

# The Regulatory Status of Cultivated Meat: Overview of Regulatory Best Practices with Recommendations for India

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Image credit: BlueNalu Inc

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# Table of contents

<b>Introduction</b>	3
Technology and Production Overview	4
Benefits of Cultivated Meat	5
Growing Consumer Demand	5
<b>Creating a Level Playing Field for Cultivated Meat: Global Regulatory and Policy Developments</b>	<b>6</b>
<b>A Well-Defined Regulatory Framework</b>	6
Singapore	6
Australia & New Zealand	9
Israel	9
The United States	10
European Union	11
Canada	12
United Kingdom	13
Brazil	14
<b>Policy Support and Proactive Industry Engagement</b>	14
Singapore	14
The United States	15
Israel	16
Japan	17
European Union	18
United Kingdom	18
Greater China	19
Qatar	20
Developments in Cultivated Meat: India	20
<b>Effects of Labelling on Consumer Perception</b>	22
The Ideal Nomenclature	23
<b>Regulatory and Policy Considerations for Cultivated Meat in India</b>	<b>24</b>
<b>Policy and Regulatory Recommendations</b>	24
Leveraging Global Best Practices and Harmonising Regulatory Requirements	25
Strengthening Regulatory Communication with the Industry	26
Building Transparency and Familiarity with the Consumers	27
Public Investments and Interagency Coordination for Ecosystem Building and Increased R&D in Food Innovation	27
<b>Conclusion</b>	<b>28</b>
About the Authors	29
Acknowledgements	29
About GFI India	29

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# Introduction

Meat, traditionally sourced from slaughtered animals, has been a staple in societies worldwide for thousands of years. Our existing protein supply chain, involving the rearing and slaughter of livestock, presents several pressing challenges to human and planetary health. Large-scale animal agriculture is one of the major drivers of ecosystem loss and environmental degradation worldwide.<sup>1</sup> With the increased awareness of the health benefits of plant-based diets and concerns about meat production on the environment and animal welfare in many countries, trends are leading to overall meat reductions.<sup>2</sup> However, the consumption of animal-sourced foods is still at an all-time high.<sup>3</sup>

The smart protein (also known as alternative protein) sector represents a significant opportunity to enable the diversification of sources of protein. Smart protein foods are food products that can reliably and predictably substitute the consumption of animal-derived meat, eggs, and dairy, while vastly lowering impacts on planetary and public health. Smart protein products can be made using one or a combination of cultivated meat, plant-based protein, and/or fermentation-derived protein from a product, cost, and infrastructure perspective.

This report provides an overview of the regulatory landscape present in several countries to regulate cultivated proteins. In addition to national efforts to provide regulatory clarity, the report also calls attention to activities by multiple governments and their policy-makers in an effort to recognise smart protein by including it within their national climate goals, increasing the public funding towards R&D, participating in public-private partnerships, and by playing a pivotal role in educating consumers about the emerging categories within the sector. The report concludes with a set of policy and regulatory recommendations and considerations for the Government of India and stresses that a well-developed and flexible regulatory framework in addition to proactive government support is essential for encouraging innovation in smart protein.

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<sup>1</sup> Benton T., Bieg C., Harwatt H., Pudasaini R., and Wellesley L, "Food system impacts on biodiversity loss-Three levers for food system transformation in support of nature." Chatham House (2021) available at

<[https://www.chathamhouse.org/sites/default/files/2021-02/2021-02-03-food-system-biodiversity-loss-benton-et-al\\_0.pdf](https://www.chathamhouse.org/sites/default/files/2021-02/2021-02-03-food-system-biodiversity-loss-benton-et-al_0.pdf)>

<sup>2</sup> Sanchez-Sabate R, Sabaté J., "Consumer attitudes towards environmental concerns of meat consumption: a systematic review" International Journal of Environmental Research and Public health. (2019) available at

<<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6479556/>>

<sup>3</sup> Sadhnani S., Rocque N., Bhat A., Basoya S., "Building an Eco-system for Cultivated Meat in India" Good Food Institute CIIE.CO (December 2021) available at

<<https://gfi-india.org/wp-content/uploads/2022/01/Building-an-ecosystem-for-cultivated-meat-in-India.pdf>>

## Technology and Production Overview

Cultivated meat, also known as cultured or cell-based meat, involves a novel method to produce genuine animal meat from cell cultures. The meat produced through this process is identical to animal meat at the cellular level. Thus, it can provide the same sensory and nutritional profile of conventionally produced meat through a safer, repeatable, and sustainable production system.<sup>4</sup>

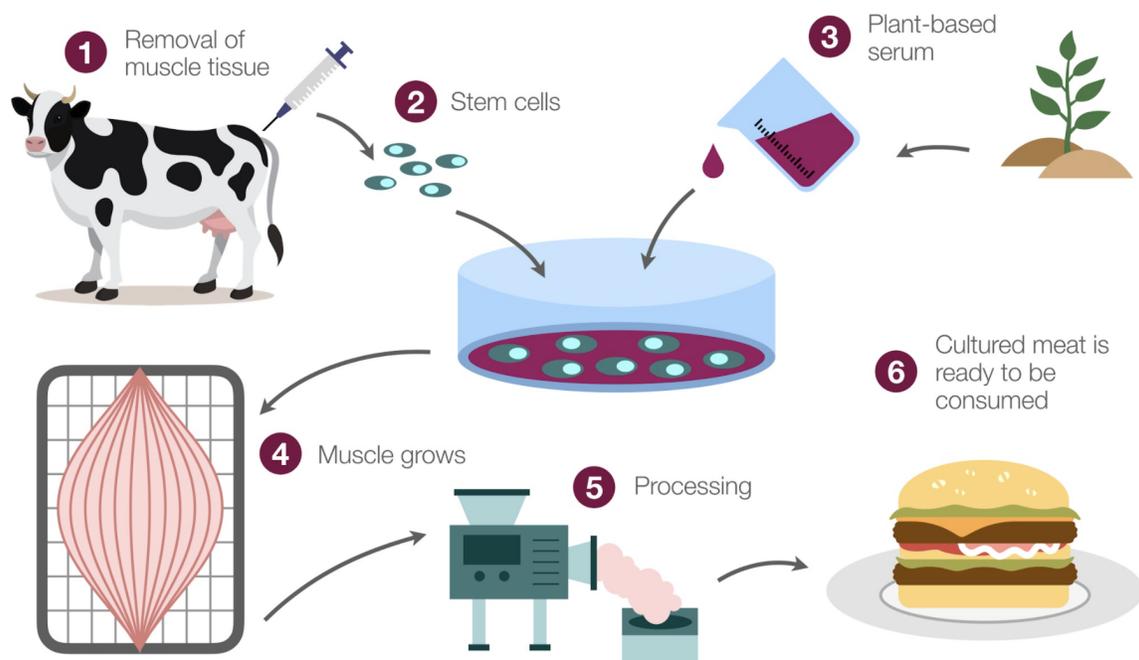


Figure: Brief overview of the production of cultivated meat | Credit: Shutterstock

This report also examines the regulatory status and process for food and food ingredients derived from genetic modification or genetically modified organisms (GMO), although there is no absolute need to utilise genetic modification or GMOs for most smart protein products, including cultivated meat products. Several major cultivated meat companies internationally have stated that they do not utilise genetic modification for their products<sup>5</sup> and have declared their products GMO free.<sup>6</sup>

<sup>4</sup> Read more about the science of cultivated meat at <<https://gfi.org/science/the-science-of-cultivated-meat/>>

<sup>5</sup> "Mosa Meat CEO on choosing non-GMO, differentiation & pricing the novelty factor" AgFunderNetwork (April 1st 2021) available at <<https://agfundernews.com/mosa-meat-ceo-maarten-bosch-on-choosing-non-gmo-partnering-for-expansion-and-choosing-beef.html>>

<sup>6</sup> Aleph Farms, "[The science behind the world's first cultivated steak – grown directly from cells](#)"

## Benefits of Cultivated Meat

Research has found that cultivated meat can have a lower carbon footprint than conventionally produced meat and can reach price parity with conventional meat in less than ten years.<sup>7</sup> In a report published by the World Economic Forum titled “Top 10 Emerging Technologies of 2018”, cell-based meat/cultivated meat has been considered as a promising solution to mitigate concerns related to livestock agriculture.<sup>8</sup>

	 Cultivated meat compared to conventional chicken	 Cultivated meat compared to conventional pork	 Cultivated meat compared to a conventional beef
<b>Carbon footprint</b>	<b>17% reduction</b>	<b>52% reduction</b>	<b>Up to 92% reduction</b>
<b>Land use</b>	<b>63% reduction</b>	<b>72% reduction</b>	<b>Up to 95% reduction</b>

Figure: Cultivated meat environmental impact comparison (when produced via renewable energy)

## Growing Consumer Demand

The cultivated meat industry is projected to grow to around US \$25 billion by 2030.<sup>9</sup> The industry growth is supported by regulatory approvals, increased public and private investments, open-access research, and efforts by governments to recognise the growth and importance of this category within their national development plans. Companies at the forefront of the industry are manufacturing cultivated meat at a pilot-scale – a crucial early step to determine the viability of industrial-scale production. In India, there has been growing entrepreneurial activity and government-funded grants and research initiatives in the field of cultivated proteins.

