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***In vitro* food production from animal cell cultures as a meat alternative (selected legal aspects)**

1. In order to specify the subject of this paper, it is necessary to explain the notions used in its title. “Food” means any substance or product that is processed, partially processed or unprocessed that people can eat or may be expected to eat, as well as beverages, chewing gum and all substances, including water, consciously added to food during its production, preparation or processing, excluding substances and products listed in Regulation No 178/2002.¹ Typically, food comes from agricultural products made within agriculture. According to the definition of agricultural products included in the Treaty on the Functioning of the European Union, agricultural products are “the products of the soil, of stock farming and of fisheries and products of first-stage processing directly related to these products.”² At the level of EU regulations there is an obvious relation between agriculture and the “soil.”

The issue to determine is to what extent meat, being typical food, is related to cell cultured meat. The term “meat” denotes edible parts of animals referred to in points 1.2 to 1.8 of the definition from Annex 1 to Regulation No 853/2004, including blood.³ The term “production,” in turn, means at least

¹ Art. 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January, 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, p. 1, hereinafter referred as Regulation.

² Art. 38 of the Treaty on the Functioning of the European Union, OJ 2004, no 90, item 864/2, hereinafter referred to as TFEU.

³ 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 139, p. 55, hereinafter referred to as Regulation No 853/2004.

one of the following activities: acquiring, breeding, making, cleaning, cutting up, processing, packaging, repackaging, storing or transporting.⁴ Production of traditional food from agricultural products requires, then, the use of soil and water resources and leaves carbon footprint. Food production from animal cell cultures (*in vitro*), on the other hand, is not common. However, such meat products appeared on the market a few years ago. In the process of production from animal cell cultures, animal cells are first retrieved and then cultured in the laboratory. Cell lines may be based on primary cells (for instance muscle or fat cells) or on stem cells.⁵ After the right cell line has been chosen, the sample is placed in a bioreactor, a culture medium tank, in which cells multiply and may be harvested. The animal cell pulp that emerges as a result can be formed into different shapes, e.g. sausages. So far *in vitro* meat products have included burgers⁶ and “3D printed” food.⁷

The issue formulated in the title of this article is relatively new and it has not been discussed in the Polish legal literature so far. However, it enjoys interest in the popular science literature.⁸

Among arguments for consideration of this issue there are in particular cognitive purposes and arguments related to environmental protection.

As far as cognitive purposes are concerned, *in vitro* food production from animal cell cultures is an issue that has not been examined from various viewpoints, in particular from the perspective of consumer health protection. There is no certainty as to what the possible health effects of long-term consumption of meat products that have not been acquired through animal slaughter are.

⁴ Art. 5 point 1 of the Act on products of animal origin of 16 December, 2005, Journal of Laws of 2019, item 824, hereinafter referred to as Act on products of animal origin; cf. the definition of “production” in the PWN Polish Dictionary: “organized activity whose goal is to manufacture goods, services or cultural assets; also: what has been produced,” <https://sjp.pwn.pl/szukaj/produkcja.html> (accessed on: 20 December 2019).

⁵ Cf. Z. Corbyn, *Out of the lab and into your frying pan: the advance of cultured meat*, „The Guardian” 19 January 2020, <https://www.theguardian.com/food/2020/jan/19/cultured-meat-on-its-way-to-a-table-near-you-cultivated-cells-farming-society-ethics> (accessed on: 20 January 2020).

⁶ *In vitro* meat production consists in extraction of cattle stem cells which are placed in a bioreactor where muscle tissue can be cultured from one cell. In 2013 the first *in vitro* hamburger in the world was cultured at the Maastricht University (by Mark Post), J. Ostaszewski, *Will in vitro meat be soon available in stores?*, <https://foodfakty.pl/czy-mieso-in-vitro-bedzie-wkrotce-dostepne-na-polkach-sklepowych> (accessed on: 18 December 2019).

