel food. Moreover, when authorized novel food products enter the market, they should firmly comply with the labeling requirements as approved. In the EU, novel food developers label their new products in accordance with the general labeling requirements for all food under the Regulation (EU) No 1169/2011, which provides that additional labeling information may be required, "in particular regarding the description of the food, its source, its composition or its conditions of intended use to ensure that consumers are sufficiently informed of the nature and safety of the novel food, particularly with regard to vulnerable groups of the population."[181] For any novel food, labeling requirements should be indicated when it is authorized and included in the Union List, and its addition to the Union List is subject to timely updates.[182] In China, the approval of novel food is officially announced by the National Health Commission, and the decision may outline pertinent labeling requirements. The novel food should also be labeled in compliance with national laws, regulations, food safety standards, and the announcement released.[183] In Singapore, labels must provide clear information about pre-packed alternative proteins with suitable "qualifying terms such as 'mock', 'cultured' or 'plant-based' to indicate [the food product's] true nature,"[184] and when selling non-prepacked foods, dealers should inform customers about the true nature of food they are buying.[185]

Based on our examination, we have established that each jurisdiction, while having some general provisions, has yet to issue specific and detailed regulations on novel food labeling. The existing general provisions basically require clarifications regarding the nature of novel food, which satisfy basic criteria about keeping consumers apprised of novel food products and facilitating their informed choices. With this in mind, we conclude that current regulatory frameworks may provide some guidance in addressing CCEBN labeling issues. However, considering the technical characteristics of CCEBN, the existing labeling requirements are far from sufficient to comprehensively resolve labeling considerations regarding CCEBN products, and significant efforts are needed from oversight authorities to ensure legal compliance.

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[179] Katie Justison, *Which Came First: The Chicken or the Chick'n? An FDA Amendment Proposal to Reconcile Conflicting Interests in Plant-Based Meat Labeling*, 64 WM. & MARY L. REV. 1863, 1872–73 (2023); Katherine McKeen, *Are Vegan "Butter" and "Meat" Labels Protected as Free Speech?*, THE REGUL. REV. (Dec. 9, 2020), https://www.theregreview.org/2020/12/09/mckeen-vegan-butter-meat-labels-protected-free-speech/ (last visited Sept. 7, 2024).

[180] Kettenmann & Lamb, *supra* note 27.

[181] Regulation 2015/2283, *supra* note 43, at (33).

[182] *Id.* at art. 6.

[183] Xin Shipinyuanliao Anquanxing Shencha Guanli Banfa, *supra* note 47, at art. 20.

[184] *Safety of Alternative Proteins*, SING. FOOD AGENCY, https://www.sfa.gov.sg/food-information/risk-at-a-glance/safety-of-alternative-protein (last visited Sept. 7, 2024).

[185] *Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients*, *supra* note 45.

Specifically, in cases when the GM and cell culture technologies converge, labeling matters will need to be cautiously addressed. After all, complex information related to GM and cell culture clustered in one label may impact public acceptance in a negative way, as it has been demonstrated by a recent study of German and French citizens' attitudes towards cultured meat, which showed that "genetically modified cultured meat (or cultured meat that contains genetically modified ingredients) is likely to be met with far more resistance from consumers compared to non-genetically modified cultured meat."[186] Studies have shown that labeling is closely linked to consumers' acceptance of certain cell-cultured products, and thus affects the success of commercialization.[187] Therefore, appropriate directives and requirements for labeling are needed to support the commercialization and market acceptance of novel foods.

V. MEETING REGULATORY CHALLENGES REGARDING THE COMMERCIALIZATION OF NOVEL TONIC FOOD

Our analysis of the five key jurisdictions indicates that the commercialization process of NLAC cell-cultured tonic food may encounter legal challenges under the current novel food regulatory regimes. However, we have demonstrated that in some cases new mechanisms have been established to mitigate the regulatory challenges brought by innovative methods for producing food. For example, a consultation process between authoritative agencies and food developers has been established and adopted in jurisdictions such as Singapore, the United States, and the EU, as an effective way of communication about new technologies and pre-market approval preparations. Based on the examination of regulatory regimes that apply to CCEBN and the identification of legal challenges, we recommend the following steps towards appropriate regulation of tonic foods.

