Ann. Anim. Sci., Vol. 23, No. 4 (2023) 927–938 *DOI : 10.2478/aoas-2022-0092*

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CELL-BASED MEAT LABELING – CURRENT WORLDWIDE LEGISLATION STATUS – A REVIEW

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Abstract

A growing interest has been noted among both industry operatives and consumers in cell-based meat (CBM), as visible in the increasing investment into this technology by major food industry corporations. However, in almost all countries worldwide, there is a lack of clear legislation with regard to the labeling of such products. The aim of the article is to collect and review current legal regulations concerning the international approval and labeling of these types of products. In the manuscript, we review and analyze the legal situation of CBM and its labeling in countries from 4 different continents (EU members, the UK, the USA, Canada, Australia and New Zealand, Japan, Singapore and Israel). Aside from Singapore, no other country has approved CBM for placement on the market. The US has reached an agreement and established regulatory frameworks on CBM matters, where both the USDA and the FDA will be the control institutions. Within the European Union, CBM products will be evaluated under the Novel Food Regulation. The most anticipated process in other countries is the evaluation of CBM under the legislation on novel foods and subsequent amendments. Since local laws are still being developed, special care should be taken by the policymakers to avoid implementing local laws which could cause a negative approach to the technology by the consumers.

Key words: cell-based meat, legislation, labeling, food law

According to current statistics and forecasts, the world will have to feed up to 10 billion people by 2050 and produce twice as much protein-rich food as it does today. Meat is currently a common source of easy digestible complete protein, as it contains all essential amino acids. On the other hand, according to current estimates, conventional methods of meat production are unsustainable (Ong et al., 2020). Current large-scale farming methods are associated with public health complications, environmental degradation and animal welfare issues. As far as human health is concerned, the animal industry is associated with food-borne and diet-related diseases, as well as growing antibiotic resistance (ECDC et al., 2015; Thumbi et al., 2015; Smit and Heederik, 2017; Heredia and García, 2018; Rubio et al., 2020; Pokharel et al., 2020). Livestock production, to the extent visible today, contributes to the burden on the environment, in particular, by producing greenhouse gases and utilizing excessive amounts of land or water (Hilborn et al., 2018; Clark et al., 2019; Dopelt et al., 2019). It is estimated that up to 14% of global greenhouse gas emissions come from livestock farming (Rubio et al., 2020; The Regulatory Institute, 2020). Therefore, today we are witnessing a trend in the development and marketing of alternative sources of protein and food from them such as plant-based meat substitutes, cell-based meat (CBM) as well as insects as sources of protein and microorganisms (Stephens et al., 2018; Grossmann and Weiss, 2021). It is the production of cellular meat that seems to be a suitable solution to these problems. According to various studies, as much as 65.3% of respondents would be willing to use this technology, while 31.5% would eat cultured meat as replacement for those traditional (Wilks and Phillips, 2017). CBM consists of real muscle fibers unlike meat analogues of plant origin. CBM is produced by the *in vitro* culturing of animal cells, where they are fed a mixture of nutrients and growth factors causing them to proliferate and differentiate into a final product (Choudhury et al., 2020). CBM production process begins by obtaining and storing stem cells from an animal. These cells are then cultured in bioreactors during a process similar to that occurring in the animal's body. The cells are fed a culture medium rich in essential nutrients (amino acids, glucose, vitamins, inorganic salts, proteins and other growth fac-

tors). Changes in the composition of the medium, often in tandem with stimuli from the scaffold structure, trigger immature cells to differentiate into the skeletal muscles, fat and connective tissues that make up the flesh. The differentiated cells are then harvested, prepared and packaged into final products (Howie, 2016). CBM offers many advantages compared to conventionally produced sheep, beef, pork and poultry, while emissions are lower by 78–96%, land use by 82–96% and water consumption is reduced by 7–45% (Stephens et al., 2018; Chriki and Hocquette, 2020). There are also benefits in terms of contamination risk by microorganisms and related foodborne illnesses, as CBMs are produced in sterile conditions because CBMs do not come into contact with the risk of contamination from the gut, skin, slaughterhouse environment, etc., as in the case of carcass processing (Stephens et al., 2018; Chriki and Hocquette, 2020; Rubio et al., 2020).

Major changes on the meat market and the potential to increase the demand for meat substitutes are an opportunity for startups and innovators, but the market share of such alternatives still remains low (Gravely and Fraser, 2018). However, the question relates to the legislative side of the CBM, that is, what regulatory framework the CBM will be subject to or what kind of food can be considered as CBM and what information should be provided on the label for the final consumer? The aim of this paper is to summarize the current legislation on labeling of CBM products present in different countries on 4 different continents. The countries included in this review have expressed interest in the production of CBM products or have already started to market such products. This in-depth analysis of the existing legislation on the labeling of products containing CBM allows clarifying the current legal status and availability of these types of products on the selected markets and forming conclusions as well as guidelines for the industry stakeholders and policymakers in regard to labeling CMB, which is a secondary objective of this paper.

