GE Free New Zealand

In Food And Environment Inc.

PO Box 13402, Wellington, NZ

5 February 2024

SUBMISSION RE: **A1269 - Cultured Quail as a Novel Food**

Tēnā koutou Food Standards,

We ask that you decline the application A1269 - Cultured Quail as a Novel Food due to the lack of regulatory guidelines on cell-based meat, a lack of safety testing and no comprehensive scientific evaluation required by the FSANZ staff and Authority.

There is no scientific assessment of the basal media and its genetically modified ingredients for cell culture. There also appear to be no clear indicators that cultured products from precision fermentation are safe for human consumption.

FSANZ is being asked to approve the large-scale production of a novel technology that has no history of viability at scale. FSANZ is permissive in allowing the manufacturer to change both the growth media and the genetic modification processes, without any oversight. They are allowing Vow to self-monitor the production without accountability to an external regulatory body, and it is not within the power of FSANZ to permit this.

Cultured Quail is not comparable to quail meat or chicken meat. It is a synthetic, processed product that uses quail cells as a growth bio product for ingredients in the final product. The synthetic GM, vitamin culture media is a larger component than that quail cell biomass in the final product.

We have concerns over the poor and misleading information, leading people to believe that FSANZ has adequately assessed the novel nature of the quail cells and the media culture for safety.

1. FSANZ body is mandated with ensuring a high standard of health protection for the consumer and ensuring the quality and safety of the food produced, processed, and sold, has high a consumer confidence. The FSANZ Act states -

    - *All assessment of applications must be effective, transparent, and accountable this means providing adequate information relating to food that enables consumers to make informed choices. It also must not reduce the safeguards applying to public health and consumer protection. The documents open to public submission are misleading and deceptive due to the lack of safety assessment and information required for consumer protection. (Object of the FSANZ Act, 2018)*

Furthermore, the guidelines that FSANZ are to follow are set out in the Code -

- *FSANZ deals with new types of foods, including foods produced by new technologies, but its Food Standards Code does not contain permissions or requirements for cell-based meats (FSANZ, 2021).*[1]

- *The Food Standards Code defines a novel food as a non-traditional food that requires an assessment of the public health and safety considerations, whereby non-traditional food means: (a) a food that does not have a history of human consumption in Australia or New Zealand; or (b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or (c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand (FSANZ, 2017).*

- *The information should cover potential food safety risks, such as toxicity, allergenicity, the safety of its production method, and dietary exposure arising from consumption. Companies must also provide detailed information on the materials used in their manufacturing processes and how these manufacturing processes are controlled to prevent food safety risks.*

In the presented documents, the assessment of the novel engineered food product is lacking in important detail and insufficient in its evaluation. Such important detail includes components of the basal media, additives and substances that are used in processing the engineered fermentation product. As stipulated in section 5 of the FSANZ Act, it must be fit for human consumption. The information provided in this application does not demonstrate that the product meets food safety standards due to the lack of evaluation and testing of the final product.

2. Regarding the Supporting document 1 - Hazard Risk Assessment, A1269.[2]

The novel quail cell-engineered processed product does not have a history of safe use. The engineered culture media also does not have a history of safe use.

Section **3.1 Basal Media (p.18)** The cell culture media contains a cocktail of novel engineered/modified growth factors. These are not differentiated from the many other growth factors that are able to be used. Each growth factor has a different mode of action in the cell. From this arises the possibility of a cytokine storm effect in the consumer, that could trigger anaphylactic shock, possibly leading to death. Recombinant growth factors present in the cell culture media have not been approved for food consumption (as an additive).

The cell culture media contain confidential substances that are not divulged to the submitters. This directly contravenes the responsibility of the FSANZ Act for consumers' information. It is unacceptable that the media components are not revealed for assessment The assessment states that "many" of the components are similar and mimic natural environment, such an approach is not scientific and does not give confidence in the expertise of the assessment staff protecting the public safety of consumers. It appears that FSANZ is deliberately keeping consumers in the dark over the basal media components.

[1] https://www.foodstandards.gov.au/consumer/safety/Cell-based-meat
[2] https://www.foodstandards.gov.au/sites/default/files/2023-12/SD1%20-%20Hazard%20and%20risk%20assessment_2.pdf

FSANZ has not specified whether the cow/pig growth factors (GF) are hormones, cytokines, or chemokines. These GF engineered into barley have not been assessed for safety from zoonotic infectious diseases or microbial contamination. It is not sufficient for safety to say that the gluten in barley is so low it would not trigger allergens. This must be experimentally verified, not just assumed.

