Frankenburgers, Risks and Approval

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This piece critically analyses the development of a novel food technology: the Frankenburger, a type of cultured/in vitro meat (or 'shmeat', which stands for 'sheet of meat'). It assesses the risks raised by cultured meat as well as the role it could play to alleviate environmental and food security concerns. The article argues that the current EU regulatory structures for cultured meat, and for novel foods more generally, ought to be strengthened. There is a necessity to transfer and develop food innovations in partnerships with all the relevant stakeholders (the public, scientists, the food industry, policy-makers and regulators). Including interested parties from the inception of a technology as well as within the decision-making process would provide a supporting framework for cultured meat.

I. Introduction

On the 5th of August 2013, the first stem-cell burger developed by Professor Post from the University of Maastricht was presented at the Riverside Studios in Hammersmith, London, in front of more than 200 journalists and guests. The testers observed that the £250,000 (€300,000) burger did not have much flavour, although the experts said that this could be easily rectified. One of the two testers said that: 'the absence of fat makes a big difference. It has the texture, which I was not expecting. It was like an animal-protein cake' and remarked that the whole experience was rather unnatural.[1] Evidently, the burger was close to meat in flavour and texture but not as juicy, and overall was not that pleasant. Since the event, various names have been given to this burger: test-tube; lab-grown; cultured; in vitro; proof of principle; cruelty-free; laboratory; and the Frankenburger. The Frankenburger falls under the general classification of synthetic meat or 'shmeat' ('sheet of meat') and for regulatory purposes, it constitutes in the European Union (EU) a 'novel food'.[2] 'Shmeat' was a runner-up for word of the year for Oxford Dictionaries in 2013.

It can be argued that this revolutionary technological breakthrough constitutes a triumph for science and ethics. Because cultured meat has the potential to generate life changing societal implications and contributions (in particular to help assuage world hunger and animal cruelty), it tends to generate, like genetic engineering (GE) and animal cloning, strong reactions, both positive and negative. The debate over cultured meat raises similar issues and challenges to the debate over modern agricultural biotechnologies and their resulting products.[3] New technologies generally give rise to recurrent issues and cultured meat is no exception to the rule: How does it operate? How does it differ from previous technologies? What are the benefits? What are the impacts on the environment, human health and society? Is it safe? Are there risks? Who decides its development and marketing? What is the role of the public in its evolution process? And, as a result can it be regulated adequately and efficiently?

Part II will provide a critical overview of what constitutes shmeat, and in particular cultured beef, and the technology behind it. It will also evaluate the possible dangers and merits of cultured meat. Part III will analyse public perceptions of this new technology and identify possible solutions to foster public

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1 Mark Brown, "'Frankenburger': It May Be What's for Dinner in 2035", Chicago Sun Times, 5 August 2013, available at http://www.suntimes.com/news/brown/21751235-452/frankenburger-it-may-be-whats-for-dinner-in-2035.html (last accessed on 1 April 2014).

2 Cultured meat falls under the scope of the Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning Novel Foods and Novel Food Ingredients, OJ 1997 L 43/1 (Novel Foods Regulation).

3 And to a certain extent with nanotechnology and its derived foods.

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acceptance. Part IV will assess the EU oversight and regulation of cultured beef as a novel food under the Novel Foods Regulation, including any potential problems and gaps. Part V will critically examine the new EU policy framework on Responsible Research and Innovation (RRI) and its role in the transfer and development of food innovation to gain the public and the food industry's backing, before concluding in Part VI.

II. What is cultured meat, its risks and benefits?

1. Growing meat outside the animal body: a new tool

Cultured meat consists of muscle tissues taken from farm animals grown in the lab – without the rest of the animal. The idea of growing meat in a laboratory can be traced back to Winston Churchill who predicted in 1931 that in fifty years time: '[w]e shall escape the absurdity of growing a whole chicken in order to eat the breast or wing, by growing these parts separately under a suitable medium'.[4] Willem van Eelen pursued the idea of growing meat outside the body from an animal to produce it in a laboratory, mainly to prevent animal suffering. It was in 1981, after the discovery of stem cells in mice that van Eelen saw their potential use for developing cultured meat. In 1999, he received US and international patents for the Industrial Production of Meat Using Cell Culture Methods.[5] The promotion of cultured meat was intensified when, in 2001, NASA funded an experiment, led by Morris Benjaminson, to produce fresh meat for space flights.[6] While the results were not meat, they demonstrated that growing food outside the body was possible. Then, in 2004, after continued lobbying from van Eelen, the Dutch government awarded two million Euros to a consortium of universities and research facilities spread throughout the Netherlands to research on cultured meat, led by Professor Post.[7]

The raw ingredients of the Frankenburger might not sound particularly appealing: 0.5 mm thick strips of stem cells, which are then cultivated in a nutrient broth, allowing them to proliferate 30-fold.[8] The 'broth' is actually a gel-like growth medium that contains antibiotics and a serum extracted from cow foetuses.[9] They are later on combined with an elastic collagen in a culture dish where the cells form into chunks of muscle tissues. Electrical stimulation is used to make the muscle strips contract and compact before the thousands of beef strips are crushed, jointly with 200 pieces of lab-grown animal fat, and moulded into a patty.[10] About 20,000 meat muscle fibres are needed to make one burger. Other ingredients of the Frankenburger include salt, egg powder and breadcrumbs. Red beetroot juice and saffron are added to provide authentic beef colouring and to make it more palatable and pleasing to the eye. The Frankenburger is pure protein: it has no fat or blood, this is why without the additives it would be tasteless.

Cultured meat constitutes another toolkit, like GE and animal cloning, and goes beyond the capabilities of natural mechanisms and processes; such processes could not be achieved naturally. These technologies push forward genetic tinkering. Cultured meat is created by adhering animal stem cells onto biodegradable edible scaffolds, and immersing them into a nutrient bath, causing the growth of muscle cells.[11] This technology borrows an engineering tech-

4 Winston Churchill, "Fifty Years Hence", Strand, December 1931, available at http://teachingamericanhistory.org/library/document/fifty-years-hence/ (last accessed on 1 April 2014).

5 Michael Specter, "Test-Tube Burgers: How Long Will it Be Before You Can Eat Meat that Was Made in a Lab?", New Yorker, 23 May 2011, available at http://www.newyorker.com/reporting/2011/05/23/110523fa_fact_specter (last accessed on 1 April 2014).

6 Morris A. Benjaminson et al., "In Vitro Edible Muscle Protein Production System (MPPS): Stage 1, Fish", 51 *Acta Astronautica* (2002), pp. 879 *et sqq.*, at p. 881. See also, Zachary Schneider, "In Vitro Meat - Space Travel, Cannibalism, and Federal Regulation", 50 *Houston Law Review* (2013), pp. 991 *et sqq.*, at p. 998.

7 Steve Connor, "Special Report: 'In Vitro' Beef – It's the Meat of the Future", Independent, 28 July 2013, available at http://www.independent.co.uk/news/science/special-report-in-vitro-beef--its-the-meat-of-the-future-8735104.html (last accessed on 1 April 2014). See also, Schneider, "In Vitro Meat - Space Travel, Cannibalism, and Federal Regulation", *supra* note 6, at p. 998.

8 Giles Sheldrick, "Try the 'Frankenburger': £250,000 Test-Tube Burger Made Using Stem Cells", Express, 5 August 2013, available at http://www.express.co.uk/news/uk/419837/Try-the-Frankenburger-250-000-test-tube-burger-made-using-stem-cells (last accessed on 1 April 2014).

9 Alok Jha, "Synthetic Meat: How the World's Costliest Burger Made it on to the Plate", The Guardian, 5 August 2013, available at http://www.theguardian.com/science/2013/aug/05/synthetic-meat-burger-stem-cells (last accessed on 1 April 2014).

10 Sheldrick, "Try the Frankenburger", *supra* note 8.

11 Linda MacDonald Glenn and Lisa D'Agostino, "The Moveable Feast Legal, Ethical, and Social Implications of Converging Technologies on Our Dinner Tables", 4 *Northeastern University Law Journal* (2012), pp. 111 *et sqq.*, at p. 122.

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nique that is used to replicate and reproduce cells in regenerative nanomedicine.[12] Cultured meat as a biotechnological technique is therefore closer to cloning as a procedure than GE per se.[13] Genes are not modified or do not move from one species to another. Cells are only replicated.[14]

2. Pros and cons

Biotechnology and in particular the GE of animals and crops and animal cloning are already used with the intention of helping to ease the burdens on the world food supply. For instance, a genetically engineered salmon, the AquAdvantage™ salmon (AAS) developed by AquaBounty Technologies, has the potential to grow to market size in half the time of a conventional Atlantic salmon.[15] The EnviroPig™ also produces lower levels of phosphorus pollution than traditional pigs.[16] Such techniques could increase food yields, reduce production costs and reduce strains on the environment. However, these techniques still put incredible pressure on land, energy, water and natural resources, as well as producing greenhouse gases (GHG). In this sense, they suffer from similar limitations and drawbacks as conventional farming but with potentially less negative impacts. Alternative sources of food must be found and cultured meat is one of the solutions: it has the potential to alleviate environmental and food security issues facing the world.

Meat production is one of the major sources of global environmental degradation and climate change. Livestock raised to produce meat use 30% of ice-free land and 8% of global freshwater, while producing 18% of global GHG, which is more than the worldwide transport sector.[17] Meat is highly inefficient at converting vegetable protein into animal protein. Because of the increasing world population size and higher demands for meat in the developing world, meat consumption on an international scale is expected to double between 1999 and 2050.[18] In contrast, it is estimated that cultured meat requires around 7 to 45% lower energy use (only poultry has lower energy use), 78 to 96% lower GHG emissions, 99% lower land use, and 82 to 96% lower water use, depending on the types of conventional meat compared.[19] Cultured meat would further lead to less ammonia contamination due to livestock waste. Stem cells taken from just one farm animal could, speculatively, be used to produce a million times more meat than could be obtained from a single beef carcass.[20] Cultured meat could lead humanity a step closer to food and environmental sustainability and could be part of the solution to the 'food versus fuel' debate.[21] This is why there exists a tendency in developed

12 Ibid.

13 For more on cultured meat, see: The In Vitro Meat Consortium, "Primer on Technology", available at http://invitromeat.org/content/view/30/51/ (last accessed on 1 April 2014); and The In Vitro Meat Consortium, "Why In Vitro Meat?", available at http://invitromeat.org/content/view/12/55/ (last accessed on 1 April 2014).

14 See e.g., Schneider, "In Vitro Meat - Space Travel, Cannibalism, and Federal Regulation", *supra* note 6, at p. 997. As a result, animal cloning as well as its regulation have the potential to offer insights in cultured meat and its regulation.