Consumer familiarity and interest in this category are also growing, as demonstrated by research that shows that in India, 56.3% of respondents were very or extremely likely to

<sup>7</sup> Swartz, E., “New studies show cultivated meat can have massive environmental benefits and be cost-competitive by 2030” Good Food Institute  
<<https://gfi.org/il/new-studies-show-cultivated-meat-can-have-massive-environmental-benefits-and-be-cost-competitive-by-2030/>>

<sup>8</sup> Cann, O., “These are the top 10 emerging technologies of 2018”. World Economic Forum (2018)  
<<https://www.weforum.org/agenda/2018/09/top-10-emerging-technologies-of-2018>>

<sup>9</sup> Brennan T., et al, “Cultivated meat: Out of the lab, into the frying pan” McKinsey and Company (June 16 2021) available at  
<<https://www.mckinsey.com/industries/agriculture/our-insights/cultivated-meat-out-of-the-lab-into-the-frying-pan>>

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purchase cultivated meat, whereas, in the United States, 29.8% of respondents were very or extremely likely to purchase cultivated meat.<sup>10</sup>

Companies and researchers are working on responding to consumer demand in India and globally, and regulations will need to be inclusive and keep pace with market developments to ensure that these foods are able to reach the consumer through a predictable and clear regulatory path to market.

## **Creating a Level Playing Field for Cultivated Meat: Global Regulatory and Policy Developments**

In this section, we highlight a few case studies of countries that have recently demonstrated leadership through clear regulatory frameworks or policy initiatives to support the research and development, production, and/or authorisation of cultivated meat products. Our comparative analysis of regulatory frameworks provides guidelines and best practices for regulators to support emerging categories, such as smart protein, and increase the scope for greater harmonisation of laws and opportunities for international trade and investments. The progressive developments outlined additionally equip countries, like India, that are monitoring global progress to employ similar policy-level initiatives.

### **A Well-Defined Regulatory Framework**

Several countries, such as Singapore, Canada, Israel, Australia, New Zealand, Israel, the U.S., and Canada, have regulatory provisions applicable to the manufacture, production, and sale of cultivated meat. While some governments have stated that cultivated meat would fall under existing novel food frameworks, a few regulators have gone a step further to define cultivated meat and its production process in detail, thereby enabling greater regulatory clarity for the product.

#### **Singapore**

*“The Requirements for Safety Assessment of Novel Foods”<sup>11</sup>* is the current regulatory framework adopted by Singapore for cultivated meat. The regulatory framework defines cultivated meat

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<sup>10</sup> Bryant, C., Szejda, K., Parekh, N., Deshpande, V., & Tse, B., “A Survey of Consumer Perceptions of Plant-Based and Clean Meat in the USA, India, and China” *Frontiers in Sustainable Food Systems* (2019) 3, 1. <https://doi.org/10.3389/fsufs.2019.00011>

<sup>11</sup> S4.6 Cultured Meat, Singapore Food Agency, *Requirements for Safety Assessment of Novel Foods Regulation (Version 13th December 2021)*  
<[https://www.sfa.gov.sg/docs/default-source/food-import-and-export/Requirements-on-safety-assessment-of-novel-foods\\_13Dec2021\\_final.pdf](https://www.sfa.gov.sg/docs/default-source/food-import-and-export/Requirements-on-safety-assessment-of-novel-foods_13Dec2021_final.pdf)>

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as “meat developed from animal cell culture. The process to produce cultured meat involves growing the selected cell lines (or stem cells) in a bioreactor. The cells are grown in a suitable growth media, and may subsequently be assembled on a “scaffold” to produce products resembling meat muscle.”

Food business operators that intend to manufacture, import, or sell cultivated meat must conduct and submit a safety assessment of the products to the Singapore Food Agency (SFA) for review and approval. SFA focuses on regulating the product more than the process but still recognises the significance of establishing overall product safety. For pre-market approval, SFA currently requires the following details<sup>12</sup>:

- Information on the identity and source of the cell lines or stem cells and the chemicals used for their induction.
- Information to demonstrate that biopsies comply with Singapore’s animal health and food safety requirements, and are free from animal diseases.
- Information and details on the identities, composition, and purity of culture media, growth promoters, modulating factors, and antimicrobials (if used in the production process, and if used, whether the antimicrobials would contribute to antimicrobial resistance.) Additional clarification is sought on whether the culture media remains in the finished cultivated meat product or is removed completely. If culture media is removed, companies must provide information demonstrating its removal.
- Information related to the identity and purity of scaffolding materials, solvents, enzymes, and processing aids used in the production process.
- Information on how the purity and genetic stability of cell culture are ensured during the manufacturing process and if it would result in any food safety risks.
- Safety assessment covering food safety hazards that are at high risk of occurrence based on the nature of the cell line used to produce cultivated meat and the measures proposed to mitigate the potential food safety concerns. For example, certain species of shellfish are known to be at a higher risk of containing marine biotoxins. Companies utilising cell lines related to these species should include genomic, transcriptomic, or proteomic analyses; measures that could be implemented to mitigate these risks; and/or any other information to address this potential safety concern.
- Information on the aseptic processing steps established to ensure that the culture media and cell lines are free from infectious agents (e.g. viruses, bacteria, fungi, prions)

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<sup>12</sup> Ibid n11, for the full list of legal requirements under SFA’s regulatory framework, please refer to the [Requirements for Safety Assessment of Novel Foods Regulation \(Version 13th December 2021\)](#). The list mentioned in this report is not comprehensive.

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throughout the cell line selection, cell adaptation, cell proliferation, scaffolding, extraction, concentration and washing.

- An investigation, if genetic differences between starter cell lines and finished cultivated meat is observed, to determine whether these would result in food safety risks (e.g. increased production of allergens) and require additional risk mitigation measures.
- If the cultivated meat product contains an ingredient or additive that is derived from GM, additional details will be sought.<sup>13</sup> SFA would refer to the CODEX Alimentarius guidelines to conduct the food safety assessment for foods produced using recombinant DNA microorganisms or DNA animals. If the GM organism is present in the finished food product, the food itself will be subject to the review of the Genetic Modification Advisory Committee of Singapore (GMAC). Companies can also consult SFA if a review by GMAC is required for those products where the organism is present in the finished product or is obtained by other biotechnologies or through new breeding technologies.

SFA does not charge any fees for evaluating applications for the use of novel foods. SFA estimates a timeline of between three to six months to complete an assessment of the novel food application. Producers are required to label their cultivated meat products with qualifying terms such as “cultured” which would dispel any confusion that consumers may have about the nature or origin of the product. SFA ensures that confidential information and trade secrets submitted by companies will be kept confidential and not shared outside of SFA without the companies’ consent.

Entrepreneurs working in emerging categories are encouraged to consult SFA early in the product development phase to understand the materials that must be presented to establish the safety of their products successfully. Interested entrepreneurs are invited to refer to the guidelines to understand SFA’s requirements regarding safety assessments and the overall application process for novel foods such as cultivated meat.

Singapore’s regulatory framework is one of the most developed frameworks for smart protein. The framework goes deeper than a general assessment criterion for novel foods and recognises subcategories of emerging food technologies, such as cultivated meat products, and the specific requirements for that product technology. This category recognition not only provides entrepreneurs with certainty on how their product will be regulated but also ensures that there is a framework to fall back on for the entire production value-chain of that product, including the source of the cell-line(s) and information on the type of scaffolding used in cultivated meat products.

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<sup>13</sup> Ibid n11, s 3.9 “Use of genetic modification (GM) organisms to produce novel foods”

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This regulatory framework is a great example for regulators in India as they seek to regulate emerging food categories and continue developing their novel food frameworks.

