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An Impossible Task? Australian Food Law and the Challenge of Novel Meat Analogues

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Abstract

This paper asks what the regulatory assessment of the novel processed meat analogue products reveals about the nature of food regulation in Australia. We analyse Food Standards Australia and New Zealand's ('FSANZ') assessment of the recent application by Californian technology company Impossible Foods Inc to sell its proprietary burger products which contain a genetically modified protein that is said to make their burger 'bleed'. We show that FSANZ's assessment process has little capacity to engage with broader and longer term, social, ecological and public health implications of novel foods and changing food markets. FSANZ's regulatory pre-approval process focuses almost exclusively on the safety of individual ingredients rather than the impact of novel foods on the food supply as whole and leaves broader issues to the market and consumer choice with limited support from laws addressing misleading labelling and marketing of foods. Extending the capacity of Australia's regulatory regime for food to deal with more than the safety of individual ingredients will become more urgent as other novel foods, such as cell-based meats, enter the marketplace.

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I Introduction

Impossible Foods Inc ('Impossible'), a Californian-based tech start-up that develops, manufactures and markets novel meat analogues, describes its mission as: 'To drastically reduce humanity's destructive impact on the global environment by completely replacing the use of animals as food

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production technology'.[1] Its signature product is its 'bleeding' plant-based burger, the 'Impossible Burger'[2] available at major supermarkets and restaurants throughout the US, Hong Kong and Singapore. In July 2019, Impossible applied to the statutory authority Food Standards Australia New Zealand ('FSANZ') for approval to sell its products in Australia and New Zealand ('the Impossible application').[3] Eighteen months later, after two calls for submissions and a notably 'high volume of stakeholder interest in broader issues relating to the applicant's Impossible meat analogue products',[4] FSANZ recommended that the product be approved.[5]

This paper shows that FSANZ's assessment process for novel food pre-market regulatory approval has a narrow scope of considerations that defines out many concerns of stakeholders, and the most pressing social, ecological and justice issues facing the food system. FSANZ's regulatory pre-approval process focuses almost exclusively on the safety of individual ingredients rather than the impact of novel foods on the food supply as a whole. It leaves broader issues to the market and consumer choice with limited support from laws addressing misleading labelling and marketing of foods.

Under Australian and New Zealand food law, Impossible needed to apply for approval to sell its meat analogue products because they contain a novel protein ingredient, *soy leghemglobin,* naturally present in the root nodules of soy plants and now mass produced by Impossible using genetically modified yeast.[6] According to Impossible, *soy leghemglobin* mimics the molecules in animal flesh that are 'what makes meat taste so meaty'.[7] As we shall show, Impossible, and other novel meat analogue developers and proponents, claim that their novel meat analogue products will disrupt the food system for the better by replacing animal-derived meat with foods that are more

1. Impossible Foods, 'The Mission That Motivates Us', *Medium* (12 March 2018) <https://medium.com/impossible-foods/the-mission-that-motivates-us-d4d7de61665>
2. 'Impossible Burger' is the term used by Impossible to refer to its burger mince, and Impossible has registered the term as a trademark in various jurisdictions. In the US, Impossible sells its burger in ground mince and patty versions and it also sells a sausage patty ('Impossible Sausage') and another mince product ('Impossible Pork'). When we are referring specifically to the burger patty or mince, we will use the term 'Impossible Burger' whereas references to Impossible products encompass any of its range.
3. Impossible Foods Inc, *Application to Amend the Australia and New Zealand Food Standards Code to Allow for the Use of Soy Leghemoglobin* (No A1186, FSANZ, 12 July 2019) <https://www.foodstandards.gov.au/code/applications/Documents/A1186Application_Redacted.pdf>. As we explain below, technically the application was to amend the Food Standards Code to permit the voluntary use of soy leghemoglobin in meat analogue products. The application, *A1186 — Soy Leghemoglobin in Meat Analogue Products*, and all related materials are available at: FSANZ, 'A1186 — Soy Leghemoglobin in Meat Analogue Products', *Food Standards Australia New Zealand* (24 December 2020) <https://www.foodstandards.gov.au/code/applications/Pages/A1186.aspx>
4. Food Standards Australia and New Zealand, *2nd Call for Submissions — Application A1186: Soy Leghemoglobin in Meat Analogue Products* (No 131–20, 6 August 2020) 11 <https://www.foodstandards.gov.au/code/applications/Documents/A1186_2ndCFSreport.pdf>
5. FSANZ, *Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products* (No [145–20], Food Standards Australia and New Zealand, 15 December 2020) <https://www.foodstandards.gov.au/code/applications/Documents/a1186-approval-report.pdf>. The Ministerial Forum on Food Regulation ('the Forum') accepted FSANZ's recommendation at its meeting on 12 February 2021: Australia and New Zealand Ministerial Forum on Food Regulation, *Communiqué of Outcomes from the Australia and New Zealand Ministerial Forum on Food Regulation Meeting Held on 12 February 2021* (Forum 16, 12 February 2021) 1 <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/DEC2AE832E9CCCB4CA25867A0016FD36/$File/Forum16-FINALCommuniqu%C3%A9-12Feb2021.pdf> This means *the Code* will be changed to allow Impossible products that contain *soy leghemoglobin*. For more discussion on this regulatory process, see the explanation in Part IIIA.
6. See notes 115 to 117 below and accompanying text.
7. Impossible Foods, 'What Is Soy Leghemoglobin, or Heme?', *IF* <https://faq.impossiblefoods.com/hc/en-us/articles/360019100553-What-is-soy-leghemoglobin-or-heme->. See further explanation and discussion below at notes 31 to 33 and accompanying text, 128 to 130 and accompanying text.

healthy, sustainable and ethical. These claims have gained significant traction due to the increasing institutional and academic support for interventions that enable more healthy and environmentally sustainable diets, as well as growing awareness regarding ethical issues with intensive animal agriculture.

The claim that novel meat analogues will positively disrupt the food system has sparked debates in a multitude of jurisdictions, especially in the US, the EU and now Australia and New Zealand. Public health advocates, proponents of alternative, including agro-ecological, food systems and the meat industry have all contested the idea that novel meat analogues represent a positive future for food.[8] Their various criticisms of novel meat analogues include that the novel analogue products are unhealthy, unwholesome and inferior compared to either animal-derived flesh, or whole food vegetarian products (such as vegetables and legumes), the way the novel products use food processing technology (including GM) and the fact that they are promoted by corporate interests (Silicon Valley tech companies, fast food retailers, supermarkets and even in some cases meat companies wishing to diversify their portfolio). These critiques extend to whether novel meat analogues should replace meat derived from animals including whether novel meat analogues can bring about healthier diets and make the food system more ethical and ecologically sustainable.

The promise of a better food claimed by proponents of novel meat analogues, and the contestation of these claims, raise urgent public interest issues for the food system which deserve serious legal and policy attention. The debate extends beyond novel meat analogues as a new food category raising questions about how to address the interlinked social, environmental and ethical issues associated with food systems and the role of regulation in addressing these challenges. As a slew of new meat analogues, including new products based on cultured animal cells, are developed, the Impossible application can be seen as a 'test case' as to how FSANZ's pre-market regulatory assessment system addresses these policy issues.[9]

Part II introduces and explains what we mean by 'novel meat analogues' and 'novel proteins'. We show how novel meat analogue products, and their novel protein ingredients, are contested in public discourse around the world, and specifically within Australia, and the kinds of issues to which regulators are being called on to respond. In doing so, we draw on academic literature and our own thematic analysis of submissions to FSANZ's assessment of the Impossible application.[10]

Part III analyses the relevant provisions of the *Food Standards Australia New Zealand Act 1991* (Cth) ('*FSANZ Act*'), the *Australia New Zealand Food Standards Code* ('*the Code*') and FSANZ's assessment of the Impossible application to demonstrate the narrow scope and application of Australian pre-market regulatory assessment for novel foods. We show that the process is geared towards a narrow scientific risk assessment of the acute, direct safety and toxicity of individual novel ingredients and processes. This process is inadequate to address the policy concerns raised in public discourse over novel meat analogues in general and Impossible's application in particular. In practice, the assessment process over-values economic interests and consumer choice and only deals with health and safety issues that are amenable to direct, biomedical measurement. FSANZ's focus on particular issues and evidence, and to disengage from other social and ethical issues and evidentiary bases, seems neutral and apolitical, but has important political and policy ramifications.

8. See Part IIC for further explanation and discussion.
9. In December 2020, the Singapore Food Agency approved, for the first time in the world, the sale of cell-based 'chicken' meat analogues by Eat Just, a US company partly based in Singapore. See, Singapore Food Agency, 'Safety of Alternative Protein', *Singapore Food Agency* (9 December 2020) <https://www.sfa.gov.sg/food-information/risk-at-a-glance/safety-of-alternative-protein>.
10. See Part IIA for further explanation and discussion, as well as for the Table of Submissions.

These debates are already spilling over into debates over how novel meat analogue products should legally be allowed to be described (for example through petitions to prohibit the use of terms such as 'burgers', 'sausages' and 'plant-based meat'), and feed into ongoing concern about what FSANZ could be doing to limit the consumption of other processed foods.

Part IV of the paper concludes that Australia's food law and policy provides little opportunity to assess and debate the impact of novel food products (eg the Impossible burger as distinct from the novel ingredient, *soy leghemoglobin*) and whole categories of food (such as novel meat analogues and ultra-processed foods) including their combined effects on the diet of the population. It also provides very limited avenues for assessing the social, economic, ethical and environmental impacts of novel food ingredients, products and categories on the food system as a whole. The current regulatory approach leaves it to the market and consumer choice to determine the future of the food system, rather than providing for public democratic policy fora in which to discuss and debate larger questions of the desirable qualities and trajectory of food systems and technological change.[11]

II Novel Meat Analogues, Novel Proteins, Promissory Narratives and their Critics

A *Meat Analogues and Novel Proteins*

The term 'meat analogue' refers to a relatively new category of products that are designed to replace traditional meat and dairy in Western meals.[12] In public, scholarship, activist, institutional and mainstream media discourse, other descriptors are interchangeably used including 'plant-based',

11. Food law and policy scholarship has examined the ends food systems governance should be trying to achieve, and has critiqued the emphasis on individualised, market-based approaches to food systems change. See, eg, Christine Parker and Hope Johnson, 'Sustainable Health Food Choices: The Promise of "Holistic" Dietary Guidelines as a National and International Policy Springboard' (2018) 18(1) *QUT Law Review* 1 ('Sustainable Health Food Choices'); Rachel Carey et al, 'Opportunities and Challenges in Developing a Whole-of-Government National Food and Nutrition Policy: Lessons from Australia's National Food Plan' (2016) 19(1) *Public Health Nutrition* 3 ('Opportunities and Challenges in Developing a Whole-of-Government National Food and Nutrition Policy'); Christine Parker and Hope Johnson, 'From Food Chains to Food Webs: Regulating Capitalist Production and Consumption in the Food System' (2019) 15(1) *Annual Review of Law and Social Science* 205; Tim Lang and Pamela Mason, 'Sustainable Diet Policy Development: Implications of Multi-Criteria and Other Approaches, 2008–17' (2018) 77(3) *Proceedings of the Nutrition Society* 331 ('Sustainable Diet Policy Development'). Human rights scholarship has also elaborated upon what food systems should be aiming to achieve, and how governments can regulate food to achieve these ends in accordance with human rights principles. See, eg, Olivier De Schutter, *The Right to an Adequate Diet: The Agriculture-Food-Health Nexus* (Report of the Special Rapporteur on the right to food No A/HRC/16/49, United Nations General Assembly, 20 December 2010) 21.
12. The meaning of 'a meal', ie what meals are comprised of, and the sequence of meals are socially determined. In Western cultures, meat is often a component of meals and preferences, traditions, skills and knowledges relating to food and meals are typically based in the use of meat and dairy. Mary Douglas, 'Deciphering a Meal' (1972) 101(1) *Daedalus* 61; Joop de Boer and Harry Aiking, 'Favoring Plant Instead of Animal Protein Sources: Legitimation by Authority, Morality, Rationality and Story Logic' (2021) 88 *Food Quality and Preference* 104098 ('Favoring Plant Instead of Animal Protein Sources').

'cell-based', 'lab-grown', 'alternative' or 'novel' with the terms 'meats' or 'proteins'.[13] 'Meat analogue', however, reflects the terminology used by Australian food regulators.[14]

Alternatives to meat and dairy extend from traditional and comparatively unprocessed plant-based products, like beans, mushrooms and lentils, to more processed alternatives like tofu (based on soy), seitan (wheat gluten) and falafels (based on either chickpeas or fava beans) that have been part of human diets since antiquity.[15] In the 1960s advances in food processing technologies led to the creation of textured vegetable protein (TVP), a precursor to contemporary meat analogues, which became mainstream in Western markets during the 1990s popularised by US brands like Tofurky.[16] TVP results from extrusion, that is, the industrial heating and moistening of extracted components from plants like soybeans or peas, until the extracts become jelly-like, and are then re-shaped and dyed.[17]

The newest generation of meat analogues have been designed to more closely mimic the texture, taste, action and look of conventional animal-based meat and dairy, and therefore to appeal to a broader (meat-eating) consumer base.[18] As He et al observed, 'In recent years, corporations … have developed a new generation of plant-based meat alternatives to satisfy meat eaters. The newest versions … have similar structures, comparable smells and even a bloody appearance to help mimic animal meat.'[19] These new meat analogues do so using advanced processing techniques that often include biotechnologies (such as precision fermentation, genetic modification or cell culturing),[20] other advanced food processing methods and/or a high use of food additives, that is, various

13. See, eg, Garrett M Broad, 'Making Meat, Better: The Metaphors of Plant-Based and Cell-Based Meat Innovation' (2020) 14(7) *Environmental Communication* 1 ('Making Meat, Better'); Bruce Friedrich, 'Why GFI Uses the Term "Cultivated Meat" — The Good Food Institute', *Good Food Institute* (13 September 2019) <https://gfi.org/blog/cultivatedmeat/>; Björn Witte et al, *Food for Thought: The Protein Transformation* (Boston Consulting Group, 24 March 2021) <https://www.bcg.com/en-au/publications/2021/the-benefits-of-plant-based-meats> ('*Food for Thought*'); World Economic Forum, *Alternative Proteins* (White Paper, World Economic Forum, January 2019) <http://www3.weforum.org/docs/WEF_White_Paper_Alternative_Proteins.pdf>; Chase Purdy, *Billion Dollar Burger: Inside Big Tech's Race for the Future of Food* (Portfolio, 2020) ('*Billion Dollar Burger*').
14. This term is not defined in the Food Standards Code, but it is used in various official policy documents. For example, FSANZ uses the terms in its documentation regarding the Impossible application. It is also used by the Forum on Food Regulation.
15. Stephanie Tai, 'Legalizing the Meaning of Meat' (2020) 51(3) *Loyola University Chicago Law Journal* 743; Carol J Adams, *Burger* (Bloomsbury Publishing USA, 2018) 87–109.
16. See, eg, M Tziva et al, 'Understanding the Protein Transition: The Rise of Plant-Based Meat Substitutes' (2020) 35 *Environmental Innovation and Societal Transitions* 217 ('Understanding the Protein Transition').
17. MN Riaz, 'Texturized Vegetable Proteins' in Glyn O Phillips and Peter A Williams (eds), *Handbook of Food Proteins* (Elsevier, 2011) 395.
18. World Economic Forum (n 13) 9 where it states 'A continuum can be drawn from protein rich plants that are used in unprocessed forms to substitute for meat in meals (lentils, for example) through more processed products such as soy based tofu and wheat based seiten to recent innovations seeking to make vegetable burgers and other products that are as indistinguishable as possible from real meat. Innovation is occurring across this spectrum … to create a "mouth feel" and experience that closely mimics meat'. See also, Sarah P F Bonny et al, 'What Is Artificial Meat and What Does It Mean for the Future of the Meat Industry?' (2015) 14(2) *Journal of Integrative Agriculture* 255, 256.
19. Jiang He et al, 'A Review of Research on Plant-Based Meat Alternatives: Driving Forces, History, Manufacturing, and Consumer Attitudes' (2020) 19(5) *Comprehensive Reviews in Food Science and Food Safety* 2639, 2644 ('A Review of Research on Plant-Based Meat Alternatives').
20. Food biotechnologies refer to the knowledges, technologies and processes applied to microbes and cells from plants or animals to produce new food products or ingredients. Byong H Lee, *Fundamentals of Food Biotechnologies* (John Wiley & Sons, Ltd, 2015) Preface <http://onlinelibrary.wiley.com/doi/abs/10.1002/9781118384947.ch1>.

chemical compounds added for sensory, freshness or nutritional purposes.[21] In some cases, novel meat analogues are created through combinations of existing ingredients and processes. For instance, Beyond Meat, another Silicon-Valley company that competes with Impossible, uses specific combinations of pre-existing additives and pre-existing food processing techniques in a novel way to produce its 'Beyond Burgers'.[22] Because it uses pre-existing processes and additives, Beyond Meat's products did not need pre-market regulatory approval to be sold in Australia and New Zealand.

Other novel meat analogues, like the Impossible products, contain, or are projected to contain, a proprietary 'novel protein' ingredient, which is a particular in-put created using biotechnologies. These may be based on plants or fungi or both (as in the case of Impossible).[23] 'Lab' or 'cell-based' meats are made from tissue grown by culturing animal cells using processes broadly similar to those used to engineer human flesh in biomedical fields.[24] The fact that these products produce a kind of animal flesh raises particular ontological, political and legal questions that are beyond the scope of this paper.[25] Currently, FSANZ expects that this type of novel meat analogue will be regulated under the same regime and processes which apply to all novel foods, including the Impossible burger.[26] Hence, our analysis of the Impossible pre-market approval process is applicable to cell-cultured products.