15 Scott Gottlieb and Matthew B. Wheeler, "Genetically Engineered Animals and Public Health: Compelling Benefits for Health Care, Nutrition, the Environment, and Animal Welfare", Biotechnology Industry Organization, (2011), at p. 21. For more on the AAS, see Council for Agricultural Science and Technology (CAST), "The Science and Regulation of Food from Genetically Engineered Animals" (2011); and Michael B. Homer, "Frankenfish... It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology", 45 *Columbia Journal of Law & Social Problem* (2011), pp. 83 *et sqq*. 93.

16 Gottlieb and Wheeler, "Genetically Engineered Animals and Public Health", *supra* note 15, at p. 20.

17 Food and Agriculture Organization, "Livestock's Long Shadow" (2006), available at http://www.fao.org/docrep/010/a0701e/a0701e00.HTM (last accessed on 1 April 2014), at p. 4.

18 Ibid.

19 Hanna L. Tuomisto and M. Joost Teixeira de Mattos, "Environmental Impacts of Cultured Meat Production", 45 *Environmental Science & Technology* (2011), pp. 6117 *et sqq*., at p. 6117. Confirmed in Hanna L. Tuomisto and Avijit G. Roy, "Could Cultured Meat Reduce Environmental Impact of Agriculture in Europe?", presentation held at 8th International Conference on "LCA in the Agri-Food Sector", Rennes (France), 2-4 October 2012.

20 Connor, "Special Report: 'In Vitro' Beef", *supra* note 7.

21 The 'food versus fuel' debate highlights the dilemma addressing the risks of using farmland and crops for the production of biofuels to the detriment of the food supply. Two reports link higher food prices to increased biofuel demands. See Food and Agriculture Organization, "State of Food and Agriculture 2012" (2012), available at www.fao.org/docrep/017/i3028e/i3028e.pdf (last accessed on 1 April 2014), at p. 100; and Organisation for Economic Co-operation and Development and Food and Agriculture Organization, "The OECD-FAO Agricultural Outlook 2013-2022" (2013), available at http://www.oecd.org/site/oecd-faoagriculturaloutlook/ (last accessed on 1 April 2014), at p. 9. See also, R. Wes Harrison, "The Food versus Fuel Debate: Implications for Consumers", 41 *Journal of Agricultural and Applied Economics* (2009), pp. 493 *et sqq*.; and, David J. Tenenbaum, "Food vs. Fuel: Diversion of Crops Could Cause More Hunger", 116 *Environmental Health Perspectives* (2008), pp. A254 *et sqq*.

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countries to assert that science has a moral obligation to back this kind of high-tech research.[22]

Relying on cultured meat would create less animal slaughtering and suffering.[23] There could be fewer livestock to care for and these could be probably better looked after, resulting in increased animal health and welfare. For instance, People for the Ethical Treatment of Animals (PETA) offered from 2008 to March 2014 a one million dollar prize for devising a method to produce in vitro chicken in marketable quantities and prices.[24] PETA's provision of funding for the development of the technology shows its approval of the innovation. Consequently, cultured meat could possibly be supported by the scientific, animal rights, vegetarian and environmental (green) communities.

Cultured meat is a 'meat-like' product. Currently, the best known meat substitute is a mycoprotein produced by the fungus Fusarium venenatum, called Quorn, which has been first commercialised in the UK in 1985.[25] This mycoprotein is now contained in a wide range of products worldwide. Arguably, cultured meat could be perceived as a further development from Quorn, veggie sausages, vegetarian bacon made from soya or boca burgers: it 'only' constitutes another technological extension of meat substitutes, which can open many doors to future food innovations.

In vitro meat could reduce many of the public health issues associated with livestock-based meat, in particular deadly foodborne pathogens, such as E. coli and Salmonella, which pose serious health risks.[26] Cultured meat offers the potential to modify meat for health purposes, including boosting levels of polyunsaturated fat, such as omega 3, and reducing the amount of saturated fat present in meat,[27] to obtain more nutritious food. This recalls the pro-vitamin A Golden Rice innovation, the second generation of genetically modified (GM) crops, which presents traits benefiting the consumer, including enhanced nutrition.[28] Cultured meat could allow for more subtle applications of meat that are currently impossible. The 2011 UK Foresight Report on The Future of Food and Farming: Challenges and Choices for Global Sustainability is, however, more cautious, as it warns against the human and environmental safety of any new technology to be rigorously established before its use.[29]

The perceived disadvantages of cultured meat are varied. Professor Post asserted that one of his goals was to have a narrow herd of donor animals that would be kept in the world.[30] Such a practice could be defendable for animal health and welfare reasons but having fewer livestock could, however, lead to a reduction of the gene pool. Genetic diversity would have to be carefully managed.[31] Moreover, cultured meat should not be developed with the sole aim of replacing conventional livestock.[32] While meat production is one of the main contributors to GHG emissions and can lead to the depletion of natural resources, it must not be forgotten that animals, includ-

22 Nuffield Council on Bioethics, "Genetically Modified Crops: The Ethical and Social Issues" (1999), available at http://www.nuffieldbioethics.org/gm-crops (last accessed on 1 April 2014), at p. 131.
See also, Willy De Greef, "Agricultural Biotechnology and Moral Imperatives", 36 *In Vitro Cellular & Developmental Biology - Plant* (2000), pp. 309 *et sqq*.

23 See e.g., MacDonald Glenn and D'Agostino, "The Moveable Feast Legal, Ethical, and Social Implications of Converging Technologies on Our Dinner Tables", *supra* note 11, at p. 123.

24 PETA is now 'eager to move on to yet more innovative ways to combat animal suffering in the meat industry'. See PETA, "PETA's 'In Vitro' Chicken Contest", available at http://www.peta.org/features/vitro-meat-contest/ (last accessed on 1 April 2014). See also, B. George Walker, "Double Trouble: Competing Federal And State Approaches to Regulating the New Technology of Cloned Animal Foods, and Suggestions for the Future", 14 *Journal of Technology Law & Policy* (2009), pp. 29 *et sqq.*, at p. 48; John Schwartz, "PETA's Latest Tactic: $1 Million for Fake Meat", New York Times, 21 April 2008, available at http://www.nytimes.com/2008/04/21/us/21meat.html?_r=0 (last accessed on 1 April 2014).

25 Food Standards Agency, "Emerging Food Technologies: Novel Protein Sources as Food" (2011), at p. 1.

26 Food and Agriculture Organization, "Livestock's Long Shadow", *supra* note 17, at p. 17.

27 P.D. Edelman et al., "Commentary: In vitro-Cultured Meat Production", 11 *Tissue Engineering* (2005), pp. 659 *et sqq*.

28 See e.g., Golden Rice Project, "Golden Rice Is Part of the Solution", available at http://goldenrice.org/ (last accessed on 1 April 2014). Golden rice is a type of GM rice that contains beta-carotene. In countries where rice is a dietary staple, this rice may reduce the incidence of blindness caused by vitamin-A deficiency.

29 UK Government Office for Science, "Foresight Report on The Future of Food and Farming: Challenges and Choices for Global Sustainability" (2011), at p. 167. In the conclusions of the report, a more cautious approach seems to be given to new technologies, such as genetically modified organisms (GMOs) and animal cloning, to think very carefully about the impact of such technologies on the public, farmers and other stakeholders along the food chain.

30 Connor, "Special Report: 'In Vitro' Beef", *supra* note 7.

31 Animal cloning raises the same concern. See e.g., the UK National Standing Committee on Farm Animal Genetic Resources, "Statement on Cloning of Farm Animals" (2011), available at http://archive.defra.gov.uk/fangr/documents/100914-cloning-statement.pdf (last accessed on 1 April 2014), at p. 1.

32 Schneider, "In Vitro Meat - Space Travel, Cannibalism, and Federal Regulation", *supra* note 6, at p. 1024.

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ing livestock, play a crucial role in maintaining ecosystems and biodiversity.[33] The exorbitant cost of cultured meat is also a significant challenge. Another potential impediment is the public willingness to buy such foods: as illustrated by the relationship between European citizens and biotech foods, this could prove difficult.[34]

Numerous risks linked to food safety and human health could potentially arise from cultured meat. Because there are various steps that have to be performed and carried out, cell cultivation can be dangerous: risks of contamination or error during the production and processing of the meat could occur.[35] It can also be argued that cultured meat is underpinned by scientific uncertainty: after all, it is a meat that is produced entirely in a laboratory by using animal stem cells to which additives, antibiotics and colouring are inserted. More importantly, the very simple fact that this technology is so new and that not much scientific evidence has been gathered in relation to its safety raises further concerns. Causal links are 'not always linear and activities may not cause adverse effect[s] until far into the future'.[36]

One of the main tool that can be used by the government when a new technology is released is regulation.[37] The regulation of cultured meat, and more generally of technological risks, is a problem for states, especially when different stakeholders have differing views over the existence of risks and how they should be regulated, as well as which factors should be relevant to regulation-making.[38] The world has become a 'risk society' where 'the unknown and unintended consequences come to be a dominant force in history and society'.[39]

If a new regulation is proposed, opponents of the technology will welcome the regulation (or even a potential ban) while supporters raise the issue of scientific uncertainty to delay or prevent regulation.[40] Some anti-technology activists may argue that the risks posed by cultured meat (and novel food technologies more generally) are too great for these technologies to be pursued.[41] They could call for the strong version of the precautionary principle to be used in order to stop the technology from the outset.[42] An 'overreaction' resulting in a strict application of the principle could produce detrimental effects as it would stop the development of the technology, and could result in a moratorium, creating its own set of counterproductive consequences, i.e. preventing the expansion of an innovation which could provide a solution to world hunger and food security.

Cultured meat, like nanotechnology, is 'suited to ameliorate or eliminate current problems that plague

33 Specter, "Test-Tube Burgers", *supra* note 5. See also, UK National Ecosystem Assessment, "The UK National Ecosystem Assessment: Synthesis of the Key Findings" (2011), available at http://uknea.unep-wcmc.org/Resources/tabid/82/Default.aspx (last accessed on 1 April 2014); His Royal Highness Prince Charles declared that 'the land needs the presence of feeding animals and their droppings for the cycle to be complete, so that soils and grassland areas stay productive'. See Joanna Blythman, "Miracle? No, the New Frankenburger Turns my Stomach", Daily Mail, 5 August 2013, available at http://www.dailymail.co.uk/debate/article-2385137/Miracle-No-new-Frankenburger-turns-stomach.html (last accessed on 1 April 2014).

34 Public acceptance will be the focus of section III.

35 Christina Agapakis, "Steak of the Art: The Fatal Flaws of In Vitro Meat", Discover, 24 April 2012, available at http://blogs.discovermagazine.com/crux/2012/04/24/steak-of-the-art-the-fatal-flaws-of-in-vitro-meat/#.Uwdrds4UDGd (last accessed on 1 April 2014).

