

Beyond the Butcher: Navigating the Legal Landscape of Cultured Meat

Cultured meat, produced from cell cultures rather than slaughtered animals, is nearing consumer tables. Despite its potential for sustainability, animal welfare, and food security, cultured meat faces regulatory challenges. In 2023, Aleph Farms filed the first Europe-wide application for market access in Switzerland. This paper analyses the Swiss legal framework concerning cultured meat. It focuses on food product taxonomy and the market access authorization procedure for novel foods. It emphasizes the need for regulation to evolve with technological advancements while ensuring consumer safety.

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I. Introduction

- 1 The dawn of the 21st century has witnessed remarkable innovations in the food industry, one of the most notable being the development of cultured meat.¹ Also known as cultivated, lab-grown, in-vitro, or cell-cultured meat,² this breakthrough represents a significant paradigm shift in food technology and production.³ Created by nurturing animal cells in a meticulously controlled setting, cultured meat presents a pioneering approach that may well transform the meat industry. Its importance extends beyond the mere advancement of technology; cultured meat has the potential to address some of the most pressing challenges of our time, including environmental sustainability, animal welfare, and food security.
- 2 The innovation of cultured meat emerges against the backdrop of increasing global concerns about the environmental impact of traditional livestock farming.⁴ Conventional meat production is resource-intensive, contributing to greenhouse gas emissions, land degradation, and water depletion. In contrast, cultured meat promises a more sustainable alternative, reducing the ecological impact associated with meat consumption.⁵ Furthermore, it offers a

humane alternative to conventional meat, eliminating the need for animal slaughter and thus resonating with growing concerns among consumers interested in slaughter-free food.⁶ Additionally, cultured meat does not contain antibiotics, salmonella, heavy metals, or microplastics.

However, the path to integrating such innovative products into the market is fraught with regulatory challenges.⁷ The product's categorization is at the heart of the debate, as with every innovation in the food sector. Should cultured meat parallel conventional meat, be deemed a novel food, or warrant a distinct classification altogether? This determination is critical, as it dictates the nature and rigour of the legal requirements for market access. Moreover, the alternative protein industry raises concerns about food safety and quality.⁸ With cultured meat's origins in cell cultures rather than animal slaughter, there is a pressing need to recalibrate current food safety frameworks and inspection protocols to accommodate this new mode of production. Furthermore, crucial questions arise about regulating labelling and importing such products to ensure consumer trust and transparency.

The first lab-grown meat suitable for human consumption was produced at Maastricht University in 2013.⁹ Since then, companies worldwide have embraced this technology, and a few select countries have granted market access.¹⁰ Cell-based chicken nuggets were approved in Singapore in December 2020, and the US Food and Drug Administration (FDA) completed its voluntary pre-market consultation for the same product in November 2022.¹¹ In Europe, the approach is markedly divergent, with the Netherlands committing sixty million Euros to cell-based meat research in 2022,¹² contrasted by Italy's complete prohibition of such products in November 2023.¹³

1 NEIL STEPHENS / LUCY DI SILVI / ILLTUD DUNSFORD / MARIANNE ELLIS / ABIGAIL GLENCROSS / ALEXANDRA SEXTON, Bringing cultured meat to market: Technical, socio-political, and regulatory challenges in cellular agriculture, *Trends Food Sci. Technol.* 2018, p. 155; MARK J. POST / SHULAMIT LEVENBERG / DAVID L. KAPLAN / NICHOLAS GENOVESE / JIANAN FU / CHRISTOPHER J. BRYANT / NICOLE NEGOWETTI / KARIN VERZIJDEN / PANAGIOTA MOUATSOSU, Scientific, sustainability and regulatory challenges of cultured meat, *Nat. Food* 2020, p. 403.

2 The food industry uses various terminologies for novel technologies surrounding meat. The FAO and WHO report established a list of all modifier terms used to describe "animal cell-based food products", including "cultured meat", "lab-grown meat", "fake meat", "clean meat", and "cultivated meat". See Food and Agriculture Organization (FAO) & World Health Organization (WHO), Food safety aspects of cell-based food, Rome 2023. This diversity seems to arise from industry attempts to influence public perception of a new, potentially controversial product. See The Good Food Institute (ed.), *State of the Industry Report: Cultivated Meat*, Arlington 2020. In December 2023, Singapore was the only country to have implemented novel food regulations for cell-based food products, referring to the term "cultured meat". In Switzerland, the Swiss Federal Food Safety and Veterinary Office has opted for the term "cultured meat product" in the market access authorization procedure for Aleph Farms' product.

3 JONATHAN VERSCHUUREN, Cultured Meat and Dairy as a Game-Changing Technology in the Agricultural and Food Transition in the EU: What Role for Law?, in: Zahar/Reins (eds.), *Climate Technology and Law in the Anthropocene*, Bristol forthcoming 2025.

4 CHARLOTTE E. BLATTNER / ODILE AMMANN, Agricultural exceptionalism and industrial animal food production: Exploring the human rights nexus, *J. Food Pol.* 2019, p. 92; VERSCHUUREN (n. 3).

5 STEPHENS et al. (n. 1); POST et al. (n. 1); SOPHIE HUBALEK / MARK J. POST / PANAGIOTA MOUATSOSU, Towards resource-efficient and cost-efficient cultured meat, *Curr. Opin. Food Sci.* 2022. However, cultured meat production requires a significant amount of energy, which might offset some of its ecological advantages. See JOHN LYNCH / RAYMOND PIERREHUMBERT, Climate impacts of cultured meat and beef cattle, *Front. Sustain. Food Syst.* 2019, p. 5. For a nuanced analysis of available data on emissions, see DERRICK RISNER / YOONBIN KIM / CUONG NGUYEN / JUSTIN B. SIEGEL / EDWARD S. SPANG, *Environmental impacts of cultured meat: A cradle-to-gate life cycle assessment*,

Davis 2023; PELLE SINKE / ELLIOT SWARTZ / HERMES SANCTORUM / COEN VAN DER GIESEN / INGRID ODEGARD, Ex-ante life cycle assessment of commercial-scale cultivated meat production in 2030, *Int. J. Life Cycle Assess.* 2023, p. 234.

