FOOD STANDARDS
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Te Mana Kounga Kai - Ahitereiria me Aotearoa

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Supporting document 1

Risk assessment – Application A1341

Cell-cultured duck (*Anas platyrhynchos domesticus*) biomass

Executive summary

Suprême SAS (Gourmey) applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of cell-cultured duck biomass as a food ingredient. The cell-cultured duck biomass is made from embryonic stem cells sourced from *Anas platyrhynchos domesticus* (Pekin duck) and is not genetically modified.

The source cells were originally isolated from fertilised duck eggs and established as an embryonic stem cell line, designated as cell line 8516-Duck-DP. The cell line is pluripotent, ensuring the cells can proliferate indefinitely under appropriate culture conditions.

The cell-cultured duck biomass will be mixed with other ingredients to be used in products such as ‘cell-cultured foie gras’ and ‘cell-cultured duck pâté’. It is the applicant’s responsibility to ensure these ingredients are safe and suitable for human consumption, including meeting any requirements of Australian and New Zealand food laws, including the Code. This risk assessment therefore does not cover other ingredients used in the final food product.

FSANZ assessed the safety of the harvested cell-cultured duck biomass with respect to toxicological, microbiological and nutritional considerations, including dietary exposure. This assessment confirmed the genetic and phenotypic stability of the cells, as well as the safety of the end-to-end production process, including media inputs. FSANZ also assessed the microbiological safety of cell-cultured duck biomass, including the production process, excluding the harvesting and washing stages, and the final biomass. FSANZ concluded that cell-cultured duck biomass, does not pose any stability, toxicological or microbiological safety concerns based on the information provided.

No process control was identified to minimise the elevated microbial risk associated with increased handling and environmental exposure during cell harvest and washing. The food manufacturer is responsible for managing this risk and ensuring the biomass is safe and suitable for human consumption. This includes post-harvest handling of the biomass. A specification is proposed for Schedule 3, which the food manufacturer will need to meet to ensure the food is safe.

The nutrition assessment did not identify any nutritional concerns associated with the consumption of cell-cultured duck biomass at the assessed nutrient levels, particularly given its expected infrequent consumption.

Table of contents

1 Introduction

Suprême SAS (Gourmey) applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of cell-cultured duck biomass[1] as a food ingredient. The cell-cultured duck is made from embryonic stem cells sourced from *Anas platyrhynchos domesticus* (Pekin duck) and is not genetically modified. The cell-cultured duck biomass will be mixed with other ingredients to be used in products such as 'cell-cultured foie gras' and 'cell-cultured duck pâté'.

FSANZ's risk assessment followed the production process outlined in Figure 1 below and focused on the following:

- cell line, designated by Gourmey as 8516-Duck-DP
- production process, including the inputs used to grow and propagate the cells
- harvested cells.

The post-harvest food processing stage was not assessed from a production perspective; only the production of the biomass and the biomass itself were evaluated. This approach provides the applicant with flexibility in the types and range of final foods in which the biomass may be used. Assessing every potential end food would be impractical and unnecessary, as these foods will generally contain other ingredients that do not require specific regulation. Responsibility therefore remains with the applicant to ensure that any additional ingredients are safe and suitable for human consumption and meet all requirements of Australian and New Zealand food laws, including the Code. The assessment of the cell-cultured duck biomass is performed in a manner similar to that of a novel food as defined in the Australia New Zealand Food Standards Code Standard 1.5.1.

The frozen cell biomass is intended to be thawed and used as an ingredient in a final mixed food product, with consumption of harvested cells at certain serve sizes used for the risk assessment as outlined further below.

Some information evaluated by FSANZ as part of the assessment is Confidential Commercial Information (CCI[2]) under Section 114 of the Food Standards Australia New Zealand Act 1991 and cannot be disclosed in this report.

[1] In this application, the term 'cell-cultured duck biomass' is used interchangeably with terms 'cell-cultured duck' or 'harvested cells' as short forms or due to context.

[2] Section 4 of the FSANZ Act defines CCI as:

(a) a trade secret relating to food; or

(b) any other information relating to food that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.