## **Australia & New Zealand**

The joint regulatory authority for Australia and New Zealand is the Food Standards Australia New Zealand (FSANZ). FSANZ has recognised that cultivated meat is distinct from plant-based meat alternatives, and that cultivated meat is produced using animal cell culture technology which seeks to resemble traditional meat and is an alternative to farmed meat products.<sup>14</sup> FSANZ has maintained that cultivated meat would be captured within existing standards of their Food Standards Code under the Novel Food Regulation.<sup>15</sup>

FSANZ defines cultivated meat as “...produced using animal cell culture technology, where meat is produced from animal cells using a combination of biotechnology, tissue engineering, molecular biology and synthetic processes. Cell culture technology does not reproduce the animal itself, but produces a product that is intended to resemble traditional meat from an animal, such as steak, minced meat, etc.”

Cultivated meat would require a health and safety assessment during the pre-market approval process. The safety assessment would include testing to check for potential adverse effects in humans, the composition and structure of the food product, the process by which the food has been sourced and prepared, the patterns and labels of consumption of that food product, and any other relevant information for the approval process. A novel food can be sold in the retail market only after it is permitted for sale under the pre-market approval and is listed within the regulation under the ‘Permitted Novel Foods’ register. If a novel food product is permitted for the first time, certain conditions may be laid down, such as providing details on the cooking or preparation instructions, specific compositional or purity requirements that need to be met, or the brand under which the food is to be sold. Currently, this regulation does not have information on timelines for the pre-market approval process which would be beneficial for producers to know as they plan for their product application.

## **Israel**

Israel’s National Food Service (NFS) under the Ministry of Health evaluates requests for approval of “new foods”. New foods are defined as “foods or food components that have not been used significantly in Israel (unless it is a dietary supplement, a dietary supplement component, a food supplement, a flavouring substance and a manufacturing aid)” including “foods that contain or is isolated from plants, animals, microorganisms, fungi or algae.” The

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<sup>14</sup>Food Standards Australia and New Zealand, *Cell-Based Meat*  
<<https://www.foodstandards.gov.au/consumer/generalissues/Pages/Cell-based-meat.aspx>>

<sup>15</sup> Standard 1.5.1 Novel Foods, Australia New Zealand Food Standards Code  
<<https://www.legislation.gov.au/Details/F2017C00324>>

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NFS has maintained that cultivated meat would come under the regulatory definition of “new foods.”<sup>16</sup>

The NFS has recognised the recent growth of alternative proteins, including "cultured meats" and has defined cultivated meat as a *“food product created following the growth of animal cells in a controlled environment, using laboratory technological means, unlike animal husbandry in a conventional agricultural interface.”*

The NFS’ Risk Management Unit has created a dedicated team to study and research the unique characteristics of emerging categories to promote Israel's position as a leader in the smart protein industry.<sup>17</sup>

A pilot program between the Risk Management Unit at the Ministry of Health and the Israel Innovation Authority (IIA) is being established to construct a framework for Novel Foods regulatory approval submissions, especially for cultivated meat and fermentation-derived products. Currently, four Israeli startups are part of this pilot program. Once completed, entrepreneurs interested in producing, marketing or importing cultivated meat products will be able to request a permit from the Risk Management Unit at the Ministry of Health.

The approval process determines if the product is safe and fit for human consumption, meets the requirements under the law and the specified hygiene standards, and if it is labelled appropriately. If approval is authorised, the food product is added to the list of approved products maintained by the NFS. The NFS may cancel the approval if any information is found indicating that the new food may endanger public health or is non-compliant with the conditions and requirements under the law. The NFS specifies a time period of six months to a year for approval and does not prescribe any fee for the process.<sup>18</sup>

## The United States

In 2018, the United States (U.S.) Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) announced their intent<sup>19</sup> to implement a joint regulatory framework for cultivated meat. In 2019, the USDA’s Food Safety and Inspection Services (FSIS) and the U.S. Department of Health and Human Services (HHS) announced a formal agreement<sup>20</sup> that

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<sup>16</sup> National Food Service, New Foods Regulation available at <https://www.health.gov.il/UnitsOffice/HD/PH/FCS/NovelFood/Pages/default.aspx>

<sup>17</sup> Ibid n 16

<sup>18</sup> National Food Service, New Food Registration available at [https://www.health.gov.il/Subjects/FoodAndNutrition/food/Pages/Novel\\_Food\\_Registration.aspx](https://www.health.gov.il/Subjects/FoodAndNutrition/food/Pages/Novel_Food_Registration.aspx)

<sup>19</sup> US FDA “Public Meeting on Foods Produced using Cell Culture Technology” <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-foods-produced-using-animal-cell-culture-technology>

<sup>20</sup> US FDA, “Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species” <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell>

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mentions that the production and regulatory framework of food products derived from the cells of livestock and poultry will be jointly overseen by the two agencies. FDA will maintain oversight over cell collection, cell banks, and all cultivation inputs and processes, including cell growth and differentiation, up through the stage of “harvest” from the bioreactors.

USDA will then oversee further processing and labelling of food products derived from the cells of livestock and poultry. The agreement is a significant step forward in providing a clear and predictable regulatory framework for cell-based meat and signals that USDA and FDA will work together to ensure that cell-based meat and poultry products are safe and accurately labelled.

Since then, USDA and FDA have formed three interagency working groups on cultivated meat and have confirmed the framework of the formal agreement. USDA-FSIS has announced that<sup>21</sup> with respect to the parts of the cultivated meat production process that are under its jurisdiction for products derived from livestock and poultry cells: *“Other than new labeling regulations concerning this product, FSIS does not intend to issue any other new food safety regulations for the cell-cultured food products under its jurisdiction. Current FSIS regulations requiring sanitation and Hazard Analysis and Critical Control Point (HACCP) systems are immediately applicable and sufficient to ensure the safety of products cultured from the cells of livestock and poultry.”*

## European Union

In the European Union (E.U.), there have been several developments in the smart protein sector. The current regulations and policies are seemingly supportive of investments and innovation in smart protein.<sup>22</sup> The Novel Foods Regulation EU 2015/ 2283<sup>23</sup> governs the process for gaining pre-market approval for *“food consisting of, isolated from or produced from cell culture or tissue culture derived from animals.”*<sup>24</sup>

The pre-market approval would be issued by the European Food Safety Authority (EFSA) after conducting a thorough risk assessment process. During the risk assessment process, the EFSA verifies information about the compositional, nutritional, toxicological and allergenic properties of the product and information on respective production processes and the proposed uses. Post the risk assessment process, if the opinion given by the EFSA is positive, the European Commission drafts an implementing act that lays out the specific conditions of use, e.g., specific labelling requirements and monitoring arrangements, after which the European

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<sup>21</sup>USDA “USDA Seeks Comments on the Labeling of Meat and Poultry Products Derived from Animal Cells” (September 02, 2021) available at

<https://www.usda.gov/media/press-releases/2021/09/02/usda-seeks-comments-labeling-meat-and-poultry-products-derived>

<sup>22</sup> Froggatt A., Wellesley L., “Meat Analogues– Considerations for the EU” Chatham House (February 2019) available at

<https://www.chathamhouse.org/2019/02/meat-analogues/4-regulatory-landscape-eu>

<sup>23</sup> Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods available at

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283>

<sup>24</sup> 2(a)(vi) of Regulation (EU) 2015/2283 of the European Parliament

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Commission places the product under the Union list of novel foods.<sup>25</sup> The implementing act then needs to be adopted by a Committee representing all EU member states.<sup>26</sup> It is estimated that the time duration for the approval process for novel foods would take any time between eighteen months to over three years, and all EU member nations are involved in the decision-making process.

If genetic engineering is used in the production of cultivated meat, a separate regulation on genetically modified food and feed<sup>27</sup> will apply instead.