36 Elizabeth Fisher, *Risk Regulation and Administrative Constitutionalism* (Oxford: Hart Publishing, 2010), at p. 8. This expanding rupture in the causality chain is paralleled with the increase use of the precautionary principle in the regulatory process as the precautionary principle aims at preventing future hazard when scientific uncertainty is present.

37 To evaluate the possible risks created by such foods, risk analyses are to be undertaken. A risk analysis is a three-tier process: the risk has to be assessed, then managed, as well as being communicated to all stakeholders. At the end of a risk analysis, decision-makers are, arguably, able to decide about the position to adopt and which type of regulation is desirable. See Codex Alimentarius Commission, "Procedural Manual" (2010), at p. 86. It is the same process for analysing the safety of biotech foods, see Codex Alimentarius Commission, "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology" (2008), at p. 1.

38 For more on risk regulation, see: Robert Baldwin (ed.), *Law and Uncertainty: Risks and Legal Processes* (Berlin: Kluwer, 1997); Fisher, *Risk Regulation and Administrative Constitutionalism*, *supra* note 36; Christopher Hood et al., *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford: OUP 2001); Robert G. Lee, "Look at Mother Nature on the Run in the Twenty-First Century: Responsibility, Research and Innovation", 1 *Transnational Environmental Law* (2012), pp. 105 *et sqq.*; Pat O'Malley, *Risk, Uncertainty and Government* (London: Cavendish Press, 2004); Jenny Steele, *Risks and Legal Theory* (Oxford: Hart Publishing, 2004); and Cass R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: CUP, 2005).

39 Ulrich Beck, *Risk Society: Towards a New Modernity* (London: Sage, 1992), at p. 22.

40 See e.g., Daniel Sarewitz, "How Science Makes Environmental Controversies Worse", 7 *Environmental Science and Policy* (2004), pp. 385 *et sqq*, at p. 386; and Sheila Jasanoff, "Biotechnology and Empire: The Global Power of Seeds and Science", 21 *OSIRIS* (2006), pp. 273 *et sqq*, at p. 283.

41 Glenn H. Reynolds, "Nanotechnology and Regulatory Policy: Three Futures", 17 *Harvard Journal of Law & Technology* (2003), pp. 179 *et sqq*, at p. 186 (referring to nanotechnology).

42 The precautionary principle will be developed to a greater extent in section IV.1.

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human health and the environment'[43] and adopting a precautionary approach would 'allow these problems to remain unsolved'.[44] A balance needs to be struck between short term advantages, including reducing food insecurity and achieving sustainability, and long term uncertainties. This situation is similar to the regulation of biotech foods, which is also underpinned by approaches to risk, where the evaluation of the impacts of these foods is also undertaken through science-based risk assessment but still creates several problems for regulators, in particular improving consumer acceptance.[45]

3. An innovation reinforcing the industrialisation of the food chain

Cultured meat further increases dependence on science and business. It may constitute a threat to small farms as it broadens the gap between the food source and the consumer.[46] If the technology became widespread, it could mean that fewer livestock farmers would be needed. In the long term, it could lead to the demise of farmers in the 'Farm to Fork' food supply chain and strengthen the industrialisation of the food chain with highly processed foods, especially processed meat substitutes, in our daily diet. Nonetheless, considering the prohibitive price of cultured meat and in the aftermath of the horsemeat scandal, which reflects the food industry's pressure to obtain cheaper meats, doubts can be cast as to whether the technology will actually take off.

In May 2013, Kanayo Nwanze, the president of the International Fund for Agricultural Development (IFAD), presented another solution to food security and sustainability: small-scale farming. According to him, small farmers must be the first beneficiaries of investment, not big science, because small farmers can feed the people, while highly engineered and costly Western burgers cannot.[47] Small farmers can become the 'key suppliers to Africa's burgeoning urban markets, as well as supplying rural markets'.[48] In contrast, Professor Post argues that his Frankenburger would cut overall energy use by 70%[49] but this figure appears not to factor the cost of transporting the meat from developed to developing countries and the resulting carbon footprint to the environment, as developing countries might not have the adequate laboratory facilities to produce such food.

Nwanze's criticism reveals the increased reliance on the knowledge and bio-economies and highlights the 'grass-fed versus the laboratory-bred' (meat) dichotomy, which has been triggered by the development of cultured meat. Technological systems pose threats to 'long-settled patterns of living', in particular in the global South.[50] This further possible ramification of cultured meat strengthens the analogy with biotech foods. Modern biotechnology appears to offer a 'discourse of development that continues colonial traditions',[51] where the products commercialised by Western high-tech companies, such as Monsanto or Pioneer, lead to the establishment of an 'empire'.[52]

Cultured meat is identified as another pathway to increase the dependence of developing countries on developed countries, their corporations, their technologies and their patents (as is occurring with GMOs). It does not appear to be the solution to food security in developing countries considering the costs of the technology (transportation, patent, laboratory production). Subsistence and small-scale farm-

43 Dorothea K. Thompson, "Small Size, Big Dilemma: The Challenge of Regulating Nanotechnology", 79 *Tennessee Law Review* (2012), pp. 621 *et sqq.*, at p. 662.

44 Ibid.

45 For more on the regulation of biotech foods, see Luc Bodiguel and Michael Cardwell (ed.), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford: OUP, 2010); and Maria Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (Cheltenham: Edward Elgar, 2008).

46 MacDonald Glenn and D'Agostino, "The Moveable Feast Legal, Ethical, and Social Implications of Converging Technologies on Our Dinner Tables", *supra* note 11, at p. 124.

47 John Vidal, "Lab-Grown Burgers Cannot Provide a Secure Future for Africa", The Guardian, 6 August 2013, available at http://www.theguardian.com/global-development/poverty-matters/2013/aug/06/lab-grown-burgers-stem-cell-africa (last accessed on 1 April 2014). For similar arguments in relation to how small-scale agriculture constitutes a more suitable alternative to reduce hunger and poverty, see the World Bank, "World Development Report: Agriculture for Development" (2008); and Communication from the EU Commission, An EU Policy Framework to Assist Developing Countries in Addressing Food Security Challenges, COM (2010) 127.

48 John Vidal, "Lab-Grown Burgers Cannot Provide a Secure Future for Africa", *supra* note 47.

49 Alok Jha, "Synthetic Meat: How the World's Costliest Burger Made it on to the Plate", *supra* note 9.

50 Jasanoff, "Biotechnology and Empire", *supra* note 40, at p. 288. See also, Fikremarkos Merso Birhanu, "Genetically Modified Organisms in Africa: Regulating a Threat or an Opportunity?", in Luc Bodiguel and Michael Cardwell (ed.), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford: OUP, 2010), pp. 227 *et sqq*.

51 Jasanoff, "Biotechnology and Empire", *supra* note 40, at p. 290.

52 Ibid.

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ing, combined with sustainable intensification,[53] would have better chances to secure food in developing countries.

III. Towards consumer acceptance?

A 2013 Irish study on 'Consumer and Industry Acceptance of Novel Food Technologies' showed that consumers knowledge of cultured meat was low but that consumers associated it with animal cloning, GE, stem cells research and science fiction, and in particular Star Trek.[54] Respondents considered cultured meat to be potentially extremely unnatural and questioned the texture and quality of the meat, as well as its prohibitive price, and consequently called for strict monitoring and controls to ensure that no unforeseen consequences emerge.[55] Participants perceived no clear personal benefits and felt that the food industry would primarily benefit from such a technological revolution.[56] This raised further questions as to the technology's potential impact on traditional farming practices and the farming landscape.[57] It clearly indicates that the public can perceive the potential socio-economic impacts of cultured meat on farmers.

Yet, participants also clearly identified the positives of the technology. They considered the potential environmental, animal welfare and food supply benefits, including the possibility of bringing a certain 'standardisation (e.g. of fat content) and efficiency in meat production'.[58] These results demonstrate that consumers reflect on the importance of relying on a sustainable food production chain. Respondents identified cultured meat as a potential solution to the ethical dilemma inherent in slaughtering animals for consumption and observed that cultured meat 'redefine[d]' the concept of meat.[59] Like Quorn and other meat substitutes, it blurs the line between what looks natural and what appears to be artificial. Generally, respondents had, however, greater concerns about the technology than positive reactions. Such results are not surprising because they parallel those of surveys on modern agricultural biotechnology, particularly GMOs, animal cloning and their derived foods.[60] Uncertainties, ethics, morals, values and interferences with nature seem to be common points of contention.

Notwithstanding the prospects for significant environmental and societal improvements, public discourse remains principally fixed on the challenges and concerns over safety assessment and how to manage and regulate cultured meat. It can be argued that the artificial aspects raised by the technology, especially the fact that the animal stem cells grow in a gel-like growth medium containing antibiotics and a serum extracted from cow foetuses, call for 'feelings of disgust'. This 'yuck factor' or 'wisdom of repugnance' appeals to emotion rather than reason when dealing with new technologies and can engender consumer resistance.[61]

When scientists find opposition to their claims, they tend to see that hostility as misinformed or irrational and discard these claims because they are based on non-scientific grounds.[62] As asserted by Jasanoff, there is a profound discrepancy in con-

53 Sustainable intensification of crop production is one of the strategic objectives of the Food and Agriculture Organisation. See FAO, "Stategic Framework 2010-2019" (2009), available at www.fao.org/uploads/media/C2009K5864EnglishStrategicFr_1.pdf (last accessed on 1 April 2014). See generally on sustainable intensification: Tara Garnett and H. Charles J. Godfray, "Sustainable Intensification in Agriculture: Navigating a Course Through Competing Food System Priorities" (Food Climate Research Network and the Oxford Martin Programme on the Future of Food, 2012); UK Government Office for Science, "Foresight Report", *supra* note 29; and the UK Royal Society, "Report on Reaping the Benefits: Science and the Sustainable Intensification of Global Agriculture" (2009).

54 Department of Agriculture, Food and the Marine, "Irish Consumer and Industry Acceptance of Novel Food Technologies: Research Highlights, Implications and Recommendations" (2013), at p. 19.

55 Ibid, at p. 21.

56 Ibid.

57 Ibid, at p. 19.

58 Ibid, at p. 21.

59 Ibid.

60 58% of the respondents to a 2005 eurobarometer opposed GM food while 42% did not. See George Gaskell et al., "Europeans and Biotechnology in 2005: Patterns and Trends" (May 2006), at p. 20. In a 2008 eurobarometer on Europeans' attitudes towards animal cloning, a majority of EU consumers said that it was 'unlikely that they would buy meat or milk from cloned animals, even if a trusted source stated that such products were safe to eat'. See Gallup Organization, "Europeans' Attitudes Towards Animal Cloning" (October 2008), at p. 39.

