



Journal Homepage: -www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI:10.21474/IJAR01/11147
DOI URL: <http://dx.doi.org/10.21474/IJAR01/11147>



RESEARCH ARTICLE

UNRAVELLING THE REGULATORY ACCEPTANCE OF “IN- VITRO MEAT CULTURE”

Sristi Roy and Anushka Mandal

Students, Amity Law School, Amity University Kolkata, India.

Manuscript Info

Manuscript History

Received: 07 April 2020

Final Accepted: 10 May 2020

Published: June 2020

Key words: -

In-Vitro Meat Culture, Legal Regimes,
Government Policy

Abstract

The consumption of meat has been under strict scrutiny in the recent past. This phenomenon has affected the production and consumption of meat, globally. It is observed, the increasing demand for slaughtered-meat resulted in an increase in food borne illnesses, ecological problems, and factory farming. Therefore, this led to the technological evolution of the “In-vitro” meat culture. An expected increase in meat consumption has been proposed by several international actors and in several Government policies and thus there exists pressing need to devolve and understand the actual viability of the new process. This comparative research is limited to the existing and evolving legal regime of the United States and the EU. Hence, investment in in-vitro meat culture is cumulatively increasing. Recent reports of World Economic Forum emphasized that this innovation of Science and Technology in in-vitro meat culture shall result in a Fourth Industrial Revolution. TIFAC in India is working on the technology growth for in-vitro meat. The study shall give an insight into the legal regime concerning the production, trade, and consumption of cultured meat, and its effects in India. Further, this research draws a nexus with international instruments and policy, and its acceptance in the US and the EU. Through this study we have uncovered the glaring disparity in legalisation of the process in different parts of the world and have also tried to make relevant suggestions for India to break the chains of research and examine the culture through economic means.

Copy Right, IJAR, 2020.. All rights reserved.

Introduction:-

Objective:

To appreciate the need of novel and more sustainable methods of Food production. It is also aimed to understand and compare the global scenario of the research and development of Lab - grown meat or clean meat to further analyze the legal regime that governs or should govern the market of the product in the near future.

Scope:

We have limited our study to secondary information analysis and thus it extends to mainly India with comparison to the legal provisions having been implemented in the in the United Nations as well as the European Union.

Corresponding Author:- Sristi Roy

Address:- Students, Amity Law School, Amity University Kolkata, India.

Methodology: -

The paper reflects secondary, doctrinal research and the main methods relied upon and qualitative analysis of secondary data has been used to extrapolate the information gathered by our literary research. Moreover, this being a rather novel topic, we had to study the global trends and analyses future prospects best suited to implement the food goals of the Country and thus this area was dealt through using the Delphi methodology of analyzing trends.

Tools:

Research Journals, Observations of ongoing researches, Parliamentary Declarations, Surveys, Website articles, NGO Reports amongst other secondary sources. We have also used comparative analysis.

Outline

The paper firstly tries to analyse the theory of Lab-cultured meat and its relevance with animal rights protection and efficiency in attainment of basic sustainability goals of different nations. Second, it deals with the current scenario in the world order reflecting the acceptance, research and use of the novel product and last we appreciate the scope India has with the product in the recent future. Through the entire study, the researchers have tried to examine and outline the basic regulations needed for the production, consumption and marketing of the product.