In popular discourse the whole meat analogue, such as the Impossible Burger or the Beyond Burger, is often referred to as a 'novel protein' or 'alternative protein', even though the product also consists of other nutrients and substances.[27] In technical scientific discourse, 'protein' refers to specific macromolecules consisting of amino acids. 'Protein' in the context of food is one of the three broad kinds of macromolecules (ie macronutrients) that humans consume besides fats and carbohydrates (and as opposed to micronutrients such as iron). Novel meat analogues, as well as meat and dairy products, contain carbohydrates and/or fats as well as protein and other micronutrients and substances. Because animal products tend to be high in protein, they have often played a role in meeting that macronutrient requirement in diets. In popular discourse novel meat analogues are, therefore, often characterised as 'alternative [sources of] protein' to emphasise their role as replacements for traditional animal products.

The reason 'protein' is emphasised over other macronutrients is because it has taken on an expanded meaning whereby foods high in protein (meat, dairy, legumes and some meat and dairy analogues) are discursively connected to health, morality and bodily appearance, as opposed to

21. An alternative pathway is the use of insects (which may have been a traditional part of the diet in some places). We do not discuss the use of insects in this paper. Marie C Boyd, 'Cricket Soup: A Critical Examination of the Regulation of Insects as Food' (2017) 36(1) *Yale Law & Policy Review* 17 ('Cricket Soup').
22. Beyond Meat, 'Our Ingredients', *Beyond Meat — Go Beyond®* <https://www.beyondmeat.com/about/our-ingredients/>.
23. Fungi are not plants. As explained below, Impossible's novel ingredient is based on genetically modified yeast (a fungi) into which genetic material from soy plant root nodules has been inserted. Quorn, see text accompanying note 195 below, is based on fungi.
24. Neil Stephens et al, 'Bringing Cultured Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture' (2018) 78 *Trends in Food Science & Technology* 155 ('Bringing Cultured Meat to Market').
25. Hope Johnson, 'From "Meat Culture" to "Cultured Meat": Critically Evaluating the Contested Ontologies and Transformative Potential of Biofabricated Animal Material on Culture and Law' (2019) 22(2) *M/C Journal* <http://journal.media-culture.org.au/index.php/mcjournal/article/view/1504> ('From "Meat Culture" to "Cultured Meat"'); Hope Johnson, 'The Future of Animal Agriculture? Legal and Environmental Implications of Biofabricating Animal Material' (2019) 34(4) *Australian Environment Review* 83; Hope Johnson, 'Regulating Cell-Cultured Animal Material for Food Systems Transformation: Current Approaches and Future Directions' (2021) 13(1) *Law, Innovation & Technology* 108.
26. FSANZ, 'Cell Based Meat', *Food Standards Australia New Zealand* (2019) <https://www.foodstandards.gov.au/consumer/generalissues/Pages/Cell-based-meat.aspx>.
27. See note 34 and accompanying text.

foods high in fats or carbohydrates.[28] FSANZ mostly uses the term 'novel protein' consistent with the scientific meaning and, therefore, to refer to a specific macromolecule used as an ingredient within a novel meat analogue.[29]

Impossible products provide a prime example of a novel meat analogue that contains a novel protein, in this case *soy leghemoglobin*.[30] *Soy leghemoglobin* can technically be extracted from the roots of soy plants in minute quantities. Impossible developed a way to mass-produce the protein using genetically modified yeast (a fungi).[31] In its application to FSANZ, Impossible noted '*Soy leghemoglobin* is a key ingredient' that is responsible for some of the meat-like qualities of its products including nutrition (iron).[32] Notwithstanding this claim, Impossible's form of *soy leghemoglobin* is only one ingredient that constitute Impossible's products as meat analogues. Impossible's products are made from highly-processed soy proteins, vegetable oils and a range of binders and food additives commonly used in highly processed food products to make the food hold together, to colour and flavour it, to fortify it with relevant vitamins and minerals and to make it resemble burger or sausage meat.[33]

As we show below in Part III.A., the regulatory process responds to novel proteins (a specific molecular ingredient in the product), or other new substances, within novel meat analogues by performing a scientific and regulatory assessment of their safety. The regulatory process does not respond merely to the fact that there is a new product that differs from other products. Nevertheless, the submissions to the Impossible application reflected broader contestation regarding novel meat analogues not merely specific concerns about the novel protein component, *soy leghemoglobin*.

The process attracted 60 submissions[34] made by 48 separate parties.[35] Table 1 summarises which parties made submissions, and whether they were for or against, or neither. Five government agencies who would have responsibility for implementing and enforcing the new rules submitted:

28. Göran Eriksson and David Machin, 'Discourses of "Good Food": The Commercialization of Healthy and Ethical Eating' (2020) 33 *Discourse, Context & Media* 100365 ('Discourses of "Good Food"'); Ariel Chen and Göran Eriksson, 'The Mythologization of Protein: A Multimodal Critical Discourse Analysis of Snacks Packaging' (2019) 22(4) *Food, Culture & Society* 423 ('The Mythologization of Protein').
29. For example, FSANZ uses the term 'novel protein' in its second call for submissions to refer only to the specific protein molecule produced by Impossible's GM process ie *soy leghemoglobin*: Food Standards Australia and New Zealand (n 4).
30. According to Impossible, 'soy leghemoglobin' is short for 'legume haemoglobin'. Impossible Foods, *What Is Soy Leghemoglobin, or Heme?* (n 7).
31. Impossible explain that *soy leghemoglobin* is naturally present in soy plant root nodules but is now mass produced by Impossible via genetically modified yeast in the form of 'LegH Prep'. In theory Impossible could grow or purchase soy (not the bean, the root nodules) and harvest and refine the molecules without the use of GM technologies. But this is neither economically nor practically feasible at scale: Impossible Foods, 'Heme — The Magic Ingredient in the Impossible Burger' (YouTube, 2017) <https://www.youtube.com/watch?v=n6U4H8WC9jg>.
32. Impossible Foods Inc (n 3) 5.
33. The list of ingredients can be found here: Impossible Foods, 'What Are the Ingredients?' *Impossible Foods* <https://faq.impossiblefoods.com/hc/en-us/articles/360018937494-What-are-the-ingredients->.
34. FSANZ lists two less individual submitters in than we do. We had only the redacted versions to work from whereas FSANZ had the full version. We believe the discrepancy is because two individual submissions that are expressed as being from members of community groups were probably considered by FSANZ as part of the relevant consumer group submissions. Some aspects of the publicly available submissions are redacted so it is not possible to completely reconcile with FSANZ's account.
35. The first call for submissions was required under s 44 of the *Food Standards Australia New Zealand Act 1991* (Cth) ('*FSANZ Act*'), as part of FSANZ's assessment of Impossible's application. The second call for submissions related to the variation of *the Code* proposed by FSANZ to allow the approval of Impossible product: *FSANZ Act* s 31. All the supporting documents and submissions received are located at: FSANZ, *A1186 — Soy Leghemoglobin in Meat Analogue Products* (n 3).Forty-five separate parties submitted to the first call for submissions, and seventeen to the second call (including 3 parties who had not previously submitted). These were Impossible Foods, Milky Lane (a fast food retailer) and one private individual.

the New Zealand agency was in favour, the state of Victoria against, and New South Wales, Queensland and South Australia expressed no opinion but raised various issues.

Groups in favour of the Impossible application included eight food retailers who supported consumer choice, and four organisations (including the applicant) with a mission or commercial purpose to promote meat analogues. Two submissions by private individuals were in favour of approval, one by a consumer (who was keen to eat Impossible burgers) and one by prominent New Zealand citizens, Sir Peter Jackson (the director of the Lord of the Rings movie franchise) and Dame Fran Walsh (screenwriter and producer), who have also separately set up a private company to promote meat analogues ('Fart-free Ltd NZ'), which had also made a separate corporate submission. Two Australian allergy groups concerned about the potential for allergenic new food ingredients also made submissions in which they expressed concern but came down in favour of approval.

Twelve groups argued against approval including two New Zealand meat industry groups, three groups that promote organic or agro-ecological farming and food and six environmental or community groups with an anti-GM agenda. The vast majority (16) of the 18 submitters who were individuals[36] were also against approval of Impossible's application, mainly on the basis of their opposition to GM foods.[37]

B *Promissory Narratives Supporting Impossible*

In their public communications Impossible position their meat analogue products as both a natural evolution in conventional meat and a transformative force for food systems. With the tagline 'Eat Meat. Save the Planet', Impossible explains 'We make delicious meat … products, from plants, so you can eat what you love, and save the planet you love too'.[38] In their application to FSANZ, Impossible's claims were more subdued but, nonetheless, consistent with this narrative. The company noted, consistent with consumer studies,[39] that its products are for people who seek out meat analogues for 'health, ethical, religious, environmental' reasons,[40] and suggested its products would give Australian and New Zealand consumers:

> the option to purchase meat analogue products designed to mimic the nutrition (i.e. provide a source of iron), flavour and aroma of the animal-derived counterpart. Consumers will benefit from having access to a nutritious and flavourful alternative to foods derived from animals, with a much-reduced environmental impact.[41]

36. FSANZ's 2nd Call for Submissions names each of the individual submitters, but the names are not available on the website where the submissions can be downloaded. They are redacted to initials. We do not have ethics clearance to name individuals and have not done so except in the case of Sir Peter Jackson and Dame Fran Walsh who are public figures.
37. A number used the same template for submission.
38. Impossible Foods Inc, 'Sustainability', *Impossible* (June 2020) <https://www.impossiblefoods.com/sustainable-food>.
39. Patrick Schenk, Jörg Rössel and Manuel Scholz, 'Motivations and Constraints of Meat Avoidance' (2018) 10(11) *Sustainability* 3858; Chrysostomos Apostolidis and Fraser McLeay, 'It's Not Vegetarian, It's Meat-Free! Meat Eaters, Meat Reducers and Vegetarians and the Case of Quorn in the UK' (2016) 6(3) *Social Business* 267.
40. Impossible Foods Inc (n 3) 6.
41. Ibid 5.

Table 1. Summary of parties submitting to Impossible pre-approval process.

Type of party making submission	Parties making submissions (n = 48)	For or against?
Government		
Implementation and enforcement bodies under the bi-national food regulation scheme	New Zealand Food Safety	For
	Victoria Departments of Health and Human Services and of Jobs, Precincts and Regions and PrimeSafe	Against
	Queensland Health, Food Safety Standards & Regulation Unit	Not stated
	NSW Food Authority	
	South Australia Health	
Primary producer associations		
NZ meat industry bodies	Beef + Lamb New Zealand	Against
	Meat Industry Association of New Zealand (MIA)	
No Australian primary producer body other than AFSA made any submission to the process		
Organic and Agro-Ecological Organisations		
NZ organic industry body	The Soil & Health Association NZ	Against
NZ organic food retailer	Kerikeri Organic	
Not for profit representing smaller farmers with emphasis on agro-ecological farming in Australia	Australian Food Sovereignty Alliance (AFSA)	
Food retail industry		
Industry associations for food, beverage and grocery manufacturers	Australian Food & Grocery Council (AFGC)	For
	New Zealand Food & Grocery Council (NZFGC)	
Major Australian supermarket	Woolworths	
Australian & NZ catering company	Beak & Johnston (B&J)	
Australian quick service food retailers	Funlab	
	Grill'd Pty Ltd	
	Milky Lane	
Meat analogue organisations		

(continued)

Table 1. (continued)

Type of party making submission	Parties making submissions (n = 48)	For or against?
Not for profits working to promote research, market development and investment in meat analogues	Food Frontier (Australian) The Good Food Institute (US)	For
Company (owned by filmmakers Peter Jackson and Fran Walsh) to promote plant-based meat in NZ	Fart Free Limited (NZ)	
Applicant and US plant-based meat manufacturer	Impossible Foods	
Non government organisations		
Pro-GM lobby group	Life Sciences Network Inc NZ	For
Non-profit allergy groups	Allergy and Anaphylaxis Australia National Allergy Strategy AU	
Environmental and anti-GM groups	Friends of the Earth (FOE) AU and Gene Ethics (Australia)	Against
	Friends of the Earth (FOE) NZ	
	GE Free NZ	
	Grey Power Combined NZ	
	Physicians & Scientists for Global Responsibility NZ	
	Carbon Neutral NZ Trust	
Individuals (18)		
	Sir Peter Jackson and Dame Fran Walsh (also submitted as Fart Free NZ)	For
	'Private JM' (potential consumer)	
	16 individuals (11 from NZ; 7 from Australia)	Against

In support of its claims that Impossible products are a pathway to better food systems, Impossible primarily relies on a commissioned life cycle analysis that compares its burger patty to conventionally produced US ground-beef.[42] The analysis indicates that Impossible burgers require significantly less resources and emit far less greenhouse gases.

Submissions in support of approving Impossible products adopted Impossible's narratives to varying degrees. Some proponents emphasised consumer choice and the creation of new markets via biotechnological innovation as economic ends in themselves that approving Impossible products

42. It found that Impossible products use dramatically less land (99 per cent less) and water (79 per cent less) and avoids water pollution (by 79 per cent) and GHGs (60 per cent). Broadly, these findings align with common knowledge about the environmental impacts of producing and processing plants versus meat, with the latter being far less resource-intensive. Sofia Khan et al, 'Comparative Environmental LCA of the Impossible Burger with Conventional Ground Beef Burger' (Final Report, 27 February 2019) <https://assets.ctfassets.net/hhv516v5f7sj/4exF7Ex74UoYku640WSF3t/cc213b148ee80fa2d8062e430012ec56/Impossible_foods_comparative_LCA.pdf>.

would serve.[43] Other submitters emphasised how enabling consumer choice and technoscientific innovation via approval of novel meat analogues would improve health and ecological sustainability. The Australian Food and Grocery Council submitted that approving the application 'will assist consumers to construct healthy diets aligned to the Australia and New Zealand Dietary Guidelines with a meat substitute that potentially has superior attributes'.[44] Meanwhile, the Good Food Institute submitted that products like Impossible's products are 'expected eventually to yield benefits in terms of resource use and greenhouse gas emissions … all while benefiting the food industry and consumers with greater availability and choice'.[45]

The growing body of academic work examining the discourses surrounding the marketing of novel meat analogues to investors and consumers indicates that it is common for proponents to emphasise how a novel process or ingredient offers consumers a uniquely 'meaty' analogue product, and to expand from there out to a claim that consumer making this product choice can transform food systems. Specifically, developers promote novel meat analogues as able to achieve better health outcomes, improve environmental sustainability and reduce food safety risks as compared with intensive animal agriculture.[46] Thus these products are proffered as a solution to the environmental, health and ethical costs of human reliance on intensively produced and consumed animal-derived products.[47]

The positioning of novel meat analogues observed in the literature and evidenced in Impossible marketing and submissions can be read as a form of promissory narrative. Promissory narratives are discursive constructions of future possibilities.[48] These narratives are often studied in social scientific studies of emerging technologies, including now, new meat analogues.[49] These discursive constructions are significant because they influence how technologies develop, such as by inspiring

43. In summarising its support, Woolworths submitted that 'If we limit these innovations, it is the Australian and New Zealand consumer that is disadvantaged': Woolworths, submission to the 1st Call for Submissions ('CFS1') (14 February 2020), 2.
44. Australian Food and Grocery Council, CFS 1 (14 February 2020) 3.
45. Good Food Institute, CFS 1 (14th February 2020) 3.
46. In Australia there are two major empirical studies of promotion and marketing claims: Tasmin Dilworth and Andrew McGregor, 'Moral Steaks? Ethical Discourses of In Vitro Meat in Academia and Australia' (2015) 28(1) *Journal of Agricultural and Environmental Ethics* 85 ('Moral Steaks?'); Jennifer Lacy-Nichols, Gyorgy Scrinis and Rob Moodie, *The Australian Alternative Protein Industry* (Report, Future Food Hallmark Research Initiative, 21 May 2020) <https://research.unimelb.edu.au/__data/assets/word_doc/0039/179877/Report-The-Australian-Alternative-Protein-Industry-Lacy-Nichols.docx>, which examined the promissory narratives deployed by 16 companies. International studies with similar findings include: Alexandra E Sexton, Tara Garnett and Jamie Lorimer, 'Framing the Future of Food: The Contested Promises of Alternative Proteins' (2019) 2(1) *Environment and Planning E: Nature and Space* 47 ('Framing the Future of Food'); Julie Guthman and Charlotte Biltekoff, 'Magical Disruption? Alternative Protein and the Promise of de-Materialization' (2021) 4(4) *Environment and Planning E: Nature and Space* 1583 <http://journals.sagepub.com/doi/full/10.1177/2514848620963125> ('Magical Disruption?').
47. A germinal report on the issues with intensive meat production and consumption is Henning Steinfeld et al, *Livestock's Long Shadow: Environmental Issues and Options* (The Livestock, Environment and Development (LEAD) Initiative, Food and Agriculture Organization, 2006) <ftp://ftp.fao.org/docrep/fao/010/a0701e/a0701e00.pdf>; see also, Joyce D'Silva and John Webster, *The Meat Crisis: Developing More Sustainable and Ethical Production and Consumption* (Routledge, 2017) ('*The Meat Crisis*'). Note though that the issues with intensive meat production and consumption are contested, Ulrika Olausson, '"Stop Blaming the Cows!": How Livestock Production Is Legitimized in Everyday Discourse on Facebook' (2018) 12(1) *Environmental Communication* 28 ('"Stop Blaming the Cows!"').
48. See, eg, Mads Borup et al, 'The Sociology of Expectations in Science and Technology' (2006) 18(3–4) *Technology Analysis & Strategic Management* 285.
49. Neil Stephens and Martin Ruivenkamp, 'Promise and Ontological Ambiguity in the In Vitro Meat Imagescape: From Laboratory Myotubes to the Cultured Burger' (2016) 25(3) *Science as Culture* 327; Robert Magneson Chiles, 'If They Come, We Will Build It: In Vitro Meat and the Discursive Struggle over Future Agrofood Expectations' (2013) 30(4) *Agriculture and Human Values* 511 ('If They Come, We Will Build It').

