



gene ethics
working for a GM-free future

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Re: Comments on A1269 novel junk food substances derived from cultured quail cells

To FSANZ via the Consultation Hub:

GeneEthics makes these comments to our food regulator FSANZ, on behalf of its 14,000 members, subscribers and constituents. We would welcome an opportunity to discuss our many concerns with FSANZ staff and the applicant company.

Recommendations to FSANZ

- **Abandon all proposals** to amend the Food Standard in response to A1269 until all the deficiencies in the documentation and processes are completely resolved. Stop the clock;
- **Publish all Confidential Commercial Information (CCI)** in the Vow application now withheld from the public, so it is available for independent expert evaluation;
- **Assess Vow's experimental and commercial scale** production processes and require the company to make further applications for approval if it seeks to scale up to large commercial quantities from the present small-scale experiments, as the full risks of microbiological and other foreseeable hazards can't now be fully assessed;
- **Label all cell-cultured, fake meat substances** as they have no history of safe use in the human food supply. This must include all those products for which FSANZ proposes: "exemptions for prepared filled rolls, sandwiches, bagels or similar products and a fund-raising event". Such exemptions have no logical or evidence-based justification;
- **Remove the growth factors from Vow's cell-culture media** where they are used to promote the cancer-like proliferation of immortalised animal cells¹ in vats. Growth factors are major regulators of cancerous tumour progression as: "Although departure from homeostasis and tumour initiation are instigated by oncogenic mutations rather than by growth factors, the latter are the major regulators of all subsequent steps of tumour progression, namely clonal expansion, invasion across tissue barriers, angiogenesis, and colonization of distant niches." Furthermore: "growth factors are frequently involved in evolvment of resistance to therapeutic regimens." A big increase of the growth factors in junk food would be risky and not evidence-based so must be disallowed;²
- **Require rigorous evidence on immortalised cell line safety and efficacy.** "Despite the informal scientific consensus around the safety of immortalized cells, there just aren't any long-term health studies to prove it." With such uncertainty: "Several prominent (US) startups have chosen to avoid using immortalized cells entirely."³ Also, "there are few existing cell lines made of species and cell types appropriate for cultured meat" and "cultured meat cell lines will need to be approved as safe for consumption as food,

¹ Lab-Grown Meat, Immortalised Cells in Lab-Grown Meat. <https://labmeat.com/health-effects/>

² Witsch, E, et al. Roles of Growth Factors in Cancer Progression, Physiology (Bethesda). 2010 April ; 25(2): 85–101. doi:10.1152/physiol.00045.2009

³ Fassler, J. Lab-Grown Meat Has a Bigger Problem Than the Lab, Bloomberg, February 7, 2023. <https://archive.md/6VCUN#selection-3919.315-3919.396>

proliferate and differentiate efficiently at industrial scales.”⁴ Until the body of comprehensive safety evidence is large and compelling, FSANZ must reject A1269.

- **Heed warnings in the UN's FAO report** on the: "Food safety aspects of cell-based food" which acknowledges unresolved scientific uncertainties confronting regulators of cell-cultured substances e.g. "it is still uncertain whether the protein content/profile of cell-based meats is the same as traditional meat."⁵ FSANZ claims (SD1, P1) to have 'had regard' for the FAO document. However, it marginalises the several potential food safety hazards/concerns mentioned in the FAO report (P50) - animal serum in the culture media may introduce pathogens; antibiotic residues may remain in the final product; after many generations of propagation, genetic or epigenetic drift may occur in the cultures; differentiation protocols for livestock cells remain elusive.
- **Consider** the: "potential hazards in the four stages of cell-based food production: 1) cell-sourcing; 2) cell growth and production; 3) cell harvesting; and 4) food processing."⁶ Indeed, FSANZ expressly ignores stage 4 and allows the other three stages to be hidden behind unjustified CCI claims! The FAO map shows the potential for microbiological contamination, and unspecified residues and by-products, at every step of the long process from harvesting cells from live animals to processing and selling the final junk food product. FSANZ must fully assess the industrial food assembly phase, where synthetic processing aids, additives, colours and flavours are added to concoct the cell-derived slush. It is then integrated with scaffolding materials to confer the slush with the appearance and texture of conventional food, for sale and trade to unwitting customers.