6 BLATTNER/AMMANN (n. 4).

7 KATE SOLLEE, The Regulation of Lab-Grown Meat under Existing Jurisdictional Authority, *J Health Care Pol* 2022, p. 289; STEPHENS et al. (n. 1).

8 STEPHENS et al. (n. 1); POST et al. (n. 1).

9 [bbc.com](https://www.bbc.com/news/health-2013-08-05) from 5 August 2013 (World's first lab-grown burger is eaten in London).

10 The Good Food Institute (n. 2).

11 U.S. Food & Drug Administration (FDA), FDA Completes First Pre-Market Consultation for Human Food Made Using Animal Cell Culture Technology, 16 November 2022. For more details on US food regulation, see NEAL D. FORTIN, *Food regulation: law, science, policy, and practice*, 3rd edit., Hoboken 2022.

12 [forbes.com](https://www.forbes.com/news/2022/03/17/dutch-parliament-approves-cultured-meat-tasting-in-the-netherlands/) from 17 March 2022 (*Dutch Parliament Approves Cultured Meat Tasting In The Netherlands*).

13 The Good Food Institute (n. 2); [reuters.com](https://www.reuters.com/news/world/italy-parliament-approves-ban-lab-grown-food-amid-tensions-2023-11-20/) from 16 November 2023 (*Italy's parliament approves ban on lab-grown food amid tensions*); DAVID NAGODE, *A Franco-Italian ploy to protect the carnivore consumer*, europeanlawblog.eu from 20 November 2023.

- 5 Switzerland presents a unique case study, as the company Aleph Farms filed the first Europe-wide application preceding a market access authorization request with Swiss authorities in July 2023.¹⁴ The Swiss regulatory approach to a novel technology such as cultured meat is pivotal in determining the trajectory of this innovation within the domestic market and, potentially, the European and global food industry more generally.¹⁵
- 6 This paper aims to critically analyse the status of cultured meat within the Swiss legal framework, focusing on the challenges and opportunities presented by this innovative product in the context of food regulation. By examining the Swiss approach to cultured meat regulation, this paper seeks to contribute to the broader discourse on how legal systems can adapt to and facilitate emerging food technologies while safeguarding public health and consumer interests.
- 7 The paper unfolds as follows. It first delves into cultured meat technology, delineating the scientific underpinnings, biotechnological advancements, and production processes that distinguish it from conventional meat production. The paper then proceeds with the case study of the first market access authorization request filed in Switzerland in 2023, highlighting the company Aleph Farms and its context. The paper scrutinizes the Swiss food regulatory framework, analysing the existing food products taxonomy and the specific category of novel foods relevant to cultured meat. Finally, the paper examines the procedural mechanisms preceding market access authorization for such novel foods. It concludes by emphasizing the legal challenges beyond market access authorization, such as animal welfare, product labelling, and cultured meat importation.

II. Cultured meat technology

1. Production process

- 8 Cultured meat is predicated on the principles of tissue engineering applied to food production.¹⁶ Meat cultivation is based on a biotechnological process. It involves the following steps: the harvesting of stem cells, their cultivation and expansion, the guided differentiation within bioreactors, and the collection of the matured tissue for the final meat product.¹⁷

14 Federal Food Safety and Veterinary Office (FSVO) and Federal Department of Home Affairs (FDHA), *Applications for placing on the market novel and novel traditional foodstuffs*, 23 July 2024 (cit. Federal Food Safety and Veterinary Office and Federal Department of Home Affairs).

15 VERSCHUUREN (n. 3).

16 STEPHENS et al. (n. 1); POST et al. (n. 1); Food and Agriculture Organization (FAO) (ed.), *Thinking about the Future of Food Safety: A Foresight Report*, Rome 2022.

17 LUIZ ALBERTO JUNIOR LETTI / SUSAN GRACE KARP / CARLA FORTE MAIOLINO MOLENTO / BRIGITTE STHEPANI OROZCO COLONIA / RAPHAEL

The process begins with extracting stem cells or micro-satellite cells from a living animal.¹⁸ Aleph Farms uses a “one-time collection” of a cow’s fertilized eggs directly from its womb. These totipotent cells can replicate and differentiate into embryonic and extraembryonic cell types to construct a complete, viable organism.¹⁹ The fertilized eggs are left to grow for a short period before being differentiated into the “different types of cells that make up meat, like muscle and collagen-producing cells”.²⁰ Alternatively, some companies extract their stem cells from a biopsy done on the cow, which might be more invasive for the animal.²¹

Then, under laboratory conditions, the cells are nurtured in a bioreactor, an apparatus designed to support a biologically active environment that is temperature-controlled, clean, and closed, allowing the cells to thrive. Aleph Farms describe their cell feed as containing “water, oxygen, nutrients and growth medium”.²² Their growth medium comprises, more specifically, “carbohydrates, fats, amino acids, vitamins, minerals, and non-animal proteins” that mimic the natural growth conditions within an animal.²³ Some growth mediums contain Fetal Bovine Serum (FBS) derived from a cow fetus’ blood. FBS has been one of the controversial aspects surrounding cultured meat.²⁴ However, Aleph Farms guarantees not to use “FBS or any other animal-based ingredients aside from angus cow cells”.²⁵

Aleph Farms offers a “structured meat product”, meaning that cells are structured into an appropriate configuration and need a scaffold.²⁶ Technological advancements have allowed meat cultivation in three-dimensional forms, enhancing the resemblance to traditionally farmed meat. This development is similar to medical scientists’ process of growing artificial organs. As the cells proliferate, they are guided to develop into muscle fibres and collagen, the primary constituents of meat, through a scaffolding

APARECIDO BOSCHERO / VANETE THOMAZ SOCCOL / LEONARDO WEDDERHOFF HERRMANN / RAFAELA DE OLIVEIRA PENHA / ADENISE LORENCI WOJCIECHOWSKI / CARLOS RICARDO SOCCOL, *Cultivated meat: Recent technological developments, current market and future challenges*, *Biotechnol. Res. Innov.* 2021, p. 1.