investment and shaping consumer responses.[50] They can also influence what stakeholders, including regulators, understand the problems (such as climate change or food security) that a new technology is supposed to solve and the range of potential regulatory responses to a new technology.[51]

The promissory narratives accompanying and bolstering novel meat analogues have gained traction against the backdrop of certain policy and public discourses in relation to animal production and consumption. There has been an increase in the gathering and disseminating of evidence about the high rate of animal meat consumption in some high-income countries (eg the US and Australia) and on developing projections about the rapidly increasing meat consumption in some middle-income countries.[52] A related trend is an increased focus on the problems with an over-consumption of animal products on a population level, which centre on human health, resource intensiveness and pollution including contributions to greenhouse gas emissions.[53] The increasingly prevalent discourses regarding the problems with over-consumption of animals has led to increasing interest in novel meat analogues. These concerns overlap to some degree with public and activist discourses that identify ethical concerns with the way intensive food production uses animals.[54] Submitters to FSANZ's pre-market approval process emphasised the health and sustainability argument for meat analogues. There were however no submissions from animal advocacy groups and ethical concerns about the use of animals in food production went largely unmentioned.[55] This absence is especially notable as concerns

50. See, eg, Neil Pollock and Robin Williams, 'The Business of Expectations: How Promissory Organizations Shape Technology and Innovation' (2010) 40(4) *Social Studies of Science* 525 ('The Business of Expectations').
51. See, eg, Sheila Jasanoff and Sang-Hyun Kim, 'Sociotechnical Imaginaries and National Energy Policies' (2013) 22(2) *Science as Culture* 189; Anthony M Levenda et al, 'Regional Sociotechnical Imaginaries and the Governance of Energy Innovations' (2019) 109 *Futures* 181; Kornelia Konrad and Carla Alvial Palavicino, 'Evolving Patterns of Governance of, and by, Expectations: The Graphene Hype Wave' in Diana Bowman, Elen Stokes and Arie Rip (eds), *Embedding New Technologies into Society: A Regulatory, Ethical and Societal Perspective* (Taylor & Francis, 1st ed, 2017) 187 <https://www.taylorfrancis.com/chapters/evolving-patterns-governance-expectations-graphenehype-wave-kornelia-konrad-carla-alvial-palavicino/e/10.1201/9781315379593-9>.
52. Food and Agriculture Organization, *World Agriculture Towards 2030/2050: Prospects for Food, Nutrition, Agriculture and Major Commodity Groups* (Interim Report, Food and Agriculture Organization of the United Nations, June 2006) 45 <http://www.fao.org/fileadmin/user_upload/esag/docs/Interim_report_AT2050web.pdf>.
53. International Agency for Research on Cancer, *Red Meat and Processed Meat* (World Health Organisation, 2018) vol 14 <https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Red-Meat-And-Processed-Meat-2018>; EAT-Lancet Commission, *Food in The Anthropocene: The EAT-Lancet Commission on Healthy Diets* (The Lancet, 2019) <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31788-4/fulltext>.
54. D'Silva and Webster (n 47); Richard Twine, 'Revealing the "Animal-Industrial Complex": A Concept & Method for Critical Animal Studies?' (2012) 10(1) *Journal for Critical Animal Studies* 12 ('Revealing the "Animal-Industrial Complex"').
55. Nevertheless, see the Grey Power Combined NZ, submission to CFS1 (11 February 2020) 1 quoted below at footnote 90, stating that the submitters prefer vegetarian food because of the way animals are treated in intensive agriculture. By contrast in the US, both ecological sustainability and the ethics of using animal ethics for food have been central to policy debates and legal contestation. See, eg, USDA Food Safety and Inspection Service, *USDA and FDA Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry | Food Safety and Inspection Service* (online), 23 October 2018 <http://www.fsis.usda.gov/news-events/events-meetings/usda-and-fda-joint-public-meeting-use-cell-culture-technology-develop>, which contains the transcripts from the public hearing attended by various interest groups including animal activists who were in support of cell-based animal material as a solution to intensive animal agriculture.

over animal interests are a key reason for consumers to purchase novel meat analogues[56] and the 'animal-free' nature of such products are emphasised in the marketing of, and related public discourses around, novel meat analogues. It is also increasingly the subject of literature on novel meat analogues.[57] The expectation that novel meat analogues represented, at least to some extent, a future option for consumers to replace meat in their diet was seen by some submitters as a reason for FSANZ to approve Impossible products and ensure Australia and New Zealand were not 'left behind' in the development and expansion of a new food category. FSANZ reasoned that: 'Permitting the use of soy leghemoglobin as proposed would promote a competitive food industry, as fast developing new technologies in the production of alternative protein sources take off around the world'.[58]

C *Critiques Contesting Approval of Impossible Products*

Public health advocates, proponents of alternative, including agro-ecological, food systems and the meat industry have all contested the promissory narratives accompanying novel meat analogues in broader public discourse,[59] and in submissions to the Impossible application process. The following sub-sections identify the four main critiques of novel meat analogues raised in submissions — namely, their safety (II.C.(1)), healthfulness (II.C.(2)), identity (II.C.(3)), and other ethical and justice implications (II.C.(4)). We show how each of these reflect concerns about novel meat analogues in broader scholarship and public discourse.

56. Isaac Cheah et al, 'Drivers and Barriers toward Reducing Meat Consumption' (2020) 149 *Appetite* 104636; Christopher Bryant and Julie Barnett, 'Consumer Acceptance of Cultured Meat: A Systematic Review' (2018) 143 *Meat Science* 8 ('Consumer Acceptance of Cultured Meat'). Lacy-Nichols, Scrinis and Moodie (n 46) 6–7 found that, of the 16 novel meat analogue companies examined, 10 made reference to the ethical attributes of the product using terms such as 'animal free'.
57. Josh Milburn, 'Chewing Over In Vitro Meat: Animal Ethics, Cannibalism and Social Progress' (2016) 22(3) *Res Publica* 249 ('Chewing Over In Vitro Meat'); Lisa M Keefe, '#FakeMeat: How Big a Deal Will Animal Meat Analogs Ultimately Be?' (2018) 8(3) *Animal Frontiers* 30 ('#FakeMeat'); Marina Sucha Heidemann et al, 'Uncoupling Meat From Animal Slaughter and Its Impacts on Human-Animal Relationships' (2020) 11 *Frontiers in Psychology* 1824.
58. FSANZ, 'Approval Report — Application A1186: Soy Leghemoglobin in Meat Analogue Products' (n 5) 43.
59. A number of empirical studies of the contestation of analogues have been published recently and are forthcoming: see Sexton, Garnett and Lorimer (n 46) 60–1; Tai (n 15); Lacy-Nichols, Scrinis and Moodie (n 46); Jareb A Gleckel and Sherry F Colb, 'The Meaning of Meat' (2020) 26(1) *Animal Law* 75; Annika Lonkila and Minna Kaljonen, 'Promises of Meat and Milk Alternatives: An Integrative Literature Review on Emergent Research Themes' (2021) 38 *Agriculture and Human Values* 625 ('Promises of Meat and Milk Alternatives').

1 Safety of GM. The first critique of new meat analogues commonly raised by submitters was that Impossible products, as is common in novel meat analogues, carry safety risks associated with genetic modification ('GM'). Concern with the safety of GM foods and distrust of scientific studies purporting to demonstrate their safety has characterized debates over food law and regulation in Australia and around the world for several decades now.[60] Twenty-four of the sixty submissions expressed opposition to GM food, including almost all of the submissions by private individuals, many of whom submitted based on a template created by NZ anti-GM group, 'GE Free NZ' (see Table 1 and accompanying text). Various community and environmental groups and groups concerned with promoting organic food and farming were also all against GM foods (see Table 1). These submitters expressed concerns about (a) the lack of long-term data underlying safety assessments and (b) the lack of independent evidence of safety.[61] Their concerns with the safety testing of Impossible's novel protein is a risk that the Australian pre-market approval process does consider but in a way that is too narrow to adequately address concerns, as we show below in Part III.B.

2 Healthiness of ultra-processed analogue products. A second critique reflected in both public discourse concerning novel meat analogues and submissions to FSANZ is that the combination of advanced processing techniques with the addition of other ingredients, make the whole meat analogue product unhealthy.[62] This reflects a more general public health concern with the increasing preponderance of 'ultra-processed foods' in people's diets.[63] Over the last decade, public health

60. Note that safety is not the only long-standing concern about GM varieties and technologies, but it was a main concern in the submissions. Other concerns with GM relate to corporate consolidation, the accuracy of its environmental claims, and the access to, and usefulness of, GM varieties for lower-income farming communities. For a summary of the issues raised in Australia about the safety of GM, see Rosemary Polya, *Genetically Modified Governance Issues* (Research Paper No 17 2000–01, Australian Parliament, Science, Technology, Environment and Resources Group, 6 February 2001) prt 6 <https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/pubs/rp/rp0001/01RP17>; these issues are still part of the mainstream discourse about GM in Australia. See, eg, Rachel Clemons and Alison Porter, 'Are You Eating Genetically Modified Food?' *CHOICE* (online), 9 June 2017 <https://www.choice.com.au/food-and-drink/food-warnings-and-safety/food-safety/articles/are-you-eating-gm-food>; for analysis of the broader, global contestation regarding GM, see Mathew D Marques, Christine R Critchley and Jarrod Walshe, 'Attitudes to Genetically Modified Food over Time: How Trust in Organizations and the Media Cycle Predict Support' (2015) 24(5) *Public Understanding of Science* 601 ('Attitudes to Genetically Modified Food over Time'); Andy Stirling and Sue Mayer, 'Precautionary Approaches to the Appraisal of Risk: A Case Study of a Genetically Modified Crop' (2000) 6(4) *International Journal of Occupational and Environmental Health* 296 ('Precautionary Approaches to the Appraisal of Risk'); Marion Nestle, *Safe Food: The Politics of Food Safety* (University of California Press, 2010) ch 8 ('*Safe Food*').
61. See, eg, Friends of the Earth (FOE) Australia, CFS1, 2; FOE NZ CFS1 (11 February 2020) 2; GE Free NZ CFS1 (11 February 2020) 2; Grey Power, CFS1 (11 February 2020) 2; KerriKerri Organics, CFS1 (11 February 2020) 2; Oraora Retreat, CFS1 (10 February 2020) 2; Soil and Health Association NZ, CFS1 (13 February 2020) 1; FOE Australia and Gene Ethics, submission to the 2nd Call for Submissions ('CFS2') (17 September 2020) 3; GE Free NZ, CFS2 (17 September 2020) 3.
62. Nicole E Negowetti, 'A Planetary Health Approach to the Labelling of Plant-Based Meat' (2020) 75 *Food and Drug Law Journal* 142. See also, William Park, 'Why Vegan Junk Food May Be Even Worse for Your Health', *BBC Future* (online), 30 January 2020 <https://www.bbc.com/future/article/20200129-why-vegan-junk-food-may-be-even-worse-for-your-health>; Emalie Rosewarne and Clare Farrand, *Salt Levels in Meat Alternatives in Australia (2010-2019)* (Report, VicHealth Salt Partnership; The George Institute for Global Health; WHO Collaborating Centre on Population Salt Reduction, September 2019) <https://www.georgeinstitute.org/sites/default/files/meat_alternatives_key_findings_report.pdf>.
63. The problems with high ultra-processed food consumption are well-explored in public health literature. See, eg, Phillip Baker and Sharon Friel, 'Food Systems Transformations, Ultra-Processed Food Markets and the Nutrition Transition in Asia' (2016) 12(1) *Globalization and Health* 80; Carlos A Monteiro et al, 'Ultra-Processed Products Are Becoming Dominant in the Global Food System' (2013) 14(S2) *Obesity Reviews* 21.

nutritionists,[64] and broader food policy scholarship and discourse, have identified issues with the emphasis in nutritional advice, policies and studies, as well as food marketing, on the nutrient content of foods alone.[65] These critiques centre on how an over-emphasis on individual nutrients, an ideology described as 'nutritionism',[66] overlooks complexities in food, human bodies, as well as context and culture.[67] In particular, scholars have increasingly examined the complex links between the degree of food processing and the overall healthfulness of food with a focus on the composition of foods and the ways in which various components within food interact (ie the whole food matrix).

Public health nutritionists use the term 'ultra-processed' foods to categorise foods that consist of a combination of substances exacted from whole foods. These substances are then subjected to further industrial processes (eg high temperatures and moulding), and then mixed with additives (eg colours and flavours).[68] Ultra-processed foods also contain sugars, oils and fats and salts that home or restaurant kitchens do not often use, such as high-fructose corn syrup or hydrogenated oils.[69] A significant body of research has found relationships between the over-consumption of ultra-processed foods with increased risk of non-communicable diseases and other adverse health outcomes.[70] Australian diets and food environments have been shown to be high in the consumption of ultra-processed foods,[71] with an estimated 79.5 per cent of Australians over-consuming 'discretionary' foods and beverages, which include ultra-processed foods.[72]

Thirteen submissions specifically used the term 'ultra-processed' as a criticism of Impossible products. It was a particularly common critique among those who also expressed opposition to GM. This dynamic

64. Gyorgy Scrinis, 'On the Ideology of Nutritionism' (2008) 8(1) *Gastronomica* 39.
65. Michael Pollan, *In Defence of Food: The Myth of Nutrition and the Pleasures of Eating* (Penguin, 2008) ('*In Defence of Food*').
66. Gyorgy Scrinis, *Nutritionism: The Science and Politics of Dietary Advice* (Columbia University Press, 2013) ('*Nutritionism*').
67. See, eg, Amy McLennan, 'The Rise of Nutritionism and Decline of Nutritional Health in Nauru' (2020) 23(2) *Food, Culture & Society* 249.
68. Carlos Monteiro et al, *Ultra-Processed Foods, Diet Quality and Health-Using the NOVA-Classification System* (Report, Food and Agriculture Organization of the United Nations, 2019) <https://www.researchgate.net/profile/Geoffrey_Cannon/publication/334945695_FAO_Ultra-processed_foods_diet_quality_and_health_using_the_NOVA_classification_system/links/5d45a462a6fdcc370a79b7aa/FAO-Ultra-processed-foods-diet-quality-and-health-using-the-NOVA-classification-system.pdf>.
69. Carlos A Monteiro et al, 'Ultra-Processed Foods: What They Are and How to Identify Them' (2019) 22(5) *Public Health Nutrition* 936, 937–8 ('Ultra-Processed Foods').
70. See, eg, Bernard Srour et al, 'Ultra-Processed Food Intake and Risk of Cardiovascular Disease: Prospective Cohort Study (NutriNet-Santé)' (2019) 365 *British Medical Journal* l1451 ('Ultra-Processed Food Intake and Risk of Cardiovascular Disease'); Leonie Elizabeth et al, 'Ultra-Processed Foods and Health Outcomes: A Narrative Review' (2020) 12(7) *Nutrients* 1955 ('Ultra-Processed Foods and Health Outcomes'), which reviewed 47 studies on the association between UPF and health outcomes. Of these, 37 studies found at least one adverse health outcome associated with UPF consumption and no studies identified positive health outcomes.
71. Priscila P Machado et al, 'Ultra-Processed Foods and Recommended Intake Levels of Nutrients Linked to Non-Communicable Diseases in Australia: Evidence from a Nationally Representative Cross-Sectional Study' (2019) 9(8) *British Medical Journal Open* 029544 ('Ultra-Processed Foods and Recommended Intake Levels of Nutrients Linked to Non-Communicable Diseases in Australia'); Stephanie R Partridge et al, 'Junk Food on Demand: A Cross-Sectional Analysis of the Nutritional Quality of Popular Online Food Delivery Outlets in Australia and New Zealand' (2020) 12(10) *Nutrients* 3107 ('Junk Food on Demand'); Sheree A Spiteri, Dana Lee Olstad and Julie L Woods, 'Nutritional Quality of New Food Products Released into the Australian Retail Food Market in 2015 — Is the Food Industry Part of the Solution?' (2018) 18(1) *BMC Public Health* 222.
72. Gilly A Hendrie et al, 'Understanding the Variation within a Dietary Guideline Index Score to Identify the Priority Food Group Targets for Improving Diet Quality across Population Subgroups' (2021) 18(2) *International Journal of Environmental Research and Public Health* 378.

aligns with empirical studies on political and regulatory debates about GM, which show that such debates are not merely about the safety of an individual GM ingredient, but also represent conflicting ideas about the healthfulness of the types of food that contain GM ingredients,[73] and about how the food system as a whole should develop.[74] As one private individual wrote in their submission:

> I am not a scientist, however I am … an aware member of the public who is watching our population become fatter and less healthy as the consumption of processed foods and food additives increases. We do not need to add to this dilemma by allowing [GM meat analogues]. It does not require a degree to see how damaging it is to our society to be consuming less healthy vegetables and more processed foods. Please take a responsible stand on this issue and save New Zealanders from this misguided degradation of our food.[75]

The appropriateness of categorising the healthfulness of foods based on their processing is debated.[76] There is room for argument about whether novel meat analogues are always 'ultra-processed' and whether it would be useful to use the term in food regulation and policy as a marker of unhealthy products. The substantive point however remains that novel meat analogues are not whole grains, legumes, vegetables or fruits, which are the most highly-recommended foods for dietary and planetary health.[77] The under-consumption of fresh whole foods is a significant dietary problem in Australia,[78] and also New Zealand.[79] The Impossible burger also has significantly more sodium than an unseasoned beef burger or legumes,[80] and has similar saturated fat levels to beef (both of which have far more saturated fat than legumes).[81] Both those advocating a vegetarian diet and those advocating for meat pointed this out. Beef and Lamb NZ submitted that Impossible's products:

> are ultra-processed products and therefore would be considered by Ministry of Health eating and activity guidelines as a food to limit. As an example, its burger patty has a long ingredient list with a high level of

73. See, eg, Deborah A Lupton, 'Lay Discourses and Beliefs Related to Food Risks: An Australian Perspective' (2005) 27(4) *Sociology of Health & Illness* 448 ('Lay Discourses and Beliefs Related to Food Risks').
74. See, eg, Guy Cook, *Genetically Modified Language: The Discourse of Arguments for GM Crops and Food* (Routledge, 2004) 7 ('*Genetically Modified Language*').
75. Private VD, Submission to CFS1 (12 February 2020) 1 (errors have been corrected in this quote).
76. See, eg, Michael J Gibney, 'Ultra-Processed Foods: Definitions and Policy Issues' (2019) 3(2) *Current Developments in Nutrition* nzy077 ('Ultra-Processed Foods').
77. Anna Herforth et al, 'A Global Review of Food-Based Dietary Guidelines' (2019) 10(4) *Advances in Nutrition* 590; Parker and Johnson, 'Sustainable Health Food Choices' (n 11); Negowetti (n 62).
78. See, eg, Hendrie et al (n 72).
79. New Zealand Ministry of Health, *Eating and Activity Guidelines for New Zealand Adults* (Report, 2020) 23 <https://www.health.govt.nz/system/files/documents/publications/eating-activity-guidelines-new-zealand-adults-updated-2020-jul21.pdf>.
80. Sue Klapholz, 'Our Commitment to Nutrition and Health: Sodium and the Impossible Burger', *Impossible Foods* (Blog Post, 20 December 2019) <https://impossiblefoods.com/blog/sodium-and-the-impossible-burger>.
81. Emily Gelsomin, 'Impossible and Beyond: How Healthy are These Meatless Burgers?' *Harvard Health Blog* (Blog Post, 15 August 2019) <https://www.health.harvard.edu/blog/impossible-and-beyond-how-healthy-are-these-meatless-burgers-2019081517448> ('*Impossible and Beyond*').