Table 4. A generic map of potential hazards/concerns in cell-based food production processes

	<i>Transmission of zoonotic infectious diseases</i>	<i>Residues and by-products</i>	<i>Novel* inputs</i>	<i>Microbiological contamination</i>
Cell selection	X	X		X
Production	X	X	X	X
Harvesting		X		X
Food processing		X	X	X

* A novel input means an added step, material, technology or technique that has not commonly been used in conventional food production (i.e. scaffolds or modified cell properties).

- **Change FSANZ' methods** by requiring life-cycle assessments of novel foods, including systematic followup monitoring and reporting after their commercialisation, to follow their long-term health and wellbeing impacts on those people who eat them. An FAO food safety workshop report notes that "no consensus has yet emerged as to when cell-based food products require a separate risk assessment" but it calls for: "a shift from reactionary to anticipatory approaches. Traditional monitoring and surveillance ... are only effective in identifying immediate hazards and risks in the food safety landscape; therefore, there is also a need to identify important medium- to long-term issues to facilitate preparedness for effective actions."⁷ We agree.
- **Publish the full specifications for cell-cultured quail** that are now unavailable, so they are: 1. accessible to independent expert evaluation, and 2. so the Food Standards Code can be enforced as it is "the responsibility of food enforcement agencies in Australia and New Zealand"⁸ not FSANZ;

⁴ Soice, E and Johnston, J. Immortalizing Cells for Human Consumption. *Int. J. Mol. Sci.* 2021, 22(21), 11660; <https://doi.org/10.3390/ijms222111660>

⁵ FAO & WHO. 2023. *Food safety aspects of cell-based food*. Rome. P61. <https://doi.org/10.4060/cc4855en>

⁶ Ibid. Page ix.

⁷ FAO. 2022. *Thinking about the future of food safety – A foresight report*. Rome. P5.

<https://doi.org/10.4060/cb8667en>

⁸ FSANZ, Novel Foods, June 2022, <https://www.foodstandards.gov.au/business/novel>

- **Disallow the unreliable “weight-of-evidence approach”⁹** that Vow used to evaluate growth factor safety as its assumptions of substantial equivalence are unfounded. Moreover, the growth factor comparisons are hidden under CCI in Appendix 28.
- **Produce evidence to justify the unfounded assumptions** that: “overestimation of serving size and expected infrequent consumption of harvested cells” are likely (SD1, P50). SD1 also claims “There were no nutritional risks identified from the consumption of the harvested cells containing the levels of nutrients provided in the application, particularly given the likely infrequent consumption of the harvested cells.” (SD1 P3) Such claims, repeatedly made in FSANZ SD1 hazard and risk assessment are refuted in an Australian study of the average dietary content of food nutrients which found: “Ultra-processed foods had the highest dietary contribution (42.0% of energy intake), followed by unprocessed or minimally processed foods (35.4%), processed foods (15.8%) and processed culinary ingredients (6.8%).”¹⁰
- **Fully assess the Post-harvest processing and cell-cultured final product** that would be for sale and consumed if scale up occurs. FSANZ chose not to consider the final phase of the process - a clear dereliction of its responsibilities to protect and promote food safety, health and community well-being. Despite this huge lapse in safety assessment, FSANZ consumer and labelling documents (SD2,3 and 4) shamelessly advance the proponents’ promotional and commercial interests.

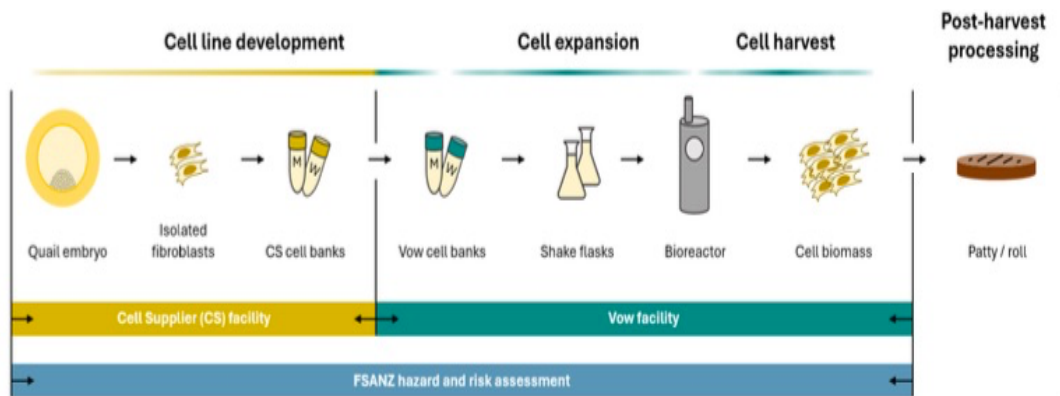


Figure 1 A schematic overview of the production of cultured quail cells and the scope of FSANZ's assessment. M = Master cell bank. W = Working cell bank