In vitro meat culture**Origin and development**

Human lives are based upon exploitation, but with exploiting resources, we have to delve in the aspect of sustainability. It is our duty to put a stop to limitless exploitation of depleting resources or exploitation in violation of the basic fundamental of humanity. Back in the late 80s, Abraham Gazner took up the small initiative of using kerosene instead of Whale oil to put a stop to the inhumane trait of shooting whales. Over a century has passed and although many animal rights violative instances have been revoked, there still is a big lacuna in putting their rights before our needs. One of the main sustainability problems today is yet again related to animals. The United Nations reports that the Greenhouse gas emissions in animal agriculture is statistically more than the emission from locomotives. The practices of animal husbandry followed today is not only environmentally depletion but most importantly inefficient.¹ Livestock production is imposing a serious burden and threat to the environment in considering their present demand as a result of the increase in population. The industry linked with such products has become the largest user of the agricultural land which is ending up to huge climate change problems and draining out world resources. With that, the global demand for meat is seen to surpass the present producing method.² It is noticed that 18% of all greenhouse emissions are from these industries and held to monopolise most of the land in livestock farming.³ Considering the huge dependence and intense consumption on the meat industry, the solution has been found through lab culture or in-vitro cell producing meat. It is seen that producing this meat results in slaughtering fewer animals and also lowering the environmental costs that are associated with the raising and harvesting livestock.⁴ To develop appreciation for this, first, let us understand that lab culture (in-vitro cell = lab-cultured = cell based) meat means, producing meat from the cells that are extracted out from farm animals and culturing such stem cells by advanced tissue engineering techniques.⁵ It can also be termed as the application of synthetic process where through cell technology the product that resembles as traditional meat is produced and not the animal itself.⁶ The techniques involved in vitro meat is termed to be basic methodology where muscle tissues are cultured in liquid medium at large scale. By this process, myosatellite cells or muscles stem cells are substrate which helps in harvesting mature cells⁷ and proliferated a small amount of muscle cell to a large amount. After the

¹Paul Shapiro, Clean Meat, The clean energy of Food, (Jan 4, 2018)

²Cassandra Lee, What is In Vitro Meat?, McGill-office for Science and Society, (March 13, 2020, 12:45 PM), <https://www.mcgill.ca/oss/article/technology-health-and-nutrition/what-vitro-meat>

³Daphne Ewing-Chow, Is Cultured Meat The Answer To The World Meat Problem?, Food & Drink- Forbes (March 03, 2020, 2:00 PM), <https://www.forbes.com/sites/daphneewingchow/2019/06/20/is-cultured-meat-the-answer-to-the-worlds-meat-problem/#35cfd9614468>

⁴Carolyn Wilke, A new spin on a lab-grown meat, ScienceNewsforStudents, (March 19, 2020, 11:00 AM), <https://www.sciencenewsforstudents.org/article/new-spin-lab-grown-meat>

⁵Vol no. 12, Zuhair Fayaz Bhat, Sunil Kumar, Hina Fayaz, In vitro meat production: Challenges and Benefits over conventional meat production .2, (2015)

⁶Anonymus, Cell based meat, Food Standards Australia New Zealand, (March 13, 2020, 09:00 AM) <https://www.foodstandards.gov.au/consumer/generalissues/Pages/Cell-based-meat.aspx>

⁷Supra.5

muscle's tissues are accumulated, they are combined with fat cells and additives of flavour, texture, and colour to make it as similar to ordinary meat.⁸ Hence, with the newly proposed technique animal-free meat is feasible. To facilitate the emerging technology world's first cultured burger made up of cow muscle tissue produced by Maastricht University and funded by Mosha Meats in Netherlands⁹ and beef products in Israel by BioFood Systems using bovine embryonic stems.¹⁰ Therefore, leading nations like Israel, Japan, Netherlands where the government is supporting the companies who are in lab-cultured meat production and it is seen that efforts from their government while US is developing regulatory paperwork for regulating the cell meat production. Thus, it's portraying a good initiative for both the planet and people.¹¹ Before going to the topic let us discuss the needs for lab-cultured meat.

Requirements for lab-cultured meat:

1. Environmental impact: According to the UN FOOD and agricultural Organization (FAO)¹², it is stated that livestock agriculture is responsible for large extend to the emission of the world's total Greenhouse gases such as methane whose potential for global warming is more than 25 times of carbon dioxide. The notice by the United Nations Environment Programme (UNEP) reduce the emission of gases is required to avoid the impact of climate change by 2050.¹³ On the other hand resources inefficiency in terms of the land used for raising the livestock where 70% of the lands are used for livestock farming¹⁴ and usage of antibiotics potential restraints to convert the livestock into edible meat are highly inefficient. Also, taking into account the amount of water consumption is done for production purposes became a great deal raising ecological problems.¹⁵
2. Animal welfare: Tradition meat production is typically a harsh process regarding their process of raising, farming and animals are harmed and slaughtered. High demand for meat consumption often brings torture on them through the process of injecting hormonal injections for the fast growth of biomass. In presence of the standards provided still for proper welfare the process is still weak in regard to their well-being.¹⁶
3. Human Health: It is seen that human diseases are transmitted mostly through animals like flu, swine, and influenza. The reason behind such transmission is the usage of antibiotics injected on these animals to accelerate the growth of tissues in them. Such increase usage worsens these animal situations. Thus, it has become a great threat to human lives and future generation according to the World Health Organization (WHO).¹⁷
4. Considering the requirement of lab-grown meat in 2019, the World Economic Forum had made an intense discussion on the consumption of meat with an alternative source to increase the sustainability of human and meet sustainable goals.¹⁸ The discussion where on the emerging economy in the livestock sector to 2030 and beyond goals were set.¹⁹

⁸ Supra.3

⁹Pallab Ghosh Science, World's first lab grown burger is eaten in London, BBC News, (Aug 5, 2013), <https://www.bbc.com/news/science-environment-23576143>

¹⁰ Creating Sustainable & healthier world by 2050, Biofood Systems, (March 19, 2020, 04:00 PM),<https://www.biofood-systems.com/>

¹¹Chand Ahmed, No more slaughtering of animals for meat, BusinessLine, (April 25, 2019),<https://www.thehindubusinessline.com/news/science/no-more-slaughtering-of-animals-for-meat/article26943218.ece#>

¹²Agricultural's greenhouse gas emissions on the rise, Food and Agriculture Organization of the United Nation, (published- April 11, 2014, Rome) available at <http://www.fao.org/news/story/en/item/216137/icode/>

¹³Rorheim, A., Mannino, A., Baumann, T., and Caviola, L., Cultured Meat: An Ethical Alternative To Industrial Animal Farming, Policy paper by Sentience Politics, pg 1 (2016)

¹⁴Supra.8

¹⁵Supra.13

¹⁶ Prof Prabhat Ranjan, Achla Khanna, Prof Pawan K.Dha, Varun Deshpande, Dr ArunaTiwary and Aayushi Sharma, Cellular Agriculture The Future Of Food Cellular Agriculture The future food, Report by TIFAC (2018)

¹⁷ Id.16

¹⁸Yann Zopf, Saving Lives and the Planet: Balancing Diet with Alternative Proteins Can Cut Deaths by 5% and Emissions by 25%, World Economic Forum, press releases, (Jan 03, 2019) available at https://www.weforum.org/press/2019/01/saving-lives-and-the-planet-balancing-diet-with-alternative-proteins-can-cut-deaths-by-5-and-emissions-by-25#_msocom_2

¹⁹Meat: the Future series Options for the Livestock Sector in Developing and Emerging Economies to 2030 and Beyond, International Livestock Research Institute for the World Economic Forum (March 16, 2020, 05:00 PM) http://www3.weforum.org/docs/White_Paper_Livestock_Emerging%20Economies.pdf

Delphi Methodology of Research

This was developed in the late 1960s and has been used time and again for analysing future prospects of novel products and also been rapidly used to judge the viability of animal husbandry and plant agriculture. The success of this method is usually attributed to its anonymity. In the recent past, researchers have given a new scope to this method of research by using secondary data as input and maintaining similar anonymity. Our analysis is subject to the acceptance and promotion of consumption awareness of cultured meat in the future market. As for the current scenario, we have included the study of trade and other nascent business concerns reflecting ample interest in this phase by comparing the major players and further drawing a connection with that of the situation in India.

A Cross-Border Comparison

It is as early as 1971 that Russell Ross had developed in vitro cultivation of muscle fibre followed by the first patent which was filed in 1999 by Willem Van Ellen and with the advent of the 20th century, the environmental concerns were alarming and correspondingly NASA came up with its first research in this field. In the last 10 years, the culture has not only received moral appreciation but it has also vigorous growth in setting up hubs for research and development.