> sodium (approximately 6 times higher than fresh meat), over double the saturated fat of lean red meat, and a health star rating of 1.5 [out of 5]. (reference omitted)[82]

This perspective aligns with public comments made by meat industry groups in Australia.[83]

Citizens who had chosen a vegetarian diet for health and ethical reasons also argued against the introduction of alternative 'proteins' (meaning novel meat analogues) that are GM and ultra-processed:

> Many New Zealanders are endeavouring to have clean foods, rather than chemically damaged foods. For many, animal meat is no longer an option, as many animals no longer even see the sunshine or green grass, and are fed antibiotics to stop disease evidence. Therefore, we strongly urge you keep one protein free from the whims of mad scientists![84]

We argue in Part III.C. below that this critique of the introduction of new processed products and indeed a whole new food category (novel meat analogues) into the diet is not however considered in FSANZ's pre-market approval processes due to the excessively narrow focus of Australian food law and regulation on whether a new nutritive substance in the form of an individual novel ingredient (in this case haem iron from the novel protein, *soy leghemoglobin*) should be allowed.

3 Identity as Meat Replacement. A third critique explicitly questions the narrative that novel analogues can and should replace animal-derived meat. As reflected in the quotation above from Beef and Lamb New Zealand, animal agriculture industry groups have argued that analogues are inferior in nutrition and health to animal-derived meat products. Of the 60 submissions, 17 argued that Impossible products are not nutritionally equivalent to meat but that the representation of the product as a replacement for meat may mislead consumers into believing the product is equivalent (or even superior) to animal-derived meat.[85] One respondent explained 'It is critical that people are not misled to interpret that this soy-based ultra-processed product is equivalent to naturally produced meat protein'.[86]

This reflects the fact that since 2018 some Australian meat industry groups have been campaigning, with the support of the National Party, for new laws to restrict the way analogues can be marketed and described.[87] Similar developments have already occurred overseas. A reported 24 US states have considered or already passed laws to prohibit the use of descriptors like 'burger',

82. Beef and Lamb NZ, submission to CFS1 (14 February 2020) 1.
83. Anna Henderson, 'Food Fight over "traitorous Protein" in Meat Fridge', *ABC News* (online), 22 June 2018 <https://www.abc.net.au/news/2018-06-22/food-fight-over-vegetarian-product-in-meat-fridge/9899404>; Marty McCarthy and Matt Brann, 'Cattle Industry Looks to Defend "meat" Label from Lab-Grown and Plant-Based Products', *ABC Rural* (online), 7 May 2018 <http://www.abc.net.au/news/rural/2018-05-07/australian-cattle-lobby-group-considers-calling-for-meat-change/9728928>; this perspective was also observed in, Lacy-Nichols, Scrinis and Moodie (n 46).
84. Grey Power Combined NZ, submission to CFS1 (11 February 2020) 1.
85. As Lacy-Nichols, Scrinis and Moodie (n 46) point out, however, the lead industry group Meat & Livestock Australia have, at least initially, framed meat analogues as non-threatening because they are largely non-disruptive, inferior and synthetic.
86. KerriKerri Organics, submission to CFS1 (11 February 2020) 2.
87. See, eg, Lucy Barbour, 'Nationals Push for Ban on Plant-Based, Alternative Products Being Called "Milk", "Meat", "Seafood"', *ABC News* (online), 15 September 2019 <https://www.abc.net.au/news/2019-09-15/push-to-ban-milk-meat-seafood-labels-on-plant-based-produce/11513754>; McCarthy and Brann (n 83); 'Marshall's Tough Talk on Food Labelling', *NSW Nationals* (online), 28 October 2019 <https://www.nswnationals.org.au/marshalls-tough-talk-on-food-labelling/>; Shan Goodwin, 'Let's Not Mince Words, It's Everything but Real Beef', *Farm Online* (online), 30 June 2018 <http://www.farmonline.com.au/story/5497586/lets-not-mince-words-its-everything-but-real-beef/>.

'sausage', 'cheese' and 'butter' on non-animal sourced and novel protein products, although some have subsequently been overturned as unconstitutional.[88] The US Congress is also currently considering two similar bills.[89] Across the Atlantic, the European Court of Justice decided in 2017 that novel dairy substitutes cannot use the descriptors 'milk', 'cream', 'butter', 'yoghurt' and 'cheese' unless a non-dairy product is mentioned in the list of exceptions, which products like soy and tofu are not.[90] The EU is currently considering an amendment to the Common Agricultural Policy that would prohibit on non-dairy products any images or words, like 'creamy', that evoke dairy.[91]

These developments reflect the campaigns of meat industry advocates to contest (a) the broader social, environmental and ethical promises of novel meat analogues to positively disrupt the food system[92] and (b) the increasing institutional support for, and mainstream emphasis on, reducing animal consumption in high-income countries in order to enable sustainable diets[93] and address the public health and environmental impacts of intensive animal agriculture.[94] Animal agriculture industries and related scholarship have argued that a combination of better management systems and

88. See, eg, Jonah Engel Bromwich and Sanam Yar, 'The Fake Meat War: What's Milk Now? Vegan Food Companies Are Fed up with an Onslaught of pro-Meat, pro-Dairy Laws', *The New York Times* (online), 25 July 2019 <https://www.nytimes.com/2019/07/25/style/plant-based-meat-law.html>; Negowetti (n 62). The most recent judgment is: *Turtle Island Foods SPC v Michael G Strain in his official capacity as the Commissioner of Agriculture and Forestry* (MD, No. 20-00674-74-BAJ-EWD, 28 March 2022). This case concerned Louisiana's *Truth in Labelling of Food Products Act,* Louisiana Rev. Stat. §§ 3:4741–6. The Court found that the legislation was unconstitutional because it restricted free speech. The law prohibited the use of terms like 'burger' and 'sausage' on meat and dairy analogues whether qualified with terms like 'plant-based' or not. The Court emphasised that the Defendant did not show why less restrictive means would not achieve the same goal of preventing consumer confusion such as a disclaimer eg 'does not contain animal products'.Cell-cultured new meat analogues have been a particular focus following the filing of conflicting petitions with the US Department of Agriculture and the US Food and Drug Administration, which led to public hearings and a joint agreement in 2019 about how federal agencies should co-regulate these meat analogues: United States Department of Agriculture (USDA) and Food and Drug Administration (FDA), *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-Amenable Species* (7 March 2019) <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell>.
89. Dairy Pride Act, S Res 792, 116th Congress (2019); Real Meat Act, HR Res 4881, 116th Congress (2019). These laws are however unlikely to survive constitutional challenges (on the basis of commercial free speech): Eryn Terry, 'The Regulation of Commercial Speech: Can Alternative Meat Companies Have Their Beef and Speak It Too?' (2020) 23(1) *Vanderbilt Journal of Entertainment & Technology Law* 223 ('The Regulation of Commercial Speech').
90. *Verband Sozialer Wettbewerb eV v TofuTown.com Gmbh* (C-422/16) [2017] CJEU 458.
91. European Parliament, *Amendment 171- Proposal for a regulation- article 1 para 1, point 32, Regulation (EU) No. 1308/2013 Annex VII- Part II- Point 19-point C*, Doc No A8-0198/2019. These proposed amendments passed the European Parliament in October 2020, and are now awaiting approval by the EU Council of Ministers.
92. See, eg, Negowetti (n 62).
93. EAT-Lancet Commission (n 53).
94. Katherine Sievert et al, 'Understanding the Political Challenge of Red and Processed Meat Reduction for Healthy and Sustainable Food Systems: A Narrative Review of the Literature' (2020) 10(12) *International Journal of Health Policy and Management* 1 ('Understanding the Political Challenge of Red and Processed Meat Reduction for Healthy and Sustainable Food Systems'); Parke Wilde et al, 'Legal Feasibility of US Government Policies to Reduce Cancer Risk by Reducing Intake of Processed Meat' (2019) 97(2) *The Milbank Quarterly* 420; Frédéric Leroy et al, 'Meat in the Post-Truth Era: Mass Media Discourses on Health and Disease in the Attention Economy' (2018) 125 *Appetite* 345 ('Meat in the Post-Truth Era').

technological advancement will make traditional meat and dairy production safer, healthier, more environmentally sustainable and ethical, and that large-scale dietary transitions away from meat and dairy are therefore unnecessary.[95] They also emphasise the ethical value of continuing production of animal-sourced foods for rural livelihoods, national identity and recognising the value of farmers as stewards of the land.[96]

Submissions against approving Impossible's products however remained focused on distinguishing analogues from meat for consumers, rather than prosecuting the case as to whether meat is in fact superior to analogues. This meant that submissions in support of the environmental benefits of Impossible's novel meat analogues went largely unchallenged in substance.

As we show below in Part III.E., FSANZ did consider labelling issues but concluded that the current law and standards were sufficient. FSANZ carefully avoided questions about what role traditional meat and novel meat analogues should play in diets and the implications for broader food systems issues at the intersection of public health and environmental concerns.

4 Ethics and Justice Concerns. Proponents of alternative, including agro-ecological, food systems and food justice provide extensive critiques of globalised, industrial food systems organized around capitalist principles. These groups therefore criticise the advent of novel meat analogues, and their accompanying promissory narratives, for being a continuation of dominant, market-based food systems with high corporate consolidation. These critiques centre on the argument that food systems organized primarily around corporate capitalism are not well-designed to enable public interests in ecological sustainability, economic equity and ethical relations between eaters, producers and ecologies. Specifically, these critics of novel meat analogues argue that the production and consumption of novel meat analogues will (a) legitimate and enable further corporate consolidation in food systems through high-tech, proprietary technologies[97] and (b) inappropriately reinforce the current ideological emphasis on individual responsibility, market-based change in food systems governance.[98] Novel meat analogues, they argue, are ill-suited to addressing complex social-

95. Dianne Mayberry et al, 'Pathways to Carbon-Neutrality for the Australian Red Meat Sector' (2019) 175 *Agricultural Systems* 13; Tony Weis and Rebecca Ellis, 'Animal Functionality and Interspecies Relations in Regenerative Agriculture: Considering Necessity and the Possibilities of Non-Violence' in Jessica Duncan, Michael Carolan and Johannes S C Wiskerke (eds), *Routledge Handbook of Sustainable and Regenerative Food Systems* (Routledge, 2020) 141, 148, where the authors argue 'The recognition that some animal functions in agriculture might be necessary, or that heritage breeds have a right to existence after long histories of domestication, does not mean that the goal of enhancing animal autonomy and reducing exploitation as far as possible need be abandoned'.
96. Brodie Evans and Hope Johnson, 'Contesting and Reinforcing the future of "meat" through problematization: Analysing the discourses in regulatory debates around animal cell-cultured meat' (2021) 127 *Geoforum* 81, 87.
97. Philip H Howard, David Goodman and Michael K Goodman, *Concentration and Power in the Food System: Who Controls What We Eat?* (Bloomsbury Academic, 2016) ('*Concentration and Power in the Food System*'); Sophia Murphy, 'Globalization and Corporate Concentration in the Food and Agriculture Sector' (2008) 51(4) *Development* 527; Philip McMichael, 'The Land Grab and Corporate Food Regime Restructuring' (2012) 39(3–4) *The Journal of Peasant Studies* 681.
98. Guthman and Biltekoff (n 46); Michael J Mouat and Russell Prince, 'Cultured Meat and Cowless Milk: On Making Markets for Animal-Free Food' (2018) 11(4) *Journal of Cultural Economy* 315 ('Cultured Meat and Cowless Milk'); Chiles (n 49); Nathan Clay et al, 'Palatable Disruption: The Politics of Plant Milk' (2020) 37(4) *Agriculture and Human Values* 945 ('Palatable Disruption'); Joanna Goven and Vincenzo Pavone, 'The Bioeconomy as Political Project: A Polanyian Analysis' (2015) 40(3) *Science, Technology, & Human Values* 302 ('The Bioeconomy as Political Project'); Sophia Murphy, 'Op-Ed: We Don't Need a "Moonshot" for Faux Burgers — We Need To Hold "Big Meat" Accountable', *Civil Eats* (5 May 2021) <https://civileats.com/2021/05/05/opinion-we-dont-need-a-moonshot-for-faux-burgers-we-need-to-hold-big-meat-accountable/>.

ecological issues that are in part caused by capitalist approaches to food systems and which approaches are inherently unable to distribute costs and benefits equally.

This critique of novel meat analogues, while increasingly prevalent in scholarship, was largely lacking from the public submissions about Impossible products. FSANZ's regulatory assessment process positioned innovation (associated with competition) and market-based consumer choice as normatively desirable, and this was not critically questioned.

As we explain further below in Part III.F., FSANZ's pre-market approval process intentionally discourages the raising of broad ethical and justice concerns and privileges economic innovation considerations.

III Novel Meat Analogues in Australia's Food Regulation System

A *Pre-Market Approval Process for New Foods and Ingredients*

In this Part we show that FSANZ's assessment of applications for new foods is largely focused on the direct and immediate toxicity and allergenicity of novel ingredients and heavily weights the goal of enabling markets in agricultural biotechnologies.[99] In the case of Impossible products, only the novel protein in Impossible's meat analogue products was subjected to direct regulatory scrutiny, and not the broader issues raised by meat analogues, and specifically by submitters, identified in Part II. This restricted remit followed from both the categories of food that are subjected to regulatory scrutiny and the kinds of scrutiny prescribed in the regulation. Thus, the approach taken by FSANZ, and supported by the regulatory context, was narrowed in multiple ways: by the focus on specific components in a food, by an emphasis on public health issues of a short-term nature and by assigning special importance to particular benefits. The absence of capacity to engage with the array of issues raised by novel meat analogues reflects a broader institutional and regulatory context for food in Australia,[100] and internationally, that has long emphasised particular biophysical risks, knowledges and priorities over broader public health and social equity considerations.[101]

99. Note that under s 18(2)(c), FSANZ must have regard to the 'desirability of an efficient and internationally competitive food industry'.

100. Alanna Linn, 'Raw Milk Is Always Risky: Stabilising the Danger of Raw Milk in Australian Food Safety Regulation' (2019) 21(5–6) *Health, Risk & Society* 304 ('Raw Milk Is Always Risky'); Kristen Lyons and Naomi Smith, 'Governing with Ignorance: Understanding the Australian Food Regulator's Response to Nano Food' (2018) 12(1) *NanoEthics* 27 ('Governing with Ignorance'); Paula O'Brien, 'The Contest over Valuable Label Real Estate: Public Health Reforms to the Laws on Alcohol Beverage Labelling in Australia' (2014) 37(2) *University of New South Wales Law Journal* 565, 576 ('The Contest over Valuable Label Real Estate').

101. Erik Millstone and Patrick Van Zwanenberg, 'The Evolution of Food Safety Policy-Making Institutions in the UK, EU and Codex Alimentarius' (2002) 36(6) *Social Policy & Administration* 593; Martha McMahon, 'What Food Is to Be Kept Safe and for Whom? Food-Safety Governance in an Unsafe Food System' (2013) 2(4) *Laws* 1 ('What Food Is to Be Kept Safe and for Whom?'); Patrick Baur, Christy Getz and Jennifer Sowerwine, 'Contradictions, Consequences and the Human Toll of Food Safety Culture' (2017) 34(3) *Agriculture and Human Values* 713.