## Canada

In Canada, there are several biotech-related regulatory pathways. Companies are encouraged to engage with Health Canada's Food Directorate to discuss the nature and content of a novel food<sup>28</sup> submission for cultivated meat or seafood. In addition, along with Health Canada's oversight, the Canadian Food Inspection Agency (CFIA), Environment and Climate Change Canada (ECCC),<sup>29</sup> and Fisheries and Oceans Canada are also involved in ensuring novel products meet environmental responsibilities. There are also non-regulatory considerations for biotech products, such as market access and socio-economic impacts, which are governed by Agriculture and Agri-Food Canada, Global Affairs Canada, and Innovation, Science and Economic Development Canada.<sup>30</sup>

Cultivated meat products will be required to undergo a mandatory pre-market safety assessment before being made available for sale. The required information for the novel food submission includes:

- Evidence that the food is safe for consumption, including molecular characterisation, nutritional composition, toxicology and allergenicity, and types and levels of chemical contaminants.
- A three-part approval includes (i) a letter of no objection for human food use through the novel food assessment process; (ii) a pre-market assessment for new animal feed (due to the possibility of supply chain crossover, and regardless of whether the product

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<sup>25</sup> European Commission, Union List of Novel Foods

<[https://ec.europa.eu/food/safety/novel-food/authorisations/union-list-novel-foods\\_en](https://ec.europa.eu/food/safety/novel-food/authorisations/union-list-novel-foods_en)>

<sup>26</sup> Derbes E., "Cultivated meat is gaining momentum—and pathways for regulatory approval" (June 3, 2021) Good Food Institute US, available at <<https://gfi.org/blog/cultivated-meat-regulation-2021/>>

<sup>27</sup> Regulation (EC) No 1829/2003 of the European Parliament and Of the Council of 22 September 2003 on Genetically Modified Food and Feed available at

<<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02003R1829-20080410&qid=1607596540771>>

<sup>28</sup> Canada, Food and Drugs Act (R.S.C., 1985, c. F-27) <<https://laws-lois.justice.gc.ca/eng/acts/f-27/>>

<sup>29</sup> Netta Fulga and Yadira Tejada Saldana, Panel Event Report "First Steps Towards a Regulatory Framework for Cultured Food Products in Canada" Cellular Agriculture Canada (December 2021) <<https://www.cellag.ca/regulatory-framework-report>>

<sup>30</sup> Ibid n 22

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is intended for use as animal feed); and (iii) an environmental assessment under the New Substances Notification Regulations. Companies may not market their products in Canada until they have all three approvals.

Cultivated meat produced with the use of genetic engineering (GE) will likely be considered “genetically modified,” defined broadly to include any “*change [to] the heritable traits of a plant, animal or microorganism by means of intentional manipulation.*” For cultivated meat produced using GE techniques, certain additional information may be required in the novel food application.<sup>31</sup>

Approved cultivated meat products must comply with the mandatory labelling requirements, where the food may have a common name that adequately describes the product. The CFIA has guidance to assist with labelling, based on the methods of production claims (e.g., genetically engineered) and compositional claims.<sup>32</sup>

## United Kingdom

The United Kingdom (U.K.) no longer subscribes to the regulatory procedures laid down by the E.U. but has retained several provisions under the E.U. law specifically for the risk assessments of both novel foods and genetically modified food authorisations. The risk assessment and prior approvals would be given by government officials under the U.K. Food Standards Agency (FSA). Currently, a few companies like IvyFarm have approached the FSA for regulatory support on their cultivated meat products.<sup>33</sup> Although the FSA has not provided a regulatory definition for cultivated meats, they have shared guidance on the process to make an application.<sup>34</sup>

## Brazil

In Brazil, the General Food Office at the National Health Surveillance Agency (ANVISA) and the Animal Products Inspection Department, under the Ministry of Agriculture, would scrutinise the applications for cultivated meat.

ANVISA is committed to understanding the food safety and labelling challenges of cultivated meat and is in the process of developing a regulatory framework that would include cultivated

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<sup>31</sup> Ibid n 22

<sup>32</sup> Ibid n 25, page– 9

<sup>33</sup> Morrison O., “UK start-up predicts lab-grown sausages on shelves by 2023 after technology ‘breakthrough’” FoodNavigator (May 19, 2021) available at

[https://www.foodnavigator.com/Article/2021/05/19/UK-start-up-predicts-lab-grown-sausages-on-shelves-by-2023-after-technology-breakthrough?utm\\_source=copyright&utm\\_medium=OnSite&utm\\_campaign=copyright](https://www.foodnavigator.com/Article/2021/05/19/UK-start-up-predicts-lab-grown-sausages-on-shelves-by-2023-after-technology-breakthrough?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright)

<sup>34</sup> UK Food Standards Agency “Novel foods authorisation guidance– Novel foods authorisation requirements and what you need to submit as part of a novel food application.” (December 31, 2020) available at

<https://www.food.gov.uk/business-guidance/regulated-products/novel-foods-guidance#ongoing-applications>

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meat products. According to ANVISA, Brazil would adopt a model similar to the U.S. and E.U. Throughout 2021, scientific debates and discussions on regulatory best practices were held with international regulators. Certain measures under a regulatory impact analysis (regulated by a decree in Brazil) are expected to occur in 2022. It has been proposed that companies would first make an application with information about their product to the regulator at an initial stage, which would be analysed under the existing novel foods regulatory framework.<sup>35</sup>

## Policy Support and Proactive Industry Engagement

Many governments have made public investments in the research and development of cultivated meat production to increase the scalability and accessibility of products. Several governments through various agencies or bodies interact with the industry players through consultative processes to preempt pain points and to support companies with their approval processes for this emerging category. This section highlights a few notable developments.

### Singapore

In December 2020, Singapore became the first nation to approve the sale of cultivated meat produced by Eat Just – a company based in the United States.<sup>36</sup> Singapore Food Agency (SFA)'s proactive engagement with entrepreneurs and adopting a science-based regulatory approach led to this momentous milestone.

Under the “30 by 30 Vision” to build Singapore’s agri-food industry capabilities locally and sustainably, smart protein is recognised as one of the means to achieve a more resilient food future. To drive the food innovation ecosystem, the Future Ready Food Safety Hub (FRESH) was established in partnership with the SFA, Nanyang Technological University (NTU) and the Agency for Science, Technology and Research (A\*STAR).

Singapore regularly conducts focused group discussions in collaboration with agencies such as Enterprise Singapore, which is a statutory body under the Singapore government’s Ministry of Trade and Industry. Focused group discussions is a constructive way to involve the industry in regulatory discussions to analyse current bottlenecks and clarify procedural ambiguity that may exist for emerging industries. Focused group discussions are also a mechanism for the food regulator to gain feedback on frameworks instituted and take suggestions on what could be altered to support innovation while also recognising consumer interests.

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<sup>35</sup> Brazil, [Resolution - RES No. 16 of 04/30/1999](#) and [Resolution - RES No. 17 of 04/30/1999](#)

<sup>36</sup>Gilchrist K., “This multibillion-dollar company is selling lab-grown chicken in a world-first” CNBC (March 2021) <<https://www.cnbc.com/2021/03/01/eat-just-good-meat-sells-lab-grown-cultured-chicken-in-world-first.html>>



Image Credit: Eat Just’s GOOD Meat cultivated chicken nuggets

Singapore is primed to be one of the leading destinations for cultivated meat entrepreneurs to launch their products, with promising local infrastructure and a regulatory framework already in place.

## The United States

The government has made attempts in getting the industry involved in the rule-making process for concerns such as labelling. The FDA requested public comments through an input gathering process for appropriate labelling of cultivated products such as seafood,<sup>37</sup> ensuring consumer awareness and participation<sup>38</sup> and promoting public acceptance of cultivated meat products. Additionally, the FDA suggests that the labelling requirements for cultivated meat, poultry, and seafood will be consistent.<sup>39</sup>

The U.S. government has supported the advancement of cultivated meat through policy initiatives such as the US \$10 million (INR 74.7 crore) grant from the U.S. Department of

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<sup>37</sup> The Daily Journal of the United States Government Notice Labeling of Foods Comprised of or Containing Cultured Seafood Cells; Request for Information, (2020) available at <https://www.federalregister.gov/documents/2020/10/07/2020-22140/labeling-of-foods-comprised-of-or-containing-cultured-seafood-cells-request-for-information>

<sup>38</sup> Elaine Watson, “What’s in a name? FDA requests info on labeling of cell-cultured seafood” (Food Navigator 2020) available at <https://www.foodnavigator-usa.com/Article/2020/10/07/What-s-in-a-name-FDA-requests-info-on-labeling-of-cell-cultured-seafood#>

<sup>39</sup> Derbes E., “Cultivated meat is gaining momentum—and pathways for regulatory approval” (June 3, 2021) Good Food Institute US, available at <https://gfi.org/blog/cultivated-meat-regulation-2021/>

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Agriculture<sup>40</sup> and a US \$3.55 million (INR 26.5 crore) research grant from the National Science Foundation<sup>41</sup> for research and development. Government funding is critical for the recognition and growth of sustainable technologies such as cellular agriculture.

## Israel

The ex-Prime Minister of Israel Benjamin Netanyahu became the first head of state to taste cultivated steak in December 2020. The cultivated meat tasting was organised by Aleph Farms<sup>42</sup> and the Good Food Institute, Israel<sup>43</sup> as a part of Israel's National Policy Plan<sup>44</sup> presentation, focusing on promoting Israel as an R&D leader in alternative proteins. Thereafter, the Prime Minister directed the State Secretary to appoint a coordinator to serve the growing industry.