Current cultured meat regulations around the world

The rapid onset of "cell-cultured meat" as a new method of producing edible protein gives rise to numerous issues, not only those technological, but also social and economic ones. These, in turn, spur legal (especially regulatory) challenges (Stephens et al., 2018). Under practical discussion is actually the novel technology used for obtaining an edible product that has identical or indiscernible properties as animal meat (Kamalapuram et al., 2021). However, "indiscernible" does not necessarily mean "identical". This philosophical issue of identifying "indiscernible", has remained significant for a strictly practical reason – this being the legal status of cultivated meat in particular legal systems. Now, two main approaches seem to arise.

The first of these approaches assumes that cultivated meat is a type of meat; hence, any and all regulations concerning meat should apply to it – considering potential – mostly technical changes that the existing statutory law would require. The second approach involves treating cultivated meat as a *sui generis* category of food products. This, in turn, means that, either: a) cell-based meat must be subjected to the regulations dealing with certain other, already-existing categories of products, or b) a completely new legal framework must be created to cover the production and distribution of cell-based meat. A separate issue is whether to impose a set of specific regulations pertaining to genetically-modified foods (bioengineered foods) on the production and distribution of cultivated meat – in this category of products demonstrating similarities to cultivated meat lies also being of anthropogenic origin.

European Union law

The basis for further considerations must be examination of how the various legal systems understand the notion of "meat" and whether, in light of those definitions, cultivated meat can be deemed a meat product. Currently, the food law in the European Union member states is closely related to European regulations, which, in turn, increasingly unifies food legislation in the EU. The basic act within this scope is Regulation (EC) No. 178/2002, which creates a framework for European food law. It is, however, a general act that does not contain any answers to the question of admissibility regarding cultivated meat or requirements for its marketing. The regulation has not attempted to define the notion of "meat". More relevant to this article will be an analysis of European food labeling and marking law, including the Regulation No. 1169/2011, which, in turn, as far as the definition of meat is concerned, refers to Regulation No. 853/2004 of the European Parliament and the Council. This latter Regulation has remained a centerpiece of European legislation regarding meat.

Meat – as defined in Annex I of Regulation No. 853/2004 – means "edible parts of the animals referred to in points 1.2 to 1.8, including blood". This is simple to understand in the context of cultivated meat, clearly excluding it from the definition of meat. Two further definitions describing "meat products" according to Regulation (EC) No. 853/2004, Annex I, point 7.1 and "meat preparations" according to Regulation (EC) No. 853/2004, Annex I, point 1.15 also render it impossible to classify cell-based meat within any of following categories. Meat products are defined according to mentioned Regulation as to cover "processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat". "Meat preparations" encompass "fresh meat, including that which has been reduced to fragments, having foodstuffs, seasonings or additives, or which has undergone processes insufficient to modify the internal muscle fiber structure, thus, eliminating the characteristics of fresh meat".

As undoubtedly follows from the above, in light of the definitions applicable in current European law, it is impossible to consider cultivated meat as a product belonging to the category of meat. Each of these definitions treats meat as a product of animal origin (excluding fish or animals other than those "warm-blooded"). Although there are certain existing arguments stating that cultured meat is indeed a product of animal origin due to the fact that it is derived from an animal product (Sachs and Kettenmann, 2019; Stephens et al., 2018), the common opinion of the EU law and practice is that cultivated meat does not fall under the definition of meat.

A vital part of food law is legislation governing the provision of food information (labeling, presenting and advertising food) (Martini and Menozzi, 2021). The remarks above must be read within the context of Regulation No. 1169/2011. The Regulation lays down the basic objectives, principles and requirements for the provision of food information, as well as the grounds for liability regarding infringement of the above. It has replaced Directive No. 2000/13/EC as well as several other pieces of legislation regulating food labeling and the modified approach towards it, with the primary aim of food labeling legislation being consumer protection. The Regulation defines "food information" as that concerning food and made available to the final consumer by means of a label, other accompanying material or any other means including modern technology tools or verbal communication. As per Article 7 of Regulation No. 1169/2011, food information, advertising and presentation shall not be misleading (section 1 elaborates on that in detail) and must be accurate, clear and easy to understand for the consumer (section 2). The Regulation divides food information into mandatory (Chapter 4) and voluntary (Chapter 5). Among mandatory information, Article 9(1) (a-b) covers the name of the food as well as the list of ingredients. A food business operator, defined in Regulation (EC) No. 178/2002, is strictly limited in its ability to establish the name of a food. In Article 17(1), it is stated that the name of the food shall be its legal name. In the absence of such a name, the name of the food shall be its customary name, or, if there is no customary name or the customary one is not used, a descriptive name of the food shall be provided. The list of ingredients, in turn, must include all components of the food, in descending order of weight, as recorded at the time of their use in the manufacturing of the food. As "meat" is defined in EU legislation, any and all meat products must use the word "meat" (Article 17(1)) and, correspondingly, due to the ban on misleading information – foods that do not fall within the definition of meat (or, obviously, the ingredients of which do not fit into the definition), may not be labeled as meat.

The above does not mean, however, that EU law excludes any space for cultivated meat. In light of binding legislation, cell-based meat is included in the definition of "novel food" and, as a result, is subject to regulations concerning novel food (itself, an umbrella term). These regulations have recently been changed by Regulation (EC) No. 2015/2283 entered into force in January 2018. It has repealed and replaced Regulation (EC) No. 258/97 and No. 1852/2001.