How food is produced and sold throughout Australia is regulated by the bi-national *Australia New Zealand Food Standards Code* (*the Code*), which is implemented by uniform legislation in each Australian state and territory and in New Zealand.[102] Relevant to the Impossible application, *the Code* sets standards as to (1) what foods and food ingredients are allowed to be sold as food (including requiring pre-market approvals for some)[103] and (2) how foods can and should be labelled for sale (ie labelling and information requirements).[104]

FSANZ administers *the Code* in accordance with the *Food Standards Australia New Zealand Act 1991* (Cth) (the *FSANZ Act*). Its role involves assessing standards and recommending new standards or varying existing ones. Therefore, FSANZ assesses and suggests variations to *the Code* to allow a food product that requires pre-market approval.[105] *The Code* prohibits the sale of products that fall into certain categories unless a product in those categories is explicitly permitted via a variation to *the Code*. These categories, discussed further in the following subsections, are: (a) a food that is a 'novel food'; (b) 'a food produced using gene technology'; and (c) food with an ingredient or components that is 'a substance used as a food additive', 'a substance used as a nutritive substance' or 'a substance used as a processing aid'.[106] The Australia and New Zealand Ministerial Forum on Food Regulation ('the Ministerial Forum') sets the overall policy for food regulation, and it makes the final decisions on new standards and variations recommended by FSANZ.[107] Anyone can apply to FSANZ to introduce a new standard or variation,[108] but mostly, only food businesses seeking to use new ingredients, processes or labelling claims otherwise prohibited by *the Code* apply.

102. These food laws follow a uniform model in accordance with an intergovernmental agreement to establish 'substantially equivalent' food laws: *Food Regulation Agreement*, signed November 2000, amended 6th December 2002, 3rd July 2008 (amendments entered into force 6 July 2010) Appendix A and B 'Model Food Provisions'. See *Food Act 2001* (ACT); *Food Regulations 2002* (ACT); *Food Act 2003* (NSW); *Food Regulation 2015* (NSW); *Food Act* (NT); *Food Act 2006* (Qld); *Food Production (Safety) Act 2000* (Qld); *Food Production (Safety) Regulation 2014* (Qld); *Food Act 2001* (Sa); *Food Regulations 2002* (SA); *Food Act 2003* (Tas); *Food Regulations 2012* (Tas); *Food Act 1984* (Vic); *Food Act 2008* (WA); *Food Regulations 2009* (WA). The legislation in each jurisdiction sets out various offences and confers powers on state and territory authorities to monitor compliance and take enforcement action. While state regulators could enforce these laws, local governments customarily have the primary responsibility for enforcement and compliance. These various authorities receive complaints from individuals, carry out inspections of foods or food-related facilities, grant food business licenses to operate, and take enforcement action for violations of the code.
103. *The Australia New Zealand Food Standards Code ('The Code')* 1.1.1–10(2)–(7).
104. *The Code* 1.1.1–10(8),(9), 1.1.1–13. See also *Food Standards Australia New Zealand Act 1991* s 16(1) (*'FSANZ Act'*), which also includes various other permitted functions for the Code. Importantly the Code also sets standards as to the conditions in which food must be produced and sold to ensure food safety (good primary production and manufacturing process requirements), which we do not consider in this paper.
105. *FSANZ Act* ss 55, 113. The process is set out in *FSANZ Act* ss 54–79.
106. *The Code* 1.1.1–10(5) and (6). Other categories that are prohibited unless specifically named in the Code include a prohibited plant or fungus; food that has been irradiated, kava or substances derived from kava; raw apricot kernels; substances with detectable amounts of an agvet chemical or a metabolite or degradation product of an agvet chemical (note that certain maximum residual limits are prescribed by *the Code*); food containing above certain concentrations of caffeine.
107. *FSANZ Act* ss 84–94. The Forum is comprised of ten Ministers from relevant portfolios, including health and agriculture and it makes decisions by consensus or, failing that, by a majority vote. Provided the Ministerial Forum accepts (or does not seek further review of) the proposed change, FSANZ gazettes the new or amended standard as a legislative instrument. FSANZ can also initiate reviews or can be requested to do so by the Forum.
108. *FSANZ Act* s 22. Civil society organisation have, however, criticised FSANZ for making it more difficult for them to apply for the development or variation of food standards than for businesses because businesses can pay to have reviews expedited (which would generally be a tax deductible business expense). Civil society groups however lack the resources to do so.

There is no general pre-market approval process for the entry of new food products, and therefore meat analogues, into the marketplace. New products and their marketing claims are not necessarily proactively scrutinised or vetted by any regulatory authority. Rather, the pre-market approval process is brought about by, and focused on, applications by businesses. As we will show, the categories of ingredients that require pre-market approval have been narrowly interpreted and many novel meat analogues will not be captured by them. Even where novel meat analogues do fall into one of these categories, the assessment has a remit that is too limited to provide the kind of regulatory oversight stakeholders seek. No other regulatory avenues exist for pro-active assessment of new products (including those produced using new food technologies) or food trends.

Impossible asked for variations to *the Code* to allow it to sell its novel meat analogue products in Australia and New Zealand, due to its products containing an ingredient (LegH prep) that in turn contains a novel protein, *soy leghemoglobin*.[109] FSANZ officially accepted Impossible's application on two grounds:[110] Firstly, the mixture (ie LegH Prep) required pre-assessment as a food produced using gene technology. Secondly, due to its nutritional function, *soy leghemoglobin* itself required assessment as a nutritive substance, that is, whether the protein would fortify the Impossible burger and other products with haem iron and could be labelled as such.[111] FSANZ declined to assess the product as a 'novel food', which some submissions directly criticized (discussed in Part II.E. below).[112]

FSANZ's assessment in each case must be guided by its main legislative objectives in section 18(1) of the *FSANZ Act*. These objectives are set in priority order as 'the protection of public health and safety', 'the provision of adequate information relating to food to enable consumers to make informed choice' and 'the prevention of misleading or deceptive conduct'.[113] While these seem broad, in practice, FSANZ interpret these objectives as requiring, firstly, an assessment only of particular risks, mainly acute direct toxicity and allergenicity, and, secondly, a

109. Originally the distinction between LegH Prep and soy leghemoglobin was unclear in FSANZ's assessment, but FSANZ later clarified the distinction FSANZ, 'Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products' (n 5) 38.

110. Under *FSANZ Act* s 21, FSANZ will consider whether to accept or reject the application having regard to whether the application meets the statutory standards, which include requirements such as that the applications be written and contain required information. As indicated, on receiving the application, FSANZ also considers whether the ingredient or food raises an issue that would require a variation of *the Code* ie whether it is something that falls within one of the definitions requiring pre-approval.

111. FSANZ declined to separately assess *soy leghemoglobin* as a flavouring and colouring agent, that is a food additive, since it was already assessing it as a GM food and a nutritive substance. This decision was critiqued by eg SA Health, CFS2, 1. See also, Qld Health, CFS1 (14 February 2020) 2.
It is a decision that also differs from the US Food and Drug Administration's focus on *soy leghemoglobin* preparation as a food additive to 'optimize flavour in ground beef analogue products': Food and Drug Administration (FDA), *GRAS Notice No. GRN 000737* (23 July 2018) 1 <https://www.fda.gov/media/116243/download>. However, FSANZ justified its decision to not assess *soy leghemoglobin* as a food additive on the basis that it would not alter their assessment, as they would not have to consider any additional or different risks: FSANZ, 'Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products' (n 5) 13, 32.

112. SA Health, CFS1 (February 2020) 1; DHHS, CFS1 (14 February 2020) 2.

113. *FSANZ Act* s 18(1). See also, FSANZ's position statement on how it applies s 18 core objectives: FSANZ, *Principles Statement on Public Health and Safety* (2014) <https://www.foodstandards.gov.au/about/Documents/Principlestatementonpublchealthandssafety.pdf>.

cost-benefit analysis[114] that emphasises the value of economic innovation and competitive markets. This approach is supported by further provisions in the *FSANZ Act* that in practice condition and modulate the operation of FSANZ's objectives in developing or varying food standards. These provisions require FSANZ to have regard to: 'the need for standards to be based on risk analysis using the best available scientific evidence', the 'promotion of consistency between domestic and international food standards', 'the desirability of an efficient and internationally competitive food industry', 'the promotion of fair trading in food' and any relevant policy guidelines formulated by the Ministerial Forum.[115] In the sections below, we consider FSANZ's approach in relation to each of the bases on which it was legally empowered to assess the Impossible application — that is, as a food produced using GM (III.B.), a food containing a nutritive substance (III.C.), a novel food (III.D), and by considering the labelling requirements for the new products (III.E.). We argue that this approach is too narrow to engage adequately with the complex issues raised by novel meat analogues discussed in Part II. We finish our analysis by showing how the narrow market-based approach to cost:benefit analysis adopted by FSANZ inflects the process with a bias towards promoting biotechnological innovation and militates against consideration of other social, ecological and economic justice issues (III.F.).

B *Assessment of Novel Meat Analogues Produced Using Gene Technologies*

A food produced using gene technology refers to a food that is 'derived or developed from an organism which has been modified by gene technology'.[116] FSANZ provides a definition of gene technology as 'recombinant DNA techniques',[117] commonly known as GM.[118] Impossible's application fell squarely into this definition. Impossible's primary innovation is the invention of a process to mass produce *soy leghemoglobin* found in the root nodules of soy plants.[119] Impossible's

114. In relation to the cost-benefit analysis, FSANZ must have regard to: (a) 'whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure'; and (b) 'whether other measures would be more cost-effective than a food regulator measure developed or varied as a result of the application': *FSANZ Act* s 29(2).
115. *FSANZ Act* s 18(2).
116. *The Code* 1.5.2–2. Like novel foods, a product is subject to pre-market approval under Standard 1.5.2 if it was produced using gene technologies or if a component of it was produced using such technologies; unless the genetically modified component has already received approval from FSANZ.
117. Ibid.
118. Note that meat analogues created using gene editing such as CRISPR do not satisfy this definition, and this creates further problems for public trust in this area: Karinne Ludlow, 'Regulation of Genome Editing in Plant Biotechnology: Australia' in Hans-Georg Dederer and David Hamburger (eds), *Regulation of Genome Editing in Plant Biotechnology: A Comparative Analysis of Regulatory Frameworks of Selected Countries and the EU* (Springer International Publishing, 2019) 63 <https://doi.org/10.1007/978-3-030-17119-3_3> ('Regulation of Genome Editing in Plant Biotechnology'). We do not further discuss gene editing in this paper as FSANZ have been reviewing this standard and consulting with stakeholders since 2018, and have declared an intention to propose a variation to *the Code* with the aim of better accommodating 'existing and emerging genetic technologies' in a manner that is 'commensurate with the risk they pose': FSANZ, *Final Report: Review of Food Derived Using New Breeding Techniques* (Final report, Food Standards Australia and New Zealand, December 2019) <https://www.foodstandards.gov.au/consumer/gmfood/Documents/NBTFinalreport.pdf>.
119. As mentioned at note 32, without the use of GM technologies, *Impossible* would have to grow or purchase soy (not the bean, the actual root nodules) and harvest and refine the molecules required, which would be neither economically nor practically possible at scale.

process genetically modifies a type of yeast (the *Pichia pastoris* yeast) by inserting DNA from *soy leghemoglobin* into the yeast cells (producing *Pichia pastoris* strains MXY0541 and MXY0291).[120] Impossible then combines the GM yeast and the *soy leghemoglobin* it produces into a mixture, which it calls 'LegH Prep'.

FSANZ assessed whether LegH prep might cause a direct, acute biophysical reaction if consumed.[121] The assessment drew predominantly on Impossible's data and research and on FSANZ's own desktop review, which is typical for such assessments.[122] FSANZ's finding that the *soy leghemoglobin* mixture raised 'no public health and safety concerns' was based on two main pillars.[123] Firstly, FSANZ placed significant weight on the fact that both haem iron (consumed in animal flesh) and soybeans have long been safely consumed without causing toxic or allergic effects (albeit, *soy leghemoglobin* is not naturally occurring in soybeans but the roots of soy plants). FSANZ therefore determined that it was likely that the protein also does not pose a risk. Secondly, FSANZ and Impossible relied on a toxicological study that involved 28-days of feeding LegH Prep to rats.[124] The study involved testing four different concentrations of LegH Prep (low to high) with each dose level being tested on 20 rats (10 from each sex and 80 rats total). The highest dose administered was 100 times more than the estimated daily intake of Impossible ground mince products. Ultimately, the study found no safety concerns including no genotoxicity concerns, that is, risk of the food causing gene mutations that may lead to cancer.[125]

Many submitters, including a handful of state-level government departments, contested FSANZ's scientific assessment of the safety of the GM ingredient due to what they saw as (a) lack of long-term, comprehensive data underlying safety assessments and (b) the lack of independent evidence of safety.

In relation to the former point, submitters focused on the lack of comprehensive and long-term scientific evidence that LegH Prep will neither cause allergic reactions nor undermine long-term dietary health. Some submitters referred generally to the lack of long-term and comprehensive data: 'The lack of long-term dietary studies requires that FSANZ make no approval'.[126] Other submitters raised more specific concerns about the scientific evidence and specifically the key toxicological study. Their concerns included the lack of a safety assessment on the other kinds of proteins that can be produced from the yeast strain,[127] the lack of dietary studies that were longer than 28 days,[128] and

120. The broad process of genetically modifying yeast and then fermenting it to produce a specific molecule is not new in food processing.Genetically modified *pista pichoria* is commonly used to produce proteins for research, the manufacture of pharmaceuticals and the creation of enzymes for industrial brewing and baking.
121. See, eg, FSANZ, *Call for Submissions — Application A1186 - Soy Leghemoglobin in Meat Analogue Products* (First Call for Submissions No 106–19, 20 December 2019) 8–9 where FSANZ details the evidence of safety focuses on potential allergenicity and toxicity of the yeast and of the novel protein. See also, FSANZ, 'Approval Report — Application A1186: Soy Leghemoglobin in Meat Analogue Products' (n 5) 29–30.
122. FSANZ, 'Call for Submissions- Application A1186 — Soy Leghemoglobin in Meat Analogue Products' (n 121) 8–9.
123. Ibid 12.
124. Rachel Z Fraser et al, 'Safety Evaluation of Soy Leghemoglobin Protein Preparation Derived From Pichia Pastoris, Intended for Use as a Flavour Catalyst in Plant-Based Meat' (2018) 37(3) *International Journal of Toxicology* 241.
125. Ibid.
126. See, eg, Private LG, submission to CFS1 (13 February 2020) 2.
127. Private MB, submission to CFSI, 42. Another concern, raised by the Victorian Department of Health and Human Services, the Victorian Department of Jobs, Precincts and Regions, and PrimeSafe (the Victorian meat regulator), submission to CFS2 (17 September 2020) 2, was that the study used by FSANZ for the risk and dietary exposure assessment concerned a different yeast strain to the application.
128. Private PSGR, submission to CFS1 (February 2020) 6.

the fact that the data used for safety assessment seemed to be specifically for *soy leghemoglobin* in ground mince products but did not cover other Impossible products, eg, sausages.[129]

Since FSANZ received public submissions in 2020, the Center for Food Safety, a civil society group, challenged, via a petition, the release of Impossible into US markets on the grounds that Impossible's toxicological study was too short-term to assess safety and that regulators should extrapolate from the history of safe consumption of soy and haem iron.[130] This petition was dismissed by US judges on the basis that the US regulator had adequately justified why it had relied on Impossible toxicological study.[131]

Evidently, stakeholders in both jurisdictions have differing interpretations of what is acceptable evidence for determining risk than regulators, proponents and developers. The divergent expectations about what risks should be evaluated, the quality of evidence required to perform such an evaluation and the length of time over which it should be assessed illustrates the narrow remit of FSANZ's technical risk-based assessment. The restricted scope, and the conclusions that followed from it, implicitly leaves out risks that are not acute and does not acknowledge or weigh the incompleteness of scientific evidence. Such an approach contrasts with a more precautionary approach to new food technologies whereby a wider range of evidence and values are evaluated.[132]

A number of submitters questioned the reliance by FSANZ on Impossible-funded studies and other data from Impossible to assess safety.[133] In their second submission, for example, the relevant state government agencies from the state of Victoria (VicHealth and PrimeSafe) noted 'a paucity of independent scientific research and a lack of alternative risk assessment reports available on LegH Prep. Almost all the information was generated by the applicant or through the applicant's funded projects and thus it is difficult to access and verify where information is missing'.[134] Reliance on industry-funded studies and related data is the norm in food regulation, since regulators like FSANZ do not have the resources and facilities to conduct relevant tests themselves. The novel ingredients and processes being assessed are also subject to intellectual property rights. Thus, increasing use of privatised food technologies (discussed in Part II.C.(4)) can limit possibilities for more open and independent regulatory analysis.