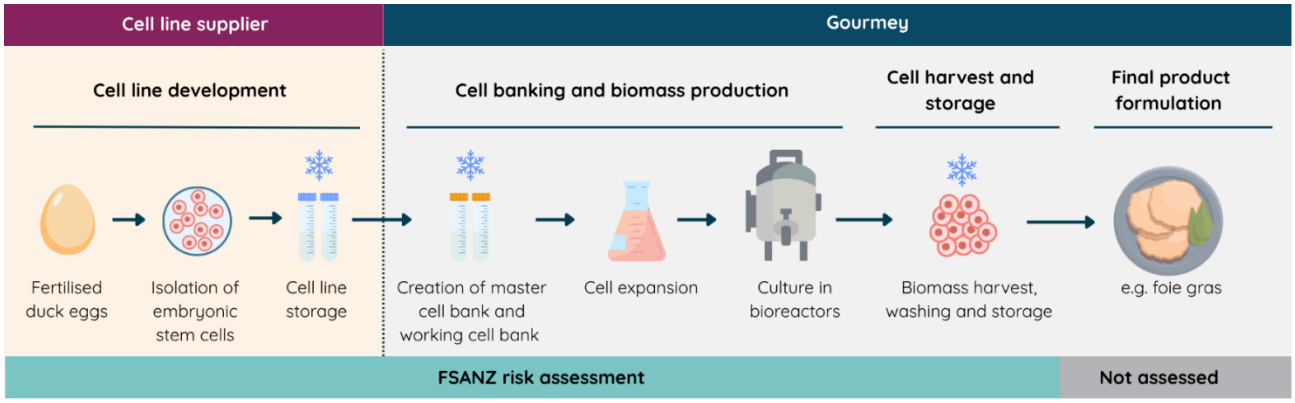

Figure 1. *A schematic overview of cell-cultured duck production and the scope of FSANZ's assessment*

2 Cell line and cell banks

Gourmey's cell-cultured duck relies on a non-GM animal cell line that can be propagated repeatedly and produce new batches of harvested cells for food use.

The focus of this section is to evaluate the identity, source and nature of the cell line and identify potential hazards. Any identified hazards then become the focus for further risk assessment.

2.1 Identity and source

The cell line is derived from Pekin duck (*Anas platyrhynchos domesticus*). It was originally isolated by a third-party supplier as a production platform for vaccines and therapeutic proteins. Gourmey has assigned this cell line the unique identifier of 8516-Duck-DP for the purposes of this application. The cell line is non-adherent, i.e. it grows in suspension culture.

2.2 History of safe consumption of the donor animal species

The domestic duck, *Anas platyrhynchos domesticus*, has a long history of safe human consumption. It was derived from the mallard, *Anas platyrhynchos*. Whole-genome resequencing from 78 individuals belonging to seven domestic duck breeds and two wild populations, supports a single domestication event approximately 2,200 years ago, with diversification into laying breeds and meat breeds around 100 generations later (Zhang et al. 2018).

2.3 Cell line establishment

The cell line was established using standard cell culture techniques. Good Cell Culture Practice (GCCP) was used during cell isolation, adaptation and banking stages.

In summary, embryonic stem cells (ESCs) were isolated from fertilised duck eggs obtained from a commercial European Union breeding farm. Cells were initially cultured with serum, antibiotics, growth factors and feeder cells to support attachment and proliferation. The cells were subsequently adapted to suspension culture in a food-safe medium free of serum, growth factors and antibiotics, but containing recombinant bovine insulin (see section 3.2).

The cell line was received as a cryopreserved bank from the supplier, from which Gourmey established a master cell bank (MCB) and working cell bank (WCB). The process for generating, storing, and validating the MCB and WCB is summarised in Figure 2, with the WCB used for production and the MCB retained to generate new WCBs as needed.