⁷ E. Była, *Mięso prędzej czy później się skończy. Co będziemy wtedy jeść?*, “Gazeta Wyborcza” 23 February 2019, <https://wyborcza.pl/7,155287,24370651,mieso-sie-skoczy-co-bziemy-jesc.html> (accessed on: 15 December 2019). California-based NASA-financed start-up Beehex developed a 3D printer which prints pizza out of plant-based protein.

⁸ P. Rzymiski, *Mięso in vitro: coraz taniej, coraz bardziej etycznie*, 24 January 2019, <https://dietetyczny.blog.polityka.pl/2019/01/24/mieso-in-vitro-coraz-taniej-coraz-bardziej-etycznie/> (accessed on: 18 December 2019).

This issue is also significant for the shape of future regulations which may turn out to be soon relevant on the EU market as well. The American Food and Drug Administration and the US Department of Agriculture carry out works on legal regulations regarding *in vitro* production of meat products and their introduction on the market. Besides, the number of companies interested in production of such products in the US, Europe and Asia keeps growing every year.⁹ However, new trends in food production are not welcomed by farmers who are meat producers, or the food industry; in particular they demand differentiation between *in vitro* products and regular meat.¹⁰ That is why the issue of *in vitro* food production from animal cell cultures also provokes the question of the potential impact of this production on the functioning of the EU agricultural sector within the common agricultural policy since the common market includes meat.¹¹ Moreover, it would also be important to guarantee to consumers that food produced by *in vitro* cell culture of animal cells, including the origin of stem cells and the manner of their storing does not have negative health effects. In each of the above-mentioned issues, legislation has an important role and, as some state regulations in the US show, the introduction of *in vitro* meat on the market has been banned for some reasons.¹²

When it comes to arguments related to environmental protection, traditional meat production obviously has big an environmental impact, consuming significant soil and water resources,¹³ contributing to climate change (it generates ca 21–37% of global greenhouse gas emissions, where as much as 80% comes from agriculture) and leading to deforestation and other consequences.¹⁴

⁹ *Ibidem*.

¹⁰ *Ibidem*.

¹¹ Regulation (EC) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organization of markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) NO 234/79, (EC) No 1037/2001 and (EC) No 1234/2007, OJ L 347, 2013, p. 671), hereinafter referred to as Regulation No 1308/2013. Art. 1 states that this Regulation establishes a common organization of markets for agricultural products, which means all the products listed in Annex 1 to the Treaties with the exception of the fishery and aquaculture products as defined in Union legislative acts on the common organization of the markets in fishery and aquaculture products. Agricultural products are divided in the following sectors as listed in the respective parts of Annex 1 to Regulation No 1308/2013.

¹² Washington H-0654.2, HOUSE BILL 1519 State of Washington 66th Legislature 2019 Regular Session By Representatives Shea, McCaslin, Blake, and Chandler, <https://legiscan.com/WA/text/HB1519/2019> (accessed on: 10 January 2020).

¹³ L. Aleksandrowicz, R. Green, E.J.M. Joy, P. Smith, A. Haines, *The Impacts of Dietary Change on Greenhouse Gas Emissions, Land Use, Water Use, and Health: A Systematic Review of 3 November 2016*, PLoS ONE 11(11): e0165797, <https://doi.org/10.1371/journal.pone.0165797>, <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0165797> (accessed on: 6 January 2020).

¹⁴ *Ibidem*.

Meanwhile, the newest IPCC¹⁵ report raises the issue of guaranteeing provision of food to all residents on earth in the future. The problem results from climate change and irrational division of resources. Thus, the need to change the approach towards food production seems justified.¹⁶ These circumstances, among other things, are the reason for a search of solutions which would help reduce greenhouse gas emissions and the effects of global warming, including alternatives to typical food production and ways to satisfy humans' basic nutritional needs. *In vitro* meat production from animal cell cultures offers a chance to solve some of the above-mentioned problems related to environmental protection and animal welfare as it allows to save land and reduce water consumption as well as reduce carbon dioxide and methane emission from animal breeding. This production method may also correspond to the growing number of Polish consumers who consciously resign from meat consumption which – according to declarations – already accounts for 15 percent of population.¹⁷

The goal of this paper is to establish how to legally qualify *in vitro* meat from animal cell cultures as well as whether the current regulations guarantee that these products are safe for human health. Therefore legal problems exist at two levels here – the substantive legal sphere and the regulations regarding introduction of such food on the market as well as supervision of the food market. Such a goal determines a further course of considerations. First of all, regulations regarding in particular notions such as “meat” and “production” are discussed, and selected US state regulations are presented for comparison.