- **Reassess false serving size and intake frequency assumptions** that FSANZ claims remove any concerns from: “The levels of cobalamin and biotin in the harvested cells resulted in intakes that were up to 929 times the estimated average requirement (EAR) and 9 times the adequate intake (AI) respectively per serving,”¹¹ despite no upper levels having been set. Serious junk food eaters may be at even more health risks than they are now, from eating synthetic cell-based substances.
- **Require precautionary experiments now** to confirm the assumptions that the cell biomass inside bioreactors is “microbiologically sterile” by conducting: “challenge studies with surrogates for foodborne pathogens (that) would provide more certainty and data to inform risk assessments and risk management for these production systems in the future.” (SD1, P22) This critical information must predate approval.
- **Clarify which regulators are responsible** for monitoring and enforcement when: “there is no specific step within the production process that will reduce or eliminate microbiological contaminants ... this will require consideration of the potential for: (1) acquired cells being contaminated with bacteria or viruses from source animal, reagents, or environment; (2) contamination from manual handling; (3) contamination

⁹ Vow application, P52.

¹⁰ Machado PP, 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. *BMJ Open*. 2019 Aug 28;9(8):e029544. doi: 10.1136/bmjopen-2019-029544.

¹¹ FSANZ, SD1, hazards and risks, P2.

from any inputs during production; (4) facility environmental contamination; and (5) inadequate cleaning and sterilisation of equipment.” (SD1, P23)

Comments on A1269

1. **Cell-cultured substances like Vow’s** would add to the large mass of ultra-processed junk foods already on sale as a result of many other FSANZ approvals. Junk foods are largely responsible for the epidemic of overweight, obesity, compromised health, and reduced wellbeing among Australians and people in comparable countries.¹² “Hundreds of scientific studies provide strong evidence that consuming ultra-processed foods is linked to early death and serious diseases, including cancer, Type 2 diabetes, obesity, cardiovascular disease, Alzheimer’s disease and other forms of dementia, depression, non-alcoholic fatty liver disease, and chronic kidney disease.”^{13 14 15} FSANZ is planning a campaign to combat obesity and its deleterious effects but it can never succeed while FSANZ, other regulators and the whole food system remains under the negative influence of ultra-processed food industries like Vow, and deeply conflicted and compromised agencies such as CSIRO.
2. **If the technology for making cell-cultured, lab-grown, food substances scales up**, regulatory bodies must continuously monitor and assess both their processes and products to assess whether the substances are safe, beneficial, and sustainable. FSANZ SD1 hazard and risk assessment document (P3) notes: “The likelihood of microbiological hazards entering the cell biomass has been assessed at the current scale of production and this would change if production is scaled up.” FSANZ must therefore require further applications from Vow if its production eventually increases to commercial volumes.
3. **Most of the relevant data on its processes and products** that Vow submitted to FSANZ with its application are unavailable. Vow keeps thirty-three Appendices private, with unsupported claims that its documents contain Confidential Commercial Information (CCI). Without providing any substantial reasons for the secrecy, Vow and FSANZ deny independent experts and the interested public the opportunity to review and critique the evidence. Such secrecy is unacceptable as, according to FSANZ SD1 document, the data includes information on: “two GF (Growth Factor) combinations that were used in the basal media during the production process; the use of GCCP (Good Cell Culture Practice) during production; the identity of the individual media components and other inputs; and a literature reference that Vow claims to show “degradation of the GF would be anticipated at cooking temperatures and proteolytic degradation in human gastrointestinal fluids has also been demonstrated.”
4. **We ask FSANZ to inform the public** of the qualifications, experience and industry connections of the government assessors who conducted the hazard and risk assessment. They claim to have assessed all the: “microbiology, biotechnology, toxicology, nutrition, and dietary intake/exposure considerations,” that the application raises which would be way beyond the capacity of one or a few FSANZ officials. We are deeply concerned that FSANZ staff use regulatory science to make their assessments as these methods use best guesses and assumptions to fill the numerous data gaps that remain in the presently available scientific evidence. There were many such information gaps in the current evidence and, collectively, they cast a large doubt and uncertainty over the veracity of document SD1.
5. **The public has the right to be fully informed** and to know the origins and provenance of all foods, especially those that are novel and have no history of safe use in the human food supply. Yet the FSANZ SD4 document on labelling says that for these ultra-processed products that there would be: “exemptions for prepared filled rolls, sandwiches, bagels or