The Israel Innovation Authority (under the Ministry of Science, Technology and Innovation) is currently working on a strategic plan to develop and promote the alternative protein sector in Israel. In October 2021, during the United Nations 26th Conference of Parties (COP26) Climate Talks, Israeli President Isaac Herzog became the first president<sup>45</sup> to try cultivated chicken produced by the company Future Meat and remarked that the product was not only delicious but also critical to global food security.<sup>46</sup>

Israel has identified that cultivated proteins are key in Israel's plans for a healthy, equitable and sustainable food system. The Office of the Chief Scientist under the Ministry of Environment Protection<sup>47</sup> stated that *"a substantial budget would be allocated to study the health and sustainability impacts of foods based on alternative proteins- including plant and plant-based proteins, cultivated meat, milk and eggs, and fermentation-derived proteins. The knowledge emanating from these studies will form the basis for updating the national nutrition recommendations as well as future national food security plans."*

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<sup>40</sup>Nicholas I., Silver M., "Tufts Receives \$10 Million Grant to Help Develop Cultivated Meat" Tufts University (October 15, 2021) available at <<https://now.tufts.edu/articles/tufts-receives-10-million-grant-help-develop-cultivated-meat>>

<sup>41</sup>Fell A., "UC Davis Establishes Research, Training in Cultivated Meat" UC Davis (September 2020) available at <<https://www.ucdavis.edu/food/news/uc-davis-establishes-research-training-cultivated-meat>>

<sup>42</sup>Visit Aleph Farms at <<https://www.aleph-farms.com/>>

<sup>43</sup>Alla Voldman, "Israeli Prime Minister Benjamin Netanyahu became the first head of state to taste cultivated meat in a tasting event hosted by GFI Israel and Aleph Farms" Dec 8, 2020 (GFI USA) <<https://gfi.org/blog/cultivated-meat-tasting-israel/>>

<sup>44</sup>Israel's Prime Minister Tastes Aleph Farms Cultivated Steak (PR NEWSWIRE) <<https://www.prnewswire.com/il/news-releases/israels-prime-minister-tastes-aleph-farms-cultivated-steak-301187468.html>>

<sup>45</sup>Surkes S., "Israel sending 120-strong delegation to Glasgow climate talks" The Times of Israel (October 25, 2021) available at <<https://www.timesofisrael.com/israel-to-be-represented-at-glasgow-climate-talks-by-120-strong-delegation/>>

<sup>46</sup>Spence M., "The National Security Case for Lab-Grown and Plant-Based Meat" Slate (December 29, 2021) available at <<https://slate.com/technology/2021/12/plant-cultivated-meat-national-security.html>>

<sup>47</sup>The Office of the Chief Scientist, Ministry of Environment Protection under the State of Israel, "Israel National Pathway Document for Healthy, Equitable and Sustainable Food Systems" available at <<https://summitdialogues.org/wp-content/uploads/2021/09/Israel-National-Pathway-document.pdf>>



In figure: GFI Israel managing director Nir Goldstein presents the Israeli Alternative Protein National Policy Plan to Israeli Prime Minister Benjamin Netanyahu in 2020| Image Credit: GPO Kobi Gideon

## Japan

In April 2020, Japan's Ministry of Agriculture, Forestry and Fisheries (MAFF) launched the Food Tech Research Group,<sup>48</sup> which aims to support the food industry and strengthen Japan's food security through technological advancements. The group is anticipated to dive deep into various food technology areas, including cultivated meat. The Japan Association for Cellular Agriculture (JACA) was initiated and is led by a think-tank named the Center for Rulemaking Strategy (CRS) at Tama University. JACA was created as a collaboration between the industry, government, and academia to create rules for cultivated meat, egg, and dairy products to foster the commercialisation of these products.

Cultivated meat (depending on the technique of production) may already come under the purview of existing regulations in Japan and may not require a pre-market review or clearance. That being said, the Japanese government is attempting to create a specialised regulatory framework in order to properly shape the market while assuring food safety and customer

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<sup>48</sup> Ministry of Agriculture, Forestry and Fisheries "Fostering a sustainable industry using food tech, etc. About the launch of "Food Tech Public-Private Council" <<https://www.maff.go.jp/j/kanbo/foodtech/kenkyukai.html>>

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approval. Industry groups are being formed to develop industry standards and to collaborate with regulators to develop a strategy to boost consumer confidence.<sup>49</sup>

The Japanese government, through Expansion Japan, has invested US \$2.7 million (INR 20.1 crore) to date in a cultivated meat company to develop production plants and to promote the entry of cultivated meat products into the Japanese market.<sup>50</sup>

## European Union

As part of the industry engagement process, EFSA has published several resources such as guidance materials<sup>51</sup> and checklists<sup>52</sup> that are publicly available. These resources are meant to aid applicants while preparing dossiers and documentation for their novel foods application. The E.U. has also invested €2 million (INR 17 crore) into a research and development project for cultivated meat under a financial recovery framework called 'Next Generation EU'.<sup>53</sup>

## United Kingdom

During COP 26, the government announced that cultivated meat could reduce carbon emissions and help the country achieve their targets by 2040.<sup>54</sup>

In December 2021, the U.K. Food Standards Agency (FSA) commissioned a consumer study<sup>55</sup> to understand consumer perception towards alternative proteins. The study revealed that one-third of citizens were willing to try cultivated meat products.<sup>56</sup> Professor Robin May, FSA's Chief Scientific Adviser, said: *"Our priority is to protect consumer interests by ensuring food is safe and what it says it is through a robust scientific process. We recognise the potential of alternative proteins for improving dietary health and as part of a sustainable food system. This*

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<sup>49</sup> Yamaguchi N., "Japan: Regulatory Updates on Shaping the Cultivated Meat Market" GFI APAC (October 28, 2020)

<<https://www.gfi-apac.org/blog/japan-regulatory-updates-on-shaping-the-cultivated-meat-market/>>

<sup>50</sup> Marvell H., "Japanese Government Part of \$2.7 Million Investment in New Clean Meat Brand" Livekindly available at

<<https://www.livekindly.co/japanese-government-part-of-2-7-million-investment-in-new-clean-meat-brand/>>

<sup>51</sup> EFSA, "Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283" <<https://www.efsa.europa.eu/en/efsajournal/pub/4594>>

<sup>52</sup> EFSA, "Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283" available at <<https://www.efsa.europa.eu/en/supporting/pub/en-1381>>

<sup>53</sup> Fortuna G., "Commission stands by €2 million EU grant for synthetic meat" Euractiv (November 2021) available

at <<https://www.euractiv.com/section/agriculture-food/news/commission-stands-by-e2-million-eu-grant-for-synthetic-meat/>>

<sup>54</sup> Askew K., "UK government backs cellular meat innovator: 'Developing cultivated meat is one of the most significant advances we can make'" FoodNavigator (November 2021) available at

<[https://www.foodnavigator.com/Article/2021/11/05/UK-government-backs-cellular-meat-innovator-Developing-cultivated-meat-is-one-of-the-most-significant-advances-we-can-make?utm\\_source=copyright&utm\\_medium=OnSite&utm\\_campaign=copyright](https://www.foodnavigator.com/Article/2021/11/05/UK-government-backs-cellular-meat-innovator-Developing-cultivated-meat-is-one-of-the-most-significant-advances-we-can-make?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright)>

<sup>55</sup> Ibrahim Jarchlo A., King L., "Alternative Proteins: Consumer Study" (2021) UK Food Standards Agency

<<https://www.food.gov.uk/research/behaviour-and-perception/survey-of-consumer-perceptions-of-alternative-or-novel-sources-of-protein>>

<sup>56</sup> "A third of UK consumers are willing to try lab-grown meat and a quarter would try insects" (January 2022)

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*important survey highlights that, while many consumers are considering trying alternative proteins, they will quite rightly only do so if they are confident that these products are safe and properly regulated. Consequently, we are working closely with businesses and trade bodies to ensure they make effective use of the FSA's existing regulatory framework so that consumers can benefit from innovative food products whilst still having full confidence in their safety."*

This is a significant development by a food regulatory agency to understand consumer interest towards alternative proteins on a deeper level. FSA is also looking to bring key stakeholders to analyse how companies entering this space can be supported and guide them through existing regulatory frameworks and processes.