2. Cells for *in vitro* meat production may come from many sources: biopsy of living animals, pieces of fresh meat, cell banks and even feather stems.¹⁸ It is emphasized that the benefit of stem cells is the fact that, thanks to various nutrients or genetic modifications, they can mature to become all types of cells and their life span is not limited. They can be used endlessly. The cell line choice, on the other hand, should take into consideration the flavor or growth rate.

¹⁵ The Intergovernmental Panel on Climate Change (IPCC).

¹⁶ Climate Change and Land, An IPCC Special Report on climate change, desertification, land degradation, sustainable land management, food security, and greenhouse gas fluxes in terrestrial ecosystems, <https://www.ipcc.ch/srccl/> (accessed on: 20 December 2019).

¹⁷ A. Rokicka-Żuk, *Wegetarianizm: dieta bez mięsa – rodzaje, zasady, jadłospis i wpływ na zdrowie*, “Strona zdrowia” 25 September 2018, <https://stronazdrowia.pl/wegetarianizm-dieta-bez-miesza-rodzaje-zasady-jadlospis-i-wplyw-na-zdrowie/ar/c14-13521902> (accessed on: 20 December 2019).

¹⁸ Cf. Z. Corbyn, *Out of the lab...*

Conventional meat has many types of cells which give it the flavor, including muscles and fat.¹⁹

The first legal regulations regarding *in vitro* meat in the discussed scope can be found in the US. Regulations that are to prevent labeling plant-based products and *in vitro* products from animal cell cultures as “meat” or “beef,” which have been introduced in some US states (e.g. Mississippi, Oklahoma, Arkansas, Missouri, Montana, South Carolina, North Dakota and South Dakota).

For instance, Louisiana Act 273 states that this law regards “the truth in labeling of food products.”²⁰ § 4742 of this Act states that the goal of this law is to “protect consumers from misleading and false labeling of food products that are edible by humans.” Legal definitions, in turn, emphasize that an “agricultural product” is “any beef, pork, poultry, crawfish, shrimp, meat, sugar or rice that is edible by humans.” A “cell cultured food product” is “any cultured animal tissue produced *in vitro* from animal cell cultures outside of the organism from which it is derived.” “Meat,” according to the Act, means “a portion of a beef, pork, poultry, alligator, farm-raised deer, turtle, domestic rabbit, crawfish or shrimp carcass that is edible by humans but does not include a synthetic product derived from a plant, insect or other source, or cell cultured product grown in a laboratory from animal cells.” A “meat product means a type of agricultural product that is edible by humans and made wholly or in part from meat or another portion of a beef, pork, poultry, alligator, farm-raised deer, turtle, domestic rabbit, crawfish or shrimp carcass.” As can be seen, the criterion for permission to use the name “meat” in trade is whether it is an agricultural product or not. A cell cultured food product is not an agricultural product.

The law of Washington, in turn,²¹ defines “cell cultured meat product” as “any meat product artificially grown from cell cultures of animal muscle of organ tissues.” At the same time this law bans entirely advertising, selling or offering for sale a cell cultured meat product in the state of Washington. The ban includes state funding for research or development of cell cultured meat products. Violation of this ban is considered a misdemeanor and a second or subsequent violation amounts to a gross misdemeanor.

¹⁹ *Ibidem*.

²⁰ 2019 Regular Session, Provides for truth in labeling requirements of agricultural products. (10/1/20), Senate Bill No. 152 By Senator Thompson and Representatives Abraham and Stefanski, <https://legiscan.com/LA/text/SB152/2019> (accessed on: 20 December 2019).