Article 3(2) of Regulation (EC) No. 2015/2283 defines novel foods as "any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories: (...) (vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae". In light of the wording of this act, there is no doubt that cultivated meat falls into the category of novel foods. This provides the possibility for significantly easier access to its introduction on the market – and this was also the aim of the EU legislator. Additionally, Commission Implementing Regulation (EU) No. 2017/2470 establishes a Union list of novel foods, which is updated with the approval of each novel food and actually indicates novel foods that are approved for placement on the EU market. CBM is currently not registered on the Union list of novel foods or the relevant application.

The regulation of cultivated meat was also the subject of a parliamentary question from 18 April 2019 (European Parliament, 2019 b). In response, it was pointed out that the innovation of *in vitro* cultured meat was already identified in 2018 in a report created for the EC as "an important pathway to achieving the Commission's Food 2030 Initiative, to deliver a climate-smart and sustainable food system for a healthy Europe" (European Parliament, 2019 a). The above-mentioned Food 2030 Initiative adopted as one of its priorities, for health and climate reasons, the reduction of the consumption of "traditional meat"; the "*in vitro* lab meat" was directly named as one of "alternative proteins sources in our daily diets" (European Commission, 2018).

Finally, a vital piece of European legislation, namely the Commission Implementing Regulation (EU) No. 2018/456, has been adopted. It lays down various procedural steps comprising the consultation process, the aim of which is to determine whether cell-based meat falls within the scope of the Novel Food Regulation. If a food business operator (FBO) desires to place its novel food on the market in more than one member state, an application for authorization to sell novel foods will be sent to only one of the member states. Following the adoption of a conclusion on a certain food item's status as a novel food, the Commission shall publish such a conclusion on its website (ec.europa.eu). A request for the consultation process by FBO is not mandatory according to Regulation (EC) No. 2015/2283, however, it is highly recommended according to Point 3 in Preamble of the Commission Implementing Regulation (EU) No. 2018/456, where is stated that: "In order to determine the novel food status of a particular food, a consultation request should be submitted. The Member States should verify the validity of such requests". Further on, the FBO shall

send an application directly to the EC for authorization to place and sell novel foods on the EU market. The Commission Implementing Regulation (EU) No. 2017/2469 lays down rules regarding the administrative and scientific requirements of the application. The European Food Safety Authority (EFSA) will then issue its recommendation after evaluation, of course, if EFSA is requested for such an opinion from EC. This opinion must provide the following information:

- the identity of the novel food,
- assessment of the production process,
- compositional data,
- specifications,
- the history of use of the novel food and/or its source,
- the proposed uses and use levels as well as anticipated intake,
- absorption, distribution, metabolism and excretion (ADME),
- nutritional information,
- toxicological information,
- allergenicity,
- overall risk assessment for the novel food under the proposed uses and use levels, highlighting uncertainties as well as limitations where relevant,
- when the dietary exposure exceeds the health-based guidance value identified in the overall risk assessment, the dietary exposure assessment of the novel food shall be detailed, providing the contribution to the total exposure of each food category or foodstuff for which the use is authorized or has been requested,
- conclusions.

Generally, the EFSA is a European authority providing scientific opinions in regard to food safety based on risk analysis of the EC, based on which the EC is able to make decisions. The EFSA has issued guidance, directed to FBOs, facilitating the preparation and submission of applications for novel food status. This is a document called "Guidance on the preparation and presentation of an application for authorization of a novel food in the context of Regulation (EU) No. 2015/2283" (Turck et al., 2016). Applications submitted beginning 27 March 2021 are subject to the requirements of the new Commission Implementing Regulation (EU) No. 2020/1772, which amends Implementing Regulation No. 2017/2469. The legislation has been updated due to changes in several regulations to enhance the transparency and sustainability of EU risk assessment in all areas of the food chain, where EFSA provides scientific risk assessment. The changes in question are set out in Article 1 of that Regulation. Accordingly, the EFSA has issued a guideline called "Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) No. 2015/2283". In the guidance, the procedure and timetable are described for processing applications, the possibilities for interacting with the EFSA and the support initiatives available in the pre-application phase until the adoption and publication of an EFSA scientific opinion (EFSA, 2021). Following evaluation by the EFSA and the publication of its opinion, the Commission shall submit a draft implementing an act to the Standing Committee on Plants, Animals, Food and Feed, authorizing the placement of the novel food on the market and updating the Union list. After a positive vote by the committee and publication by the Commission, the novel food can be legally placed on the EU market. Subsequently, member states carry out food safety supervision through their official authorities and inform each other through the Rapid Alert System for Food and Feed (RASFF) if hazards are identified. The Commission may also, in accordance with Chapter IV, Article 24 of Regulation (EU) No. 2015/2283, for reasons related to safety and consumer protection, considering the opinion of EFSA, lay down requirements for post-market monitoring (PMM) of a specific novel food. Such requirements may include identification of the FBOs in question. The application of the PMM strategy in the case of novel foods is particularly important, although not currently mandatory. The Commission, however, has the legal option to require a PMM be in accordance with the above-mentioned regulation on novel foods. In principle, the PMM is based on the specific attention of regulatory authorities paid to specific foods, in this case new foods and FBOs who place the given foods on the market. The monitoring is focused on the actual intake of the new food and whether the intake is within the expected range, also monitoring if there are any unexpected effects in relation to the consumer (Hepburn et al., 2008). Currently, a similar strategy to PMM is applied within observing, mainly in the case of plants from Genetically Modified Organisms (GMO), following the "Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants" (EFSA, 2011; ADAS, 2015).