First, we suggest that the current model of government-led assessment and approval of novel foods could be enhanced by including non-governmental organizations (NGOs), such as industry associations, scientific communities, research institutions, and consumer groups, in the process of developing regulations on novel tonic food, including NLAC cell-cultured tonic food. Scientific communities, along with industry associations, can be tasked with formulating industrial standards and best practices to provide technical support and training for risk assessment of novel tonic food in the early stage of development. They can also assist in the completion of corresponding novel food self-testing and submission to governmental agencies for pre-market approval. The engagement of non-governmental organizations can potentially bridge communication gaps between governments and the novel food developers. For instance, encouraging novel tonic food developers' early engagement in the NGO-included government-led consultations can help develop a more efficient regulatory approach towards novel tonic food and support developers to prepare applications for

[186] Christopher Bryant, Lea van Nek & Nathalie C. M. Rolland, *European Markets for Cultured Meat: A Comparison of Germany and France*, 9 FOODS, 2020, at 12.

[187] Christopher J. Bryant, Joanna E. Anderson, Kathryn E. Asher, Che Green & Kristopher Gasteratos, *Strategies for Overcoming Aversion to Unnaturalness: The Case of Clean Meat*, 154 MEAT SCI. 37, 39 (2019); Keri Szejda, Christopher J. Bryant & and Tessa Urbanovich, *US and UK Consumer Adoption of Cultivated Meat: A Segmentation Study*, 10 FOODS, 2021, at 3.; Meng Zhang, Lei Li & Junfei Bai, *Consumer Acceptance of Cultured Meat in Urban Areas of Three Cities in China*, 118 FOOD CONTROL, 2020, at 1, 5–6.

safety assessment of their products. Such engagement could promptly convey food developers' actual needs and concerns to regulatory bodies and enable them to make adjustments to relevant policies and regulations.[188] Meanwhile, information sharing between the authoritative agencies and non-governmental organizations can contribute to a better regulatory outcome. It is worth noting that governments can better mitigate an overly strict and onerous assessment and approval process by allowing NGOs to participate in the regulation. By allowing the inclusion of such non-government agencies in tracking and analysis of novel tonic food at the pre-assessment stage, a more comprehensive understanding of new products can be achieved, thereby increasing assessment accuracy and reducing the length of approval procedures.

A good example of government-led consultations is Singapore's model. The Singapore government has strengthened the dialogue with commercial enterprises and research teams working on novel food. SFA, for instance, holds the Novel Food Virtual Clinics regularly to establish a platform for enterprises to maintain close relationship and communication with the SFA.[189] These events help food developers in the early stages of research and development to keep up with the latest regulatory developments. In addition, the Future Ready Food Safety Hub was jointly established by the Singapore government agencies and the university, so that enterprises can consult with the Hub about "ascertaining and substantiating the safety of their novel food and facilitating the safety assessment later."[190] Although Singapore's model has been criticized for being too liberal and relying too much on self-testing, it provides a feasible and practical way to promote a good governance of the application of novel technologies in food industry.

Secondly, since tonic food products are not part of essential food consumption, less restrictive pre-market regulation with a strict product tracing system might be more suitable for oversight of their marketing. Novel tonic food may be less likely to expose the public to uncontrollable risks due to its limited consumption, especially as the establishment of a tracing system allows for close and accurate monitoring of approved manufacturers and qualified products. As we mentioned earlier, the expenses on tonic novel food are typically high, and their consumers may be more sensitive to the nature and quality of such food products. By adopting tracing techniques, consumers can easily access information about the products on their personal devices, such as mobile phones, enabling them to make informed choices and verify the authenticity of the tonic food product. In addition, the high price of tonic food could cover the cost of developing and maintaining the tracing system. In fact, a tracing system has been applied in China for supervising traditional EBN import and quality control. The Chinese Bird Nest Traceability Management Service Platform has been operating since December 2013 under the Chinese Academy of Inspection and Quarantine. The platform provides consumers with traceability services for imported EBN from overseas bird's nest enterprises registered in China and for EBN products processed by raw materials exported to China.[191] Through this service, the whole supply chain

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[188] Li et al., *supra* note 27, at 218–19.

[189] *Requirements for the Safety Assessment of Novel Foods and Novel Food Ingredients*, *supra* note 45.

[190] *Id.*; *FRESH: Future Ready Food Safety Hub*, NANYANG TECH. UNIV.: SING., https://www.ntu.edu.sg/fresh (last visited Sept. 7, 2024).