C Assessment of Novel Meat Analogues Containing Food Additives, Nutritive Substances and Processing Aids

Under *the Code*, specific kinds of substances added to a food will require pre-market approval if *the Code* has not already been varied to permit the substance. These are:

129. NSW Food Authority, submission to CFS1, 4.
130. *Center for Food Safety Combined Reply Brief (Center for Food Safety v United States Food and Drug Administration et al and Impossible Foods Inc)* (On Petition for Review from the United States Environmental Protection Agency No. 20-70747, US Court of Appeals For the Ninth Circuit, 28 January 2021) <https://www.centerforfoodsafety.org/files/2021-01-28–ecf-45-cfs-combined-reply-brief_82674.pdf>.
131. *Center for Food Safety v US Food & Drug Administration* (Unpublished Opinion No. 20-70747, US Court of Appeals for the Ninth Circuit, 3 May 2021).
132. This reflects divisions between approaches to new technologies and the law in a wide range of areas beyond food. See, eg, Andy Stirling and David Gee, 'Science, Precaution, and Practice' (2002) 117(6) *Public Health Reports* 521; Sheila Jasanoff, *Risk Management and Political Culture* (Russell Sage Foundation, 1986).
133. See, eg, PSGR, submission to CFS1 (February 2020) 6; FOE Australia, CFS1, 1; KerriKerri Organics, CFS1 (11 February 2020) 1; AFSA, submission to CFS1 (14 February 2020) 4.
134. Victoria Department of Health and Human Services and Victorian Department of Jobs, Precincts and Regions and PrimeSafe, submission to CFS2 (17 September 2020) 2.

- A substance that is a 'food additive', which is a substance added to foods that is intended to serve a technological purpose like to colour, flavour or add odour to the food;[135] or/and
- A substance that is a nutritive substance, which encompasses a substance, including but not limited to vitamins and minerals, added to food for a nutritional purpose;[136] or/and
- A substance that is a processing aid, which is a substance used 'during the course of processing' that are not intended to form part of the final food product per se.[137]

These categories capture many novel meat analogues since these products are inherently highly processed, and therefore tend to involve ingredients from high-tech processes rather than whole foods. Many processed analogues use combinations of these ingredients to create new products that create an experience like the taste and texture of meat, but FSANZ assesses each substance on a one-by-one basis. It does not consider the overall appropriateness of its place in a product or the way it is used to market the product as a replacement for meat burgers.

In the case of the Impossible application, the new substance that required approval, *soy leghemoglobin*, has a particularly important function in how the products are marketed. In its application, Impossible described *soy leghemoglobin* as an in-put that provides 'the nutrition (ie source of iron), flavour and aroma' of 'traditional animal-derived' meat products.[138] Specifically, according to Impossible, *soy leghemoglobin* replicates the effect of myoglobin in animal-derived meat. Myoglobin is a protein found in animal flesh that stores iron, and according to Impossible has a significant role in providing the complex mix of odours, appearance and flavours that are associated with cooked meat.[139] *Soy leghemoglobin* in the form of LegH prep is a red/brown colour that looks like blood in the burger. Thus, as Impossible describe it in the opening words of their application, it is 'a heme-containing ingredient that will impart meat-like characteristics to meat analogue products'.[140]

The fact that *soy leghemoglobin*, like myoglobin, stores haem iron makes it a particularly useful ingredient for positioning Impossible products as a nutritional, flavour and texture equivalent to meat.[141] As Impossible put it, 'Turns out the key to meat flavour is the same molecule that makes it a great source of iron: heme'.[142] Humans can meet their necessary dietary intake of iron through the consumption of

135. *The Code* 1.1.2–11, 1.3.1–2, sch 14.
136. *The Code* 1.1.2–12, 1.3.2–3.
137. *The Code* 1.1.2–13, 1.3.3–3.
138. Impossible Foods Inc. (n 3) 4.
139. 'Methods and Compositions for Affecting the Flavor and Aroma Profile of Consumables' *United States US9700067B2*, filed on 10 July 2015 (Issued on 11 July 2017) <https://patents.google.com/patent/US9700067B2/en>.
140. Impossible application (n 3) p 4.
141. Amy K Proulx and Manju B Reddy, 'Iron Bioavailability of Hemoglobin from Soy Root Nodules Using a Caco-2 Cell Culture Model' (2006) 54(4) *Journal of Agricultural and Food Chemistry* 1518.
142. Impossible, 'Impossible Foods: Meat made from plants - A better way to make meat- Happy Taste Buds. Happy Planet' (2021) <https://impossiblefoods.com/cn-en> ('*Impossible Foods*'). See also, Impossible Foods Inc, 'Impossible Products: Plant-Based Burger, Pork & Sausage' (2021) <https://impossiblefoods.com/food?__hstc=126476754.29fee331df837435d31360bf45c90c44.1612051200291.1612051200292.1612051200293.1&__hssc=126476754.1.1612051200294&__hsfp=2839138730> where the company explains 'We discovered what makes meat taste like meat. Then we figured out how to make meat from plants. Delicious and better for you and the planet'.

either haem-iron, found in animal (particularly mammalian) muscle and blood,[143] or/and non-haem iron, found in plants. Haem iron, however, is generally more effectively absorbed into the human body.[144]

To approve a nutritive substance, FSANZ assesses the likely bioavailability of the particular nutrient. It then decides whether to list the nutritive substance in Schedule 17 of *the Code*. Schedule 17 prescribes which nutrients in what specific forms may be added to which food products, in what exact quantities and under what conditions.

The Ministerial Forum has also provided a *Policy Guideline for the Fortification of Food with Vitamins and Minerals (2009)* ('*Fortification Policy Guideline*') to guide FSANZ decision making in this area.[145] The Fortification Policy Guideline states that the voluntary addition of vitamins and minerals to food should be permitted only in certain circumstances, including 'to enable the nutritional profile of specific substitute foods [such as meat analogues] to be aligned with the primary food (through nutritional equivalence)'.[146] In line with this policy, Schedule 17 of *the Code* already permits the addition of various forms of non-haem iron to 'meat analogues' so long as the product contains a certain amount of protein.[147]

The *Fortification Policy Guideline* goes on to state that 'Permission to fortify should not promote increased consumption of foods high in salt, sugar or fat, or foods with little or no nutritional value that have no other demonstrated health benefit'.[148] A *Policy Clarification Statement* issued in 2015 restates this limitation more strongly directing that 'FSANZ should use recognised nutrition profiling tools and initiatives that are capable of identifying foods that are high in salt, sugar or fat, or little or no nutritional value, to determine which foods are appropriate for fortification'.[149] In its assessment of the Impossible application, FSANZ's assessment was focused on determining the bioavailability of iron in the individual ingredient, *soy leghemoglobin*, and did not consider this second part of the Forum's

143. While the precise amount of haem-iron in meat is context-dependent, an estimated 72–87 per cent of the iron in mammalian ('red') meat is haem iron, while ('white') meat from birds and fish contain far less haem iron: G Lombardi-Boccia, B Martinez-Dominguez and A Aguzzi, 'Total Heme and Non-Heme Iron in Raw and Cooked Meats' (2002) 67(5) *Journal of Food Science* 1738.
144. Non-haem iron absorbs differently and its absorption is influenced by complex, contextual factors: Leif Hallberg, 'Iron Requirements and Bioavailability of Dietary Iron' in J Mauron (ed), *Nutritional Adequacy, Nutrient Availability and Needs: Nestlé Nutrition Research Symposium, Vevey, September 14–15, 1982* (Birkhäuser, 1983) 223.
145. Australia and New Zealand Ministerial Forum on Food Regulation, *Policy Guideline for the Fortification of Foods with Vitamins and Minerals (Amended 23 October 2009)* (28 May 2004) <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-for-the-Fortification-of-Foods-with-Vitamins-and-Minerals>; Australia and New Zealand Ministerial Forum on Food Regulation, *Policy Clarification Statement to Be Read with the Policy Guideline (Policy Guideline for the Fortification of Food with Vitamins and Minerals)* (20 November 2015) <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-for-the-Fortification-of-Foods-with-Vitamins-and-Minerals>.
146. Australia and New Zealand Ministerial Forum on Food Regulation, 'Policy Guideline for the Fortification of Foods with Vitamins and Minerals (Amended 23 October 2009)' (n 145) 3. Note, this is referring to purely voluntary fortification of products by food producers, and not government-mandated or encouraged fortification.
147. *The Code* Schedule 17–4 states 'no less than 12 per cent of the energy value of the food is derived from protein, and the food contains 5 g protein per serve of the food'. It also sets out a range of other permitted uses of vitamins and minerals to fortify 'Analogues derived from legumes' (covering dairy beverages, meat, yoghurt and dairy desserts, ice cream and cheese), and 'Analogues derived from cereals, nuts, seeds, or a combination of those ingredients'. This is presumably on the theory that meat analogues are primarily used as an alternative source of protein in the diet.
148. Australia and New Zealand Ministerial Forum on Food Regulation, 'Policy Guideline for the Fortification of Foods with Vitamins and Minerals (Amended 23 October 2009)' (n 145) 3.
149. Australia and New Zealand Ministerial Forum on Food Regulation, 'Policy Clarification Statement to Be Read with the Policy Guideline (Policy Guideline for the Fortification of Food with Vitamins and Minerals)' (n 145) 1.

fortification policy.[150] It simply concluded that 'Haem iron from *soy leghemoglobin* is likely to have similar bioavailability to haem iron from mammalian haem proteins (eg myglobin present in muscle) tissue'.[151] Accordingly, FSANZ did not discuss the overall nutritional profile of Impossible products, nor the healthfulness of including these products in the diets. Yet, the marketing of Impossible products concerns the whole product and its role in replacing meat, with statements from the company that it is making 'meat from plants' that are 'delicious and better for you and the planet'.[152] In not considering the overall nutritional profile and claims by Impossible, then, FSANZ is actively disengaged from the product itself and from the *Fortification Policy Guidelines* and its clarification statement.

Nevertheless, the submissions raise concerns with the nutritional claims. As identified in Part II(b) and (c), the issues raised related to whether Impossible products, and novel meat analogues as a whole food category, are healthy and a suitable replacement to meat. Some submitters directly observed the disjuncture between the regulatory focus on *soy leghemoglobin* and stakeholder concerns regarding the whole Impossible product and meat analogues more generally.[153] These critiques included the way that FSANZ's assessment does not consider how the complex mix of nutrients and non-nutrient components interact in a physical and chemical sense.[154]

The effect of FSANZ's approval is that Impossible will be able to market their products as containing haem iron.[155] *The Code* has specific provisions regarding when labels may make such 'nutrient content claims', which track the rules as to when a product may be fortified.[156] Impossible products, for instance, are allowed to claim they are a 'good source of iron' as they contain more iron per serve than the threshold amount set in the rules, and are not food for infants or otherwise a caffeinated, supplementary or sports drink.[157]

150. FSANZ, *Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products* (n 5) 43.
151. Ibid 5. FSANZ went on to state at ibid 43 'The use of a form of iron closer to that found in the traditional counterpart food more closely upholds the principle of nutritional equivalence'.
152. Impossible Foods Inc (n 142).
153. For instance, Beef & Lamb NZ, submission to CFS1 (14 February 2020) 1–2 stated that 'The FSANZ assessment has looked at dietary iron in isolation of the product, which means it overlooks the value of the entire food matrix, and what else the applicant's products contribute to the food supply and diets of New Zealanders … If FSANZ is to consider the impact of overall nutritional status of New Zealanders from imported foods to New Zealand, it needs to look at the entire food matrices of foods'. While the Soil and Health Association New Zealand, CFS1 (13 February 2020) 3 submitted 'Soil and Health consider this current application does not adequately reflect the obligations in law of the FSANZ to protect health. It is apparent that the scope of consideration is overly narrow and as a result cannot protect public health as consumers will be exposed to a fully formulated product'.
154. US Department of Agriculture, 'Food Matrix', *NAL Agricultural Thesaurus and Glossary* <https://agclass.nal.usda.gov/mtwdk.exe?k=glossary&l=60&w=6491&s=5&t=2>.
155. FSANZ, *Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products* (n 5) 20, 36.
156. *The Code* Standard 1.2.7, schs 4, 17. There is no nutrient profile score requirement in contrast with health claims discussed immediately below.
157. *The Code* sch 4.

The regulatory process permits, therefore, food marketing to draw consumer attention to one individual ingredient and its healthfulness, rather than enabling a consideration of the whole product. This emphasis in food marketing on individual nutrients tends to make consumers think that a product is generally healthy regardless of the characteristics of the total product.[158] This is referred to as the 'health halo effect'.[159] In the case of Impossible products, claims that its products are high in iron or protein do not, for instance, prompt consumers to consider the sodium content of the products or the ways in which it is less nutritious overall than, for instance, legumes.[160]

In contrast to 'nutrient content claims', *the Code's* approach to 'health claims', that is claims that a particular food would have a particular health effect, is fairly restrictive.[161] Products must have a certain nutritional profile before any health claim can be made,[162] and the nature of the claims that can be made are specified in *the Code*, together with certain conditions for making the claims.[163] As processed foods high in fat, salt and sometimes sugar, and low in unprocessed vegetable and fruit content, novel meat analogues may not meet the conditions in which health claims can be made. However, since the requirements are based on numeric calculations about the amount of certain nutrients in the product, food manufacturers are able to game the conditions. For example, they may be able to add more of a certain nutrient (eg fibre), in order to manipulate the score to be legally allowed to make health claims about the specific nutrients despite the less desirable attributes of the product. The regulation of these claims also ignore the ways in which it was intended to be eaten (eg in a fast-food burger with chips).[164]

158. This phenomenon has been observed and reported on by a large body of empirical work for decades. See, eg, J Craig Andrews, Richard G Netemeyer and Scot Burton, 'Consumer Generalization of Nutrient Content Claims in Advertising' (1998) 62(4) *Journal of Marketing* 62; Marcia Centurión, Leandro Machín and Gastón Ares, 'Relative Impact of Nutritional Warnings and Other Label Features on Cereal Bar Healthfulness Evaluations' (2019) 51(7) *Journal of Nutrition Education and Behavior* 850. As part of broader critiques of the 'nutritionism' ideology and its impacts on food law and policy discussed in Part IIC(b), food policy scholarship has critiqued the ways in which nutritionism and food law allows food companies to emphasis the inclusion of particular nutrients and their potential health benefits on the label of ultra-processed and processed foods, while other features of the product (salt, fats, sugars) are not visible nor is information about how such products compares to whole foods. Most notably, Marion Nestle, *Food Politics: How the Food Industry Influences Nutrition and Health* (University of California Press, 1st ed, 2013); Scrinis (n 66).
159. This bias is so strong that even in jurisdictions where warning labels (such as stop signs) are placed on particular foods by regulators, preliminary evidence suggests it does not reverse 'the health halo effect' of nutrient content claims: Fernanda Mediano Stoltze et al, 'Impact of Warning Labels on Reducing Health Halo Effects of Nutrient Content Claims on Breakfast Cereal Packages: A Mixed-Measures Experiment' (2021) 163 *Appetite* 105229.
160. See, eg, Catherine Fernan, Jonathon P Schuldt and Jeff Niederdeppe, 'Health Halo Effects from Product Titles and Nutrient Content Claims in the Context of "Protein" Bars' (2018) 33(12) *Health Communication* 1425, which found that nutrient product claims and product titles that inferred high protein influenced the perceived healthfulness of the bar. Even if the bar warned that it was high in sugar, this did not counteract the effect.
161. *The Code* 1.2.7. The Code distinguishes two types of claims, high level health claims (which relate to a serious disease or biomarker of a serious disease, like cancer or heart disease) and general health claims (other claims relating to health effect) with the former more strictly regulated. See also, comments from submissions at note 164.
162. In particular, they must have a certain Nutrient Profile Score Criterion ('NPSC'): *The Code* 1.2.7–18.
163. These are set out in *The Code* sch 4. In accordance with Schedule 4, a food must contain a certain average quantity of a nutrient or other quality (eg vitamins, minerals, fibre etc) or lack a particular nutrient (eg carbohydrates) before it can make particular health claims (eg 'improves lactose digestion'). Only those claims listed in Schedule 4 can be made and certain conditions are set out for when each claim can be made.
164. This has been widely observed in relation to Australia and New Zealand's health-star rating system (based on the same nutrient profile scoring system). See, eg, Mark Lawrence et al, 'The Health Star Rating system — is its reductionist (nutrient) approach a benefit or risk for tackling dietary risk factors?' (2019) 29(1) *Public Health Research and Practice* Article number: e29119061–5.

Some terms and claims are also not health claims as such, but may nonetheless infer healthfulness, and are not captured by *the Code*. For example, certain 'high level' health claims relating to fruit and vegetable content can only be made if the food contains no less than 90 per cent of vegetable by weight.[165] Novel meat analogues commonly do not meet this threshold because they tend to comprise of substances derived from plants rather than the plants themselves. Regardless, terms such as 'plant-based', arguably, infer that the product has a high vegetable content. In addition, marketing claims on a product about how the company is facilitating environmental or social outcomes has also been shown to positively influence perceptions of a products healthfulness.[166] This is especially relevant to novel meat analogues and Impossible products in particular, which claim or infer various environmental and ethical attributes. These types of claims are not directly regulated by *the Code*.

The current approach to regulating health claims does not assist consumers in clarifying to what extent Impossible products, or other novel meat analogues, should form part of their diets. Neither does it help consumers balance concerns about their own health with environmental and ethical concerns about the impact of meat products on animals and the climate.[167] Rather, it allows Impossible, and other novel meat analogue companies, to emphasise specific nutritional benefits in the broader context of uncertainty about the healthfulness of new meat analogues and common dietary advice to reduce meat consumption especially red and processed meat.

Options to address these issues are well-developed in food law and policy scholarship in Australia. There is a body of work that explores how FSANZ, *the Code* and nutritional labelling in particular can be re-designed to improve public health nutrition outcomes to reduce diet-related non-communicable diseases.[168] This area of work has especially focused on ways to make nutrition

165. *The Code* sch 4.

166. John Peloza, Christine Ye and William J Montford, 'When Companies Do Good, Are Their Products Good for You? How Corporate Social Responsibility Creates a Health Halo' (2015) 34(1) *Journal of Public Policy & Marketing* 19; Elizabeth A Minton and T Bettina Cornwell, 'The Cause Cue Effect: Cause-Related Marketing and Consumer Health Perceptions' (2016) 50(2) *Journal of Consumer Affairs* 372.