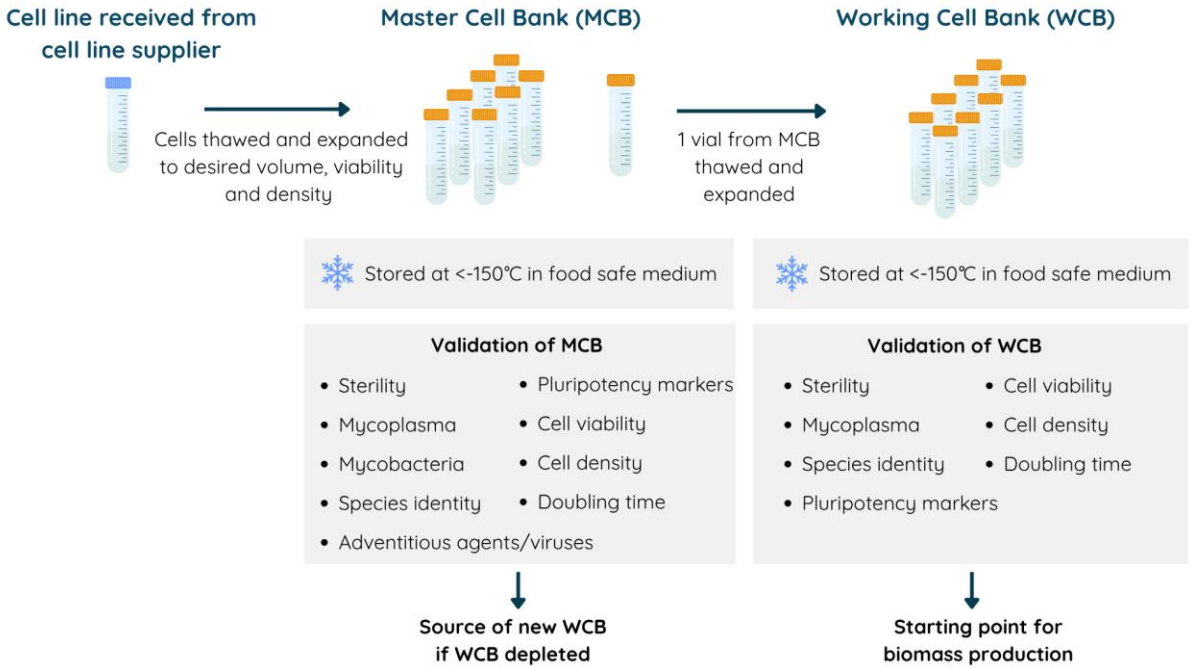

Figure 2 *An overview of the creation of the MCB and WCB, and the parameters used to validate them*

2.4 Microbiological hazard identification - cell line establishment and banking

2.4.1 Introduction

FSANZ assessed potential microbiological hazards relevant to the establishment and use of the duck ESCs, including bacteria, fungi, mycoplasma and viruses (FAO &WHO, 2023, Powell et al. 2024; Zandonadi et al, 2025). Consistent with international guidance, the assessment considered hazards associated with donor animal sourcing, cell isolation, and the development and use of master and working cell banks.

The level of microbiological risk depends in part on the origin of the specific ESCs. Avian and invertebrate cells are generally considered lower risk because species-specific transmission barriers exist (Pauwels et al. 2007; Herman and Pauwels 2014; Weiskirchen et al. 2023). However, where a zoonotic pathogen is known to infect humans, the relevant transmission routes from animal reservoir to humans would need to be considered (e.g. H9N2 influenza).

2.4.2 Source of cells and development of a qualified cell line and cell banks

Microbiological hazards can be introduced during tissue collection and establishment of the cell line. Hazard identification for the cell line development stage was informed by an integrated consideration of cell line provenance, history of passaging, and microbiological characterisation of the qualified cell bank. Information provided by Gourmey indicated cell sourcing and early handling occurred under controlled conditions. The following microbial

hazards were tested for in samples of homogenised yolk and albumin from the same batch of fertilised eggs: *Salmonella* spp*., E. coli, Proteus, Pseudomonas* spp*., Staphylococcus* spp*.* (Section B.4.2.2.3). Test results supplied for egg contents and early isolation materials did not identify any microbiological hazards relevant to food safety.

2.4.3

In general, infection of cultured avian ESC by pathogenic microorganisms (e.g. *Mycoplasma* ssp., viruses or bacteria) is most likely to impact cell growth, and consequently the yield of harvested cells (Weiskirchen et al. 2023). Changes in cell growth parameters or culture turbidity can be indicative of microbial contamination. Microbiological release testing assays were performed on both the MCB and WCB, including testing for *Mycoplasma* spp., *Mycobacterium* spp., sterility testing and viruses (Appendix-3). Test results supplied in relation to the MCB and WCB did not identify any microbiological hazards.

2.5 Cell line characterisation

2.5.1 Species confirmation

Gourmey provided DNA barcoding data generated by an external laboratory to confirm the species of the cells used in the production process. Genomic DNA was extracted from cells from the cell line supplier bank[3], MCB and WCB and used as a template for a quantitative polymerase chain reaction (qPCR) assay targeting the mitochondrial cytochrome C oxidase subunit 1 (COI) gene (Hebert et al. 2003). The results of the assay confirmed the cells from the MCB and WCB belong to the species *A. platyrhynchos*. In addition, qPCR assays of the COI gene, or other appropriate target genes, confirmed the absence of 13 other species[4] in the cell line, indicating the cell line has not been cross contaminated with these species.

2.5.2 Cell type and characteristics

The cell line under assessment are pluripotent ESCs. Pluripotency is maintained by a network of transcription factors and other pluripotency-associated genes, including NANOG, POU5F3 (also known as OCT4) and DNMT-3B (Pain et al. 2018; Chen et al. 2025), which act collectively to integrate signals that promote pluripotency and repress differentiation. They can be utilised as genetic markers to indicate pluripotency of the cell line (Section 3.3.2).