18 JONATHAN MW SLACK, *What is a stem cell?*, *Wiley Interdiscip. Rev. Dev. Biol.* 2018, p. 1.

19 WOJCIECH ZAKRZEWSKI / MACIEJ DOBRZYŃSKI / MARIA SZYMONOWICZ / ZBIGNIEW RYBAK, *Stem cells: past, present, and future*, *Stem Cell Res. Ther.* 2019, p. 1.

20 Website of Aleph Farms, *FAQ: What is Cultivated Meat?*

21 *bbc.com* from 2 June 2023 (*Why cultivated meat is still so hard to find*).

22 Website of Aleph Farms, *Our Technology*.

23 Website of Aleph Farms, *Our Technology*.

24 *slate.com* from 11 July 2017 (*The Gruesome Truth About Lab-Grown Meat*).

25 Website of Aleph Farms, *FAQ: What is Cultivated Meat?*

26 ISHA DATAR / MIRKO BETTI, *Possibilities for an in vitro meat production system*, *Innov. Food Sci. Emerg. Technol.* 2010, p. 13.

structure that supports the tissue as it matures, thereby emulating the texture and structure of conventional meat.²⁷ Aleph Farms uses a scaffolding structure made of soy and wheat. In this production stage, the specifics of the final meat product to be achieved (e.g., steak, filet, etc.) are considered to guide the growing process.

- 12 Finally, after a four-week process in the case of Aleph Farms,²⁸ the cells will be ready for harvesting, compared to a minimum of seventy-four weeks for beef raised within standard animal agriculture, from fertilization to growing the beef to slaughter weight.²⁹

2. Taste and safety

- 13 The first ever lab-grown burger in 2013 passed the blind test of consumers, according to whom it tasted like meat and “not a soya copy”.³⁰ Blind tastes seem to be a successful exercise for cultured chicken, beef, pork, or fat.³¹ The cultured cells are exact copies of naturally occurring cells, which means the taste is similar. The taste is further engineered by selecting the more flavourful cells. The most challenging aspect is the texture and how the cells are structured to make it seem like meat.³² In 2023, the Netherlands became the first country to allow taste tests before regulatory approval.³³
- 14 Beyond taste, cultured meat raises consumer safety concerns. In early 2023, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) published a report evaluating the current safety of food derived from cell-cultivated products. Potential hazards relate to four main categories: residues (whether physical, chemical, or biological) in the meat following the production process, microbial contamination, allergens, and risk of epigenetic drift.³⁴ The

27 Website of Aleph Farms, *Our Technology*.

28 Website of Aleph Farms, *Our Technology*.

29 The definition of beef in this article is based on Swiss standards. In the explanatory notes (D6) of Swiss customs tariff 0201 and 0202, veal is defined as follows: “bovine animals up to 8 months old and weighing up to 160 kg dead”. A cow’s gestation period lasts 9 months, this amounts to 17 months in total or 74 weeks.

30 [bbc.com](https://www.bbc.com) from 5 August 2013 (*What does a stem cell burger taste like?*).

31 time.com from 19 January 2022 (*Cultivated Meat Passes the Taste Test*); theguardian.com from 8 April 2023 (*‘Softer and more gelatinous’: taste testing Australia’s first lab-grown pork*); mosameat.com from 20 September 2023 (*Our latest taste test*).

32 Australian Financial Review from 14 July 2023 (*Get ready to eat unicorn meat*).

33 forbes.com from 17 March 2022 (*Dutch Parliament Approves Cultured Meat Tasting In The Netherlands*).

34 Food and Agriculture Organization (FAO) & World Health Organization (WHO) (n.2). The risk of epigenetic drift means that as cells used to produce the meat grow and multiply over time, they may undergo changes in their gene activity due to chemical modifications on their DNA. These changes can affect the quality, safety, and consistency of cultured meat, potentially leading to unexpected differences in

report concluded that most of those risks already exist in conventionally produced food and that relevant risk-mitigating tools and food safety assessments are available. Over time, the genetic stability of the immortalized cells is probably the most extraordinary risk compared to conventional meat. Even though “several unanswered questions” remain, this uncertainty does not make cultured meat intrinsically dangerous.³⁵ The literature highlights the importance of science-based harmonized legislation between countries to guarantee adequate food safety.³⁶ The cultured meat industry calls for the implementation of standardized safety assessment methods. It suggests using techniques from conventional and novel foods, foods produced with biotechnology, and pharmaceuticals.³⁷

III. Switzerland: home to the first market access request

1. The company behind the request

In July 2023, the Israeli company Aleph Farms submitted 15 its application for a consultation procedure on the novel food status of a “cultured meat product” to the Swiss Federal Food Safety and Veterinary Office (FSVO).³⁸ This consultation procedure constitutes an initial administrative stage, which, if novel food status for this “cultured meat product” is recognized, will be followed by a substantive stage in view of obtaining regulatory approval and market access authorization. Aleph Farms’ application to the Swiss FSVO is the first of its kind in Europe in the context of cultured meat market access authorization.