The whole procedure, principles and the indispensable role of EFSA with regard to novel foods are clearly based on the EU principles of consumer protection and food safety in the EU, which can already be found in the consolidated texts of the Treaty on European Union and the Treaty on the Functioning of the European Union (2016/C 202/01), followed by Regulation (EC) No. 178/2002 of the European Parliament and of the Council, as well as other regulations based on it.

Concerning the information mentioned in this section above, cultivated meat can potentially be introduced in the EU under the current legal framework. Moreover, this would be in line with and greatly facilitate the achievement of the stated objectives of European food policy. For economic reasons, however, this will probably not happen as quickly as is sometimes claimed (Foote, 2020), since the production of CBM, due to its nature, is significantly more expensive compared to conventional meat. In a study by Garrisson et al. (2022), the wholesale cost was estimated after considering all factors and assuming major technological advances for cell culture medium at $63 per kilogram, which is still greatly more expensive compared to conventional meat. The spread of this type

of product will certainly also necessitate a clarification of the regulations governing it.

Singapore

EU legislators can undoubtedly draw inspiration from other jurisdictions which have already successfully introduced cultured meat to the market, having prepared legal frameworks for this. The first (and so far only) place in the world where cultured meat has been formally authorized and introduced to the market is Singapore. There, on 3 December 2020, the Singapore Food Agency (SFA) allowed the sale of cultured chicken bites, produced by the Eat Just Californian start-up (Tan, 2020). The SFA confirmed that the product in question met all safety and quality requirements of standard poultry meat, including high protein content, relatively high content of monounsaturated fatty acids and a significantly purer microbiological content compared to conventional meat (CellAgri, 2020). Earlier in 2019, the SFA organized a regulatory forum to discuss challenges and solutions in the safety assessment of novel foods (Leck and Jun, 2021), and in November 2019, it published a guideline containing requirements for novel food registration: "Requirements for the Safety Assessment of Novel Foods" (SFA, 2021).

This short but succinct document, subsequently revised in December of 2021, is intended by Singapore's health authorities to be one of the bases for marketing new meat substitutes referred to as "alternative proteins". In this regard, the Singaporean authorities treat cultivated meat analogously to its plant-based meat and impose requirements for labeling such products as "cultured" (SFA, 2022). Thus, similar to the current European regulation, cultivated meat in Singapore is not considered a meat product.

"Requirements..." provide a definition of novel foods, similar to the European one (pt. 3), on the basis that it is "foods and food ingredients that do not have a history of safe use". In the document, three distinct categories of novel foods are distinguished, among them cultured meat ("novel foods and food ingredients in general", "novel foods that are chemically identical to naturally-occurring substances but produced by unconventional processes", "cultured meat" – pts. 12–13). In pt. 12 of the document, cultured meat is defined by describing the production process: "Cultured meat refers to meat developed from animal cell culture. The process to produce cultured meat involves growing the selected cell lines (or stem cells) in a bioreactor. The cells are grown in a suitable growth media, and subsequently, onto a 'scaffold' to produce products resembling meat muscle". At the same time, information to be submitted for the safety assessment of cultured meat is specified in pt. 13.

The SFA also formed an expert working group called the Novel Food Safety Expert Working Group in March 2020 to provide scientific advice. It is chaired by the Head of the Singapore's Centre of Regulatory Excellence, and comprises experts in food toxicology, bioinformatics, nutrition, epidemiology, public health policy, food science and food technology. This is an example of building on the expert approach to cultured meat while, at the same time, enabling the quality and safety of subsequent cultured meat products to be tested and, arguably, quickly approved.

The USA

Due to the growing popularity of cell-based meat products attaining serious levels of market popularity in the future, some states of the USA have tried to lay down relevant regulatory frameworks. Some of them could even impede the cell-based meat products and their market success.

The Midwestern state of Missouri has recently enacted the first legislation in the United States requiring that "cell-based meat" be labeled as such; the original "Missouri Meat Advertising Law" was originally passed in 1985. Its intention was to combat the misleading or deceiving advertising of meat. The law, however, had been drafted long before the biotechnological development made the controversies pertaining to the differentiation between meat products derived from slaughtered animals and those produced with cell-culturing methods. The law was amended in August 2018, with the intention to "meat" (proper) being defined as something "derived from harvested production livestock or poultry" (MO Rev. Stat. §265.494(7) (2019)). This legislation has been armed with criminal measures for so-called mislabeling, i.e. selling cell-based meat as "meat". Violators are subject to up to one-year imprisonment and a fine up to $1,000. In support of the amendments, the Missouri Department of Agriculture (MDA) argued that the legislation shall "(…) promote transparency for consumers while balancing that with common sense to minimize the market disruptions for existing products" (Tai, 2020). In order to escape penalties for misrepresentation, cell-cultured products must be sold in a manner including a prominent statement on the front of the package, immediately before or after the product name, noting that the product is "lab-grown", "lab-created" or a "comparable qualifier".