²¹ Washington H-0654.2, HOUSE BILL 1519 State of Washington 66th Legislature 2019 Regular Session By Representatives Shea, McCaslin, Blake, and Chandler, <https://legiscan.com/WA/text/HB1519/2019> (accessed on: 10 January 2020).

When it comes to supervision by food control authorities of the US market, the USDA²² and the FDA²³ announced a formal agreement to regulate cell cultured food products from cell lines of livestock and poultry.²⁴ The goal of the agreement is to establish the roles of the American Department of Health and Human Services' Food and Drug Administration (HHS-FDA) and the Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS²⁵) in terms of oversight of food produced using the technology of animal cell culturing from cell lines of species specified by the USDA and required to be labeled with the USDA control mark.²⁶

The HHS-FDA is in charge of implementation and enforcement of the Federal Food, Drug and Cosmetic Act (21 USC 301 et seq.), the Public Health Service Act (42 USC 201 et seq.) and the Fair Packaging and Labeling Program (15 USC 1451 et seq.). The HHS-FDA thus makes sure that food is not forged or inappropriately labeled with a trademark, including regulation of food ingredients used during production of meat, poultry and egg products. The HHS-FDA carries out inspections of food production, processing, packaging and storage plants, with the exception of some plants that are subject exclusively to the USDA-FSIS. The HHS-FDA also controls vehicles and other means of transport such as boats, trains and airplanes which transport food or store it in the interstate trade.

The USDA-FSIS, in turn, is in charge of implementation and enforcement of the Federal Meat Inspection Act (FMIA; 21 USC 601 et seq.), the Poultry and Poultry Products Inspection Act (PPIA; 21 USC 451 et seq.) and the Egg Products Inspection Act (21 USC 1031 et seq.). The USDA-FSIS delegates inspectors to meat and poultry abattoirs and processing plants as well as egg product processing plants. The USDA-FSIS also declares equivalence of foreign inspector systems as a condition to accept import of meat, poultry and egg products to the United States and reinspects all imported meat, poultry and egg products. The USDA-FSIS enforces regulations regarding improper trademarks and forgery in meat, poultry and egg product sales.

²² The U.S. Department of Agriculture's (USDA's).

²³ Food and Drug Administration (FDA).

²⁴ <https://www.fda.gov/news-events/press-announcements/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food-products-cell-lines-livestock-and> (accessed on: 12 December 2019).

²⁵ Food Safety and Inspection Service (FSIS).

²⁶ Formal Agreement between The U.S. Department of Health and Human Services Food And Drug Administration and U.S. Department of Agriculture Office of Food Safety of March 7, 2019, <https://www.fsis.usda.gov/wps/wcm/connect/0d2d644a-9a65-43c6-944f-ea598aacdec1/Formal-Agreement-FSIS-FDA.pdf?MOD=AJPERES> (accessed on: 12 December 2019).

Under the interinstitutional agreement, the HHS-FDA's task is also to conduct consultations on the market in order to assess materials and production processes as well as production inspections, including oversight of retrieving of tissues, cell lines and banks as well as all components and expenses and their consultation with the USDA-FSIS. The goal is to supervise properly, through regulations (rules, guidelines) the process of initial cell retrieving as well as development and maintenance of qualified cell banks, multiplication and differentiation of cells during their harvesting. It is important to establish whether the harvested cells can be processed into meat or poultry products labeled with the USDA control mark.

The authorities need to make sure that producers apply the HHS-FDA requirements, including those regarding plant registration, Good Production Practices and regulations regarding preventive inspections as well as requirements regarding substances which become an ingredient of food or affect food properties in a different way. It is important for cell banks and cell culturing facilities to operate in accordance with the HHS-FDA regulations. There is a need to formulate and implement additional requirements regarding conditions and processes of cell banks and cell cultures in order to make sure that the biological material which occurs as a result of the culturing process is safe and not forged as defined by the Federal Food, Drug and Cosmetic Act. To this end the HHS-FDA shall conduct inspections and appropriate follow-up.