Aleph Farms was founded in Israel in 2017 and unveiled 16 the “world’s first cultivated thin-cut steak” in December 2018. This beef steak received market access authorization from the Israeli Health Ministry in January 2024. Aleph Farms defines itself as a “cellular agriculture company”³⁹ and positions its product as a new category derived from cattle alongside beef and milk. Aleph Farms clearly states that its product is not vegetarian. However, company communications describe the product as “vegetarian-friendly and vegan-friendly” since it is produced “without

texture, taste, or nutritional value. Ensuring that the cells remain stable and consistent is crucial for producing high-quality cultured meat that is safe to eat.

35 EMILY SOICE / JEREMIAH JOHNSTON, *Immortalizing Cells for Human Consumption*, *Int. J. Mol. Sci.* 2021, article 11660.

36 YUXIANG GU / XING LI / ERIC CHUN YONG CHAN, *Risk assessment of cultured meat*, *Trends Food Sci. Technol.* 2023, p. 491.

37 KIMBERLY J. ONG / JEREMIAH JOHNSTON / ISHA DATAR / VINCENT SEWALT / DWAYNE HOLMES / JO ANNE SHATKIN, *Food safety considerations and research priorities for the cultured meat and seafood industry*, *Compr. Rev. Food Sci. Food Saf.* 2021, p. 5421.

38 FSVO and FDHA (n.14).

39 Website of Aleph Farms, *About*.

slaughtering or inflicting harm” and it is “not harvested from an animal carcass”.⁴⁰

- 17 Aleph Farms has an established connection to the Swiss meat market. In May 2019, the largest Swiss retail company, Migros, invested in Aleph Farms through its subsidiary “M-industry”, which includes the “Micarna” group, Switzerland’s leading meat, poultry, egg, and seafood producer, based on sales numbers.⁴¹ The amount of Migros’ investment is not precisely known. Aleph Farms raised USD 11.7M during this round, with several other companies investing in the startup.⁴² Aleph Farms and Migros have developed a “go-to-market strategy” to commercialize and distribute the product Aleph Cuts in Switzerland.⁴³ In 2021, Migros also invested in the Israeli startup “Supermeat”, which specializes in producing cultured chicken meat.⁴⁴ Furthermore, Migros developed “The Cultured Hub”, a Swiss cultured meat startup incubator, together with the flavour manufacturer Givaudan and the technology group Bühler.⁴⁵

2. Beyond the request: some European context

- 18 Why was the first application for a consultation procedure on the novel food status of cultured meat filed in Switzerland, and not in the EU? While regulations are similar and even intertwined, including in the case of (novel) food law,⁴⁶ the EU’s internal market is much larger than the Swiss one. However, administrative and political considerations seem to have influenced the decision in favour of Switzerland.⁴⁷
- 19 The European Union Food Safety Authority (EFSA) has authorized novel foods from vegetal cultured cells as dietary supplements.⁴⁸ However, no application for cultured

meat has been submitted in the EU as of January 2024.⁴⁹ Food industry stakeholders note that the EU is not a priority due to administrative obstacles, as the procedure lacks transparency and communication channels.⁵⁰ The lengthy procedure was also mentioned.⁵¹ Although the EU refined its laws in 2018, it can still take up to three years for applications to be accepted and given permission to proceed.⁵² Furthermore, industry stakeholders have commented that “Europe is sending mixed messages”,⁵³ highlighting the stark difference between countries like the Netherlands and Germany on the one hand and Italy and France on the other hand.⁵⁴

In contrast, the Swiss FSVO offers application templates, which “provide clarity and transparency for producers”, and it allows direct communication regarding the application.⁵⁵ The timeframe between application and decision is usually between 6 and 19 months. Aleph Farms expects the procedure to take “between 12–24 months”.⁵⁶ Politically, the Swiss government has cautiously welcomed cultured meat. In response to a parliamentary motion calling for a ban on cultured meat, the Swiss Federal Council responded that it would be a “pointless and disproportionate measure” from the point of view of “consumer

40 Website of Aleph Farms, FAQ: *What is Cultivated Meat?*; website of Aleph Farms, *Eyes on COP27: The Psychological Challenge in Transforming Food Production*.

41 Website of Migros Industrie, *The Micarna Group*.

42 swissinfo.ch from 14 May 2019 (*Swiss supermarket invests in Israeli lab-grown steak firm*); prnewswire.com from 14 May 2019 (*Aleph Farms Secures US\$12M*).

43 Website of Aleph Farms, *Aleph Farms Submits Application to Swiss Regulators, Marking the First-ever Submission for Cultivated Meat in Europe*.

44 Migros Magazine from 30 October 2023 (*De la vraie viande sans souffrance animale*).

45 Website of the Bühler Group, *Launch of The Cultured Hub in Kemptthal*.

46 Website of the Federal Food Safety and Veterinary Office (FSVO), *Authorisation of novel foods*.

47 Disclaimer: the facts discussed in this section of the paper heavily rely on industry communications, which may not display the most unbiased point of view.

48 Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. The specific application for market access authorization was submitted by a Swiss company, Mibelle Group Bio-

chemistry. See Commission Implementing Regulation (EU) 2023/2847 of 20 December 2023 authorizing the placing on the market of apple fruit cell culture biomass as a novel food and amending Implementing Regulation (EU) 2017/2470. For further details, see EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA), Safety of apple fruit cell culture biomass as a novel food pursuant to Regulation (EU) 2015/2283, EFSA J. 2023, article e08065; ANU LÄHTEENMÄKI-UUTELA / MOONA RAHIKAINEN / ANNIKA LONKILA / BAORU YANG, *Alternative proteins and EU food law*, Food Control 2021, article 108336.