Global Scenario of Trade and Competition

Lab Cultured meat contributes solutions to the growing problem in the world but whether such meat can be marketable and traded worldwide has become the question of economy. It is seen that there is no existence of rules or regulations in context to trade or competitiveness in this topic.²⁰ However, after the world's first lab-cultured hamburger in 2013, the shift to the cellular meat community resulted in the growth of the start-up companies. The first company that holds the series of funding to this production to an amount of \$17m, was Memphis Meats in the US. Other than the US, Mosha Meat²¹ in the Netherlands was established. Israel made a strong implementation by supporting companies like Future meat Technologies²² and AlpaFarms.²³ Others like Integriculture²⁴ in Japan and Shiok Meats²⁵ in Singapore.²⁶ Therefore, these companies are key players in the global lab-grown meat market. However, as we know cell-cultured meat economy is in the nascent stage²⁷ due to the undefined framework to regulate it²⁸. The inadequate framework of trade acted as a barrier to the growth of the lab-grown market, hence, consumer-based surveys are conducted where segments have been made on types, applications, and geography regarding the growth of lab-grown meat.²⁹ In terms of the types, the market is divided into various livestock farming such as pork, beef, chicken, duck, and others. It is been analyzed that the market for beef meat through foodservice platforms holds a dominant position to the economy under lab-grown meat concerning other types. Even Compound Annual Growth Rate (CAGR) reported the growing competition and prevailing opportunities to gain major shares in the market have expanded the product portfolio through collaborations.³⁰

Institute of Chemical Technology (ICT) in India partner with The Good Food Institute started promoting the lab-grown meat sector through commercializing the research facility to establish a lab facility unit in Mumbai by this

²⁰Victor Tiberius, Jenny Borning and Sabrina Seeler, Setting the table for meat consumers: an international Delphi study on in vitro meat, *njp Science of Food*, Published by Beijing Technology and Business University (2019)

²¹The world's first meat centre, Moss Meat, Netherland, <https://www.mosameat.com>.

²²Ns Agricultural staff, R.Dharma, Future Meat Technologies Reinventing Agriculture, (Oct.11,2019) <https://www.future-meat.com>.

²³Aleph Farms, Lending the Slaughter free meat revolution for a healthier world, Israel, available at <https://www.aleph-farms.com>.

²⁴IntegriCulture INC. at Tokyo, <https://integriculture.jp/about/?locale=en>.

²⁵Shiok Meats seafood, reinvented – Singapore available at, <https://shiokmeats.com>.

²⁶Vol. 1, Neil Stephens and Marianne, Cellular agriculture in the UK: a review, Wellcome Open Research, (2020).

²⁷The Expresswire, Press release, Lab-grown Meat Market 2019 Industry Size by Global Major Companies Profile, Competitive Landscape and Key Regions 2026, Nov 12, 2019, <https://www.marketwatch.com/press-release/lab-grown-meat-market-2019-industry-size-by-global-major-companies-profile-competitive>.

²⁸Lab-grown Meat Market Size, Share and Industry Analysis By Type (Beef, Pork, Poultry, Seafood), Application (Food Retail, Food service Channels), and Regional Forecast 2019-2026, Fortune Business Insights, Report (2018), <https://www.fortunebusinessinsights.com/industry-reports/lab-grown-meat-market-100236>

²⁹Id.29

³⁰Surpa.28

year³¹ to become a part of the economic market of lab-cultured meat. It is also been reported India will become the hub for cell-grown meat globally.³²

Due to the lack in presence of International legislature regarding the economic market and trade of lab-grown meat, analysis using Delphi Methodology has been put forwards to the different Nation States for acknowledging the urgency with meat alternatives. This methodology is a cluster of questions put forward in different heads to understand the scenarios in the economy with merging expert advice. Market and Competition was one head of discussion the study made that several companies evolving in the worldwide competition to sell the meat in processing companies and intensify worldwide competition to this trade. As this methodology is used for small scale industry, regarding to the situation of cell-based meat in the global it is satisfactory.³³

International Regime Study Comparing U.S and Eu Framework Regulatory aspects of lab-cultured meat in US