Other US states are either heavily investing in pursuing similar regulatory action or have already done so. In Nebraska, a bill "restricting insect-based, plant-based or lab-grown food from being labeled as 'meat'", was introduced in the legislature (Legis. B. 14, 106th Leg., 1st Sess. (NE 2019)). In it, meat has been defined as to "mean any edible portion of any livestock or poultry carcass or part thereof and does not include lab-grown or insect or plant-based food products". As it can be seen, not only did the state lawmaker decide to define meat as a portion of an animal, but also directly stated that cell-based meat may not fall under this definition. A similar piece of proposed legislation was introduced in Wyoming (Enrolled Act 48, 65th Leg., Gen. Sess. (WY 2019)), requiring all cell-cultured products to be labeled with information about the foodstuff containing cell-cultured

products. Similarly, Virginia (VA. Code Ann. §3.2-5400 (2019)) amended the state legislation on misbranding of food items as to state that any product made from materials other than those "made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine or goats", and intended to be sold as "meat", be labeled merely as "imitations". Similar legislation has been passed in Mississippi, clarifying that "a food product that contains cultured animal tissue produced from animal cell cultures outside of the organism from which it is derived shall not be labeled as meat or meat food products" (S.B. 2922, 2019 Leg., Reg. Sess. (MS. 2019)). This provision is coupled with an administrative remedial measure – the relevant state commissioner may "direct that [the use of a product as a food] be withheld unless the marking, labeling or container is modified in such manner as s/he may prescribe so that it will not be false or misleading". Laws akin to those described above have also been passed in Arkansas (Act 501, 92d Ark. Gen. Assemb., Reg. Sess. (AR. 2019)) and Wisconsin (S.B. 463, 2019 WI. Leg., Gen. Sess. (WI. 2019)), although the Wisconsin bill is more concentrated on restricting the mislabeling of plant-based "dairy" products, probably due to the fact that Wisconsin is a large dairy producer.

The US federal law touches upon issues of meat and meat products in a manner very similar to European law. The Federal Meat Inspection Act (FMIA) fails to address the need for a definition of "meat" as a notion, nonetheless, a definition of "meat food product" is featured – which is understood as "any article capable for use as human food which is made wholly or in substantial part from meat or other portions of the carcass of any cattle, sheep, swine or goat" (21 U.S.C., s. 601(j)). At the same time, "prepared" meat is defined as a product that has been "slaughtered, canned, salted, rendered, boned, cut up or otherwise manufactured or processed". As it can be noted, cell-based meat may not be named a meat product according to federal law. However, it has been demonstrated that cultivated meat could possibly be marketed as "prepared meat" according to this law – due to the definition including products "otherwise manufactured or processed" (Sachs and Kettenmann, 2019). Federal law penalizes the misbranding of food products, misbranding being understood as "labeling [that] is false or misleading in any particular manner" (21 U.S.C., s. 601(n)(1)). The Food Safety Inspection Service under the US Department of Agriculture (USDA-FSIS) has passed its own regulations, rendering the general rules more precisely and defining meat as "part of the muscle of any cattle, sheep, swine or goats which is skeletal or which is found in the tongue, diaphragm, heart or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing" (9 CFR 301.2).

In November 2018, the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) issued a joint statement, in which they provided information on their plans, stating that "both the USDA and the FDA should jointly oversee the production of cell-cultured food products derived from livestock and poultry". The agreement was concluded in March 2019, although the technical details regarding the framework of the parties' future co-operation was still refined at that time (FDA, 2019). According to the agreement, the FDA is authorized to supervise cell collection, cell banking, cell growth and differentiation. The supervising duties shall switch from the FDA to the USDA at the stage of cell harvesting. The USDA will be responsible for controlling the production and labeling human food products derived from the cells of livestock and poultry (Table 1).

Table 1. Division of USDA and FDA competencies in CBM matters

Institution	Tasks / competencies
USDA-FSIS	1) Participation in FDA oversight and control of FDA information on the suitability of harvested cells for meat product production. 2) Requiring the relevant facilities to obtain inspection permits. 3) Inspection activity of equipment, physical and hygienic control of products, control of HACCP compliance, product analysis. 4) Assessment and verification of product labeling, possible development of safety requirements and product labeling. 5) Detention of counterfeit and mislabeled products prior to placing on the market and possible withdrawal from the market. 6) Sharing information with the FDA.
FDA	1) Pre-market consultation and evaluation of production materials, processes and control over tissue collection, cell lines and banks. 2) Supervision over the initial collection of cells, development and maintenance of cell banks, issue regulations and guidelines, and perform inspections as necessary. 3) Supervision of cell proliferation and differentiation at the time of harvest, issuance of regulations and guidance and performance of controls as needed. 4) Informing the USDA-FSIS about the suitability of cells for processing meat products. 5) Inspection of compliance with FDA requirements for equipment registration, good manufacturing practice, inspections focused on additives and excipients. 6) Operational creation of requirements for conditions and processes of cell banks and equipment for cell culture to ensure health safety of the resulting material and prevent falsification, implementation of inspections. 7) Information sharing with USDA-FSIS.
Common	1) Developing a more detailed common framework for supervisory issues. 2) Joint identification of necessary legislative changes and their enforcement. 3) Continuous co-operation, co-ordination, communication, planning, evaluation and review of initiatives. 4) Joint development of principles for the correct labeling of products.