49 European Commission, *Summary of applications and notifications*. See also European Food Safety Authority (EFSA), *Novel food and traditional food applications*; foodsafetynews.com from 3 October 2023 (*EFSA ready to evaluate lab-meat applications whenever it gets one*).

50 agfundernews.com from 15 March 2023 (*Precision fermentation startups team up to tackle ‘black box’ EU novel foods process*); euronews.com from 18 November 2022 (*More companies are making lab-grown meat – so why isn’t it for sale in European shops?*).

51 agfundernews.com from 1 June 2023 (*Cultivated meat: Foodtech fantasy or the future of meat? ‘None of this stuff makes any commercial sense until everyone’s eating it’*).

52 politico.eu from 27 December 2020 (*Europe lags behind in lab-grown meat race*); politico.eu from 14 December 2020 (*From mealworms to ‘miracle’ berries, EU sees boom in novel food applications*).

53 foodmanufacture.co.uk from 26 July 2023 (*Europe’s first application to sell cultivated meat submitted in Switzerland*).

54 forbes.com from 17 March 2022 (*Dutch Parliament Approves Cultured Meat Tasting In The Netherlands*); foodnavigator.com from 20 November 2023 (*German Government to boost alternative proteins with € 38m investment*); forbes.com from 19 November 2023 (*Italy’s Cultivated Meat Ban Just A ‘Strategic Move’ Ahead EU Elections, NGO Say*); francetvinfo.fr from 8 December 2020 (*La viande artificielle est-elle l’avenir de l’alimentation?*).

55 agfundernews.com from 1 June 2023 (*Cultivated meat: Foodtech fantasy or the future of meat? ‘None of this stuff makes any commercial sense until everyone’s eating it’*).

56 agfundernews.com of 26 July 2023 (*Aleph Farms applies to Swiss regulator for cultivated meat approval*).

safety” and “research”. It would harm “the Swiss economy if such products were imported and placed on the market by foreign companies, instead of being manufactured in Switzerland”.⁵⁷

- 21 Following the market access authorization request from Aleph Farms, the Swiss FSVO is called upon to examine the application and decide. The question thus arises as to how Swiss food law apprehends the novel food technology of cultured meat.

IV. Positioning cultured meat in Swiss food law

1. Is it meat? Taxonomy of food product categories

- 22 The advent of cultured meat presents complex challenges concerning its categorization within the existing taxonomy of food products.⁵⁸ This innovative product compels us to reconsider the fundamental definition of meat: Is the term appropriate if no live animal has been involved in the production process? Or should it be deemed a derivative product of animal origin? Alternatively, does it necessitate the establishment of a new “sui generis” food category? These are not merely academic inquiries; the classification of cultured meat has tangible repercussions for the legal framework governing food safety and the procedural intricacies of market access authorization.⁵⁹
- 23 Meat constitutes a product embedded with substantial cultural significance and connotations. In many countries, the connection between meat and animals’ flesh/organs, “perceptions of naturalness, sustainability, religious perspectives, and affordability” is central to defining meat.⁶⁰ According to some literature, “cultured meat in general is considered a technology product rather than meat”, pointing towards a potential new food category.⁶¹ Other authors argue that cultured meat constitutes meat if the final product is indistinguishable from conventional meat from safety, taste, and nutritional perspectives.⁶²

57 Motion of Pierre-André Page (National Council) 23.3726 from 14 June 2023, *Interdiction de production de viande artificielle*.

58 TONI RYNNÄNEN / ANNI TOIVANEN, Hocus-pocus tricks and moral progressions: The emerging meanings of cultured meat in online news comments, *Food Cult. Soc.* 2023, p. 591.

59 STEPH TAI, *Legalizing the meaning of meat*, *Loy U Chi LJ* 2019, p. 743.

60 CAMERON FAUSTMAN / DEB HAMERNIK / MICHAEL LOOPER / STEVEN A. ZINN, Cell-based meat: the need to assess holistically, *J. Anim. Sci.* 2020, article skaa177.

61 JIQING HANSEN / CATALINA SPARLEANU / YAHAN LIANG / JESSICA BÜCHI / SOMYA BANSAL / MIGUEL ÁNGEL CARO / FRANK STAEDTLER, Exploring cultural concepts of meat and future predictions on the timeline of cultured meat, *Future Foods* 2021, article 100041.

62 DUSTIN D. BOLER / DALE R. WOERNER, What is meat? A perspective from the American Meat Science Association, *Anim. Front.* 2017, p. 8.

The Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act or FSA) is Switzerland’s primary legislation governing foodstuffs.⁶³ It relies on risk-based regulation, consumer protection, and food safety principles.⁶⁴ Foodstuffs are “all substances or products that are intended or may reasonably be expected to be consumed by human beings in a processed, partly processed or unprocessed state” (Art. 4 FSA). For meat production, the Swiss Federal Council “determine(s) the animal species whose meat may be used as foodstuffs” (Art. 9 FSA). The Federal Department of Home Affairs (FDHA) Ordinance on Foodstuffs of Animal Origin (AFO) supplements the FSA.⁶⁵

Cultured meat is a foodstuff under the FSA, as it is “intended to be consumed by human beings”. According to Art. 4 AFO, meat means all edible parts of animals belonging to the species listed in Art. 2 let. a to f (authors’ translation). The definition of meat thus includes two criteria: (1) animals belonging to listed species and (2) being an edible part of such animals.