The USDA-FSIS, in turn, declared that it would require obtaining a permit for inspection from every plant that retrieves cells from livestock or poultry, subject to the FMIA or PPIA, for the purpose of production of food for humans, processing of these cells into food products for humans or packaging and labeling of such products. Moreover, the USDA-FSIS undertook to conduct inspections in facilities that culture cells from livestock and poultry subject to the FMIA and PPIA, in which they are collected, processed, packaged or labeled in accordance with the FSIS regulations (including sanitary inspection of the product and HACCP – hazard analysis and critical control points) in order to make sure that the products which occurred are safe, not forged, healthy and properly labeled.

The USDA-FSIS is also obliged to require that labeling of food products obtained from livestock and poultry cell culturing is initially approved and then verified by inspection, in accordance with the FSIS regulations. If need be, the USDA-FSIS will undertake to develop additional requirements in order to guarantee safety and proper labeling of food products obtained from livestock and poultry cell culturation subject to the FMIA and PPIA. The parties mutually declared to develop more detailed framework or operational procedures in order to facilitate coordination of regulative oversight of biological material retrieving.

As it can be inferred, significant points of the agreement concluded by the above-mentioned institutions focus on the issues of potential risk for food safety, which regard the processes of initial cell retrieving as well as development and maintenance of qualified cell banks, multiplication and differentiation of cells.

3. In order to analyze this issue from the perspective of EU legal regulations, next to the quite extensive definition of “food” from Regulation No 178/2002, in search of the option to include *in vitro* meat, Regulation No 853/2004 ought to be referred to, according to which “meat” means “edible parts of domestic ungulates (including *Bubalus bubalis* and *Bison bison*), porcine, ovine and caprine animals, and domestic solipeds; poultry (farmed birds, including birds that are not considered domestic but which are farmed as domestic animals, with the exception of ratites); lagomorphs (rabbits, hares and rodents); wild game (wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the Member State concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game; and wild birds that are hunted for human consumption); fanned game (farmed ratites and farmed land mammals other than those mentioned above); small wild game (wild game birds and lagomorphs living freely in the wild); large wild game (wild land mammals living freely in the wild that do not fall within the definition of small wild game).” The definition of “meat” includes also blood.

“Products of animal origin” (including honey and blood), in turn, are “live bivalve mollusks, live echinoderms, live tunicates and live marine gastropods intended for human consumption” as well as “other animals destined to be prepared with a view to being supplied live to the final consumer,” in accordance with Annex 1 sec. 8.1 of Regulation No 853/2004.²⁷

It is also worth mentioning the requirements regarding the “raw material” regulated in reference to traditional meat and included in Chapter II of Regulation No 853/2004. In particular, these specific terms regard facilities that produce minced meat, meat products or MSM. They must ensure that the raw material used to prepare minced meat “complies with the requirements for fresh meat and derives from skeletal muscle, including adherent fatty tissues, not from scrap cuttings and scrap trimmings (other than whole muscle cuttings), MSM, meat containing bone fragments or skin or meat of the head with the

²⁷ 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 139, p. 55), hereinafter referred to as Regulation No 853/2004.

exception of the masseters, the non-muscular part of the *linea alba*, the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed).”

The legislator also decided that in order to prepare meat products, facilities can use, among other things, raw material in the form of “fresh meat; meat meeting the requirements for fresh meat and – if the meat preparation is clearly not intended to be consumed without first undergoing heat treatment – meat derived from the mincing or fragmentation of meat meeting the requirements.” When it comes to MSM, the raw material used for its production must “comply with the requirements for fresh meat” and the following material must not be used to produce MSM: “for poultry – the feet, neck skin and head, and for other animals – the bones of the head, feet, tales, femur, tibia, fibula, humerus, radius and ulna.”