The government has also invested £1 million (INR 8.5 crore) in Roslin Technologies. The investment was made through a grant funded by UK Research and Innovation (UKRI) under the Transforming Food Production Programme, and the British Innovation Fund.<sup>57</sup>

## Greater China

Although there is no fully developed regulatory framework to govern cultivated meat in Greater China (including Hong Kong), the government has demonstrated interest in supporting the advancement of cultivated meat through regulatory and policy support. Policymakers have identified cultivated meat as the most likely solution to supply meat in a clean and sustainable manner<sup>58</sup> and have expressed interest in creating a legislative framework in line with the E.U., and categorising cultivated meat under China's existing legislation for Novel Foods.<sup>59</sup>

In January 2022, China's Ministry of Agriculture and Rural Affairs released a highly anticipated five-year agricultural plan<sup>60</sup> designed to accomplish long-term national goals. The plan provides a blueprint to help strengthen innovation in "*frontier and cross-disciplinary technologies*," including the manufacturing of cultivated meat and other "*future foods*,"<sup>61</sup> and is a huge development for the APAC region.

In addition to bolstering China's domestic food security, this forward-looking plan makes clear that national leaders understand the strategic importance of including sustainable alternative

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<sup>57</sup> Matthews J., "Transforming food production through cultivated meat" UKRI (November 2021) available at <https://www.ukri.org/blog/transforming-food-production-through-cultivated-meat/>

<sup>58</sup> Neo P., "China's cell-based meat future: Calls for national strategy to accelerate sector's growth" FoodNavigator (June 2020) available at

[https://www.foodnavigator-asia.com/Article/2020/06/22/China-s-cell-based-meat-future-Calls-for-national-strategy-to-accelerate-sector-s-growth?utm\\_source=copyright&utm\\_medium=OnSite&utm\\_campaign=copyright](https://www.foodnavigator-asia.com/Article/2020/06/22/China-s-cell-based-meat-future-Calls-for-national-strategy-to-accelerate-sector-s-growth?utm_source=copyright&utm_medium=OnSite&utm_campaign=copyright)

<sup>59</sup> Sim A., "Lab-Grown or Cultured Meat: Legal in Hong Kong and China?" Lexology (February 16, 2021) available at <https://www.lexology.com/library/detail.aspx?g=31af58a3-9827-47dd-b6ea-05de0f3c7ed8>

<sup>60</sup> Ministry of Agriculture and Rural Affairs, "Five year agricultural plan", China (2022) available (in Chinese) at <http://www.moa.gov.cn/govpublic/KJJYS/202112/P020220106615353271383.pdf>

<sup>61</sup> Baker A., "China's New 5-Year Plan is a Blueprint for the Future of Meat" TIME (January 2022) available at <https://time.com/6143109/china-future-of-cultivated-meat/>

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protein production in China's green economy vision, right alongside renewable energy and battery manufacturing.<sup>62</sup> This dual carbon goal is also relevant for India to meet sustainability targets, while also bolstering economic growth through public investments and regulatory support in alternative proteins.

## Qatar

The government of Qatar through the Qatar Free Zones Authority and the Doha Venture Fund entered a partnership with the company Eat Just to build a cultivated meat production facility, which would be the first-ever in the Middle East and North-African region.<sup>63</sup> The Qatar Investment Authority, a sovereign investment agency, further invested US \$200 million (INR 1495.9 crore) in Eat Just.<sup>64</sup>

## Developments in Cultivated Meat: India

The Food Safety and Standards Authority of India (FSSAI) is the apex food regulatory authority body in India and oversees the prior approval/pre-market authorisation process for foods considered “novel”. Currently, the Food Safety and Standards (Approval of Non-Specified Foods and Food Ingredients) Regulation 2017<sup>65</sup> lays down the pre-market authorisation for novel food products/ingredients; food or food ingredients processed with the use of novel technology; any new additives or new processing aids including enzymes not previously laid down in other standards or regulations; food and food ingredients consisting of or isolated from microorganisms, bacteria, yeast, fungi, or algae; and any other non-specified food which is not covered in other food regulations.

Under this Regulation, novel food is defined as *“food or food ingredient that may not have a history of human consumption; or may have any ingredient used in it which or the source from which it is derived; may not have a history of human consumption; or a food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to a significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.”*<sup>66</sup>

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<sup>62</sup>“Xi stresses solid efforts for ‘dual carbon’ goal Top meeting reaffirms China’s climate commitment” (2022) Global Times available at <<https://www.globaltimes.cn/page/202201/1246897.shtml>>

<sup>63</sup> Albrecht C., “Eat Just Partners with Qatar Free Zones to Bring Cultured Meat Facility to the MENA Region” The Spoon (August 2021) available at <<https://thespoon.tech/eat-just-partners-with-qatar-free-zones-to-bring-cultured-meat-facility-to-the-mena-region/>>

<sup>64</sup> Marston J., “Brief: Qatar plans \$200m+ cell-cultured meat hub in partnership with Eat Just” AgFunder (August 2021) available at <<https://agfundernews.com/qatar-plans-cell-cultured-meat-hub-through-200m-investment-in-eat-just.html>>

<sup>65</sup> F. No. 12/PA Regulation/Dir (PA)/FSSAI-2016, Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulation 2017, available at <[https://fssai.gov.in/upload/uploadfiles/files/Gazette\\_Notification\\_NonSpecified\\_Food\\_Ingredients\\_15\\_09\\_2017.pdf](https://fssai.gov.in/upload/uploadfiles/files/Gazette_Notification_NonSpecified_Food_Ingredients_15_09_2017.pdf)>

<sup>66</sup>Frequently Asked Questions (FAQs) on the Food Safety and Standards (Approval of Non-Specified Food and Food Ingredients) Regulations, 2017 (2020)

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Although the current definition does not make direct references to foods derived from “animal-cell culture” like in Singapore’s or EU’s regulatory framework, however, there is a section of the Indian Regulation that requires information if the food product is derived from an animal source – “*the genus and species of the organisms must be mentioned*”<sup>67</sup> – which could potentially cover the scope of cultivated meat products.

Although there is no prescribed time frame for the prior-approval process, the FSSAI estimates it to take more than four months. It is to be noted that the FSSAI notified an amendment to this Regulation<sup>68</sup> for public comments in September 2021. If the amendment comes into force, it may alter the prior approval process for novel food products and bring in additional requirements such as mandatory post-market surveillance.

The FSSAI recently published a draft regulatory framework for foods derived from GMO,<sup>69</sup> which lays down a framework of a prior-approval process for those looking to manufacture, sell, or import products derived from or containing GM.

Multiple bodies and agencies under the Government of India such as the Department of Science and Technology (DST)<sup>70</sup> and the Department of Biotechnology (DBT)<sup>71</sup> under the Ministry of Science and Technology have shown considerable interest in the research and development of cultivated meat. In 2019, the Sanjay Gandhi Post-Graduate Institute of Medical Sciences (SGPGI), Lucknow received an INR 50 lakh grant from DST to conduct research on cultivated meat. In the same year, the Centre for Cellular and Molecular Biology (CCMB) and the National Research Centre on Meat (NRCM) with support from GFI India, secured an INR 4.6 crore grant for a joint research project to develop meat cultivated from sheep cells from the DBT.

Additionally, the Science and Engineering Research Board’s (SERB) under the DST included cultivated meat research as a category under their Competitive Research Grant Programmes.<sup>72</sup>

The Office of the Principal Scientific Advisor and the New Emerging and Strategic Technologies Division under the Ministry of External Affairs also specified cultivated meat as one of the

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<sup>67</sup> Ibid n 62

<sup>68</sup> Draft Notification of Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Amendment Regulation 2021, notified on 22 September 2021, available at [https://fssai.gov.in/upload/uploadfiles/files/Draft\\_Notification\\_Approval\\_NSF\\_24\\_09\\_2021.pdf](https://fssai.gov.in/upload/uploadfiles/files/Draft_Notification_Approval_NSF_24_09_2021.pdf)

<sup>69</sup> Food Safety and Standards (Genetically Modified or Engineered Foods) Regulations, 2021, available at [https://www.fssai.gov.in/upload/uploadfiles/files/Draft\\_Notification\\_GM\\_Food\\_17\\_11\\_2021.pdf](https://www.fssai.gov.in/upload/uploadfiles/files/Draft_Notification_GM_Food_17_11_2021.pdf)

<sup>70</sup> A report by the Technology Information, Forecasting and Assessment Council (TIFAC), Department of Science and Technology (DST) “*Cellular Agriculture: The Future of Food*” (2018) available at <https://tifac.org.in/images/pdf/pub/Cellular%20Agriculture.pdf>

<sup>71</sup> Jebaraj P., “*Centre invests ₹4.5 crore in cell-based mutton research project*” *The Hindu* (April 2019) available at <https://www.thehindu.com/news/national/centre-invests-45-crore-in-cell-based-mutton-research-project/article26945834.ece>

<sup>72</sup> Science and Engineering Research Board, *RG Special call on “Exponential Technologies”* available at <https://www.serbonline.in/SERB/emr?HomePage=New> accessed on 24th January 2022.