AFO’s positive species list includes cattle, poultry, and more unusual species (Art. 2 let. a to m). Cultured meat can thus be considered meat under the AFO, pending the “edibility” criteria. Art. 5 let. a AFO states the rules regarding animal parts in mammals that are unfit for consumption, and thus may not be processed into foodstuffs, or passed on to the consumer (authors’ translation). This negative list refers to various parts, including the entire urinary and genital system, except for the kidneys, bladder, and testicles. In the context of cultured meat, Aleph Farms starts its production process with a fertilized egg sourced from Lucy, an Angus cow. Therefore, the urinary and genital systems might be relevant. Questions arise about whether cultured meat is fit for consumption according to AFO:

— Firstly, the question arises of whether a fertilized ovum constitutes a component of the genital system. This issue is primarily anchored in biological definitions, although the AFO provides a few regulatory clues. Notably, in contrast to mammals, Art. 5 let. b AFO delineates certain parts of poultry as being unfit for consumption by specifying the organs of the genital system as opposed to the entire genital system. Such language may infer a regulatory distinction predicated on the permissibility of consuming poultry eggs, which are predominantly unfertilized ova but may occasionally be fertilized. This regulatory distinction between poultry and mammals suggests

63 Federal Act on Foodstuffs and Utility Articles of 20 June 2014 (Foodstuffs Act, FSA; RS 817.0).

64 EVELYN KIRCHSTEIGER-MEIER, Food regulations and enforcement in Switzerland, *Ref. Module Food Sci.* 2019, p. 225.

65 Federal Department of Home Affairs (FDHA) Ordinance on Foodstuffs of Animal Origin of 16 December 2016 (AFO; RS 817.022.108).

that the fertilized egg of an Angus cow might be classified under the ambit of the genital system unfit for consumption.

- Secondly, is cultured meat a fertilized egg processed into foodstuffs or a conglomerate of muscle and collagen cells that have differentiated from original genital system cells? In traditional livestock farming, the regulatory framework typically disregards the origination from a fertilized egg, focusing instead on the end product. Similarly, cultured meat aligns with this paradigm through the differentiation into muscle and collagen cells. Hence, it warrants recognition as fit for consumption.

- 27 Cultured meat thus matches the two criteria of Art. 4 AFO for meat. Based on this taxonomy, questions might arise regarding the type of meat and meat transformation it could be classified as, relevant for labelling and importing cultured meat products.

2. Novel foods: obligation to request market access authorization

- 28 Beyond the classification of cultured meat as a product of animal origin and meat, more specifically, the question of market access arises. Regulation of market access for foodstuffs in Switzerland distinguishes products and actors related to these products.

- 29 For foodstuffs of animal origin, any establishment that manufactures, transforms, processes, stores, or supplies food is subject to authorization from the competent cantonal enforcement authority (Art. 11 FSA; Art. 21 FUAO⁶⁶). This obligation is subject to various exceptions, such as for establishments whose activities are limited to primary production, establishments whose activities are limited to transportation, retail establishments whose activities are limited to the direct supply of food of animal origin to consumers, etc. (Art. 21 para. 2 FUAO).

- 30 For the products themselves, no general authorization regime is in place. Foodstuffs can, in principle, be placed on the market provided that they are safe (Art. 7 FSA; Art. 8 FUAO) and do not mislead consumers (Art. 18 FSA; Art. 12 FUAO).

- 31 However, this general regime applicable for foodstuffs is subject to exceptions. The Federal Council may introduce specific requirements (Art. 7 para. 5 FSA). For some products, the law imposes positive lists (e.g., Art. 4 para. 1 AFO: meat means all edible parts of animals belonging to the species listed in Art. 2 let. a to f), negative lists (e.g., Art. 5

⁶⁶ Federal Council Ordinance on Foodstuffs and Utility Articles of 16 December 2016 (FUAO; RS 817.02).

let. a AFO: animal parts in mammals that are unfit for consumption), notification requirements (e.g., baby formula: Art. 11, 17, 27 SDRO),⁶⁷ and authorization requirements (e.g., novel food: Art. 15 ff. FUAO; genetically modified organisms: Art. 30 ff. FUAO).

New types of products considered novel foods adhere to norms of a distinct regulatory framework. The FSVO has approved market access for insects as novel food since May 2017 for mealworms, crickets, and locusts.⁶⁸ Despite their apparent nature as foods of animal origin, these species do not figure in the AFO, which gives novel foods an exceptional status among animal foodstuffs. The norms on novel food take precedence over the general regulatory framework applicable to food products of animal origin.

According to Swiss law, the definition of novel foods contains two elements.⁶⁹ Art. 15 para. 1 FUAO defines novel foods as foodstuffs that have not been used for human consumption to a significant degree in Switzerland or any member state of the European Union before 15 May 1997 (authors' translation). Cultured meat matches this temporal criterion.

In addition, foodstuffs must belong to one of the novel food categories enumerated by the FUAO (Art. 15 para. 1 let. a to j). Two novel food categories among the enumerated list are particularly relevant to cultured meat: Art. 15 para. 1 let. e FUAO mentions foodstuffs consisting of, isolated from, or manufactured from animals or parts thereof, and let. f. foodstuffs consisting of, isolated from or manufactured from cell or tissue cultures derived from animals, plants, micro-organisms, fungi, or algae.

Genetically modified foodstuffs do not fall into the category of novel foods (Art. 15 para. 2 let. a). However, Aleph Farms states that they “do not genetically modify or immortalize” any cells used to cultivate steaks.⁷⁰

Art. 16 FUAO regulates the conditions under which novel foods may be placed on the market. The Federal Department of Home Affairs (FDHA) has either designated them

⁶⁷ Federal Department of Home Affairs (FDHA) Ordinance of 16 December 2016 on Foodstuffs for Persons with Special Dietary Requirements (SDRO; RS 817.022.104).

⁶⁸ See website of the Federal Food Safety and Veterinary Office (FSVO), Les insectes comme denrée alimentaire.