Since *in vitro* meat is a product (substance) intended for human consumption, it would be considered as an element of the general notion of “food.” As the literature indicates, “food” has a very extensive definition.²⁸ However, doubts about this direction arise in connection with the uniqueness of the method and the name – both elements referring to the specific food category that meat is. Due to the atypical method of production – *in vitro* – this product is not included in the definition of meat which, from a legal viewpoint, comes from animals.

4. Besides the problem with legal qualification of *in vitro* meat, there is also difficulty in finding a proper name for these products. The name should in principle correspond with the proper qualification. In this respect it is necessary to include provisions of Regulation No 1169/2011²⁹ as well as conclusions drawn by the Court of Justice of the European Union in the course of its work – it opposes to the practice of naming products not related to animals with names attributed to products of animal origin.

For instance, when it comes to provision of information on products, the ban on misleading consumers obliges producers to inform about food properties

²⁸ Cf. K. Leśkiewicz, *Wokół prawnego pojęcia żywności*, “Przegląd Prawa Rolnego” 2015, vol. 1 (16), pp. 179–192.

²⁹ Regulation (EU) of the European Parliament and of the Council No 1169/2011 of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, p. 18), hereinafter referred to as Regulation No 1169/2011.

honestly.³⁰ It is banned to suggest, through appearance, description of graphic representations, that this is a specific foodstuff or ingredient, even though in reality the component or ingredient that is naturally present or usually applied in a given foodstuff has been replaced with another component or ingredient. It is obvious, then, that marking of a cell cultured product lawlessly suggests that it is meat against the legal definition of meat. Every foodstuff must have its name. Firstly, this is a name included in regulations and in case of lack thereof – a common name and if one does not exist or is not used, this foodstuff should be given a descriptive name. Currently regulations do not include a name for *in vitro* meat so it seems justified to consider descriptive names but in such a way to reflect the actual character of a product. However, it seems that using the name “meat” for these products, even in combination with other descriptive elements, violates the regulations on meat definition.

Considering rulings of the Court of Justice of the European Union regarding application of names proper for products of animal origin for e.g. plant-based products, it must be mentioned that in one of the cases, the Court pointed out – for marketing or advertising purposes – that regulations state that the name “milk” shall be used exclusively for milk of animal origin.³¹ The Court also pointed out that considering – in the context of evaluation of the rightfulness of application of the name “milk” or reserved names under Regulation No 1308/2013 exclusively to milk products to mark plant-based products – possible meaning of additional expressions that constitute an explanation or a description indicating plant origin of a given products such as “made from soy” or “made from tofu,” it must be noted that point 3 of part III of Annex VII to this Regulation states that “the term milk and the designations used for milk products may also be used in association with a word or words to designate composite products of which no part takes or is intended to take the place of any milk constituent and of which milk or a milk product is an essential part either in terms of quantity or for characterization of the product.” In the Court’s opinion, plant-based products such as products that do not contain milk or milk products, do not meet these conditions.

³⁰ Art. 7 sec. 1 of Regulation No 1169/2011.

³¹ Ruling of the Court of Justice of the European Union of 14 June 2014 in case C-422/16 *Verband Sozialer Wettbewerb e.V. vs. TofuTown.com GmbH.*; the Court interpreted Art. 78 sec. 2 and point 1 and 2 of the part II of Annex VII to Regulation No 1308/2013. In the case *TofuTown* claims that its advertisement of plant-based products which have disputable names does not violate the law of the European Union since, on the one hand, the way consumers understand these notions has changed significantly and, on the other hand, it does not use names such as “butter” or “cream” in an isolated way, but always in connection with other notions that indicate plant origin of a given product, e.g. “tofu butter” or “rice spray cream.” The Court did not share this opinion, www.curia.europa.eu.