¹² Conley, M. Ultra-processed foods: obesity and weight gain, US Right to Know, February 1, 2024 <https://usrtk.org/ultra-processed-foods/obesity-weight-gain/>

¹³ Crimarco, A., et al. Ultra-processed Foods, Weight Gain, and Co-morbidity Risk. *Curr Obes Rep* 11, 80–92 (2022). <https://doi.org/10.1007/s13679-021-00460-y>

¹⁴ Conley, M. Ultra-processed foods tied to cancer, diabetes, dementia, depression and early death, US Right to Know, February 1, 2024 <https://usrtk.org/ultra-processed-foods/cancer-diabetes-dementia-depression-early-death/>

¹⁵ Elizabeth, L., et al. Ultra-Processed Foods and Health Outcomes: A Narrative Review. *Nutrients* 2020, 12(7), 1955; <https://doi.org/10.3390/nu12071955>

similar products and a fund-raising event." These are precisely the ways in which Vow proposes to present its lab-grown products.

6. **The application notes** under: "Specification for identity and purity for a novel food ingredient" that "A published specification is not available for cultured quail. Vow proposes specifications that establish the qualitative and quantitative parameters for each batch of cultured quail."¹⁶ This is untenable as the regulators are asked to abdicate their responsibility to assess and approve a product for which there is no set formulation.
7. **In the absence of any solid evidence**, FSANZ' recklessness and dereliction of duty are clear. For example, it asserts: "Due to the severity of illness, the potential for growth and the lack of critical control points available, *L. monocytogenes* is characterised to be a medium to high risk to public health and safety. *L. monocytogenes* is controlled through an effective heat treatment. Vow advise the final product will be 'cooked' however no data was provided on this stage and it was not assessed as part of this application." Don't look, don't find.
8. **FSANZ assessors also state**: "It is not possible to characterise the risk level at commercial production scale due to the uncertainty associated with elements of production process that would influence the microbiological outcomes and therefore any associated risk to public health." FSANZ made no commitment to require Vow to reapply if it scales up its operation to commercial size, though it says: "As noted for Section 5.1.2 it is not possible to characterise the risk at production scale based on current data that is available." (SD1 P49)
9. **FSANZ failed to assess many important aspects of the processes and products**, was not supplied with essential data, and ignored contentious parts of the post-harvest processing e.g. several scaffold materials and processes¹⁷ such as 3D printing may be used to construct and texture the final products for sale but none of this was in the application as FSANZ does not consider it. In Appendix-IV of SD1 FSANZ variously dismisses serious data vacuums with comments such as: "Not assessed, Not tested or data not supplied, No monitoring data provided, assessed harvested cells data as proxy for in process monitoring, Not assessed beyond scale in application, No microbiological data assessed; Not assessed as final food product was not part of this application." For a radical new product such as this, such evidence gaps are inexcusable.
10. **"In Australia, the importation of a cell line** for the purposes of laboratory use or for food production is assessed for compliance under the Biosecurity Act 2015, and this is managed by Department of Agriculture, Fisheries and Forestry (DAFF). DAFF also administer the Imported Food Control Act which checks imported food for compliance with the Code and public health and safety" (SD1, P10). We can find no record of any such approvals and have asked DAFF to supply the application and any approval that may have been issued.

Summary and Conclusion

The full participation of independent experts and the informed public are essential to the success and credibility of food regulatory processes but we are deliberately excluded in the case of A1269 as most of Vow's evidence is classified as CCI and is hidden.

FSANZ is captive of ultra-processed food industries though it has the responsibility to rigorously assess and regulate their processes and products. The FSANZ SD1 hazard and risk assessment is a sloppy, deficient document, while SD2,3 and 4 merely reconfirm that the public interest is marginalised. Providing complete and credible information is essential but A1269 fails.

We call on FSANZ to abandon its intention to amend the Food Standard in response to A1269. The deficiencies of all the documentation require FSANZ to stop the clock on all review and approval processes.

¹⁶ Vow Application A1269, P 26.

¹⁷ Good Food Institute, Deep dive: Cultivated meat scaffolding. <https://gfi.org/science/the-science-of-cultivated-meat/deep-dive-cultivated-meat-scaffolding/>