⁶⁹ EVELYN KIRCHSTEIGER-MEIER, Carte Blanche: die Komplexität der Neuartigkeit, Lebensm.-Ind. Fachmag. Für Manag. Nahrungsmittel-Getränkeind. 2023, p. 12.

⁷⁰ Cf. Website of Aleph Farms, FAQ. There are additional legal considerations if genetic modifications are involved in cell lines. The FUAO contains specific provisions on genetically modified organisms in Section 6, Article 30 ff. In its Article 30, it defines GMPs as “any organism whose genetic material has undergone a modification that does not occur naturally, either by multiplication or by natural recombination”.

in an ordinance as foodstuffs that may be placed on the market (Art. 16 let. a),⁷¹ or the FSVO has authorized them under Art. 17 (Art. 16 let. b).⁷²

- 37 Art. 17 FUAO specifies the market access authorization procedure. An authorization is granted if two cumulative conditions are met. The FSVO first determines whether the requirements for safety and non-deception of consumers stated in Art. 3 para. 1 are fulfilled (Art. 17 para. 1 let. a). Second, the new type of foodstuff, when it is intended to replace an existing foodstuff, does not differ from the old type to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer (Art. 17 para. 1 let. b) (authors' translation). This condition is highly relevant to cultured meat.
- 38 The formal requirements for the application for market access authorization are laid out in Art. 2 para. 2 of the FDHA Ordinance on Novel Foods⁷³, which describes the necessary information to be submitted: let. a a proposal for a specific name; let. b a description; let. c composition and specifications; let. d where appropriate, methods of analysis; let. e scientific data proving that the new type of foodstuff meets the safety and non-deception requirements of Art. 17 para. 1 FUAO; let. f where applicable, the intended use and the conditions of use; let. g presentation and labelling; let. h the manufacturing process or multiplication or reproduction practices.
- 39 In practice, the application form submitted to the FSVO consists of two parts.⁷⁴ Part A concerns the consultation procedure for determining the novel food status of a product. Aleph Farms' application is currently at this stage.⁷⁵ Part B involves the documents for the application's substantive assessment. Documents relating to composition and specification, analytical methods, scientific data, intended use, and production process must be prepared and submitted following the "Administrative

guidance on the submission of applications for authorization of a novel food pursuant to Art. 10 of Regulation (EU) 2015/2283".⁷⁶ In general, documentation must be provided for each potential safety hazard, particularly the "composition of the novel food, its manufacturing process, its history of use, the results of animal and/or human studies".

This administrative guidance provides a "completeness checklist", recommending specific documents for each type of novel food. In the case of cultured meat, the applicant needs to specify the key steps of the production process; quality and safety assurance and standardization criteria; organ and tissue or part of the organism sourced; laboratory or culture collection sourced; information on the identity of cells; information on the handling of the sources, use of pesticides, antimicrobials, and antiparasitic agents; growth medium and culture conditions; qualitative and quantitative data on the composition, including impurities, byproducts, residues and contaminants; whether the novel food is intended to replace another food and if so, demonstration that the novel food does not differ in a nutritionally disadvantageous way; toxicological information; allergenicity. This list is completed in more detail by the "Guidance on the preparation and submission of an application for authorization of a novel food in the context of Regulation (EU) 2015/2283".⁷⁷

The purpose of these requirements is to guarantee safety and quality standards to protect consumers. The heart of the FSVO examination of Aleph Farms' application lies in the scientific data proving that cultured meat is safe and nutritionally equivalent to traditional meat. This examination ensures that the methods and substances used in the cell culturing process meet established food safety standards. Beyond the nutritional standards that must be similar to traditional meat, no regulatory benchmarks relate to texture, taste, and other quality parameters associated with meat products.

Without access to Aleph Farms' scientific data, it is difficult to predict the outcome of the current market access authorization procedure. Should cultured meat be classified as a novel food and authorized by the FSVO, a permit is issued. Such a permit can only be granted to individuals or entities with a domicile or registered office in Switzerland. Applicants established abroad must be represented in Switzerland; the representative submits the

71 See Annex Federal Department of Home Affairs (FDHA) Ordinance of 16 December 2016 on Novel Foods (RS 817.022.2). This annex contains a list of recognized novel foods which may be placed on the market in Switzerland without authorization.

72 Federal Food Safety and Veterinary Office and Federal Department of Home Affairs (n. 14).

73 Federal Department of Home Affairs (FDHA) Ordinance of 16 December 2016 on Novel Foods (RS 817.022.2).

74 Federal Food Safety and Veterinary Office (FSVO), Application According to Article 16 Letter b of the Ordinance on Foodstuffs and Utility Articles (FUAO; SR 817.02) in Regard to Placing on the Market a Novel Foodstuff Pursuant to Article 15 Paragraph 1 Letters a-j of the FUAO, June 2020. See also: Federal Food Safety and Veterinary Office and Federal Department of Home Affairs (n. 14).

75 Federal Food Safety and Veterinary Office (FSVO), Application According to Article 16 Letter b of the Ordinance on Foodstuffs and Utility Articles (FUAO; SR 817.02) in Regard to Placing on the Market a Novel Foodstuff Pursuant to Article 15 Paragraph 1 Letters a-j of the FUAO, June 2020. See also: Federal Food Safety and Veterinary Office and Federal Department of Home Affairs (n. 14).

76 European Food Safety Authority (EFSA), Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283, EFSA Support. Publ. 2021, article 6488E. This guidance is currently being revised.

77 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) Products, Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/22831 (Revision 1), EFSA J. 2021, article e06555.

authorization request and undertakes to comply with the requirements (Art. 4 FUAO).