Table 2. Summary of legislative frameworks in relation to cell-based meat

Country	Authority	Legislation	Perceptions
Singapore	Singapore Food Agency (SFA)	Sale of Food Act 1973 Wholesome Meat and Fish Act 1999 Requirements for the Safety Assessment of Novel Foods	The world's first CBM-approved product The product met all the requirements of poultry meat Significant microbiological purity compared to conventional meat
European Union	European Food Safety Authority (EFSA)	Regulation (EC) No 178/2002 Regulation (EC) No 853/2004 Regulation (EU) No 1169/2011 Regulation (EU) 2015/2283 Commission Implementing Regulation (EU) 2018/456 Commission Implementing Regulation (EU) 2017/2469 Commission Implementing Regulation (EU) 2020/1772	EFSA published document "Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283" to help FBO with novel food applications No application for approval of a CBM-novel food yet
USA	U.S. Department of Agriculture – Food Safety and Inspection Service (USDA-FSIS) U.S. Food and Drug Administration (FDA)	U.S. Code: Title 21 U.S. Code: Title 15	Formal agreement on the division of competencies between the USDA and the FDA in the field of CBM
Great Britain	Food Standards Agency (FSA)	Food Standards Act 1999 Food Safety Act 1990 The General Food Regulations 2004 The Novel Foods (England) Regulations 2018 The Novel Foods (Wales) Regulations 2017 The Novel Foods Regulations (Northern Ireland) 2017 The Food Information Regulations 2014 The Food Information (Wales) Regulations 2014 The Food Information Regulations (Northern Ireland) 2014	Application of EU food law even after Brexit
Canada	Canadian Food Inspection Agency (CFIA) Health Canada government agency	Food and Drug Regulations (C.R.C., c. 870)	Developing guidelines for simulated meat imitations
Japan	Ministry of Health, Labour and Welfare of Japan Pharmaceutical Affairs and Food Sanitation Council (PAFSC)	Food Sanitation Act (Act No. 233 of February 24, 1947) Food Safety Basic Act (Act No. 48 of 2003) Health Promotion Act (Act No. 103 of August 2, 2002)	No definition of novel food in Japan legislation Not requiring but only recommending a consultation before placing the food on the market
Australia–New Zealand	Food Standards Australia New Zealand (FSANZ)	Food Standards Code	Statement by FSANZ, that their regulation system has solutions in terms of approval and regulation of novel foods, including CBM
Israel	The National Food Services (NFS)	Regulations for the Protection of Public Health (Food)	First CBM test restaurant in Tel Aviv Religious debate regarding possible inclusion of CBM under Kosher

Despite the fact that discussion about the proper labeling of cell-based meat will be continued, perhaps the biggest summary from the analysis of procedures in the USA is emphasis on a holistic approach to CBM products (Faustman et al., 2020) and their production, considering the individual stages of the production process from cell harvesting up to the final materialization of the product itself.

Canada

Since November 2020, the Canadian Food Inspection Agency (CFIA) has been discussing and developing guidelines for simulated meat, simulated poultry products and certain plant-based protein foods (CFIA, 2020 a). The aim of these guidelines is to clarify what simulated meat and simulated poultry products are, within the context of the Food and Drug Act and the Act of Safe Food for Canadians. According to the CFIA, simulated meat and poultry are products that are purposefully made to resemble meat or poultry products as closely as possible, which is done in order to replace them. Obviously, such products must meet the relevant requirements regarding minimal protein, fat, vitamin and mineral con-

tents of the product it is intended to replace. The exact labeling requirements for these products are also set out in Annex 1, Category 2 of the Guidelines for simulated meat and poultry products (CFIA, 2020 b). Such a product must contain the word "simulated" in its market label. However, it is questionable whether CBM products can be covered by the notion of simulated meat, as understood in Canadian law and food guidelines. According to a report in which the law status was analyzed with regard to CBM in Canada Campden BRI (2021), CBM would probably be considered a novel food under the current Food and Drug Regulations (section B.28.001). Therefore, the authority responsible for regulating CBM would be the Health Canada government agency. Nonetheless, the definition and regulation of CBM is not yet registered in Canadian legislation.

The United Kingdom

In the United Kingdom, Ivy Farm Technologies plans to develop cultivated meat products that will be available at retail chains and restaurants in 2023. The company is currently negotiating with UK Food Standards Agency (FSA) and the government ways to support the rapidly evolving cultured meat sector (Morrison, 2021; Ridler, 2021). However, various unresolved issues still exist regarding the procedures of approval, labeling, consumer acceptance and the transfer of production from small laboratory conditions to large-scale manufacturing. Potential CBM products are currently covered by the legislation on novel foods, which have remained the same even after the Brexit and thus, the UK still applies the requirements arising from the Commission Implementing Regulation (EU) No. 2017/2469 and EFSA guidelines (FSA, 2020). The United Kingdom records regulatory uncertainties, including whether CBM foods should be labeled in the same way as GMOs, and if they can be labeled as meat products. It is also necessary to designate a central authority responsible for the supervision of CBM. According to Short et al. (2021), the FSA should work with other regulatory authorities to create an appropriate regulatory framework covering all aspects of the manufacturing process. Until this is done, there are potential constraints of investments on the development and potential production of CBM.