[191] *Yanwo Suyuan (燕窝溯源) [Edible Bird's Nest Tracing]*, CHINESE BIRD NEST TRACEABILITY MGMT. PLATFORM (中国燕窝溯源管理服务平台), http://ebn.caiq.org.cn/birdTracing (last visited Sept. 7,

of imported EBN can be traced, which effectively suppresses EBN fraud and addresses important safety concerns.[192]

VI. CONCLUDING REMARKS

Cell culture technologies enable the production of tonic food in a way that eliminates negative effects caused by traditional cultivation and collection methods. The end products of this process are more quality-stabled and nutrition-assured. Under existing legal frameworks, NLAC cell-cultured tonic food represented by CCEBN may be recognized as food in four of the five jurisdictions we examined—the United States, European Union, China, and Singapore. NLAC cell-cultured tonic food is likely to fall under the category of novel food because of its cell culture characteristics. If genetic modification techniques are involved in the process of NLAC cell-cultured tonic food production, they would be deemed "GM foods" in both China and the EU, while the United States and Singapore are likely to exclude NLAC cell-cultured tonic food from the category of GM food and regulate it under novel food regimes. Without a clear recognition of NLAC cell-cultured tonic food either as food or as drug, a legal vacuum emerges in Hong Kong regarding both novel food and GM food.

In this paper, we examined the pre-market regulation of CCEBN, focusing on the issues of pre-market safety assessment and labeling. As far as its pre-market safety assessment was concerned, legal challenges were identified in all five jurisdictions. Specifically, the U.S. current regulatory model, which was built upon the regulation of cell-cultured meat, appears inappropriate for regulating NLAC cell-cultured tonic foods such as CCEBN. The EU has taken a very stringent regulatory approach, including an onerous administrative review and assessment process, which can cause significant burdens to CCEBN developers in commercializing their product and is likely to suppress the advancement of this novel food in the EU. China's novel food regulation presents less clarity about whether CCEBN will be considered a novel food, and China's rules in regulating novel foods are not sufficient to guide the commercialization of NLAC cell-cultured tonic food in the near future. Singapore provides a lax regulatory environment that could make the market placement of CCEBN more promising, while concerns arise as to whether such less stringent administrative oversight and heavy reliance on self-regulation will cause damage to the accuracy and scientific validity of safety assessments and will ultimately result in food safety risks. Hong Kong purports to apply its general food laws to regulate novel food, rather than enacting any novel food laws or guidelines. Therefore, even if NLAC cell-cultured tonic food can be identified as food, it is still unclear what legal compliance measures need to be implemented for its market placement in Hong Kong. In addition to identifying legal challenges, we have also discussed some regulatory practices in the jurisdictions under consideration that provide foundation for further improvement of oversight. For the issue of labeling, all jurisdictions have put forward their own requirements on novel food labeling, which are general and can only meet basic regulatory needs. Hence, better directives and requirements for labeling are urgently needed in the context of NLAC cell-cultured tonic food.

2024); Aly Farag El Sheikha, *Why the Importance of Geo-Origin Tracing of Edible Bird Nests Is Arising?*, 150 FOOD RSCH. INT'L, 2021, at 1, 7–9.

[192] *Yanwo Suyuan (燕窝溯源) [Edible Bird's Nest Tracing]*, *supra* note 191.

Based on our analysis of legal challenges and common oversight practices in the context of regulating CCEBN, we have proposed some recommendations to improve the pre-market safety assessment regulation of novel tonic foods in a broader sense. We believe that novel food regulations and guidelines should be timely updated to ensure the inclusion of newly developed cell-cultured tonic foods such as CCEBN. Since the limited consumption of novel tonic food is less prone to bring significant safety risks to large numbers of consumers, a favorable market entry regulation, combined with a post-market product tracing system, may be a good regulatory approach to support its commercialization. At the same time, it is desirable to hold government-led consultations that involve key stakeholders. In the pre-assessment stage, such a consultation platform can support cell-cultured tonic food developers to gain better understanding of scientific research, regulation, and self-testing. Engagement between the government and key players in the field can enable regulatory bodies to react quicky to new developments related to novel tonic food and ultimately improve the efficiency and effectiveness of the safety assessment and approval of new products.