61 Leon Kass, "The Wisdom of Repugnance", 216 *New Republic* (1997), pp. 17 *et sqq*. See also, Sheila Jasanoff, "Constitutional Moments in Governing Science and Technology", 17 *Science and Engineering Ethics* (2011), pp. 621 *et sqq*., at p. 634.

62 See e.g., Howard F. Chang, "Risk Regulation, Endogenous Public Concerns, and the Hormones Dispute: Nothing to Fear but Fear Itself?", 77 *Southern California Law Review* (2003-2004), pp. 743 *et sqq*.; and Marsha A. Echols, "Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws", 4 *Columbia Journal of European Law* (1998), pp. 525 *et sqq*.; and Robert Howse, "Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organisation", 98 *Michigan Law Review* (2000), pp. 2329 *et sqq*.

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demning one person's repugnance but not another person's admiration towards new technologies, while both are 'normative judgments, and both are rooted in affect, not reason'.[63] Why should every decision that consumers make be rational? After all, even Sunstein, admits that 'when public fear about new technologies is irrational, scientists and policymakers cannot ignore it'.[64]

The public's apprehension is often attributed to the fact that there is no dialogue between society and scientist, no common language.[65] This lack of interaction between the public and scientists can lead to public fears towards new technologies.[66] For Sunstein, the 'persistent split between experts and ordinary people'[67] regarding risks, 'raises some of the most interesting problems in all of social science'.[68] This remark is even more salient as scientific uncertainty permeates scientific innovations.

Consumer concerns or fears are 'considered to be signs of a decrease in trust'.[69] EU consumers tend to fear novel food technologies as a result of the food scares of the 1990s, and more recently, the horsemeat scandal.[70] These events led to diminished trust in scientists and regulators.[71] The lack of a transparent and accountable regulatory system threatens public trust in novel food technologies (as well as their acceptance) and more fundamentally in the government itself.[72]

In order to restore public confidence, regulators and scientists will 'utilise', at 'decisive' times, their own flesh and blood to convince the public that food is safe. For instance, after the tasting event of the Frankenburger, Professor Post promised that he would give the leftovers to his children.[73] This recalls the image of the then UK Agriculture Minister John Gummer feeding his daughter a beef burger in front of TV cameras at the very start of the bovine spongiform encephalopathy (BSE or 'mad cow' disease) crisis in 1996 in order to reassure the public of the safety of the beef sold on the food shelves.[74] Although such behaviour aimed at reassuring the public, John Gummer's action failed to strengthen public confidence and resulted in a lasting decline in public confidence towards the government both in Britain and the rest of the EU.[75]

Another approach for governments to rebuild trust is to communicate with the public about current risks as well as regulations. Surveys have shown that 'popular fear or rejection of new technology often rests, at bottom, on an uneasiness about the ways in which technology is managed or, more accurately, governed'.[76]As advocated by the deficit model of the public understanding of science and technology (PUST), any deficiency and illiteracy in knowledge of science and technology is a problem, where information and education appear as the solution to trans-

63 Jasanoff, "Constitutional Moments in Governing Science and Technology", *supra* note 61, at p. 635.

64 Sunstein, *Laws of Fear* (2005), *supra* note 38, at p. 54.

65 See e.g., Jenny Steele, "Participation and Deliberation in Environmental Law: Exploring a Problem-Solving Approach", 21 *Oxford Journal of Legal Studies* (2001), pp. 415 *et sqq*.

66 See e.g., Theofanis Christoforou, "The Regulation of Genetically Modified Organisms in the European Union: the Interplay of Science, Law and Politics", 41 *Common Market Law Review* (2004), pp. 637 *et sqq*.

67 Cass R. Sunstein, "The Laws of Fear", 115 *Harvard Law Review* (2002), pp. 1119 *et sqq*., at p. 1120. Also, for Beck, 'reflexivity is excluded from the social and political interactions between experts and social groups over modern risks, because of the systematic assumption of realism in science'. Beck, *Risk Society: Towards a New Modernity*, *supra* note 39, at p. 4.

68 Sunstein, "The Laws of Fear" (2002), *supra* note 67, at p. 1120.

69 Frans W.A. Brom, "Food, Consumer concerns, and Trust: Food Ethics for a Globalizing Market", 12 *Journal of Agricultural and Environmental Ethics* (2000), pp. 127 *et sqq*., at p. 131. See also, Rebecca Bratspies, "Some Thoughts on the American Approach to Regulating Genetically Modified Organisms", 16 *Kansas Journal of Law and Public Policy* (2007), pp. 393 *et sqq*., at p. 395.

70 In the EU in the 1990s, three food scares occurred concomitantly: the bovine spongiform encephalopathy (BSE) scandal, GMO imports from the US to the EU, and recombinant bovine somatotropin (rBST).

71 This has led to an enduring public mistrust of institutional declarations (both at national and EU levels) in food and public health on food scares, which was reignited with national and EU support for GM foods. For more on the relationship between institutions, public (confidence) and science, see Matteo Ferrari, *Risk Perception, Culture, and Legal Change: A Comparative Study of Food Safety in the Wake of the Mad Cow Crisis* (Farnham: Ashgate, 2009); Richard Packer, *The Politics of BSE* (London: Palgrave Macmillan, 2007); and European Environment Agency, "Late Lessons from Early Warnings: The Precautionary Principle 1896-2000" (2002), available at http://www.eea.europa.eu/publications/environmental_issue_report_2001_22 (last accessed on 1 April 2014), at p. 157.

72 Bratspies, "Some Thoughts on the American Approach to Regulating Genetically Modified Organisms", *supra* note 69, at p. 395.

73 Specter, "Test-Tube Burgers", *supra* note 5.

74 BBC, "Phillips Report Packs a Punch", 26 October 2000, available at http://news.bbc.co.uk/1/hi/uk_politics/992883.stm (last accessed on 1 April 2014). For more on the 2000 UK BSE Inquiry Report, see http://www.regulation.org.uk/bse.shtml (last accessed on 1 April 2014).

75 See e.g., Terry Marsden et al., *The New Regulation and Governance of Food* (London: Routledge, 2010).

76 Jasanoff, "Biotechnology and Empire", *supra* note 40, at p. 283.

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fer knowledge from science to the public.[77] This model emphasises that the public should be informed and educated to 'eliminate fears' about scientific innovations,[78] such as shmeat. Thus, it would be in the interest of the EU institutions as well as national governments to start enlightening and familiarising the public with the processes of shmeat now.

Over the years, the EU has tried to correct the lack of communication over new technologies by employing different PUST methods: first, by assessing the actual knowledge of European citizens through the use of eurobarometers;[79] second, by rethinking the relationship between science and society, as advocated by the EU and its 'Science and Society' programmes.[80] PUST provides further backing for the deficit model by providing the data that confirms the need for citizen education and information.[81] Thus, PUST appears to be both the solution and the means to achieve science and technology literacy. A third PUST mechanism utilised by the EU to inform its citizens has been the development and strengthening of its consumer policy. Consumer protection together with an 'informed consumer' policy are now central to EU law and policy.[82] The current EU Consumer Policy Strategy 2007-2013[83] (currently under review[84]) aims at empowering EU consumers and focuses on five priority areas, two of which are of particular importance with the emergence of shmeat: first, putting consumers at the heart of other EU policies; and, second, better informed and educated consumers.[85]

A crucial example, which contrasts and weakens the arguments advanced by the deficit model of PUST and its use by the EU, is that for decades now, the EU institutions have been trying to convince EU citizens that GMOs and their resulting foods are safe but they have been largely unsuccessful, as demonstrated by the various eurobarometers and surveys,[86] as well as public protest.[87] The resistance of European consumers towards GM products is not diminishing and foods from cloned animals appear to attract the same level of resistance, if not more, due to animal health and welfare issues.[88] Once new technologies and their products are about to be released onto the markets, in the case where the public did not know in advance about their developments, consumers react suspiciously and think that something is wrong with the new technology, because it has been

77 See e.g. for an explanation and a critique: Brian Wynne, "Public Understanding of Science Research: New Horizons or Hall of Mirrors", 1 *Public Understanding of Science* (1992), pp. 37 *et sqq*.; and Brian Wynne, "The Public Understanding of Science", in Sheila Jasanoff et al. (ed.), *The Handbook of Science and Technology Studies* (London: Sage, 1995), pp. 361 *et sqq*. For another critique, see Steven Yearley, "Computer Models and the Public's Understanding of Science: A Case-Study Analysis", 29 *Social Studies of Science* (1999), pp. 845 *et sqq*.

78 Chang, "Risk Regulation, Endogenous Public Concerns, and the Hormones Dispute", *supra* note 62, at p. 752.

79 See section III.

80 European Commission, "Science in Society in FP7", available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1321&lang=1 (last accessed on 1 April 2014); European Commission, "Why 'Science in Society'?", available at http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1223 (last accessed on 1 April 2014); CORDIS, "Ethical, Legal and Social Aspects of the Life Sciences and Technologies of the Fourth RTD Framework Programme 1994-1998", available at http://cordis.europa.eu/elsa-fp4/src/about.htm (last accessed on 1 April 2014); and CORDIS, "Science and Society in FP6", available at http://cordis.europa.eu/science-society/fp6.htm (last accessed on 1 April 2014).

81 Mark L. Flear and Anastasia Vakulenko, "A Human Rights Perspective on Citizen Participation in the EU's Governance of New Technologies", 10 *Human Rights Law Review* (2010), pp. 661 *et sqq*., at p. 687.

82 See Articles 12 and 169 Consolidated Version of the Treaty on the Functioning of the European Union (TFEU) [2008] C115/47. Article 169 on consumer protection stipulates that 'in order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests'. This interest in consumer protection and information originates in the Council Resolution of 14 April 1975 on a Preliminary Programme of the European Economic Community for a Consumer Protection and Information Policy OJ 1975 C92/1.

83 European Communities, "EU Consumer Policy Strategy 2007-2013" (2007), at p. 7. The strategy was established by Communication of 13 March 2007 from the Commission to the Council, the European Parliament and the European Economic and Social Committee, EU Consumer Policy Strategy 2007-2013, COM(2007) 99.

84 Communication of 25 May 2012 from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, A European Consumer Agenda - Boosting Confidence and Growth, COM(2012) 225; and a Proposal of the European Parliament and of the Council for a Regulation on a Consumer Programme 2014-2020, COM(2011) 707.

85 European Communities, "EU Consumer Policy Strategy 2007-2013", *supra* note 83, at p. 7. This policy is also in line with the Europe 2020 Strategy, which calls for citizens to be empowered to play a full role in the single Market. See Communication of 3 March 2010 from the Commission, Europe 2020: A European Strategy for Smart, Sustainable, and Inclusive Growth, COM(2010) 2020, at p. 20.