The competence to grow meat without growing the entire animal has secured the imaginations and acquired the interest of a varied spectrum of people. The vision for cultured meat had already obtained the first patent in 1999 by trio Dutchmen.³⁴ With the growing concern on potential health and environmental benefits later evolved the methods for growing cultured in-vitro cell meat in 2005.³⁵ Therefore, to effect the emerging trend both the United States and the European Union have tried to proceed to anticipate the regulatory framework to give effect. The regulatory routeway for lab-cultured meat in the US and the EU differ in different analogies³⁶. The Delphi Methodology study is being made on the lab-cultured meat to examine these regulatory issues.³⁷

Regarding the US at first, there was an inappropriate substantial equivalence between livestock meat and cultured meat. The arguments were raised regarding the production, techniques, and suggestions followed upon whether or not cultured meat should comply with the additive provisions of the Food Drug Administration (FDA).³⁸

Regarding the US at first, there was an inappropriate substantial equivalence between livestock meat and cultured meat. The arguments were raised regarding the production, techniques, and suggestions followed upon whether or not cultured meat should comply with the additive provisions of the Food Drug Administration (FDA).³⁹ Later on 7th March 2019, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) announced an established framework for regulating the in vitro cell-based meat and poultry.⁴⁰ The formal agreement is based on the food processing, distribution and labelling under the set rules aforesaid by the FDA for safety checks.⁴¹ FDA is the sole advocate for cell-cultured meat and its regulations are termed to be safe and the best choice to regulate lab-cultured meat. The only risk factor which is pointed out in lab-cultured meat is the contamination of meat during the production stage. Therefore, such a risk-based approach will be regularised either by FDA or FSIS Hazard Analysis and Critical Control Point (HACCP) for product testing, record reviews, and verification.⁴² As the regulatory pathway is still in preliminary stage therefore, the important question of labelling the product still became the

³¹Preeti Kulkarni, You could get to eat 'clean' meat in India by next year, Economic Times, press release, (Feb 18, 2019) available at <https://economictimes.indiatimes.com/news/politics-and-nation/you-could-get-to-eat-green-meat-in-india-by-next-year/articleshow/68043360.cms?from=mdr>

³² Pearly Neo, Affordable lab grown meat: India looks to become global cell-based, (Mar. 16, 2020, 09:00 PM) <https://www.cleanmeats.com.au/ailink/1714/>

³³ Surpa.20

³⁴ Kooten William Jan wan, paptent application: WO9931222,999-06-24, <https://worldwide.espacenet.com/publicationDetails/biblio>.

³⁵ Pieter Edelman, Douglas McFarland, Vladimir and Jason Matheny, In Vitro-Cultured Meat Production (2005)

³⁶ Karin Verzijden, Regulatory pathways for clean meat in the EU and the US-differences & analogies, Food Health Legal legal and regulatory blog, (March 15, 2020, 07:00 PM), <http://foodhealthlegal.com/?p=985>

³⁷ Latia Mertez, In vitro meat: regulatory issues in the US and the EU, Lexology, Blog, (Dec. 12, 2018)

³⁸ Neil Stephens, Lucy Di Silvio, IlltudDUnsford, Marianne Ellis, and Abigail Glencross, Bringing cultured meat to market_ Technical, socio-political, and regulatory challenges in cellular agriculture, Trends in Food Science & Technology, (Aug 2018)

³⁹ Volume 78, Neil Stephens, Trends in Food science and Technology 15 (2018).

⁴⁰ Kelsey Piper, The lab - grown industry, regulatory insight, (Mar. 9, 2019, 8.00 A.M), <https://www.vox.com/future-perfect/2019/3/9/18255806/fda-usda-lab-grown-meat-cell-based-vegan-vegetarian>.

⁴¹ U.S Food and Drug Administration, USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry (Mar. 7, 2019).