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emerging technologies under the Emerging Technologies Initiative (ETI).<sup>73</sup> The ETI identifies technologies that are of importance and relevance to India and forms policy initiatives to support their development.

The Chief Minister's Office of the Government of Maharashtra sanctioned a partnership between GFI India and the Institute of Chemical Technology (ICT), Mumbai, to set up a Centre of Excellence (CoE) in cellular agriculture in 2019.

The above examples are an indication of the Government's intent to promote the sector, and several such initiatives continue to be undertaken by the Government to promote cultivated meat in India. Such public investments in science and technology are critical to overcoming technological bottlenecks that prevent smart protein products from permeating beyond the initial consumer adopter segments to the mass market, and challenges present with scaling the domestic production capabilities.

Increased research through government bodies under the Ministry of Science and recognition in initiatives like the ETI helps foster technological developments in an inclusive and participatory manner.

## Effects of Labelling on Consumer Perception

As innovators around the world have demonstrated, it is possible to provide the same meat-centric dishes that people love by cultivating meat directly from animal cells. Not only must a food product taste and look appetising but its name needs to be enticing to the consumers, especially for emerging food categories such as cultivated proteins. Labelling a product appropriately is important for consumers, regulators, and the industry as a whole.

A critical part of consumer education is labelling food products accurately and suitably. Consumers are becoming more interested in understanding the production process of the food they are consuming and demand greater transparency in the supply chain. Companies that create next-generation products need to explain the science and production process both accurately and succinctly while presenting a desirable product.<sup>74</sup>

Much of consumer and the regulator's understanding and acceptance will rely on accurate nomenclature, shaped by regulatory guidelines.<sup>75</sup> If a standard of identity does not cover a

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<sup>73</sup> New Emerging and Strategic Technologies Division, Ministry of External Affairs- *Emerging Technologies Initiatives (ETI)* available at <<https://thesciencepolicyforum.org/initiatives/eti/>>

<sup>74</sup> Poinski M., "Technology is revolutionizing food, but how can it be explained to consumers?" Food Dive (September 20, 2021) available at <<https://www.fooddive.com/news/food-tech-explain-marketing/606401/>>

<sup>75</sup> Friedrich B., "Cultivated meat: Why GFI is embracing new language" Good Food Institute (September 2019) available at <<https://gfi.org.in/cultivated-meat-why-gfi-is-embracing-new-language/>>

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product, basic labelling principles should apply first where the product name is clear, precise, easy to understand, and not misleading to consumers.

## The Ideal Nomenclature

The industry currently uses a range of terms: “cultivated”, “cell-based”, “cultured”, “clean”, and “slaughter-free.” While some terms convey positive and generalisable traits of cultivated meat products, names like “lab-grown” or “clean meat” are less desirable, and in some cases, inaccurate. Cellular agriculture will not happen in a lab at a production scale, and therefore “lab-grown” is not factual. Terms like “clean meat” could reflect a bias for or against other meat products.<sup>76</sup> The ideal nomenclature would meet the criteria of neutrality and descriptiveness/differentiation (i.e., understandability) while optimising for consumer appeal.<sup>77</sup>

A recent study conducted by Rutgers University in the U.S.<sup>78</sup> evaluated seven terms including “cultured”, “cell-based”, “cultivated”, “produced using cellular aquaculture”, “grown directly from the cells of”, and “cultivated from the cells of” to determine which could serve as a ‘common or usual name’ for cultivated seafood products. The study indicated that “cell-based” is the terminology that created the greatest differentiation from conventional animal meat for consumers when it comes to seafood. Prior research and nomenclature testing conducted by the Good Food Institute and Mattson<sup>79</sup> (and as advised by Memphis Meats) found that, among 400 different names, the term “cultivated” rated more highly for a combination of differentiation and consumer appeal. It is important to note that this is an evolving landscape, and the names used may differ across geographies and for product types. Therefore, regulators must familiarise themselves with multiple names.

Another aspect of labelling to consider is religious and cultural certification, such as “halal” or “kosher.” Currently, there are no established religious guidelines, but they may be developed for companies looking to obtain voluntary compliances with cultural or religious standards. There are ongoing academic discussions globally on ways to cater to consumers who adhere to religious traditions. The criteria for halal certification may include (a) obtaining the cultivated meat through the stem cells of a *halal* animal that has followed the prescribed slaughter method and, (b) not using blood or serum during the cultivation process.<sup>80</sup>

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<sup>76</sup> Pelonis C.E, Rainer. N, Potter C., “Cell-Cultured Protein: Regulatory Considerations and Opportunities” Keller & Heckman (April 2021) <<https://www.khlaw.com/insights/cell-cultured-protein-regulatory-considerations-and-opportunities>>

<sup>77</sup> Ibid n57

<sup>78</sup> Hallman, W. K., & Hallman, W. K. “A comparison of cell-based and cell-cultured as appropriate common or usual names to label products made from the cells of fish” Journal of Food Science. (2021)

<sup>79</sup> GFI US Draft Project “Meat Cultivation: Embracing the Science of Nature” (January 2020) available at <<https://gfi.org/wp-content/uploads/2021/01/Jan-2020-GFI-Draft-Meat-Cultivation-Report-v9.pdf>>

<sup>80</sup> Hamdan, et al “Cultured meat in Islamic perspective” Journal of Religion and Health, 57(6), (2018) 2193-2206.

The guidance on the labelling of cultivated proteins could be present within a regulatory framework by taking into consideration the global best practices, cultural preferences, and industry suggestions. Clarity on the nomenclature requirements would help companies understand the regulatory specifications early on as they are preparing to present their pre-market approval applications, and reduce any potential ambiguities and inconsistencies in the future.

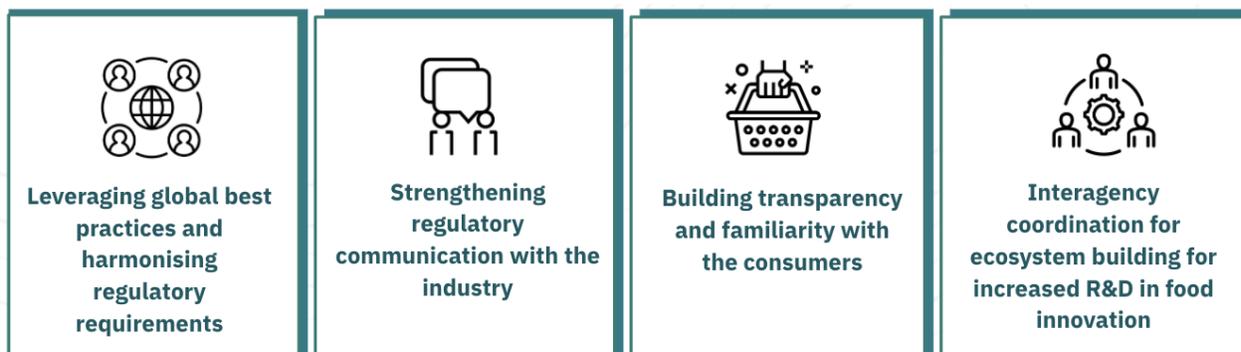
## Regulatory and Policy Considerations for Cultivated Meat in India

Existing food regulations governing meat, poultry, and fish typically address food safety in environments high in bacterial contamination and other sources of infectious disease, as well as concerns around safety for slaughterhouse workers. Because cultivated meat production occurs in a sterile environment and does not entail slaughter, the policy considerations underlying these laws and regulations may not necessarily apply to cultivated meat and should only be applied where appropriate.

The regulatory approval process for cultivated meat manufacturing and marketing should be clearly specified in line with global best practices. Similarly, aspects of safety testing, labelling, and inspections should be well established to reduce regulatory uncertainty.

### Policy and Regulatory Recommendations

The following are some considerations for regulators while developing a regulatory framework for cultivated meat and promoting the industry in India.