86 See section III.

87 Luc Bodiguel and Michael Cardwell, "Genetically Modified Organisms and the Public: Participation, Preferences, and Protest", in Luc Bodiguel and Michael Cardwell (ed.), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (Oxford: OUP, 2010), at p. 11.

88 See section III.

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hidden from them. Worryingly, the more the governing institutions will wait to communicate with the public, the greater public opposition to shmeat commercialisation will exist, as demonstrated by the GM and cloned foods experiences.

The deficit model of PUST is not sufficient as it constitutes a one-way, top-down communication process[89] rather than a bottom-up approach combined with a true dialogue between the different interested parties. Greater involvement of the public into science and decision-making is arguably lacking. Discussion and public participation are crucial, first, to establish trust between consumers, experts and decision-makers because they allow better understanding of other groups' knowledge, perspectives and concerns; and, second, to strengthen transparency and accountability. As asserted by Novotny et al., '[s]cience that draws strength from its socially detached position is too frail to meet the pressures placed upon it by contemporary societies'.[90] Scientific knowledge cannot be independent of context and needs to be embedded in society, hence more accountable to the public. Science ought to be co-produced by multi-directional dialogues between researchers, the public, organisations, industry and policy-makers.[91]

To 'restore important value conflicts to the public sphere'[92] and to 'permit genuine contestation among science, state, and society',[93] public engagement should be embraced. More specifically, upstream public engagement is key as it allows a bottom-up process and sustained interactions as well as communication between stakeholders. Upstream activities should be 'linked back to the decision-making of scientists, industry, and policy makers'.[94] Decisively, the focus of engagement must be shifted towards the development of the R&D agenda, i.e. the design of new technologies. Knowledgeable publics must be moved to the commencement of scientific and technological research.[95] Scientific and technological decisions will be enhanced if they have input from the public, because citizens have relevant knowledge and understandings.[96] If citizens became active participants in the future stages of the development of shmeat, their thoughts towards the technology would be more accurate and their attitudes potentially more positive.

Public resistance towards GM and cloned foods has demonstrated the need to inform, engage and involve citizens from the start of a scientific project so that when a novel food technology, such as shmeat, is about to be commercialised, consumers will be aware and knowledgeable about the technology and can then take informed decisions.[97] The co-production of knowledge and upstream public engagement would strengthen transparency and accountability. Greater efforts by all stakeholders are needed to gain public acceptance of shmeat, similarly to any other new technologies. Discussion early on in the process would prevent problems later.[98]

IV. The regulation of cultured meat under the Novel Foods Regulation

1. The EU food safety system

Any novel food, such as cultured meat, will be (to a certain extent) already regulated as it will fall back on general principles and frameworks for EU food safety. The shaping of the EU food safety system is mainly based on two policy documents and two regulations: the 2000 White Paper on Food Safety,[99] the 2004 'From Farm to Fork' policy,[100] the 2002 Gener-

89 John Durant, "Participatory Technology Assessment and the Democratic Model of the Public Understanding of Science", 26 *Science and Public Policy* (1999), pp. 313 *et sqq.*

90 Helga Nowotny et al., *Re-Thinking Science: Knowledge and the Public in an Age of Uncertainty* (Cambridge: Polity, 2001), at p. 166.

91 Co-production highlights the simultaneous production of technical and social order as well as the interconnectedness of politics, science and social order. See generally on co-production: Sheila Jasanoff (ed.), *States of Knowledge: The Co-production of Science and the Social Order* (London: Routledge, 2006). See also, Daniel Sarewitz, "How Science Makes Environmental Controversies Worse", *supra* note 40, at p. 386.

92 Jasanoff, "Constitutional Moments in Governing Science and Technology", *supra* note 61, at p. 637.

93 Ibid.

94 Rinie van Est, "The Broad Challenge of Public Engagement in Science – Commentary", 17 *Science and Engineering Ethics* (2011), pp. 639 *et sqq.*, at p. 642.

95 Sheila Jasanoff, "Technologies of Humility: Citizen Participation in Governing Science", 41 *Minerva* (2003), pp. 223 *et sqq.*, at p. 235. See also, Jasanoff, "Biotechnology and Empire", *supra* note 40, at p. 291.

96 Yearley, "Computer Models and the Public's Understanding of Science", *supra* note 77, at p. 845.

97 Otherwise public discontent grows. See e.g., Ludivine Petetin, "Consumer Preferences and Biotech Foods in EU and US Law", 1 *EU Agrarian Law* (2012), pp. 27 *et sqq.*

98 This is further expanded in section V.

99 European Commission, White Paper on Food Safety COM(1999) 719.

100 European Commission Directorate-General for Press and Communication, From Farm to Fork: Safe Food for Europe's Consumers (Office for Official Publications of the European Communities, 2004).

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al Food Law (GFL)[101] and Regulation 1169/2011 on the Provision of Food Information to Consumers.[102] The GFL established the European Food Safety Authority (EFSA) as the keystone of the EU food safety system, where the risk assessment provided by the EFSA guarantees a high level of food safety by providing the necessary independent scientific analysis for a risk assessment.[103] A cornerstone of the GFL is the precautionary principle, which was established as an overarching principle, applicable in all food safety legislation, and as part of every risk management stage of a risk analysis.[104]

The precautionary principle modifies the role of scientific data in cases of scientific uncertainty. It directs to a decision to act or not to act and helps determine which measures should be adopted, if action is needed. The principle leads to a transformation in the evaluation *ex ante* and *ex post* of the decision-making process.[105] In its 2000 Communication on the Precautionary Principle, the Commission asserted that 'reliance on the precautionary principle constitutes an essential plank of its policy'.[106] The Communication went a step further than Article 191(2) TFEU by extending the application of the precautionary principle to human, animal or plant health.[107] Even though it is a soft law instrument, the interpretation given to the principle in the communication was adopted by the European Court of Justice, for instance in the *Artegodan*[108] and *Pfizer*[109] cases and enshrined into the GFL – as mentioned. Today the precautionary principle is central to the policy and law of the EU food safety system.

The EU usually adopts a 'better safe than sorry' or precautionary approach to manage the uncertainty created by novel food technologies. For instance, the EU prohibited the placing on the market of meat and meat products treated with recombinant bovine somatotropin (rBST)[110] for the purpose of promoting the growth of bovines.[111] Amid animal health and welfare concerns including empirical evidence on

101 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 2002 L31/1.

102 Regulation 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers, amending Regulations (EC) No 1924/2006 and (EC) 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 2011 L304/18.

103 Articles 6(2) and 22(2) and (3) GFL.

104 Article 7(4) Novel Foods Regulation. Generally, the precautionary principle is a cornerstone of EU environmental law and policy-making. See Article 191(2) TFEU. For a detailed examination on the role of the precautionary principle, see e.g., Elizabeth Fisher et al (eds), *Implementing the Precautionary Principle: Perspectives and Prospects* (Cheltenham: Edward Elgar, 2006); David Freestone and Ellen Hey (eds), *The Precautionary Principle and International Law: The Challenge of Implementation* (The Hague: Kluwer Law International, 1996); Timothy O'Riordan et al. (eds), *Re-interpreting the Precautionary Principle* (London: Cameron and May, 2001); Nicolas de Sadeleer, "The Precautionary Principle in EC Health and Environmental Law", 12 *European Law Journal* (2006), pp. 139 *et sqq.*; Nicolas De Sadeleer (ed.), *Environmental Principles: From Political Slogans to Legal Rules* (Oxford: OUP, 2007); Naomi Salmon, "A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO", 27 *European Law Review* (2002), pp. 138 *et sqq.*; and Elen Stokes, "The Role of Risk Assessment in Precautionary Intervention: A Comparison of Judicial Trends in the EC and WTO", 4 *Journal for European Environmental Planning Law* (2007), pp. 455 *et sqq*.

105 For Sunstein, the precautionary principle is 'paralysing because it forbids an activity that could be beneficial at low-level' as it can give 'rise to substitute risks, in the form of hazards that materialize, or are increased, as a result of regulation' and this is why he urges to recourse to a cost-benefit analysis tool for the assessment and management of risks as an alternative to the precautionary principle'. Respectively, Sunstein, *Laws of Fear* (2005), *supra* note 38, at pp. 30, 32 and 130.

106 European Commission, Communication from the Commission on the Precautionary Principle COM(2000) 1, at p. 12. For more on the communication, see Joseph A. McMahon, *EU Agricultural Law* (Oxford: OUP, 2007), at 6.83; and Catherine Button, *The Power to Protect: Trade, Health and Uncertainty in the WTO* (Oxford: Hart Publishing, 2004), at p. 129. For its critique, see Lucas Bergkamp, "Understanding the Precautionary Principle (Part II)", 10 *Environmental Liability* (2002), pp. 67 *et sqq.*, at p. 72.

107 Communication on the Precautionary Principle, *supra* note 106, at p. 2.

108 Joined cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00, *Artegodan GmbH and Others v. Commission of the European Communities* [2002] ECR II-4945, at para. 184.

109 Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union* [2002] ECR II-3305.

110 Bovine somatotrophin, a bovine growth hormone, is a naturally occurring hormone produced in the mammary gland of cattle. In the 1980s, scientists developed a synthetic recombinant bovine somatotropin (rBST), which increases cows' milk production.

111 Council Directive 96/22/EC concerning the Prohibition on the Use in Stockfarming of certain Substances having a Hormonal or Thyrostatic Action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC OJ 1996 L125/3, as amended by Directive 2003/74/EC of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the Prohibition on the Use in Stockfarming of certain Substances having a Hormonal or Thyrostatic Action and of ß-agonists OJ 2003 L262/17. In contrast in the US, the Food and Drug Administration approved the application of rBST in 1993. See Food and Drug Administration, Interim Guidance on Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin (1994) 59 Fed Reg 6279. The US and Canada challenged the EU ban on rBST and its resulting products in the World Trade Organization case: *EC-Hormones* case. See *EC-Hormones: Measures Concerning Meat and Meat Products* WT/DS26/AB/R, WT/DS48/AB/R, 16 January 1998.