⁴² Formal-Agreement-FSIS-FDA.

question of fact. USDA has the overriding effect of labelling authority than all the states. The unanswered question has been settled by USDA with Good Food Institution (GFI) as *clean meat*. Clean meat it describes that the real meat grown without animal slaughtered. Thus, the formal agreement provides a transparent path to market for the cultured meat product as stated by GFI.⁴³ The agreement also outlined the distinction between the legal authority of different regimes like the US and the EU in relation to the pre-market consultancies conducted by FDA to supervise the initial cell collection, cell growth and maintenance of cell banks, etc.⁴⁴ It ensures that the companies who are investing in the new technology should comply with FDA compliances to facilitate registration with Current Good Manufacturing Practices (CGMP) and other food legislations.⁴⁵ Each clean meat company needs to obtain the grant of inspection to conduct inspections of the cell-cultured.⁴⁶ Later FSIS harvest the cell to differentiate whether the cells harvested from livestock or poultry to get USDA mark of processing, labelling, and packaging in the human product.

The European View

The European parliament in its address dated 18th June, 2019, made it evident that the regulatory norms in the State do not follow upon the path of drawing 'Substantial Equivalence' with poultry meat. It does alternatively fulfil the definition of Food and the Commission further stated that, In vitro meat culture was within the scope of "Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae." and thus, reiterated the application of the norms reenacted under their Regulation on Novel Foods⁴⁷. The release also invoked the provisions of the Regulation regarding Genetically Modified Food⁴⁸ based upon the technical development which frustrates the ambit of the previous regulations. Before 2015, there is no requirement of pre-market consultancy for framing the EU Novel Foods framework. If a product is in doubtful nature then the consultation was to be taken from Member State level but in case of clean meat, such applications are to be filed before the European Commission in accordance with EFSA 'Guidance on the preparation and presentation of an authorisation of a novel food in the context of Regulation (EU) 2015/2283'⁴⁹. The company that is stepping to the production process has to register with Food Business Operator (FBO) and follow the regulations on hygiene.⁵⁰ The Government of EU refers to the general principles regarding the food law.⁵¹

The ambit of culture meat regulatory framework is not limited to research and introduction in the market and to take a positive step towards the goal of achieving a climate-smart system by using sustainable techniques of food growth and consumption. Thus, the framework includes aspects of operator's responsibility and also the consumer awareness and information. The next important Inspections are executed by Member State Level and there is no requirement for pre-approval of product label under EU framework and FBO has the sole responsibility to comply with labelling legislation as stated in Food Information to Consumers Regulation.

Thus, as Petiten⁵² had analysed, cultured meat is subject to the Novel Food Regulations but does not necessarily conform with the notion Genetically - Modified product in furtherance of which the above stated report clearly refers to adhering to the special regulation on Genetically Modified food products. Moreover, Neil Stephens raised a valid argument by stating that if cultured meat would be deemed to have animal origin, a plethora of organisations would get involved ranging from Animal Welfare to The Department for Environment and all other ancillary

⁴³Supra.,40.

⁴⁴KnobbeMartens,FDA & USDA, Enter into Formal Agreement to Jointly Regulate Cell-Culture,(Mar. 19,2019), <https://www.lexology.com/library/detail.aspx?g=aa1e8611-6c44-45b4-8910-3b0af93ed34a>

⁴⁵Karin Verzijden,Regulatory pathways for clean meat in the EU and the US, difference&analogies (Mar. 15, 2019), <http://foodhealthlegal.com/?p=985>.

⁴⁶id.,45.

⁴⁷ Regulation (EU) No.2015/2283 of 25 November 2015 on novel foods. OJ L327, 1, (2015).

⁴⁸ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 1. (2003).

⁴⁹ Regulation (EU) No.2015/2283 of 25 November 2015 on novel foods. OJ L327, 3&4, (2015).

⁵⁰ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004, laying down specific hygiene rules for food of animal origin. OJ L.1(2004).

⁵¹ Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1. (2002).

⁵² Volume 5.2 ,Petetin L. Frankenburgers, Risks and approval European. Journal of Risk Regulation. 168–186. (2014)

agencies. The entire debate on the regulatory and intellectual framework and rights surrounding this aspect is based upon the depth of research required for proving whether clean meat is cell based or genetically produced.