167. Negowetti (n 62).

168. Alexandra Jones et al, 'Front-of-Pack Nutrition Labelling to Promote Healthier Diets: Current Practice and Opportunities to Strengthen Regulation Worldwide' (2019) 4(6) *BMJ Global Health* e001882; Sarah Dickie, Julie L Woods and Mark Lawrence, 'Analysing the Use of the Australian Health Star Rating System by Level of Food Processing' (2018) 15(1) *International Journal of Behavioral Nutrition and Physical Activity* 128; Belinda Reeve and Lawrence O Gostin, '"Big" Food, Tobacco, and Alcohol: Reducing Industry Influence on Noncommunicable Disease Prevention Laws and Policies' (2019) 8(7) *International Journal of Health Policy and Management* 450; Mark Andrew Lawrence, Christina Mary Pollard and Tarun Stephen Weeramanthri, 'Positioning Food Standards Programmes to Protect Public Health: Current Performance, Future Opportunities and Necessary Reforms' (2019) 22(5) *Public Health Nutrition* 912.

labelling more comprehensive and accurate, mechanisms to improve monitoring and compliance and options to reduce industry influence on standard-setting.

D *Assessment of Novel Meat Analogues as Novel Foods*

'Novel foods' is the most general category of foods that will trigger the pre-market approval process.[169] Food regulators created the concept of 'novel foods' in the 1990s in response to public concerns about the safety of foods derived from high-technologies including irradiation and biotechnologies.[170] Under *the Code*, to be 'novel', a food must meet two criteria:

- Firstly, it must be a 'non-traditional food', which is defined as 'a food that does not have a history of human consumption in Australia or New Zealand', or a substance derived from such a source.[171]
- Secondly, it must require an 'assessment of the public health and safety considerations' having regard to various factors including 'potential for adverse effects in humans', the composition of the food, the process by which it is prepared, and 'patterns and levels of consumption of the food'.[172]

Applicants can apply to the *Advisory Committee on Novel Foods* ('ACNF') of FSANZ to obtain the committee's recommendation regarding whether a proposed food meets the definition of a novel food requiring pre-market approval.[173]

Notionally this category provides the most likely avenue for pro-active regulatory assessment of novel meat analogues. In practice however, FSANZ has interpreted the parameters of this category narrowly. Many of the new meat analogues currently appearing on supermarket shelves and fast-food chains are not captured by one or other of the two limbs of the novel food definition according to the interpretations of the FSANZ ACNF.

169. *The Code* 1.1.1–10 requires that foods for sale be neither a 'novel food' nor contain a substance in the food that is 'novel' unless (a) expressly permitted by FSANZ and (b) compliant with conditions FSANZ imposes on its production or sale.
170. Australia's regulation of novel food dates back to 1996. See FSANZ, 'History of Novel Foods Standard', *Food Standards Australia New Zealand* (Web Page, 2019) <https://www.foodstandards.gov.au/industry/novel/novelhistory/Pages/default.aspx>. How countries that are members of the World Trade Organization assess, and potentially restrict, the sale of novel foods is limited by their trade obligations. Specifically, under the *Marrakesh Agreement establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 493 (entered into force 1 January 1995) annex 1A (*SPS Agreement*) art 2.2, a member state can only restrict the sale of foods to the extent 'necessary to protect human, animal or plant life or health' and provided such restrictions are 'based on scientific principles' and are not 'maintained without sufficient scientific evidence'. Restrictions placed by the EU on the importation of GM were successfully challenged under these provisions on the grounds that the restrictions lacked sufficient scientific evidence, as the restrictions were based on a precautionary approach: WTO Panel in *European Communities- Measures Affecting the Approval and Marketing of Biotech Products,* WTO Doc WT/Ds291/R/Corr.1; WT/DS292/R/Cprr/1' WT/DS293/R/Corr.1 (29 September 2006).
171. *The Code* Standard 1.5.1 categorises novel foods as 'non-traditional' foods, or substances derived from food, and which require a public health and safety assessment. *The Code* 1.1.2–8 defines 'novel food' and 'non-traditional food'.
172. Ibid.
173. For the Terms of Reference see: FSANZ, 'Advisory Committee Novel Foods — Terms of Reference', *Food Standards Australia New Zealand* (2021) <https://www.foodstandards.gov.au/industry/novel/novelcommittee/Pages/default.aspx>; The Committee publishes a record of its opinions at FSANZ, 'Novel Food — Record of Views Formed in Response to Inquiries', *Food Standards Australia New Zealand* (11 March 2021) <https://www.foodstandards.gov.au/industry/novel/novelrecs/Pages/default.aspx>.

Novel meat analogues do not fulfil the first limb when the product's ingredients, and ingredients from such processes, are already consumed albeit in different forms.[174] For example, Impossible's main US competitor, BeyondMeat (maker of the Beyond Burger), was lawfully able to offer its products in Australia without regulatory approval because it used existing processes and ingredients and no GM ingredients. Despite this, and consistent with the discourses regarding novel meat analogue more generally, BeyondMeat position its products as representing 'the future of protein' and the outcome of 'expert innovation'.[175] There is a divergence, therefore, between the messages consumers (and investors) are receiving about the novelty of a particular product, and the regulatory meaning of novelty that triggers additional oversight.

Other novel meat analogues, or their ingredients, in principle meet the first limb of the novel food definition as 'non-traditional' foods, but do not satisfy FSANZ's interpretation of the second limb.[176] This is because public health and safety is interpreted narrowly, as discussed in Parts III.A. and B. above, as relating only to the immediate safety of an individual ingredient in terms of toxicity or allergenicity. In practice, FSANZ will decide that a novel meat analogue raises no public health and safety issues where it has been consumed previously in other jurisdictions.

For example, FSANZ did not categorise 'Quorn' as a novel food on the grounds that it did not raise public health and safety issues. Quorn was an early novel meat analogue that contains a novel protein, mycoprotein from *Fusarium venenatum*. Quorn entered the Australian marketplace in 2010, but had been available in the UK and other European countries since the early 1990s. At the time, the ACNF advised that Quorn was 'non-traditional in Australia and New Zealand', but as it had been 'widely available elsewhere for over 20 years' without raising safety concerns it did not require pre-approval.[177] The ACNF also non-controversially listed tempeh, a fermented soybean product consumed as an alternative to meat for hundreds of years in Indonesia, as a traditional food 'with no safety concerns identified' when it was introduced to Australian supermarket shelves.[178]

The amount of time a novel food has to be consumed in another jurisdiction without raising allergenicity or acute toxicity issues before FSANZ will consider that it does not raise public health

174. He et al (n 19).

175. Beyond Meat, 'Frequently Asked Questions', *Beyond Meat - Go Beyond®* (2020) <https://www.beyondmeat.com/faqs/>.

176. For example, recently, DSM Nutritional Products applied for relevant variations to the Code to permit rapeseed protein isolate that will be used in a variety of ways in different foods to replace animal protein. In its application, DSM identified the resource-intensive nature of animal agriculture and positioned its protein as one of the new 'promising protein sources': DSM Nutritional Products Asia Pacific, *Application to Amend the Australia New Zealand Food Standards Code (the Code) to Permit the Use of Rapeseed Protein Isolate as a Novel Food* (No A1175, FSANZ, 19 February 2019) 7 <https://www.foodstandards.gov.au/code/applications/Documents/A1175Application.pdf>. The application, call for submissions, approval report and associated documents are all available at: FSANZ, 'A1175 — Rapeseed Protein Isolate as a Novel Food', *Food Standards Australia New Zealand* (April 2021) <https://www.foodstandards.gov.au/code/applications/Pages/A1175.aspx>. The application was approved by FSANZ on 1 December 2020 and notified to the Australia and New Zealand Ministerial Forum on Food Regulation on 15 December 2020 (the same day as the Impossible application): FSANZ, *Approval Report- Application A1175: Rapeseed Protein Isolate as a Novel Food* (No [145–20], Food Standards Australia and New Zealand, 15 December 2020) <https://www.foodstandards.gov.au/code/applications/Pages/A1175.aspx>.

177. See FSANZ, *Novel Food - Record of Views Formed in Response to Inquiries* (n 173). Note that page numbers change every time document is updated, and that no date is provided for the Quorn application, but Quorn entered the Australian marketplace around 2010. FSANZ's acquiescence to Quorn without further review was questioned after reports of adverse reactions in 2011: Joe Lederman and Charles Fisher, 'Is FSANZ's Approach to QuornTM (Mycoprotein) Consistent with Previous FSANZ Policy?' *FoodLegal* (Web Page, March 2011) <https://www.foodlegal.com.au/inhouse/document/679>. FSANZ added a statement to its website about the safety of the product: FSANZ, 'Quorn (Mycoprotein)', *Food Standards Australia New Zealand* (Web Page, December 2011) <https://www.foodstandards.gov.au/consumer/generalissues/quorn/Pages/default.aspx>.

178. FSANZ, *Novel Food — Record of Views Formed in Response to Inquiries* (n 173).

issues is uncertain. FSANZ did note that *soy leghemoglobin* has been consumed in the US since 2016 without raising safety concerns, as one aspect of its safety assessment.[179]

At any rate, FSANZ declined to assess the *soy leghemoglobin* mixture as a 'novel food', arguing that it was preferable to focus on assessing it as a GM food and that it was not necessary to assess the product under both categories.[180] The existence of a broader category, ie, 'novel foods' compared to, for example, nutritive substances or food produced using GM technologies, may appear to promise a different and broader assessment process. However, the broader novel foods category provides no additional avenue for a more comprehensive assessment. FSANZ's assessment of novel foods is the same as its assessment of food produced using gene technology, ie a scientific risk assessment focused on acute, biophysical risks relying on industry science and a cost-benefit analysis. The assessment scope, the evidence used, and the outcome would have been the same.

The fact that 'novel foods' as a category for pre-market approval does not entail a differing, more comprehensive assessment than the other categories is particularly relevant to the likely advent of cell-based meat analogues. As FSANZ has already indicated, these products will meet the definition of 'novel' and trigger the existing pre-market approval process.[181] Because cell-based meat analogues are, in a biophysical sense, animal flesh, and the processes used are especially new, these products and the industries creating them would, arguably, be especially worthy of comprehensive assessment. In the US, for example, new regulatory frameworks are being developed to assess and regulate cell-based products.[182] FSANZ, however, have communicated a preference to facilitate a more rapid market entrance for these products noting that other jurisdictions 'appear to be moving quickly to ensure a clear path to market for this method of meat production'.[183] FSANZ appears to be planning to follow the approach of Singapore which channelled cell-based products through existing regulatory approval pathways to provide the first approval of a cell-based product in the world, a chicken nugget-like product.[184]

E *Pre-Market Approval of the Labelling for Novel Meat Analogues*

No regulator in Australia, including FSANZ, pro-actively and pre-emptively approves and monitors food labelling.[185] Enforcing *the Code's* standards around labelling falls to state and territory government departments responsible for food and consumer protection regulators. Such enforcement is not usually pro-active, that is, regulators do not usually actively monitor food labels to identify violations, although they

179. FSANZ, *Approval Report — Application A1186: Soy Leghemoglobin in Meat Analogue Products* (n 5) 6.

180. Ibid 32. In its second call for submissions, FSANZ also stated that it was because it considered it 'more appropriate' to assess LegH Prep in terms of its function as a nutritive substance, than as a novel food and at any rate the process is similar: Food Standards Australia and New Zealand, *2nd Call for Submissions — Application A1186 — Soy Leghemoglobin in Meat Analogue Products* (n 4) 30–1. See also, FSANZ, 'Call for Submissions- Application A1186 - Soy Leghemoglobin in Meat Analogue Products' (n 121) 3. In another case, a US company applied to the advisory committee for a view on whether another novel protein 'pea and rice protein fermented by shiitake mycelia (*Lentinula edodes*)' and trademarked as PureTaste™Protein was within the "novel food" category. Here, the ACNF decided it was not a novel food because it did not raise safety concerns, but they noted that the protein appears to function as a 'processing aid' and so would require approval as a 'processing aid'. An application is yet to be made: FSANZ, *Novel Food - Record of Views Formed in Response to Inquiries* (n 173).

181. FSANZ has indicated that it expects cell-based products will be subject to regulatory scrutiny through the existing pre-market approval processes: FSANZ, 'Cell Based Meat', *Food Standards Australia New Zealand* (Web Page, 2021) <https://www.foodstandards.gov.au/consumer/generalissues/Pages/Cell-based-meat.aspx>.

182. The US will regulate cell-based products via the US Department of Agriculture and the Food and Drug Administration with a focus on food safety assessments, site inspections and labelling requirements. These agencies will collaborate further around approvals: USDA and FDA (n 88).

183. FSANZ, 'Cell Based Meat' (n 181).

184. Singapore Food Agency (n 9).

185. Except that certain 'high level' health claims must be pre-approved by FSANZ under *the Code* 1.2.7.

may choose to do so if concerns are raised about a particular issue. FSANZ can, however, consider labelling when approving a new food or ingredient and make appropriate new labelling and information requirements for the new food.[186] *The Code* does set out broad standards as to how businesses should describe and label food including what names can be used to describe a food (including use of the word 'meat'), nutrient content and health claims (discussed above), and specific advisories (such as GM), warning labels (eg for allergens) or any other specific requirements. *The Code* does not, however, include standards for broader environmental, social and ethical claims. The rationale for this approach is a political preference for industry self-regulation and because misleading or deceptive representations can be the subject of enforcement action by consumer law regulators via consumer complaint mechanisms.[187]

Eight submissions in response to the Impossible application directly challenged the use of terms such as 'meat' on Impossible products. This was on the grounds that consumers would be misled into thinking that the analogue products are the 'real' animal-derived thing (ie that Impossible burgers are beef burgers), or that the use of such terms infers that Impossible products and animal derived meat are interchangeable in diets (ie Impossible burger mince can nutritionally and culturally replace the role of conventional beef mince in diets).[188] As discussed in Part II.C., meat and dairy industry groups in Australia are also directly lobbying politicians and publicly campaigning for restrictions on the use of 'meat' and 'dairy' terms on analogue products similar to those already introduced in US and EU jurisdictions. These groups position the use of terms such as 'burger', 'meat' and 'sausage' on novel meat analogues as a way for companies to unfairly exploit the reputation of, and traditional values associated with, animal agriculture.[189]

FSANZ did not directly address the health and nutrition claims that Impossible may make on its product. As discussed in Part III.C, it did not apply the *Fortification Policy Guideline* and its *Policy Clarification Statement*, which require the regulator to consider and address the 'health halo' effect that nutrient content claims may have on foods.[190]

186. *FSANZ Act* s 16(1)(d).
187. Although stakeholders have argued they should be, regulatory reviews have concluded that they should not: 'Labelling Logic: Review of Food Labelling Law and Policy', *Australia and New Zealand Food Regulation Ministerial Council* (Web Page, 27 January 2011) <http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/48C0548D80E715BCCA257825001E5DC0/$File/LabellingLogic_2011.pdf>, recommendation 2; Australia and New Zealand Food Regulation Ministerial Council, *Response to the Recommendations of Labelling Logic: Review f Food Labelling Law and Policy (2011)* (Report, 9 December 2011) 38, 41 <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/53351997D78AAC31CA258359007E80F5/$File/Forum-Response-to-the-Food-Labelling-Law-and-Policy-Review-9-12-2011.pdf>; Productivity Commission, *Regulation of Australian Agriculture* (Inquiry Report No 79, Australian Government, Productivity Commission, 15 November 2016) 28–30 <https://www.pc.gov.au/inquiries/completed/agriculture/report/agriculture.pdf>. Indeed, misleading claims about origin, manufacturing processes and nutritional representations in food marketing has been described as a priority area for ACCC enforcement action. See Rod Sims, 'ACCC 2020 Compliance and Enforcement Priorities' (Speech, Committee for Economic Development Australia, 25 February 2020) <https://www.accc.gov.au/speech/accc-2020-compliance-and-enforcement-priorities>.
188. Astrid Seehafer and Marvin Bartels, 'Meat 2.0 — The Regulatory Environment of Plant-based and Cultured Meat' (2019) 14(4) *European Food and Feed Law Review* 323; Tai (n 15).
189. Barbour (n 87); Lacy-Nichols, Scrinis and Moodie (n 46).
190. See discussion accompanying notes 171 and 173 above.

Technically, FSANZ did not need to address concerns about meat descriptors. However, the regulator did so anyway.[191] Descriptors formed the focus of its assessment of labelling. FSANZ firstly determined that Impossible's marketing and labels (from the US) are currently consistent with *the Code* on the grounds that the current labelling makes it clear the product is derived from plants, even though they use 'meat' and other such terms. Certain foods, including bread, meat, meat pies, sausages and ice cream, are recognised under *the Code* as 'named foods'.[192] Products labelled with these names must meet the relevant definition under *the Code*. However, this does not apply where the context makes it clear that it was not intended to be sold as that food.[193] Hence, if a non-dairy product has a label that describes the product as 'ice cream' or 'yoghurt' (both named foods) but clearly denotes that it is, for example, soy ice cream or coconut milk yoghurt, then it will not be in breach of *the Code*.[194] Thus, as FSANZ point out, novel meat analogues can use terms like 'meat', 'burger' and 'sausage' provided the packaging and broader marketing context makes it clear that it is 'meatless', 'animal-free' or 'plant-based' and so on.[195]

FSANZ also consulted with the Australian Competition and Consumer Commission ('ACCC') and its New Zealand counterpart about meat analogue labelling.[196] From these discussions, FSANZ found no evidence that consumers were complaining to ACCC or NZCC about being misled by other meat analogue products already on the market, although it noted the ACCC has received complaints from 'companies producing traditional meat products or rival companies'.[197] The way *the Code* operates in relation to named food also aligns with the application of Australian consumer law, where the entire context is taken into account when determining whether conduct, such as a claim on a label, is misleading and deceptive.[198] FSANZ therefore concluded that current law would deal with any potential misleading and deceptive conduct in relation to the naming of meat analogues in labelling and marketing.