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mastitis,[112] human health risks,[113] and most importantly consumer anxieties towards new technologies, scientists and regulators,[114] the EU invoked the precautionary principle as a foundation for such a ban. Another example is genetically modified (GM) foods. Their authorisation process in the EU is based on four key elements demonstrating the application of the precautionary principle: first, focus is given to the process according to which a food is produced rather than the end-product; second, a premarket approval assesses their safety; third, a single 'one-stop' authorisation procedure commercialises them within the EU internal market; and fourth, labelling and traceability are at the heart of the system.[115]

2. The Novel Foods Regulation and its inadequacies

When dealing with a new technology the issues of whether it should be regulated and, if so, how this should be undertaken always arises.[116] Governments must choose between using existing (general or analogous specific) rules and crafting new ones, considering the time and costs of drafting, the uncertainties as to achieving an actual agreement at the end of process and the danger of new technologies escaping to rigid and specific regulatory categories. There is an optimal degree of specificity of rules that needs to be reached. It is generally assumed that new technologies should trigger a new set of rules and a new framework should be created. However, very often the regulatory approach that will be relied upon will be the one currently in place.[117] This will be undertaken despite the fact that a new technology may create its own specific risks and uncertainties in relation to scientific, environmental, safety or human health impacts. This is confirmed by Lee who argues that 'it should not be assumed that a new technology can be assessed using the tool that proved effective for the last technology'.[118] For instance, the frameworks for modern agricultural biotechnology, as established for genetically engineered animals (GEAs) and for cloned products, demonstrate that relying on rules already existing offers the solution which can appear the most suitable as it will be relatively resource less, costless and quickly responsive.[119] Consequently, the new technology will inherit the regulation of a previous innovation rather than benefiting from suitably updated legislation.

A regulatory net is already in place for novel foods, like cultured meat. More specifically, cultured meat would fall under the Novel Foods Regulation. Thus, like for foods from GEAs and cloned animals, shmeat would be regulated by an already existing regime which has not been expressly drafted to deal with the specific issues raised by this novel food.

Cultured meat could fall under two novel food categories of Article 1(2) of the Novel Foods Regulation: either '(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use'; or '(f) foods and food ingredients to which has been applied a production process not currently used, where that

112 Report of the Scientific Committee on Animal Health and Animal Welfare, Report on Animal Welfare Aspects of the Use of Bovine Somatotrophin (10 March 1999).

113 Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health, Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products (30 April 1999).

114 See e.g., David Vogel, *The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States* (Princeton: Princeton University Press, 2012), at p. 43; and George Gray et al., "Beef, Hormones and Mad Cows", in Jonathan B. Wiener et al. (ed.), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe* (London: Earthscan, 2011), at p. 65. Moreover, in the *EC-Hormones* case, the European institutions relied on EU consumer anxieties to ban the use of rBST, see *EC-Hormones*, para. 10.

115 See the Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed, OJ 2003 L 268/1 (Food and Feed Regulation); and Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products produced from Genetically Modified Organisms and amending Directive 2001/18/EC, OJ 2003 L 268/24.

116 Elen Stokes, "Nanotechnology and the Products of Inherited Regulation", 39 *Journal of Law and Society* (2012), pp. 93 *et sqq.*, at p. 94.

117 Ibid, at p. 99. Although this article refers to nanotechnology, cultured meat raises similar issues. See also, Bratspies, "Some Thoughts on the American Approach to Regulating Genetically Modified Organisms", *supra* note 69, at p. 395; and Elen Stokes and Diana M. Bowman, "Looking Back to the Future of Regulating New Technologies: The Cases of Nanotechnologies and Synthetic Biology", 2012 *European Journal of Risk Regulation* (2012), pp. 235 *et sqq.*

118 Lee, *EU Regulation of GMOs*, *supra* note 45, at p. 12.

119 Foods from GEAs will fall under the scope of the Food and Feed Regulation and Regulation 1830/2003. Cloned foods are regulated under the Novel Foods Regulation – as already mentioned.

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process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances'.[120] The very simple fact that a definite novel food category cannot be attached to cultured meat shows a first hurdle in trying to fit a new food into the current framework. Furthermore, doubts can be cast as to whether either of these definitions suits the particularities and distinct attributes of cultured meat given that the Novel Foods Regulation was not designed to regulate such foods.

The 'initial' safety assessment required by Article 1(2)(f) of the Novel Foods Regulation requires a premarket approval.[121] However, this 'initial' safety assessment undertaken by a national food assessment body seems to be lacking in appropriate risk assessment criteria and procedure.[122] In contrast, if shmeat were to be regulated under Article 1(2)(e), it could benefit from the simplified procedure existing under Article 3(4) of the Novel Foods Regulation, which relies on the concept of substantial equivalence.[123] Substantial equivalence is a simplified procedure that has two implications: first, it assesses the safety of biotech foods; and, second, if substantial equivalence is established, biotech foods are regulated in the same manner as conventional foods.[124]

The concept of substantial equivalence originated with the regulation of foods deriving from modern biotechnology. The Organisation for Economic Cooperation and Development (OECD) based substantial equivalence on the idea that existing foods can be used as the 'basis for comparison when assessing the safety of human consumption of a food [...] that has been modified or is new'.[125] The starting point is therefore an assumption of equivalence: novel food technologies do not automatically result in foods that are less safe than those developed by conventional techniques.[126] The purpose of substantial equivalence is not to establish an absolute level of safety but to ensure with a 'reasonable certainty' that no harm will result from the intended uses of new food products.[127] According to the concept, novel foods are not free of risks; they involve similar types of risks to humans as conventional foods.

Substantial equivalence nevertheless generates much criticism. It is often described as a 'pseudo-scientific concept because it is a commercial and political judgement masquerading as if it were scientific'.[128] Substantial equivalence arguably suffers from significant failings, the main one being its subjectivity: 'no standardized objective tests for determining equivalence and measuring substantiality exist'.[129] There is no definition of 'substantial' and, consequently, no certainty about when two foods cease to be substantially equivalent.[130] Moreover, substantial equivalence results in a decision not to require labelling, facilitating trade at international level but restricting consumer information considerably. Yet, for many consumers, 'any foodstuffs derived from, or produced with the aid of, GMOs are perceived to be quite simply and unequivocally fundamentally different from their conventionally produced counterparts', regardless of their substantial equivalence.[131]

120 Article 1(2) (e) and (f) Novel Foods Regulation.

121 Ibid, Article 4.

122 Ibid, Article 6.

123 Like cultured meat, cloned foods could benefit from the simplified procedure existing under the Novel Foods Regulation as no difference exists between cloned and conventional foods. See e.g., Ludivine Petetin, "The Revival of Modern Agricultural Biotechnology by the UK Government: What Role for Animal Cloning?", 6 *European Food and Feed Law Review* (2012), pp. 296 *et sqq.*

124 Ibid, at p. 305.

125 OECD, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles" (1993), at p. 11.

126 Ibid, at p. 10.

127 Lucia Roda Ghisleri et al., "Risk Analysis and GM foods: Scientific Risk Assessment", 4 *European Food and Feed Law Review* (2009), pp. 235 *et sqq.*, at p. 247.

128 Erik Millstone et al., "Beyond Substantial Equivalence", 401 *Nature* (1999), pp. 525 *et sqq.* , at p. 526. For Strauss, substantial equivalence is 'an unscientific concept, however, that has never been properly defined or provided with a legal standard for implementation'. See Debra M. Strauss, "The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply", 61 *Food and Drug Law Journal* (2006), pp. 167 *et sqq.*, at p. 174.

129 Thomas O. McGarity, "Seeds of Distrust: Federal Regulation of Genetically Modified Plants", 35 *University of Michigan Journal of Law Reform* (2002), pp. 403 *et sqq.*, at p. 429.

130 For more criticism of substantial equivalence, see Mae-Wan Ho and Ricarda A. Steinbrecher, "Fatal Flaws in Food Safety Assessment: Critique of the Joint FAO/WHO Biotechnology and Food Safety Report", 2 *Environmental & Nutritional Interactions* (1998), available at http://www.psrast.org/fao96.htm (last accessed on 1 April 2014); McGarity, "Seeds of Distrust", *supra* note 169, at p. 429; and Andrew Apel, "Substantial Equivalence and the Precautionary Principle: a Challenge to Risk" (AgBioWorld, September 2000), available at http://www.agbioworld.org/newsletter_wm/index.php?caseid=archive&newsid=721 (last accessed on 1 April 2014).

131 Naomi Salmon, "What's 'Novel' About It? Substantial Equivalence, Precaution and Consumer Protection 1997-2004", 7 *Environmental Law Review* (2005), pp. 138 *et sqq.*, at p. 142. See also, eurobarometers in section III.

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Under the Novel Foods Regulation, the determination of substantial equivalence is based on the 'scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent bodies' at member state level.[132] According to the second method of determination, the EFSA is not involved in the process, only national food assessment bodies can potentially be involved in a determination of substantial equivalence. Under the first method, the burden of testing the existence of substantial equivalence is in the hands of the manufacturers, who then have a degree of control over the process, allowing them a degree of 'self-determination' for the foods they produce. If substantial equivalence is present between two foods a simple notification from the manufacturer to the European Commission is required.[133] No premarket authorisation would be required and without it, the manufacturer's determination of substantial equivalence could not be evaluated before commercialisation.

In the case where cultured meat would be declared substantially equivalent to conventional meat by a manufacturer, no premarket authorisation would result. Cultured meat would then fall outside the remit of standard authorisation under the Novel Foods Regulation, leading to possible safety concerns and to self-regulation by the food industry. In the UK, the Food Standards Agency (FSA) declared that in relation to cultured meat, 'EU consumers are given the reassurance that any new food has undergone a stringent and independent safety assessment before it is placed on the market'[134] – as required by the Novel Foods Regulation. The FSA is satisfied with the premarket authorisation for cultured meat (as with cloned foods), and appears to forget once more about the existence of substantial equivalence and its failings under the Novel Foods Regulation.[135]

In relation to labelling, Article 8(1)(a) of the Novel Foods Regulation ensures the labelling of novel foods if a food is 'no longer equivalent to an existing food'.[136] Therefore, the labelling of cultured meat could potentially not be required if it is declared substantially equivalent to a conventional food. This contrasts sharply with Schneider's argument that 'labels should include any information relevant to manipulation of in vitro meat undertaken to adjust its nutrition, taste, texture, or any of its other attributes'.[137] Nonetheless, Article 8(c) specifies that 'the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns' requires additional specific labelling.[138] Cultured meat could fall under that provision if it is thought to raise (sufficient) ethical issues. This is the only article that could allow consumers to know if the food they eat comes from a laboratory rather than an animal - if substantial equivalence was demonstrated. This absence of labelling would prevent the burdening of the industry but sacrifice consumer information by restricting traceability. This situation contravenes EU policy on 'informed consumers'[139] and could result in consumer ignorance, as well as potential consumer deception.