Comparison

Even after being two of the most developed economies in the current world scenario, it is evident that both have to bring about a positive reform in order to compete in the market with China or Netherlands amongst the eminent others.⁵³ These systems are in consonance in their main objective⁵⁴ to attain safe, wholesome and unadulterated food but contract on the procedures of obtaining the same because unlike the U.S, enforcement is nationalised in the E.U. Another disparity reveals itself in risk regulation, where the U.S already has the FDA or FSIS Hazard Analysis and Critical Control Point (HACCP) for product testing, record reviews, and verification but the Novel food guidelines reflect precautionary principle for the basis of risk regulation in the E.U.

The lacunae that shall be embraced for is lack of customer awareness in both platforms and also the spineless safety guidelines in these systems, furthermore the base of implementation of standards being steamed from International Law, it does not hold binding effect and thus in case of infringement or adverse impact, sanctioning would be preposterous.

Regulatory Framework In India

India as an economy has set up a goal of attaining “Health for all by 2030” and with the Delphi analysis of growth of population along with improving health and sanitation conditions, India is soon to face serious food scarcity and adverse environmental impact if it does not reflect the shift in its food cultivation and procurement. As discussed above, culturing meat is the most viable sustainability plan which also supports animal welfare and can be made cost effective in the long run. Thus, India sharing the same objective as a member to the United Nations is not far behind other major players in this market. It is important to also understand that this product, process, technology and governing regulations are in a rather nascent stage which has raised a keen appreciation of adding to their IP Portfolio and the Country is basing its goals on the theory of research and development being the sole guide to successful commercialisation. India is still in its stage of rapid research and experimentation but there have been no steps by the Government to set any regulatory provisions with regard to the standards, labelling or commercialisation of the product.

Research:

India is still in the research phase and it has been a while since the Indian Institutes of Technology (IIT) were reflecting a keen interest in cellular agriculture. Starting from Guwahati, Delhi, Kharagpur and even Hyderabad. But due to lack of funds it was limited to the theoretical research and limited development of the process or growth of the clean meat. Recently, there have emerged two centres for the full-fledged development of this lab culture with focus on future commercialisation.

Partnership between ICT and GFI

The Good Food Institute is a transnational non - governmental Organisation which focusses on the development of the plant and cell-based meat sector to attain environment friendly food goals mainly through research to develop products ready to market thus being the most significant party to the development of this meat. It has reflected interest in funding and aiding by setting up the 1st centre for research on lab culture in the world. With the Maharashtra Government’s nod to the partnership, India has proceeded into a new phase. The Government funded Institute of Chemical Technology joining hands with the GFI has aimed to achieve a running lab facility in the state of Maharashtra by 2020. According to the MOU signed between the 2 organisations there will be two laboratories set for this project. The first at Mumbai and the next and larger facility at Aurangabad which is the According to the panel discussion released by The Indian Express, the Dean of Research and Resource Department of the ICT exclaimed “This centre will pioneer innovation, allowing Indian businesses a chance to create products using our research.”⁵⁵ The main source of funds can be inferred both entrepreneurship and charity. It is necessary that there is

⁵³Matt Ball, Closer to your table, The Good Food Institute, Press release, (Mar. 8,2019),<https://www.gfi.org/closer-to-your-table-usda-and-fda-reach-cell>.

⁵⁴Point. 4.B(3) of the Formal Agreement.

⁵⁵Prateek Kulkarni,ICT has joined hands with The Good Food Institute to establish a lab facility in Mumbai by 2020. (Feb 18, 2019, 02.57 PM)<https://economictimes.indiatimes.com/news/politics-and-nation>.

a private-public partnership in investment just as same as that in research. As per The Hindu, The Managing Director of GFI India ensured that the second phase of the project at Jalna is a greenfield project and will provide state-of-the-art facilities for cell culturing and endow research fellowships in the various technology areas of cellular agriculture, including cell culture media, cell line isolation, scaffolding, and bioreactor design.⁵⁶

Centre for Cellular and Molecular Biology, Hyderabad

The Indian Government, Department of Biotechnology, has backed this project with a grant of Rs. 4.6 Crores. This project is a collaboration between CCMB and National Research Centre for Meat, which also includes, GFI. Moreover, this project falls in line with the object sought to achieve under the agreement of CCMB with the Humane Society International India.