Japan

Japanese legislation does not contain an equivalent term to "novel food". Furthermore, peculiarly for Western consumers, food intended to be introduced on the Japanese market is not subject to mandatory pre-market review or approval by a competent authority. There is only a recommendation to consult the Ministry of Health, Labor and Welfare (MHLW) before placing a food item on the market. The basic Japanese regulations regarding food safety are the Food Sanitation Act, Food Safety Basic Act, Food Labeling Act and Health Promotion Act (Campden BRI, 2021). Therefore, it would theoretically be possible to distribute CBM in Japan without the MHLW's approval. On the other hand, under section 7 of the Food Sanitation Act, in the case of novel food ingredients and/or novel foods that have not been generally consumed and their health safety not examined, the MHLW may, based upon the opinion of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC), prohibit their sale (Campden BRI, 2021). At the same time, the Japanese government is working on this issue to create a specific regulatory framework that would properly shape the market and ensure acceptance as well as safety of these foods (Ferrer and Green, 2021).

Israel

Israel is a country with a very positive approach to CBM. The Future Meat Technologies company has opened the first industrial cultivated meat production facility in Rehovot. The company plans to introduce its products as early as in 2022 (Lavars, 2021; Lockley, 2021). In Tel Aviv, the SuperMeat company has also opened its first test 'restaurant' serving cell-based chicken meat (Danley, 2021; Liphshiz, 2020). Due to the fact that it is a test restaurant, customers do not pay for food but evaluate its sensory properties (Liphshiz, 2020). Despite this, there is no current legislation dealing with CBM in Israel. The main food safety regulator of the State of Israel is the National Food Service (NFS) at the Ministry of Health. Israel has good trade relations with the European Union, which is why their food law is similar to that of the EU, especially regarding food safety. Most likely, CBM will be considered as "Novel Food" under the Novel Food Directive 2006 (004-08) and evaluation by the National Food Service will take place (Gross, 2021).

An important question remains whether it will be possible for CBM to award a Kosher certificate. This issue is mostly important for Orthodox Jews (Kenigsberg and Zivotofsky, 2020). According to Jewish law, in the process of considering novel foods and new technologies, decision-makers of Jewish law must decide which precedents of Talmudic case law to follow in order to make a final decision (Kenigsberg and Zivotofsky, 2020). Jewish law is very strict in accepting species suitable for meat production. Only meat from clean animals, which include ruminants with split hooves, is allowed, while wild birds and pigs are considered unclean and prohibited. There is also strong emphasis on the ritual process of killing, bleeding with a special knife and ensuring that the animal does not suffer (Della Corte et al., 2021). In the Talmud, we find the story of the "miracle flesh" that fell from heaven and was not subject to the typical order of ritual killing. We also find commentaries in the Torah that describe the creation of animals using mystical methods and do not require ritual killing either. In discussing Kosher CBM, proponents of the franchise rely on just these arguments (Kenigsberg and Zivotofsky, 2020).

Australia and New Zealand

Food Standards Australia New Zealand (FSANZ) is currently recording the establishment of a common

USDA-FDA framework for the regulation of cell-based meat and poultry. However, according to the Agency, the Food Standards Code does not issue any requirements/permission for CBM, as no entity has approached FSANZ with a request for regulatory authorization regarding such foods. Nevertheless, CBM will need to pass pre-market approval according to the existing Code standards, including norms for novel foods, processing aids, food additives, food produced using gene technology, vitamins and minerals, food additives, food safety requirements and labeling (FSANZ, 2022).

Standard 1.5.1 (Novel foods) of the Australia New Zealand Food Standards Code states that a food must not consist of or have as an ingredient or component which is considered a novel food, if the food is offered for retail sale, unless expressly permitted by this Code (Paragraphs 1.1.1—10 (5) (b) and (6) (f)). In the Standard, a novel food (Sections 1.1.2-8) is also defined as "a non-traditional food that requires an assessment of the public health and safety considerations having regard to (a) the potential for adverse effects in humans; or (b) the composition or structure of the food; or (c) the process by which the food has been prepared; or (d) the source from which it is derived; or (e) patterns and levels of consumption of the food; or (f) any other relevant matters".

In Standard 1.5.1, possible categories of novel foods are also referred to, and those categories are described with more details in the guidelines issued by FSANZ (FSANZ, 2019). CBM can probably be included under the category of foods produced from new sources or by a process not previously applied to foods (Derbes, 2021). The novel food assessment process has been reported to last 14 months or more following submission (Derbes, 2021), therefore, CBM will probably not be available on the Australian and New Zealand market in the nearest future.

Legislation labeling – future considerations and recommendations

In recent years, the interest of companies and organizations in meat substitutes has been steadily growing (Gerhardt et al., 2022). There has also been an increasing interest of big corporations in CBM. Great resources have already been invested in this technology (Geltor, 2020; Lee et al., 2022; Stephens, 2021), the result of which may be an imminent increase of its supply on the global market. The largest corporations are already investing and closing in on putting CBM on the market. As an example, Nestlé is already taking action in cooperation with the Future Meat startup and is developing meat from cell cultures (Lee et al., 2022). Cargill has invested in Puris, Memphis Meats and Aleph Farms, and is working on new technologies, including cultured meats (Stephens, 2021). Finally, Geltor has raised 91.3 million USD in series B funding to make animal-free collagen, based on cellular agriculture (Geltor, 2020).