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## Leveraging Global Best Practices and Harmonising Regulatory Requirements

- Similar to Singapore’s regulatory framework, the primary emphasis should be on testing the end product as per standard toxicity and allergenicity requirements. The requirements should focus on toxicity and allergenicity tests to confirm its safety for consumption at the end of production. Food businesses should demonstrate that there are no food safety risks associated with different components of cultivated meat production including scaffolds, culture media, and cell lines. The final product should be checked for impurities and, if found, should not result in toxicity and allergenicity.
- It may be useful for the FSSAI to confirm if cultivated meat falls under the novel food category under the current<sup>81</sup> and proposed amendment regulation.<sup>82</sup> It is suggested that the definition of ‘Novel Food’ under current regulatory frameworks should include “*food from cell culture or tissue culture derived from animals*”, in addition to categories of foods derived from microorganisms, fungi, algae, and bacteria. This specificity would be helpful for entrepreneurs and signal receptiveness towards regulating emerging categories. Indian regulators may refer to regulatory frameworks on definitions, nomenclature, and regulatory processes laid down by the regulators in Singapore, the U.S., Australia and New Zealand, Canada, and Israel.
- The government may need to balance the promotion of innovation in the industry while also protecting the intellectual property rights of entrepreneurs, especially the ones that claim the first-mover advantage in a nascent industry,<sup>83</sup> similar to SFA’s efforts towards protection of trade secrets.
- We also encourage dialogue amongst regulators from various jurisdictions to promote an early regulatory alignment to harmonise regulations in the interest of international trade and investments.

## Strengthening Regulatory Communication with the Industry

- Government bodies, regulatory authorities, and cultivated meat manufacturers should, when applicable, openly release any comprehensive regulatory frameworks, requirements, or datasets they have established or generated. Increased transparency serves multiple purposes: it can boost consumer trust whilst informing cultivated meat manufacturers and others along the supply chain (including facility construction firms and

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<sup>81</sup> Ibid n 60

<sup>82</sup> Ibid n 61

<sup>83</sup> Treich N., “*Cultured meat: Promises and challenges*” *Environmental and Resource Economics*, (2021) 79(1), 33-61.

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suppliers of cell culture media, scaffolds, cultivators, and other equipment) of the unique requirements of cultivated meat manufacturing, which are expected to lie at the nexus of established food and biopharma regulatory guidelines.

- The timeframe for premarket approvals should be adequately laid down to allow regulators to review and assess all relevant information, while also ensuring that entrepreneurs are able to bring products to market without unreasonable delay. The regulator could engage food businesses early in the application process to discuss requirements and gaps in their application forms to provide timely feedback that could reduce approval timelines. This would be similar to the efforts by the SFA in Singapore in engaging with the industry.
- The regulator may engage with industry and scientific experts to examine how there may be product nuances and technological differences in the first few products. This is especially true for products that may be developed in the short run, which may be vastly different from the ones in the longer term. Many believe that the first few products on the market may be ‘hybrid’ combinations of plant-based and cultivated protein food products, which may require scientific understanding and a differentiated regulatory approach. Such efforts may be performed through cross-government department collaboration to conduct focus group discussions, similar to SFA and Enterprise Singapore’s collaboration.
- India’s thriving biopharmaceutical sector presents opportunities for accelerating cultivated meat’s path to market internationally, which may lead to multiple partnerships and joint ventures in the coming years for manufacturing facilities and licensing models for R&D. Even if local producers do not intend to market their products within India, these partnerships may necessitate the creation of a regulatory framework for local evaluation before exporting to other markets. Hence, regulatory bodies may additionally look at creating frameworks with a lens of ensuring the ease of doing business in and with India.

## **Building Transparency and Familiarity with the Consumers**

- Efforts toward consumer education will go a long way in establishing category awareness and greater transparency about safety and production processes.<sup>84</sup> The FSSAI’s ‘Social and Behavioural Change’ department may disseminate materials educating consumers about this category to create familiarity with the technology and address concerns. Additionally, partnerships with scientific and academic institutions, similar to efforts by the SFA in partnership with other institutions such as A\*STAR can help build public awareness about emerging categories such as smart protein from a scientific perspective.

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<sup>84</sup> Taneja A., “*Overview – Regulatory Issues Surrounding Cultivated Meat*” *Ikigai Law* (April 21, 2021) available at <<https://www.ikigailaw.com/overview-regulatory-issues-surrounding-cultivated-meat/>>

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- Consumer research is also a helpful tool to understand consumer behaviour while also educating consumers. The consumer research study conducted by the FSA in the U.K. was through their Behaviour and Perception research programme.

## **Public Investments and Interagency Coordination for Ecosystem Building and Increased R&D in Food Innovation**

- Apart from forming regulatory frameworks and achieving procedural clarity, government support plays a key role in advancing the sector through supportive policies. Recognition of alternative proteins like cultivated meat in national policy plans similar to Israel or China would encourage further innovation and stimulate research and development in these categories. Additionally, government support through public funding would be critical to advance the growth in science and technology and bring these products towards price parity.
- To drive down costs for consumers and to stimulate economic development more broadly, India needs to significantly invest in open-access research aimed at accelerating the progress of alternative proteins. Such funding can help close critical research gaps, which may be difficult for individual smaller entrepreneurs to achieve in the short term. This would spur significant entrepreneurial activity, create manufacturing jobs, and potentially elevate India's position to a global hub in manufacturing. This would in turn strengthen India's global economic competitiveness in this emerging market.
- Government participation in tasting events such as the ones conducted in Israel is symbolic of the government's recognition of cultivated meat as a key pillar of future-ready food systems and signals increasing consumer confidence towards smart proteins as a whole. Similar tasting events involving new consumers and policy-makers could be hosted in India during events such as the 'Startup India Innovation Week' held by the Department for Promotion of Industry and Internal Trade (DPIIT) by the Ministry of Commerce and Industry and could be an effective means of showcasing high-quality technological innovations in smart protein. This department in collaboration with bodies like the Agricultural and Processed Foods Export Development Authority (APEDA) could play an active role in conducting and facilitating events focused on food innovation where startups participate to showcase their smart protein products.
- The Ministry of Science and Technology could incentivise and facilitate consortia building between academia and the industry for joint research proposals that allow benefit-sharing among its participants. Israel, for example, has established a consortium that will focus on

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integrating artificial intelligence and genome editing, which will enable the industry to be at the forefront of such technology internationally.<sup>85</sup> Another example is the grant from the U.S. National Science Foundation for research and commercialization of cultivated meat, which has demonstrated the efficacy of such coalitions and has resulted in the development of promising technologies and value creation for its members.

## Conclusion

Significant developments in cultivated meat occurred over the past two years globally, with milestones such as regulatory approvals, commercial restaurant launches, increased public and private investments, tasting events, and advanced product developments from several entrepreneurs.<sup>86</sup> To keep pace with growing innovation and to future-proof our food system, regulatory frameworks must be flexible enough to be modified to accommodate positive changes. We may not be able to rely on transformative technologies to transform if they are held back by rigid regulatory frameworks.<sup>87</sup>

Cellular agriculture technology has the potential to enable the production of high-quality cultivated meat and seafood, and as with conventional food production, any risks can be managed effectively through the use of well-understood and established controls by responsible producers.

As many countries are leading the regulatory way in supporting emerging food technologies, it is an opportunity for India to utilise its vast resources and manufacturing capabilities to employ resources towards these emerging categories. Many nations now recognise alternative proteins, including cultivated meat, as one of the key elements in reaching food security and achieving climate goals. There is no better time for India to showcase its technology and manufacturing capabilities and commitment towards climate-friendly innovation.

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<sup>85</sup> Reich A., 'Genome editing, AI consortium approved by Israeli Innovation Authority', June 3, 2020 (The Jerusalem Post) <<https://www.jpost.com/health-science/genome-editing-ai-consortium-approved-by-israel-innovation-authority-630179>>

<sup>86</sup> For more information on the global industry landscape of cultivated meat, please refer to the "Good Food Institute's State of Industry Report on Cultivated Meat-2020" available here <<https://gfi.org/resource/cultivated-meat-eggs-and-dairy-state-of-the-industry-report/>>

<sup>87</sup> Bond C., "We Read the Public Comments on Cell-Cultured Meat Labeling So You Don't Have To" The Spoon (December 16, 2021) available at <<https://thespoon.tech/we-read-the-public-comments-on-cell-cultured-meat-labeling-so-you-dont-have-to/>>

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## About GFI India

Since our establishment in 2017, GFI India serves as the central thought leader and convening body in the space of plant-based, cultivated, and fermentation-based meat, eggs, and dairy that are collectively known as the “alternative protein” or “smart protein” sector.

With unique insight across the scientific, policy, industry, and investment landscapes, we are using the power of food innovation and markets to accelerate the transition of the world’s food system toward smart proteins. In building the sector from the ground up in India, we’re aiming to establish a model for its growth all across the developing world. The Good Food Institute India (GFI India) is part of an international network of nonprofits with partners in Brazil, Israel, U.S., Europe, and the Asia Pacific, on a mission to build a healthy, sustainable, and just global food system.