The concept of substantial equivalence and its deficiencies, as enshrined under the Novel Foods Regulation (i.e. the lack of precautionary approach resulting in the absence of premarket authorisation and labelling, and self-regulation by the industry), were at the heart of the 2003 *Monsanto* case, which deals with GM foods.[140] Despite the ongoing criticism of substantial equivalence and the simplified procedure, the European Court of Justice validated the use of this simplified procedure.[141] Nonetheless, in July 2001, the European Commission had already put forward a package of integrated measures in the proposal of two regulations to monitor the presence of GMOs in food: the Food and Feed Regulation and Regulation 1830/2003 (which would enter in force a

132 Article 3(4) Novel Foods Regulation.

133 Ibid, Article 5.

134 Food Standards Agency, "Emerging Food Technologies", *supra* note 25, at p. 2.

135 For more on the UK policy of cloned foods, see Petetin, "The Revival of Modern Agricultural Biotechnology by the UK Government", *supra* note 123, at p. 296 *et sqq.*

136 Article 8(1)(a) Novel Foods Regulation.

137 Schneider, "In Vitro Meat - Space Travel, Cannibalism, and Federal Regulation", *supra* note 6, at p. 1025.

138 Article 8(1)(c) Novel Foods Regulation.

139 See section III.

140 Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others* [2003] ECR I-8105. For comments of the case, see Patrycja Dabrowska, "GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the Day in the recent Judgment of the European Court of Justice?", 5 *German Law Journal* (2004), pp. 151 *et sqq.*; and Ruby R. Fernandez, "Monsanto and the Requirement for Real Risks in GM Food Regulation", 28 *International & Comparative Law Review* (2006), pp. 335 *et sqq.*

141 *Monsanto* case, para. 19.

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few months after the case).[142] As mentioned, the system established for GM foods by the Food and Feed Regulation and Regulation 1830/2003 is now based on a precautionary approach.[143] Importantly, the Food and Feed Regulation removed the concept of substantial equivalence for the regulation of GM foods. But, very interestingly, this concept, its problems and consequences remain today at the heart of the Novel Foods Regulation and, therefore, the regulation of cultured meat (and cloned foods). This situation contrasts sharply with the regulation of GM foods and the precautionary approach at the centre of the EU food safety system.

It could be argued that the Novel Foods Regulation is not suited to regulate cultured meat. First, it is an old regime which has not evolved with the technologies it intends to regulate. The regime created by the Novel Foods Regulation already suffers from its own problems and failings which could, as a result, be repeated and anchored in the regulation of cultured meat. Second, the Novel Foods Regulation maintains substantial equivalence at the heart of the regulation of cultured meat, which is in itself unsustainable. This situation not only raises questions as to the adequacy of the framework to ensure the safety of cultured meat but also creates a regime akin to industry self-regulation because of its lack of sufficient premarket approval and labelling requirements. These issues are well summarised by Stokes who advances that there are 'overlooked consequences of grafting' a new technology onto an existing regulatory regime because it leads to the application of ill-suited rules and standards and the reproduction of deeply anchored traditions which technological evolution makes difficult to justify.[144] These concerns and problems raise the question of the effectiveness, efficiency and reliability of the existing regulatory regimes to deal with a new technology,[145] in this case cultured meat and the weak regulatory framework established by the Novel Foods Regulation.

3. The 2013 Novel Foods Proposal

The EU institutions have tried to amend the Novel Foods Regulation. In 2008, the European Commission adopted a proposal to revise the Novel Foods Regulation.[146] Cultured meat would have likely fallen under the definition of novel food in Article 3(2)(a)(iii) which stipulated that a novel food is 'food to which is applied a new production process, not used before 15 May 1997, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances'.[147] The proposal aimed to simplify the existing framework by creating a centralised EU-level procedure for the assessment and pre-market authorisation of novel foods and therefore established a 'one door-one key' procedure potentially facilitating the sale of cultured meat in the European market – as it exists for GM foods.[148] Decisively, substantial equivalence would have been removed from the regulation. The European institutions were meant to agree on the proposal before April 2011 but they failed to do so as the dialogue between the European Parliament, the Council and the Commission finished

142 The Novel Foods Regulation along with the Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms were at the centre of the EU de facto moratorium on the approval of GMOs – which led to the WTO *EC-Biotech* case and the establishment of the Food and Feed Regulation and Regulation 1830/2003. See Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms and repealing Council Directive 90/220/EEC OJ 2001 L 106/1; and *EC-Biotech: Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R and WT/DS293/R, 29 September 2006. For more on the *EC-Biotech* case, see Christiane R. Conrad, "The EC–Biotech Dispute and Applicability of the SPS Agreement: Are the Panel's Findings Built on Shaky Ground?", 6 *World Trade Review* (2007), pp. 233 *et sqq*.; and Denise Prevost, "Opening Pandora's Box: The Panel's Findings in the EC-Biotech Products Dispute", 34 *Legal Issues of Economic Integration* (2007), pp. 67 *et sqq*.

143 See for instance, the reactions in 2003 of the Environment Commissioner Wallström and the Health and Consumer Protection Commissioner Byrne after the European Parliament adopted its second reading opinion on the Food and Feed Regulation and Regulation 1830/2003 in Europa, "Wallström and Byrne Welcome EP Acceptance of a Trustworthy and Safe Approach to GMOs and GM Food and Feed" (2006), available at http://europa.eu/rapid/press-release_IP-03-935_en.htm?locale=EN (last accessed on 1 April 2014).

144 Stokes, "Nanotechnology and the Products of Inherited Regulation", *supra* note 116, at p. 93.

145 See generally on regulatory regimes and new technologies: Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: OUP, 2008); and Roger Brownsword and Karen Yeung (ed.), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Oxford: Hart Publishing, 2009).

146 Proposal for a Regulation of the European Parliament and of the Council on Novel Foods, COM(2007) 872.

147 Ibid, Article 3(2)(a)(iii).

148 Ibid, at p. 7 and Articles 1 and 19.

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in deadlock due to a clash on the labelling of the products from the offspring of clones.[149]

More recently, in December 2013, the Commission put forward two proposals dealing with novel foods. First, the Proposal for a new Regulation on Novel Foods (2013 Novel Foods Proposal) aims at simplifying the existing framework and, most importantly, at removing substantial equivalence.[150] It adopts a precautionary approach: first, focus is on the process according to which a food is produced rather than the end-product; second, a centralised premarket approval is obligatory where the EFSA would carry out a risk assessment (creating a harmonised safety assessment);[151] and, third, labelling and traceability are at the heart of the system. Cultured meat would fall under the scope of this proposal and would benefit from this precautionary approach,[152] and from a similar framework to that currently existing for GM foods. This new framework for cultured meat would be in line with what consumers, politicians and the food industry want. Second, the Proposal for a Directive on Cloned Foods provisionally bans the placing on the market of these products as well as their importation, mainly because of animal welfare issues, citizens' concerns and the interests of farmers and other stakeholders.[153] Here, the European Commission listened to the public and other interest groups when putting forward these proposals, indicating the impact that these actors can have on decision-making.

As demonstrated by these proposals, the EU needs to further advance towards the adoption of a contextual approach for novel foods rather than purely focussing on economic optimisation and trade benefits. Policy and decision-makers ought to balance ethical and social aspects with economic and techno-scientific factors to establish an adequate and effective framework: there is a necessity to keep novel foods in contexts, not independent of them, as advocated by the concept of co-production.[154] Agreeing on these proposed texts could take up to three years but they are less likely to end in a deadlock because stakeholders were considered during their drafting.

A 'one-stop' authorisation procedure commercialising novel foods within the EU internal market, as put forward in the 2013 Novel Foods Proposal, should, however, be combined with a safeguard allowing member states to 'opt-out', even if this could negatively affect internal trade. This could be similar to the 2010 Proposal of the Commission allowing EU member states to restrict or prohibit GMO cultivation on their territory based on broad socio-economic considerations other than those covered by the environmental and health risk assessments existing under the EU authorisation procedure.[155] As asserted by Paradise and Fitzpatrick, regulatory mechanisms should be, first, strengthened to consider the specific characteristics of innovative products and, second, should address novel aspects, as well as other considerations.[156] Such an 'opt-out' clause would allow member states to base their decision on non-scientific grounds and would introduce some flexibility in the regime.

Currently, cultured meat and cloned foods could be declared substantially equivalent to conventional

149 Euractiv, "Novel Foods Review Stumbles over Cloning", 29 March 2011, available at http://www.euractiv.com/cap/novel-foods-review-stumbles-clon-news-503610 (last accessed on 1 April 2014). See also, Petetin, "The Revival of Modern Agricultural Biotechnology by the UK Government", *supra* note 123, at p. 296 *et sqq*.

150 Proposal for a Regulation of the European Parliament and of the Council on Novel Foods, COM(2013) 894, at p. 7.

151 Ibid, Articles 9 and 10.

152 Ibid, Article 2(a)(i): a novel food means a 'food to which a new production process not used for food production within the Union before 15 May 1997 is applied, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the way it is metabolised or the level of undesirable substances'. This appears to be a broad definition and could aim at covering any future novel food to avoid regulatory gaps.

153 Ibid, at p. 6. This proposal is complemented by a Proposal for a Directive on Animal Cloning for Farming Purposes which also provisionally bans such practices. See Proposal for a Directive of the European Parliament and of the Council on the Cloning of Animals of the Bovine, Porcine, Ovine, Caprine and Equine Species kept and reproduced for Farming Purposes, COM(2013) 892.

154 See section III.

155 Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in their Territory, COM(2010) 375. In February 2011, in a staff working document, the EU Commission provided an indicative list of grounds that could be relied upon by member states. They relate to the public interest, such as public morals (including religious and ethical concerns); public order; avoiding GMO presence in other products; social policy objectives; and cultural policy. See Commission Staff Working Document Complementary Considerations on Legal Issues on GMO Cultivation Raised in the Opinions of the Legal Service of the Council of the European Union of 5 November 2010 and of the Legal Service of the European Parliament of 17 November 2010, SEC(2011) 184, at p. 2. In 2012, the EU member states, nonetheless, failed to reach an agreement on the proposal.

156 Jordan Paradise and Ethan Fitzpatrick, "Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?", 117 *Penn State Law Review* (2012), pp. 53 *et sqq*., at p. 56.

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foods and thus not subject to premarket approval, while GM foods do require such an approval. The differences in regulatory structures between cultured meat and cloned foods on one side and GM foods on the other could appear incoherent and unsustainable as they raise analogous levels of risk. This situation creates an unbalanced regime for novel food technologies. The regulation of processes should be consistent across products that have equivalent levels of risk.[157] In this sense, the regulation of GM foods and the 2013 proposals demonstrate that the tightening of the regulatory framework for novel food technologies is necessary: novel food technologies do create specific risks in comparison with conventional foods and, thus, require a premarket authorisation.

Rather than continue to fail to deal adequately with the inadequacies mentioned, moving away from the Novel Foods Regulation would create legal certainty for all the relevant actors, especially scientists, consumers and the food industry and could permit novel foods, like cultured meat, to yield substantial benefits in the future. A regulatory equilibrium has to be found, based on independent safety assessment, systematic premarket approval and mandatory labelling which concomitantly guarantees the safety of the food supply chain, the information and participation of interested parties and public involvement.