Moreover, regulations reserve names such as “cream,” “butter,” “cheese” and “yoghurt” exclusively for milk products, that is products made from milk. That is why names such as e.g. milk must not be legally used to designate products of plant origin only, unless these products are included in Annex 1 to Decision 2010/791, which regards neither soy nor tofu.³² According to the Court, interpretation of Art. 78 sec. 2 and part III of Annex VII to Regulation No 1308/2013 must be understood in such a way that these provisions make it impossible to use the name “milk” and names that this Regulation reserves exclusively for milk products to designate – for marketing or advertising purposes – products of plant origin, even if these names include explanations or descriptions which indicate plant origin of a given product, unless this product is included Annex I to Decision 2010/791.

It is also worth mentioning that the issue of application of specific names may be significant for market placement of products subject to common market organizations and may be also evaluated from the perspective of the principle of non-discrimination between producers and consumers in agriculture based on Art. 40 sec. 2 § 2 of TFEU. This principle applies not only to producers and consumers, but also to other categories of business entities subject to common market organization such as entities that place on the market fresh poultry and other types of fresh meat.³³ The Court stated that, among other things, the sector of common organization of markets in agricultural products is characterized by certain specific features. As a consequence, a comparison of technical mechanisms applied to regulate various sectors of the market shall not be a valid foundation for declaring discrimination between various products subject to different regulations. Milk and milk products belong to a different sector than sectors of various types of meat or fishery sector, which are an element of another common market organization.³⁴

5. Considering the difficulty in including *in vitro* meat in the “meat” category and using this particular name, it is essential to reach to the Regulation regarding food produced in an atypical manner or having atypical features. The food in question is “novel food,” that is

³² Court of Justice of the European Union Press Release No 63/17, Luxembourg, 14 June 2017, <https://curia.europa.eu/jcms/upload/docs/application/pdf/2017-06/cp170063pl.pdf> (accessed on: 15 December 2019).

³³ See the Ruling of the Court of Justice of the European Union of 5 October 1994, Germany/Council, C-280/93, EU:C:1994:367, point 68, <https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=ecli:ECLI:EU:C:1994:367> (accessed on: 20 December 2019).

³⁴ Ruling of the Court of Justice of the European Union (second chamber) of 30 June 2016 in case C-134/15, <https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=ecli:ECLI:EU:C:2016:498> (accessed on: 20 December 2019).

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:

– food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;

– food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;

– food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances.³⁵

It seems, then, that *in vitro* meat meets the conditions of the above-mentioned definition of “food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae” so it could potentially be considered a novel food. The obligation to verify that belongs to food business operators, and if they have doubts, “they shall consult the Member State where they first intend to place the novel food. Food business operators shall provide the necessary information to the Member State to enable it to determine whether or not a food falls within the scope of this Regulation. Member States may consult other Member States and with the Commission.”³⁶

In order to be introduced on the market, novel food must meet the requirements for this category in terms of market placement and labeling as well as a history of safe food use in a third country,³⁷ which means that safety of a given food has been confirmed “with compositional data and from experience of continues use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification.”³⁸ The procedure of placing such food on the market and evaluation of its safety for consumer health has also been regulated extensively. These procedures, assuming a long

³⁵ Art. 3 sec. 2(a) point v, vi, vii of Regulation (EU) of the European Parliament and of the Council No 2015/2283 of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, p. 1), hereinafter referred to as Regulation No 2015/2283.

³⁶ Art. 4 of Regulation No 2015/2283.

³⁷ On the aspects of novel food market placement in the light of Regulation No 2015/2283 see more: Ł.M. Sokołowski, *Wprowadzanie nowej żywności na rynek unijny w świetle rozporządzenia nr 2015/2283*, “Przegląd Prawa Rolnego” 2018, vol. 2, pp. 77–89.

³⁸ Art. 3 sec. 2(b) of Regulation 2015/2283.

period of food testing, make it practically impossible to register these products as novel food.