If the GF are sourced from IGF-1, there is evidence of serious health implications for consumers. Rahmani J,. *et al* (2022) found that both high and low IGF-1 are linked to an increased risk of tumours including prostate, pre- and postmenopausal breast, lung, thyroid, and colorectal cancers, cardiovascular diseases (CVD), diabetes mellitus, osteoporosis, and sarcopenia.[3]

D'aes J., *et al* (2022) found that in the fermentation and manufacturing of GMO's, there have been numerous contamination events with *Bacillus spp* containing viable genetic modifications as well as anti-microbial resistance genes. [4]

Zeldes B., *et al* (2023) found that horizontal gene transfer has occurred between microorganisms and culture media leading, to deletion of vital nutrient synthesis, in a laboratory environment.[5]

The use of continuous antibiotics leads to the possibility of microbial antibiotic resistance, thus endangering consumers. It also shows that bacterial contamination is always a problem. The risk of genetic and epigenetic drift in cell lines, due to continuous sub-culturing, has not been scientifically assessed. There has been no assessment of the possibility of pathogenic mutations resulting from the uptake of the cell media components by recombinant molecules.

There is no safety assessment of the chemical or biological residues, or of foreign engineered DNA in the final product. This is essential for a food safety assessment.

There is no data provided on the transfer of cryoprotectant proteins, used in the storage of cultured cells.

FSANZ says that as quail have been eaten historically, assessing the cultured, engineered quail cells products as safe. This assumption is not backed up by scientific data needed for such a safety assessment and therefore does not have any merit. Due to the serious differences in the nutritional -vitamin, mineral and GM profile this food product cannot be deemed equivalent to quail meat. It potentially puts consumers in danger.

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[3] Rahmani J, Montesanto A, Giovannucci E, Zand H, Barati M, Kopchick JJ, Mirisola MG, Lagani V, Bawadi H, Vardavas R, Laviano A, Christensen K, Passarino G, Longo VD.(2022) Association between IGF-1 levels ranges and all-cause mortality: A meta-analysis. Aging Cell. 2022 doi: 10.1111/acel.13540.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8844108/#:~:text=A%20series%20of%20studies%20have,et%20al.%2C%202001).

[4] D'aes J, Fraiture MA, Bogaerts B, De Keersmaecker SCJ, Roosens NHCJ, Vanneste K. Metagenomic Characterization of Multiple Genetically Modified *Bacillus* Contaminations in Commercial Microbial Fermentation Products. Life (Basel). 2022 Nov 25;12(12):1971. doi: 10.3390/life12121971. PMID: 36556336; PMCID: PMC9781105.

[5] Zeldes, B., Poehlein, A., Jain, S. *et al.* (2023). DNA uptake from a laboratory environment drives unexpected adaptation of a thermophile to a minor medium component. *ISME COMMUN.***3**, 2. https://www.nature.com/articles/s43705-022-00211-7

The quail cells are a totally new processed product and the components of the culture media have not been assessed for safety. Consumers through FSANZ's own consultation admitted that there was little understanding or knowledge of these cultured products.

Precision fermentation using genetically engineered cells and media from pig/cow sources cannot be claimed as safe for human consumption.

Summary:

Precision fermentation using genetically engineered cells and media from porcine and bovine sources cannot be claimed as safe for human consumption.

FSANZ does not have the permission, expertise, or protocols to assess issues arising from cell-cultured foods in their food code regulations or safety guidelines. Until these have been passed into regulation, this application cannot be approved.

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- Until there are legislated regulatory guidelines in place to comprehensively assess cell-cultured foods, FSANZ cannot allow this application to proceed.
- Evidence-based decision making requires that media from animals and genetically engineered growth factors must be properly tested before approval is given.

- As part of the necessary scientific evidence pre-approval feeding studies must be conducted and reported.

- Antibiotics should not be used routinely in cell culture, because their continuous use encourages the development of antibiotic resistant strains and allows low-level contamination to persist. This can develop into full-scale contamination once the antibiotic is removed from media and may hide mycoplasma infections and other hard to detect contaminants. Furthermore, some antibiotics may cross react with the cells and interfere with the cellular processes under investigation.
- Regulation must stipulate the labelling of cell-based food products to be clear, with a detailed list of media components used in the processing and development of the product.

We make this submission on behalf of our 1,600 members.

Regards,
Jon Muller
Secretary GE Free NZ in Food and Environment

Cc: Claire Bleakley
Jon Carapiet