- 43 The authorization is granted for five years with no option of extension. If the conditions relating to food safety and the prohibition of deception remain fulfilled after this period, cultured meat will be included in the Annex to the FDHA Ordinance on Novel Foods following re-examination by the FSVO. (art. 17 para. 2; Art. 16 let. a FUAO).
- 44 Considering that knowledge about the safety and quality of novel food might evolve due to evolving science and technology, Art. 19 FUAO specifies that any person who manufactures, processes, imports, or places on the market a novel food must communicate new knowledge on the safety of the food to the FSVO without delay and spontaneously.
- 45 For now, this novel food regulatory framework applies in Switzerland. In contrast, some countries, such as Singapore, have designed specific legal frameworks for the new foodstuff of cultured meat.⁷⁸

V. Conclusion

- 46 While promising, integrating cultured meat into the market mandates a multifaceted approach to regulation that ensures public health and consumer safety. Switzerland's encounter with the first market access authorization request for cultured meat in 2023 serves as a case study for Europe, illustrating the potential and pitfalls of navigating uncharted regulatory waters in the context of novel food technologies. The Swiss authorities' decision will impact how other authorities handle market access authorization for cultured meat, particularly in the EU.
- 47 The legal challenges of cultured meat extend far beyond the initial hurdle of market access authorization. These challenges encompass a range of complex issues that legal frameworks worldwide are only beginning to grapple with. Further research will be necessary to address regulatory issues such as animal welfare, product labelling, and importation and tariff quotas.

78 TAI (n. 59); TOMÁŠ VLČKO / KRZYSZTOF BOKWA / IWO JAROSZ / ANDRZEJ SZYMKOWIAK / JOZEF GOLIAN / MARCIN ANTONIAK / PIOTR KULAWIK, Cell-Based Meat Labeling – Current Worldwide Legislation Status, *Ann. Anim. Sci.* 2023, p. 927.

Cultured meat requires an initial harvest of animal cells. The extent to which this process must adhere to animal welfare laws needs to be clarified. Moreover, existing regulations require labelling to inform consumers about the nature and origin of meat products.⁷⁹ The challenge with cultured meat is determining how it should be labelled to avoid deception, considering it is neither plant-based nor conventionally produced animal meat.

This ambiguity extends to the product nomenclature – should it be labelled simply as “steak” or more accurately as “cultured steak”? Further, there are implications for marketing terms such as “sustainable”, prompting a debate on whether these descriptors and the claims they represent can be congruently applied to these novel products. Traditional meat producers may seek to differentiate their offerings with qualifiers like “natural” or “traditional”. Finally, stringent importation barriers and tariffs insulate the Swiss meat market. Due to the global nature of food distribution and the fact that cultured meat is currently produced outside of Switzerland, the regulatory question arises of whether cultured meat falls under the existing importation and tariff quotas for meat, and if yes, under which category.

Beyond the regulatory issues surrounding market access for cultured meat, consumers' trust in this novel food product remains to be seen. The requirement of comprehensive labelling to empower consumers and ensure transparency and informed choice will play a critical role. Cost estimates for cultured meat are relatively high (63 USD/kg).⁸⁰ Influenced by trust and price, consumers' attitudes⁸¹ will be the stepping stone in realizing the potential of this supposedly sustainable, animal-friendly novel product and the transition it may bring for agriculture and food systems.⁸²

79 VLČKO et al. (n. 78).

80 GREG L. GARRISON / JON T. BIERMACHER / B. WADE BRORSEN, How much will large-scale production of cell-cultured meat cost?, *J. Agric. Food Res.* 2022, article 100358.

81 LEONORE LEWISCH / PETRA RIEFLER, How social norms and dietary identity affect willingness to try cultured meat, *Br. Food J.* 2024, p. 1014; LEONORE LEWISCH / PETRA RIEFLER, Behavioural intentions towards cultured meat: the role of personal values, domain-specific innovativeness and distrust in scientists, *Br. Food J.* 2023, p. 1769.

82 CHARLOTTE BLATTNER, Just transition for agriculture? A critical step in tackling climate change, *J. Agric. Food Syst. Community Dev.* 2020, p. 53.

Abstract

Kultiviertes Fleisch, das aus Zellkulturen statt aus geschlachteten Tieren gewonnen wird, liegt schon bald auf den Tellern. Trotz seines Potenzials für Nachhaltigkeit, Tierschutz und Lebensmittelsicherheit steht kultiviertes Fleisch vor regulatorischen Herausforderungen. Im Jahr 2023 hat Aleph Farms in der Schweiz den ersten europaweiten Antrag auf Marktzugang gestellt. Der vorliegende Beitrag analysiert den schweizerischen Rechtsrahmen für kultiviertes Fleisch. Er konzentriert sich auf die Klassifikation und das Zulassungsverfahren für den Marktzugang neuartiger Lebensmittel. Er plädiert dafür, dass sich die Vorschriften mit dem technologischen Fortschritt weiterentwickeln, während gleichzeitig die Sicherheit der Verbrauchenden gewährleistet sein muss.

Abstract

La viande cultivée, produite à partir de cultures cellulaires plutôt que d'animaux abattus, est sur le point d'arriver dans nos assiettes. Bien qu'elle présente un fort potentiel en matière de durabilité, de bien-être animal et de sécurité alimentaire, cette viande de culture doit surmonter plusieurs obstacles réglementaires. En 2023, Aleph Farms a soumis en Suisse la première demande d'accès au marché à l'échelle européenne. Cet article examine le cadre juridique suisse applicable à la viande cultivée, en mettant particulièrement l'accent sur la taxonomie des produits alimentaires et sur la procédure d'autorisation pour les nouveaux aliments. Il souligne également la nécessité d'adapter la réglementation aux avancées technologiques, tout en garantissant la sécurité des consommateurs.