Another issue is qualification of meat production from cell cultures. It certainly cannot be qualified as an agricultural activity. Ł.M. Sokołowski expressed an opinion that qualification of novel food production as agricultural activity depends on an individual case. However, the author does not exclude the possibility of declaring in certain situations the presence of an agricultural-biological cycle, especially when animal breeding or plant cultivation takes place, which is considered by the agricultural law as a criterion determining the presence of agricultural production.³⁹ In that case, does it mean that culturing of cells retrieved from an animal in a production plant corresponds to the basic qualities of agricultural activity (agricultural production)? It seems that this production process is similar to agricultural production only in terms of its goal – for consumption by humans, provided that this is the goal of *in vitro* meat production. These days this is almost one of the most important goals of the common agricultural policy – to guarantee safety of supplies, in other words – to guarantee food security. When it comes to other aspects, it would be hard to find features of agricultural production in *in vitro* meat production, even though it is a special type of production.

6. In conclusion, it must be stated that *in vitro* food production from animal cell cultures may be considered an alternative to traditional animal production.

From a legal viewpoint there may be doubts as to the legal qualification of this type of food. According to the definitions presented above, *in vitro* animal cell culturing does not fall under typical legal definitions of meat or agricultural production. *In vitro* meat products may correspond to the criteria established by the legislator for novel food. If the proper way of classification is considered, it may be concluded that such products should be subject to the procedure of admission to the Union market included in Regulation No 2015/2283 and, thus, evaluation of their safety. However, a comprehensive evaluation under these regulations would be difficult because of the short time of use of these products.

In particular, it seems unjustified in the light of EU regulations to use the name “meat” for products produced by *in vitro* cell culture of animal cells. A special interpretative cautiousness must be maintained while applying descriptions to these products.

³⁹ See more: Ł.M. Sokołowski, *Prawne aspekty wprowadzania nowej żywności na rynek unijny*, Poznań 2017, p. 104 and the literature quoted therein.

In vitro meat production may successfully fulfill the goal of the common agricultural policy – to guarantee food security. Paradoxically, traditional industrial animal breeding does not solve the issue of guaranteeing food security in the future, but even deepens this problem due to the carbon footprint it leaves. Thus, provision of legal, economic and social grounds for initiatives regarding alternative food production methods seems very reasonable, if they can contribute to the solution of food security problem in the future. However, it must be kept in mind that these needs should be satisfied primarily by a sustainable, maximally natural agricultural production based on respect for resources, animal welfare and, consequently, human health.

IN VITRO FOOD PRODUCTION FROM ANIMAL CELL CULTURES AS A MEAT ALTERNATIVE (SELECTED LEGAL ASPECTS)

Summary

From a legal point of view, there may be doubts as to the legal qualification of food obtained *in vitro* from animal cells. An opinion is expressed in the article that meat from animal cells obtained using the *in vitro* method does not fall within the classical legal concepts of meat or agricultural production. However, meat products from cells produced by the *in vitro* method may satisfy the criteria established for novel food. If this is considered to be the correct way of qualification, then they should be subject to the EU market authorisation procedure regulated in Regulation 2015/2283, and a subsequent assessment of their safety. From a legal, economic and social point of view, it is reasonable to produce food using atypical methods if these methods are capable of ensuring food safety.

PRODUZIONE ALIMENTARE IN VITRO DA COLTURE CELLULARI COME ALTERNATIVA ALLA CARNE (ASPETTI GIURIDICI SCELTI)

Riassunto

Da un punto di vista giuridico potrebbero sorgere dubbi sulla qualificazione giuridica di alimenti ottenuti *in vitro* da cellule animali. L'autrice afferma che ottenere carne da cellule animali usando il metodo "in vitro" non si colloca nei limiti dei classici concetti giuridici di carne o produzione agricola. I prodotti a base di carne derivati dal metodo "in vitro" possono soddisfare i criteri stabiliti dal legislatore per i *novel food*. Ritenendo quest'ultimo il modo corretto di qualificazione, anche loro, di conseguenza, dovrebbero essere soggetti alla procedura di ammissione al mercato dell'UE, così come disciplinata dal regolamento 2015/2283, e quindi valutati sulla base della loro sicurezza. È del tutto razionale, dal punto di vista giuridico, economico e sociale, produrre cibo con metodi diversi da quello normale, specie se servono a garantire la sicurezza alimentare.