V. Support for research and innovation

The Frankenburger tasting event was arranged by a public relations firm and broadcast live on the Internet. It was utilised as an outreach activity, undertaken not only to inform regulators and the public but, most importantly, to gather more funding to expand the project to the next level. The aim was to show that it is a marketable innovation and can be a successful enterprise. The showcasing of the Frankenburger constituted a proof of concept (POC) that cultured meat is not science fiction. The Frankenburger can be compared to a prototype. The tasting event was a demonstration of the viability, suitability and feasibility of the technology rather than the beginning of its commercial production. The lack of funding for the technology is shown by the support of Google co-founder and entrepreneur Sergey Brin to the Maastricht project after funding from the Dutch government ran out. This is why some have nicknamed the burger, the 'Googleburger'. Brin invested £215,000 (€260,000) of his personal fortune in the project. He got involved because he shared similar interests as Professor Post relating to the sustainability of meat production and animal welfare.

This public event was key to boost the development and foster interests in the technology in order to facilitate its expansion because shmeat is currently too new and revolutionary for the food industry. It necessitates to be more viable before obtaining the food industry's support and potential partnerships. The problem is that most food companies do not have the facilities to support and take on the biological research that is needed.[158] The industry is adopting a 'wait-and-see' approach, as cultured meat is too costly at this early stage for commercialisation. The reasons for the industry's reluctance are that cultured meat may be good enough as a POC but it is far from large scale production. It is underpinned by technical problems and inefficiency issues, which must be solved to make cultured beef commercially viable. The main problems are how to turn cultured beef into a desirable and affordable consumer product,[159] the ability to grow fat,[160] and large-scale production posing acceptable safety risks. Professor Post insisted that if production could be scaled up, cultured beef could be sold in supermarkets within five to ten years and would cost around £20 (€25) a pound (0.45kg) – which is quite expensive.[161] The lack of involvement of the food industry and the reliance on philanthropists demonstrates the difficulties for scientists to develop their innovations and to gather funding. Cultured meat arguably reinforces the assertions, first, that there is an absence of dialogue between the public, regulators and scientists; and, second, that a

157 See e.g., Alison L. Van Eenennaam et al., "Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?", 3(13) *Food and Drug Policy Forum* (2013), pp. 865 *et sqq.*, at p. 14; and CAST, "The Science and Regulation of Food from Genetically Engineered Animals", *supra* note 15, at p. 7.

158 Nathan Gray, "Lab-Grown Meat: Too Revolutionary for Industry Backing?", Foodnavigator.com, 6 August 2013, available at http://www.foodnavigator.com/Science-Nutrition/Lab-grown-meat-Too-revolutionary-for-industry-backing (last accessed on 1 April 2014).

159 Connor, "Special Report: 'In Vitro' Beef", *supra* note 7.

160 Gray, "Lab-Grown Meat: Too Revolutionary for Industry Backing?", *supra* note 158.

161 Andrew C. Revkin, "Bring on the 'Frankenburger'", New York Times (The Opinion Pages), 5 August 2013, available at http://dotearth.blogs.nytimes.com/2013/08/05/bring-on-the-frankenburger/?partner=rss&emc=rss&_r=0 (last accessed on 1 April 2014).

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lack of interaction between scientists, the food industry, regulators and policy-makers exists.

Research and innovation should respond to the needs and ambitions of society, to reflect its values and to be responsible. This is the tenet of the new EU framework for Responsible Research and Innovation (RRI),[162] which covers three areas: first, science and innovation policy; second, public participation, involvement and consultation; and, third, regulators and policy makers. RRI relies on the principle of inclusiveness, where all actors are involved at an early stage, allowing 'innovation to be developed in a co-building mode that "ensures co-responsibility"'[163] and promotes a 'socially responsible science'.[164] There is an ongoing shift from attempting to assess the ethical, legal and social implications (ELSI) of technologies to approaches emphasising the co-production of research processes especially as they relate to ethically sensitive issues, such as foods. Decision-making should seek to 'integrate the "can do" orientation of science and engineering with the "should do" questions of ethical and political analysis'.[165] Public engagement of science entails 'both ethical expert commissions and the involvement of engaged citizens and of civic society organizations'.[166]

This new EU framework acknowledges the interconnectedness of politics, science and social order by attaching science and policy together with culture, values and other social dimensions, including consumer views. Co-production of knowledge is at the heart of this new policy to strengthen the bio- and knowledge-based economies. If technologies, such as cultured meat, were co-produced from their inception, they would be transferred more quickly from universities to markets, through greater partnerships, cooperation, coordination and support from different services and actors, including the public.

The transfer of innovation from universities to the private sector should be facilitated by being more efficient and rapid for the broader benefit of society.[167] Universities, research institutions, and laboratories are important productive facilities for innovations, yet the process by which their discoveries reach the marketplace is strict and unreasonably held back by deficient policies and rules, and by a lack of strategic investment that could advance their commercialisation.[168] This is demonstrated by the fact that Professor Post had to, first, obtain further funding from philanthropists and, second, attract the attention of the media and therefore of investors through the organisation of a publicity event. The idea would be to create innovation ecosystems where initiatives and inspirations would be nurtured from their commencement until their commercialisation, while keeping the public and other stakeholders informed as well as actively involved. The growth of innovation clusters and POC centres are potential solutions to overcome these barriers, combined to POC funding in technology advancement, like it has happened in the US with nanotechnology.[169] The establishment of POC centres would assist in the commercialisation of early-stage developments.[170]

The hurdles surrounding the expansion of shmeat recalls the German biotech firm BASF moving its headquarters for plant science from Germany to North Carolina in 2012 because of the absence of support for research and innovation in the EU. BASF also halted the commercialisation of all GM products for cultivation in the EU market, due to a 'lack of acceptance for this technology in many parts of Europe – from the majority of consumers, farmers and politicians'.[171] The GM food and shmeat examples reveal that the industry is alarmed and refrains from backing new food technologies within the EU. In addition, the 2013 proposals banning animal cloning and

162 The programme 'Science and Society' evolved into the 'Science in Society' programme to now RRI. RRI could be summarised as 'Science for Society, with Society'. See also, the Europe 2020 Strategy and the Horizon 2020 Strategy for the Framework Programme (which itself implements the EU 2020 flagship 'Innovation Union' initiative aiming at securing Europe's global competiveness); and Hilary Sutcliffe, "A Report on Responsible Research and Innovation" (2011).

163 Richard Owen et al., "Responsible Research and Innovation: From Science in Society to Science for Society, with Society", 39 *Science and Public Policy* (2012), pp. 751 *et sqq.*, at p. 752.

164 See e.g., Jerome R. Ravetz, *Scientific Knowledge and its Social Problem* (Oxford: Clarendon, 1971).

165 Jasanoff, "Technologies of Humility", *supra* note 95, at p. 243.

166 Van Est, "The Broad Challenge of Public Engagement in Science – Commentary", *supra* note 94, at p. 646.

167 Jay P. Kesan, "Transferring Innovation", 77 *Fordham Law Review* (2009), pp. 2169 *et sqq.*, at p. 2169.

168 Anthony P. Green et al., "Accelerating Innovation: The Nanotechnology Institute", 8 *Nanotechnology Law & Business* (2011), pp. 176 *et sqq.*, at p. 176.

169 Ibid, at p. 177. For more on nanotechnology, see Kesan, "Transferring Innovation", *supra* note 167, at p. 2169; and Reynolds, "Nanotechnology and Regulatory Policy", *supra* note 41, at p. 179.

170 Kesan, "Transferring Innovation", *supra* note 167, at p. 2201.

171 See Rebecca Trager, "BASF Pulls Out of Europe over GM Hostility", 18 January 2012, available at http://www.rsc.org/chemistryworld/News/2012/January/basf-pull-out-gm-crops-biotech.asp (last accessed on 1 April 2014).

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its resulting foods would, most likely, strengthen the worries and the resistance of the high-tech and food industries to back novel food technologies, as it appears that the EU policy and regulatory framework prevents innovation and trade. These experiences reveal the importance of involving the public, regulators and other parties as early as possible in the development of a novel food technology in order to avoid political turmoil, consumer opposition as well as trade and investment deadlocks. As promoted by the RRI framework, policy and regulation ought to allow science to develop, proceed and potentially expand while balancing both the benefits and potential harms of cultured meat.

As the GE and cloning debates have shown, discussions and engagement with the public about cultured meat should start now and develop along with the technology. It should be a paralleling and accompanying process. Stakeholder's engagement, public participation, deliberative discourse, openness and transparency, combined with adequate policy and regulation, would bring any future food technology closer to ensure public acceptance and support by the industry.

VI. Conclusion

Cultured meat holds both negative and positive capacities: unforeseeability in terms of potential risks and undesirable outcomes must be balanced against economic, environmental and societal benefits. The risks entailed by this innovation should be carefully considered by regulators and policy-makers, as well as its scope for ensuring food security. The tasting event intended to mainly alert the media and investors but also contributed to inform the public about the technology and it made decision-makers aware of the potential regulatory needs of the technology.

Under the Novel Foods Regulation, if substantial equivalence were to be engaged, cultured meat would not be regulated adequately. The Novel Foods Regulation reflects the general inadequacy of imposing outdated laws in an effort to regulate emerging technologies and their resulting foods. Regulatory frameworks require modifications to remain efficient and adequate because new developments call for unintended applications of the existing regime – as demonstrated with cultured meat under the Novel Foods Regulation. There is a clear necessity to enhance the regulatory landscape for novel foods in the EU. The EU institutions should act quickly to solve this regulatory failure – as proven by the 2013 Novel Foods Proposal. Oversight mechanisms need to account for the unique characteristics of this food based on premarket approval, mandatory labelling, enforcement and monitoring (including of genetic diversity). New regulation should be designed to achieve two fundamental objectives: effective risk management and avoid stifling innovations.

Greater participation, deliberation and involvement early in the development of a novel food as well as during the decision-making process for novel foods should be strengthened at EU level. The assertion is not that stakeholders are in a better situation to take decisions but that they have pertinent insights and expertise that bear on specific issues. Dialogue between different stakeholders, scientists and regulators should take place at the inception of a new technology, i.e. at the R&D stage, to ensure that scientific and technological developments are not simply 'imposed' on society, but emerge through public sphere debates in which the perspectives and concerns of different interest groups are accounted for. This would lead to greater engagement and governance and, ultimately, better policy and effective regulation. Decisions will be improved if they have input from interested communities, as emphasised in the EU's framework for 'Responsible Research and Innovation'. Reinforcing such initiatives would strengthen the credibility of any future regulatory regime and improve the trust and confidence of the public in these regimes.

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