FSANZ's conclusions about how the law currently applies to the use of terms such as 'meat' on novel meat analogues is technically correct but it misses the point. The debate over 'meat' descriptors is not a debate about how the law applies. It is a conflict triggered by two opposing business interests seeking to obtain the market advantage of using 'meat' terms. On one side is incumbent agriculture actors that consider continued, if not increasing, meat consumption to be healthy, ethical and ecologically sustainable, albeit that changes might need to be made to production systems (with what

191. FSANZ explained that it had 'gone beyond assessment of *soy leghemoglobin* by considering the applicant's meat analogue products and the potential for Australian and New Zealand consumers to be misled by meat analogue products' in FSANZ, *Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products* (n 5) 44; see also FSANZ, *Consumers and Plant-Based Meat Analogue Products in Australia and New Zealand* (Supporting Document 2 (at Approval), 15 December 2020) 3 <https://www.foodstandards.gov.au/code/applications/Documents/A1186_SD2atApproval.pdf>.
192. *The Code* 1.1.1–13(1), 2.2.1–2.
193. Standard 1.1.1–13(4) states that 'If a food name is used in connection with the sale of a food (for example in the labelling), the sale is taken to be a sale of the food as the named food *unless the context makes it clear that this is not the intention'* (emphasis added). See also *the Code* 1.2.2-2, which provides that the name of a food on a food label and related marketing should be 'sufficient to indicate the true nature of the food' and 'includes any additional words this Code requires to be included in the name of the food'.
194. Note that soy products that resemble dairy products are explicitly used as an example in the official commentary on Standard 1.1.1–13(4), which states 'The context within which foods such as soy milk or soy ice cream are sold is indicated by use of the name soy; indicating that the product is not dairy product to which dairy standard applies'.
195. FSANZ, *Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products* (n 5) 36–7.
196. Ibid 37.
197. Ibid.
198. See ibid where FSANZ explains 'When assessing a complaint, both the ACCC and NZCC state that they consider whether the overall representation of the product is misleading. For example, a product that is clearly and prominently labelled "vegan", "vegetarian" or "meat free" is unlikely to mislead a consumer about whether the product is meat or plant based'.

these changes are being up for further debate).[199] On the other side are food technology companies who position novel meat analogues, and the highly privatized and capital-intensive processes that underpin their production, as being good food with an indispensable role in future food systems.[200]

FSANZ's application of consumer and food law provisions assumes that consumers first choose whether they wish to eat meat-based, vegetarian or flexitarian diets, and then go into the marketplace to find suitable products.[201] It does not address the way that the promissory narratives peddled by novel meat analogues promoters and the opposing discourses created by the meat industry both seek to powerfully shape the behaviour of consumers (and investors and policy-makers and so on). The question of whether novel meat analogues are adequate and necessary replacements for the use of animals as meat is not a claim that can be adequately dealt with by the application of current consumer and food law prohibitions on misleading advertising. Rather, it requires in depth engagement with multiple perspectives on what counts as good food and a good food system.[202] In disengaging from the broader debate, the FSANZ assessment process and the regulatory framework makes the essentially political decision that such debates can be left to the market, to the lobbying of interest groups, and to consumer choice shaped by commercial advertising.

After pressure from industry groups, state and federal agriculture ministers agreed in October 2019 'that further action is needed to ensure consumers are not being misled about plant-based foods that mimic meat and dairy products'.[203] They referred their concerns to the Ministerial Forum (on Food Regulation) and the Legislative and Governance Forum on Consumer Affairs (another federal

199. This perspective was discussed in Part IIC(c).

200. This perspective was discussed in more depth in Part IIB.

201. See FSANZ, *Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products* (n 5) 37; where FSANZ stated 'The evidence suggests that some consumers in Australia and New Zealand are trying to reduce their meat intake by substituting some of the meat products in their diet with meat analogue products. Evidence also suggests that some consumers believe that meat analogue products have inferior taste and texture characteristics compared to traditional meat products. Ingredients or technologies that improve these characteristics in meat analogue products may increase their palatability to consumers'. FSANZ similarly assumed the consumer is acting largely free of marketing influences and related environmental factors when it observed '[i]f the use of this product is permitted as proposed, consumers may benefit from greater choice of foods, particularly greater choice of fortified meat analogue products. The applicant is targeting their products at 'flexitarians', who they claim (on page 62 of the application) are looking for "more ethical and environmentally friendly alternative meat products without compromising on attributes such as the taste and texture"'; ibid 41.

202. This point is supported by various bodies of work, concepts and practices associated with large-scale systems change, for instance, sustainability transitions, participatory deliberative forms of democracy, emerging technologies, and food law and policy scholarship, theories and practices. See, eg, Michael B Wironen, Robert V Bartlett and Jon D Erickson, 'Deliberation and the Promise of a Deeply Democratic Sustainability Transition' (2019) 11(4) *Sustainability* 1023; Andy Stirling, 'Pluralising Progress: From Integrative Transitions to Transformative Diversity' (2011) 1(1) *Environmental Innovation and Societal Transitions* 82; Hayley Stevenson and John S Dryzek, *Democratizing Global Climate Governance* (Cambridge University Press, 2014). For food policy scholarship, see eg, Parker and Johnson, 'From Food Chains to Food Webs: Regulating Capitalist Production and Consumption in the Food System' (n 11). It is also a recommendation consistent with regulatory studies John Braithwaite and Peter Drahos, *Global Business Regulation* (Cambridge University Press, 2000); Christine Parker, *The Open Corporation: Effective Self-Regulation and Democracy* (Cambridge University Press, 2002).

203. The quotation is from the Agriculture Ministers' Forum, *Communiques* (Department of Agriculture, Water and the Environment, 25 October 2019) <https://www.awe.gov.au/news/stay-informed/communiques/ag-ministers-forum-october-2019>. The Agriculture Ministers Forum ('AGMIN') is a regular meeting of all Australian and New Zealand Agriculture Ministers to progress priority issues for the agriculture sector. They referred their concerns to the ministerial forums that oversee both Australian and New Zealand food standards (the Australia and New Zealand Ministerial Forum on Food Regulation), and consumer protection and fair trading laws (the Legislative and Governance Forum on Consumer Affairs).

ministerial forum).[204] Subsequently, in November 2019, the Ministerial Forum on Food Regulation responded by explicitly recognising that 'both' novel and animal proteins 'have a place' in the Australian diet and economy.[205] However they also suggested that analogues represent, potentially, a problem for consumer protection and also for the 'intellectual properties of primary producers'.[206] They thus assigned their sub-committee, the Food Regulation Standing committee,[207] the task of considering 'regulatory and labelling issues relating to [novel proteins], with a view to developing a policy guideline to adequately differentiate 'synthetic' animal products from their natural or conventional equivalents'.[208] This is potentially an opportunity to consider the advantages and disadvantages of an influx of new meat analogues to the marketplace in a broader policy context. No publicly reported action has been taken on this task to date. However, it seems likely that such regulatory debates will be beholden to conflicting concerns from competing market actors with agrarian protectionism on one hand and a market-based approach to food systems change that emphasizes ultra-processed products on the other.

F *Qualitative Cost-Benefit Analysis: An Emphasis on Economic Benefits for a Few*

The sections above have been concerned with FSANZ's scientific risk assessment of the biophysical properties of the ingredient and its potential to cause acute harm in the sense of being toxic or causing allergic reactions. The second dimension of FSANZ's pre-market process centres on a cost-benefit analysis that, while broad and qualitative in nature, has some specific focuses prescribed in the *FSANZ Act*. When conducting the cost-benefit analysis, FSANZ must have regard to:

(a) whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure;
(b) whether other measures (available to [FSANZ] or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application.[209]

This cost-benefit analysis applies, therefore, not only to pre-market approval itself but also to any conditions that FSANZ is considering imposing on an approval. It also funnels potentially broad sets of concerns into the categories of either 'costs' or 'benefits', and emphasises the need for avoiding market intervention by requiring a 'cost-effective' approach to regulating.

204. There has been no public response from the latter Forum at the time of writing. See Consumer Affairs Forum, 'Communiqués', *Australian Consumer Law* (2021) <https://consumerlaw.gov.au/index.php/consumer-affairs-forum/communiques>.
205. Australia and New Zealand Ministerial Forum on Food Regulation, *Communiqué* (Web Page, 15 November 2019) <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2019-November>.
206. Ibid.
207. This committee is comprised of government officials from either health or agricultural-focused government departments, across the various jurisdictions: 'Food Regulation Standing Committee Members', *Australian Government Department of Health* (Web Page, 16 June 2020) <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/FRSC-members>.
208. Australia and New Zealand Ministerial Forum on Food Regulation, *Communiqué* (n 205) 2, where the Forum went onto state that they 'recognised the value of the meat and dairy sector to the Australian and New Zealand, diet and economy, but also recognised the growing value of the alternative products sector and agreed that both have a place in the market for consumers'.
209. *FSANZ Act* s 29(2).

This cost-benefit analysis also occurs in the context of the broader criteria that FSANZ must have regard to when developing new standards. As discussed in Part III.A, this set of criteria, besides the criterion of best available scientific evidence, are all focused on enabling an efficient and internationally competitive food industry.[210] Although the *FSANZ Act* prioritises public health and scientific evidence, the weight of the criteria elaborated upon for FSANZ to consider when varying *the Code* to allow a new product is focused on market-based concerns.

Partly because of this legislative context, FSANZ assumed and weighed heavily the idea that a new product on the market was a benefit to Australia in its cost-benefit analysis of the Impossible application. It considered that Impossible products would provide a broad economic benefit to Australia, presumably in the form of increased consumer choice and spending. Approving the product will benefit Impossible, as it will increase its revenue. As FSANZ stated, it would also benefit Australian and New Zealand businesses by providing them with 'the ability to purchase and sell Impossible branded meat analogue products containing *soy leghemoglobin* if they believe they are likely to receive sufficient revenue'.[211] Likewise, FSANZ identified that consumers would also benefit from greater choice.[212] Submitters who supported the approval of Impossible products also emphasised that Impossible products would benefit consumers and retailers. One respondent summarised their justifications for supporting the application as 'safety, product innovation and providing consumer choice'.[213] They also cited increased consumer demand for alternatives to meat and the nutritional benefits of a plant-based product high in iron.

It is likely that the final product, and certainly *soy leghemoglobin* in the form of LegH Prep, will be produced in the US, and that Impossible will remain a US-based company with intellectual property in *soy leghemoglobin*. These dynamics do not indicate a significant benefit to the Australian economy beyond the benefit of stimulating increased consumer demand for food retailers who sell Impossible products (such as a specific burger chain, like Grill'd who submitted in favour). Indeed, the US and the EU have pre-existing competitive advantage in agricultural biotechnologies and advanced food processing, suggesting that most novel meat analogues sold will benefit their economies more than the Australian and New Zealand economy.[214]

The costs identified by FSANZ did not relate to those identified by submitters, such as the ultra-processed nature of the food. Rather, FSANZ observed only one cost to varying *the Code* to allow

210. Pursuant to *FSANZ Act* s 18(2), FSANZ must have regard to: 'the need for standards to be based on risk analysis using the best available scientific evidence', but also the 'promotion of consistency between domestic and international food standards', 'the desirability of an efficient and internationally competitive food industry', 'the promotion of fair trading in food' and any relevant policy guidelines formulated by the Ministerial Forum.

211. FSANZ, *Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products* (n 5) 41.

212. Ibid.

213. New Zealand Food and Grocery Council, CFS1 (14 February 2020) 5.

214. There has been a broad and significant shift since the 1960s from publicly funded, applied agricultural research towards privately funded research focused on agricultural biotechnologies and advanced food processing. In high-income countries this trend is especially pronounced. The EU and US have long been the jurisdictions with the most private spending on agricultural biotechnologies research and development: See, eg, International Assessment of Agricultural Knowledge Science and Technology for Development, *Agriculture at a Crossroads* (Global Report, 2009) <http://www.unep.org/dewa/agassessment/reports/IAASTD/EN/AgricultureataCrossroads_GlobalReport(English).pdf>. Nevertheless, it seems likely that some jobs in sales and distribution would be generated in Australia via Impossible products, though specific estimates were not provided nor were these emphasised by FSANZ or submitters. The increase in private investment is presented as sub-optimal by international institutions and scholars because it poses a barrier to the broader distribution of benefits, shapes the kind of innovation that occurs and enables lock-in to particular kinds of food and agricultural systems. For a more recent summary of these trends and their implications, see Philip G Pardey et al, 'Agricultural R&D is on the Move' (2016) 537(7620) *Nature* 301.

soy leghemoglobin, which was the 'inconsequential' cost incurred by governments in the form of 'monitoring and enforcement to ensure the final products comply with *the Code* and various food and consumer protection laws'.[215]

The broad and brief references to economic benefits reflect a privilege granted to individual interests in the form of consumer choice and to the economic interests of one company. Combined with the narrow interpretation of costs, the cost-benefit analysis by FSANZ further reflects how the regulatory regime allows for a disengagement from public interest considerations and an over-emphasis on market-based concerns. It exemplifies the presumption in Australian food law and policy that new food technologies and products are ipso facto of economic benefit, rather than a thicker conception of what a good food system looks like or even a deeper interrogation of to whom any economic benefits will accrue.

IV Conclusion

FSANZ's pre-market approval process, viewed through the case study of Impossible, illustrates how the regulatory regime for food is designed to only pro-actively assess ingredients in food in a narrow set of circumstances. When such an assessment does occur, the emphasis is on preventing acute food safety risks and enabling markets. The process is further highly restricted when it comes to subject matter, as it only considers ingredients and individual nutrients. Finally, it relies on a limited evidential basis. By design and in effect, the pre-market approval process did not engage meaningfully with the submitters' concerns nor move the debate forward towards clarity and compromise.

This is notable because, in the context of Australia's existing system for regulating food, the pre-market approval process is important and distinct. Besides import controls,[216] it is the only regulatory process designed to pro-actively assess a food product before it enters a market. Otherwise it falls on private actors to ensure compliance. It is also the only regulatory process to formally engage the public in food regulation, through the potential to make submissions. Australian food law, therefore, provides very limited avenues for assessing the social, economic, ethical and environmental impacts of novel food products and categories such as the Impossible burger and other novel meat analogues on the food system as a whole. Yet the current regulatory approach leaves it to the market and consumer choice, shaped by the context in which such choices are made, to determine the desirable qualities and trajectory of food systems and technological change.

Novel meat analogues are, among other things, a market-based response to the issues with intensive animal production and consumption. However, transitions from unsustainable systems of production and consumption require multiple interventions beyond the market.[217] It also requires, as Arup, Dixon and Paul-Taylor posit, that 'a peak government convened agency can pay attention at

215. FSANZ, *Approval Report- Application A1186: Soy Leghemoglobin in Meat Analogue Products* (n 5) 42.

216. For imported food, however, compliance with the Code is also monitored through an inspection programme carried out by the Department of Agriculture, Water and the Environment in accordance with the *Imported Food Control Act 1992* (Cth). In practice, some shipments of novel meat analogues may be subjected to inspection, which inspection entails an examination of labelling compliance and may involve tests such as for harmful bacteria.

217. Christine Parker et al, 'Can Labelling Create Transformative Food System Change for Human and Planetary Health? A Case Study of Meat' (2020) 10(12) *International Journal of Health Policy and Management* 923 <https://www.ijhpm.com/article_3979.html>; Christine Parker, Fiona Haines and Laura Boehm, 'The Promise of Ecological Regulation: The Case of Intensive Meat' (2018) 59 *Jurimetrics* 15.

the same time to the interacting structural features of the food system, including corporate power, production systems, workforce issues, dietary choices and environmental sustainability'.[218] Moreover, novel meat analogues may aggravate existing food systems issues such as corporate consolidation and increased consumption of ultra-processed foods. Meanwhile, the controversy surrounding novel meat analogues intersects with bigger questions for societies that emerge from the multiple crises associated with intensive animal production and consumption as well as the preponderance of ultra-processed foods in diets.

These questions and the related issues and solutions reflected in the claims by novel meat analogue products are worthy of open and carefully conducted public democratic deliberation. One important reason is so that the full range of multiple policy goals at issue (ethics, sustainability and health) can be laid on the table and all the set of interventions required discussed and developed. At the time of writing, the *FSANZ Act* is being reviewed and a wide range of options have been suggested from maintaining the status quo to broadening FSANZ's objectives and improving the democratic deliberation of its processes.[219] A broadening of FSANZ's objectives to include consideration of environmental sustainability and clarification of FSANZ's remit to consider not just food safety but also longer term public health objectives have been mooted in the review and would go part way towards addressing some of the issues raised in this paper.

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218. Christopher Arup, Jane Dixon and Jo Paul-Taylor, 'The Essential Ingredients of Food Regulatory Governance' (2020) 29(2) *Griffith Law Review* 273, 295.
219. The review began in July 2020. A public consultation was conducted on what the scope of the review should be: Nous Group, *Review of the Food Standards Australia New Zealand Act 1991: Scoping Paper for Public Consultation* (Report, 2 October 2020) <https://consultations.health.gov.au/chronic-disease-and-food-policy-branch/7a3d2478/supporting_documents/FSANZActReviewscopingpaper02.10.pdf>. Further public consultations around particular issues have occurred and closed on 18 May 2021.