However, despite the growing interest in cultured meat products, as shown in our analysis of legislation, the laws of many countries are still not sufficiently prepared for the appearance of this type of product. In addition, the procedures for admission to the market of new products and technologies are complex, costly and time-consuming. On the other hand, such procedures were implemented to protect the consumer against potentially harmful products. Nevertheless, due to the emergence of animal protein alternatives, and due to the growing interest in this topic, the labeling of products containing animal protein alternatives, including cultured meat, is becoming a matter of interest. The potential labeling of meat products derived from cell technology is part of this issue. The USDA-FSIS has published an advance notice regarding proposed rulemaking – seeking comments, input and information in connection with the labeling of cell-based meat and poultry products. As stated by the USDA-FSIS: "We want to hear from stakeholders and will consider their comments as we work on a proposed regulation for labeling these products" (USDA, 2021). There is a debate among stakeholders represented by companies, scientists, lawyers and policymakers on how and what possible labels should be published, as consumer demand depends on particularly specific naming and labeling of such a product (Bryant and Barnett, 2019; Asioli et al., 2021). A summary of different names for CBM is presented in Figure 1. According to the available information, there is an apparent split between supporters and opponents of these products and the overall technology (Watson, 2021). Alliance for Meat, Poultry and Seafood Innovation has divided the names for CBM into two groups: accurate terms and those that are judgment-based as well as those not used by the coalition:

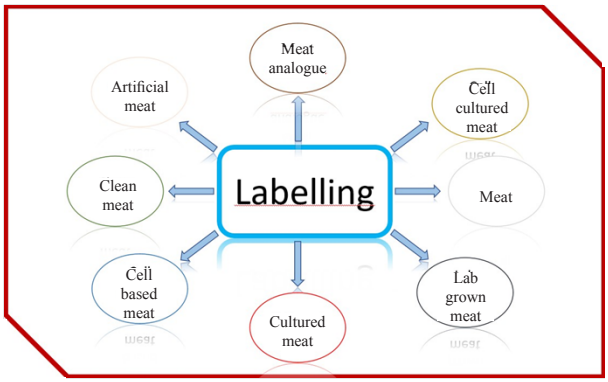


Figure 1. Different names often used for cell-based meat

Accurate terms:
- Meat/poultry/seafood or meat/poultry/seafood products,
- Cultivated meat,
- Cell-based meat,
- Cultured meat or cell cultured meat.

Judgment-based terms:
- Clean meat,
- Lab-grown meat,
- Fake meat/synthetic meat/artificial meat/faux meat (AMPS Innovation, 2022).

Negative consumer attitudes may be caused by local legislation, as demonstrated by Miller and Kerschen (2015) on the example of GMOs, where local laws can often be considered misleading and treat food produced from GMOs as less safe or of lower nutritional value. Somehow, a similar situation appeared in the case of irradiated food as poor communication from food processors and scientists, as well as a deficiency in knowledge about this technology, increased consumer confusion and adverse opinions (Cardello et al., 2007). Such a situation is also possible in CBM, if extra care is not taken by the policymakers, since this method is strictly linked with science and technology. Therefore, it may be recommended to implement legislation that would not require additional labeling information, used for regular meat products, thus preventing the unintentional stigmatization of the technology. On the other hand, CBM and products derived from it can be different from the traditional meat. Joo et al. (2022) showed that CBM had significantly different amino acid composition and taste characteristics when compared to traditional meat, those characteristics being dependent on the applied satellite cell culture method. Therefore, information about the origin of the meat, be it traditional or cell-based, might be potentially important for the consumer and thus, should not be ignored on the product label. It is now up to policymakers to establish proper balance in CBM labeling to, on the one hand avoid unnecessary stigmatization, while also providing adequate information for the potential customer on the other. For example, in case of the EU, information about meat origin could be included into the descriptive name of the food product, instead of being provided as an additional statement. Since a descriptive name, as defined in EU Regulation No. 1169/2011 "means a name providing a description of the food, and if necessary of its use, which is sufficiently clear to enable consumers to know its true nature and distinguish it from other products with which it might be confused", this also seems to be the place where information about CBM should be included. This might also help protect *in vitro* technology avoid the fate of GMOs.

Conclusion

So far, CBM has only been approved in Singapore, but there are a large number of companies announcing that they will launch CBM production on several markets around the world in coming years. The US has reached an agreement and established regulatory frameworks on CBM matters, where both the USDA and the FDA will be the control institutions. Despite this, in many states of the USA, the legal frameworks might possibly impede the introduction of CBM on the market or even provide grounds for stigmatization. Within the European Union, CBM products will be evaluated under the Novel Food Regulations. Following this Regulation, the European Union has adopted further implementing rules and guides for food business operators regarding the submission of applications for the authorization of novel foods. Nevertheless, to date, no application for CBM approval has been registered in the EU, and the process itself, including safety evaluation, takes time. In other countries, CBM is also expected to be subject to novel food legislation. Consequently, the introduction of CBM onto many of the reviewed markets is still probably a matter of months/years rather than weeks. Special care should be taken by policymakers to avoid implementing local laws which would unintentionally cause a negative approach to the technology by consumers but, at the same time, allowing the consumers to clearly distinguish the origin of a product.

Acknowledgements

This work was supported by the VEGA 1/0239/21 project.

Conflict of interests

The authors report no conflict of interest.

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Received: 30 IX 2022
Accepted: 5 XII 2022