Start-up

Clean meat start-up was the first Indian enterprise to procure a place in the global market for the development and marketing of Cultured meat. In 2018, the pitch was selected and funded by the Pro-veg Incubator, Berlin and the Glasswall Syndicate. The Enterprise further set up a lab in India in the Jawaharlal Nehru campus and aims to launch the most cost-effective environment friendly.

Another private Enterprise reflecting its interest in this field is Ahimsa Food, the first company to go into 'Mock Meat' production in the country.

Framework:

The Delphi for the Framework suggests that it has to be analysed according to the ingredients being used in the agriculture because each step would invoke specific certifications and fall under different local authorities for testing, labelling, consumer awareness and marketing strategies. Once all the authorities and provisions are outlined, the Government may take initiation for drafting specific provisions dealing with the novel practices to untangle the system.

As we have dealt, according to the cross - border comparison, not all countries follow substantial relevance and neither is this product invoking provisions of genetically modified food Regulations unless under exceptional circumstances but all the countries that introduced the culture do label it as Food. The fallacy is that a food product has to have promoter and terminator elements of GM Ingredients or contain deoxyribonucleic acid which is analysed through the PCR test whereas the genetics are being implanted through cells in case of Cultured meat products. This is a debatable topic and we have to wait for further research to get the anticipated response.

According to the statements made by the Union Minister, Ministry of Health and Family Welfare, in the Lok Sabha⁵⁷, cultured meat if proven to be genetically modified would have to be approved by the Genetic Engineering Appraisal Committee and also the FASSAI⁵⁸ and also be subject to the guidelines of FASSAI for the manufacture and import under the Food Safety and Standards Act⁵⁹, 2006 and the comments of the Dept. of Animal Husbandry is needed to be sought.⁶⁰ The recent developments in this field has been limited to plant based products and varieties and thus we lack both structure and experience in this particular food theory.

The Country needs to step into the market with the intent of setting up safety, labelling and nutrient checking authorities instead of being limited to the research.

Conclusion:-

Slaughtering of animals has been a controversial topic in considering the alternatives of meat. All the nations of the world must increase the awareness about lab-cultured meat and reduce the animal killing to reach the goals of

⁵⁶Supra at 39

⁵⁷Lok Sabha Q.117 (Feb 9, 2018)

⁵⁸Minutes of 134th meeting of GEAC, Agenda item number 6(Mar.21,2018)..

⁵⁹Section 22, FSS Act, (2006).

⁶⁰Minutes of 132nd meeting of GEAC, Agenda item number 8. (Apr. 12, 2017)

Minutes of 134th meeting of GEAC dated 21 March 2018: Agenda item number 6.

sustainable development, animal welfare. It is also important to understand the merits of lab-cultured meat to make a healthy living of humans as well as animals.

We suggest a viable regulatory framework for both land and external. Firstly, in context to the external laws must be more transparent regarding the trade and commerce for lab-cultured meat which needs to be abiding by all Nations to regulate the World Economy because in general, every country are supporting to the start-up for lab-cultured meat but there are no norms regarding the trade, competition, and market. Secondly, in India, there shall be an independent body set up under the Food Safety Act to assess the standards of such scientifically developed food products and other novel products whose ingredient consumption safety is unclear. Secondly, the board for approval should consist of researchers who have helped in the development of the product to ascertain safety. The labeling of the products shall also be handled by such Authority and most importantly, our Delphi reflects that the success of this stream will only be possible if the general mass is aware of the benefits of the food and does not neglect the scope of this market for superficial reasons of it not being natural. It is not only important to convey it to the customers that it is safe for use if not better for health but also the grave need of shifting to an efficient and more sustainable system of growing food for consumption.

It is also important for our Government to understand the essence of securing a patent upon both the process and product which promotes higher safety standards than the other competitors in the market. The market is new and every single Nation-State is on the lookout for an IP Portfolio and ensuring the IP Rights in Novel food is the most important precondition to exploit a decent market share as and when it hits the market for consumption.