Given their inherent pluripotency, the introduction of novel DNA or genome modifications to the ESCs were not required to induce immortalisation, nor was any selection protocol applied.

ESCs also exhibit unlimited self-renewal and sustained proliferation in culture without undergoing senescence (cellular aging) (Pain et al. 2018). A key factor supporting this capacity is a high level of activity of the enzyme telomerase (TERT; Jiang et al. 2025). TERT serves as an additional marker for evaluating the pluripotency of ESCs (Section 3.3.2).

An additional characteristic of ESCs is their capacity to form embryoid bodies[5] when cultured under specific conditions (Desbaillets et al. 2000; Kurasawa et al. 2007; Farzaneh et al. 2017; Chen et al. 2025). The formation of embryoid bodies *in vitro* provides a functional

[3] Termed ‘qualified bank’ in the application dossier.
[4] *Homo sapiens* (human), *Cricetulus griseus* (chinese hamster), *Mus musculus* (mouse), *Rattus norvegicus* (rat), African green monkey, *Canis familiaris* (dog), *Felis catus* (cat), *Oryctolagus cuniculus* (rabbit), *Equus caballus* (horse), *Gallus gallus* (chicken), *Sus scrofa* (pig), *Bos taurus* (cow), *Spodoptera frugiperda* (fall armyworm).
[5] Embryoid bodies are three-dimensional aggregates comprising a mixture of differentiated cell types, partially resembling the structure of an early embryo.

assay for assessing pluripotency as it demonstrates the potential of cells to differentiate into the three primary germ layers (Section 3.3.2).

Several growth parameters and morphological observations of the cell line were also used to assess the stability of the cells throughout production (Section 3.3.2). Key parameters measured were doubling time (DT), viable cell density (VCD), cell viability (%), cumulative population doubling level (PDL) and cell morphology, which was assessed by microscopy.

Gourmey has specified that their duck ESCs are not differentiated during production and that the cells retain their identity in culture as ESCs through to harvest. In the absence of growth factors in the cell-culture medium that induce differentiation, the ESCs remain in an undifferentiated state and are stable.

2.6 Cell line assessment conclusions

Gourmey's cell-cultured duck is produced using a cell line consisting of ESCs isolated from fertilised duck eggs. The donor species, *Anas platyrhynchos domesticus* has a long history of safe human consumption, providing relevant context for the assessment of microbiological hazards associated with the cell line.

Based on the evidence provided by Gourmey, including microbiological testing of the qualified cell line, MCB and WCB, no microbiological hazards of concern were identified for the cell line used for biomass production.

Gourmey has designated the cell line the unique identifier of 8516-Duck-DP and has provided data confirming the cell line supplier bank and the derived MCB and WCB belong to the species *A. platyrhynchos* and are not contaminated with any of the other animal species tested.

3 Production of the biomass

3.1 Proliferation phase to harvest

The production of cell-cultured duck biomass is summarised in Figure 3. The process begins with a single vial from the WCB (section 2.4). The cells are thawed and resuspended in food-safe culture medium (section 3.2) in a shake flask. Next, the cells are expanded in shake flasks to a sufficient volume and density to inoculate an intermediate sized bioreactor (N-1 Suspension Bioreactor, or SBN-1)[6]. A small portion of the pooled cells are retained in the shake flasks, replenished with culture medium and grown in parallel to the culture in the SBN-1 bioreactor.

The cells in the SBN-1 bioreactor are grown until they reach the desired cell density, then used to inoculate a larger N Suspension Bioreactor (SBN). A small volume of cells from the SBN-1 is retained, replenished with culture medium and grown in parallel with the SBN culture. The maintenance of parallel shake flask and SBN-1 cultures create a continuous 'seed train', whereby these cultures can be used to seed the larger sized culture vessels multiple times without the need to start from a new WCB vial each time.

Once the SBN culture reaches the target cell density, the biomass is harvested from the bioreactor, separated from the culture medium by centrifugation, washed with saline and centrifuged again. The biomass is transferred to vacuum-sealed food safe bags and frozen at -20°C.

[6] The SBN-1 and SBN bioreactors described by Gourmey have working volumes of 10 L and 200 L, respectively, i.e. the current production scale is 200 L. Gourmey has indicated that the maximum intended production scale is 2,500 L, which would be achieved by inoculating a 2500 L bioreactor using cells expanded in the 200 L bioreactor. The same inoculation steps described for inoculation of the 200 L bioreactor would be applied for inoculation of the 2,500 L bioreactor.

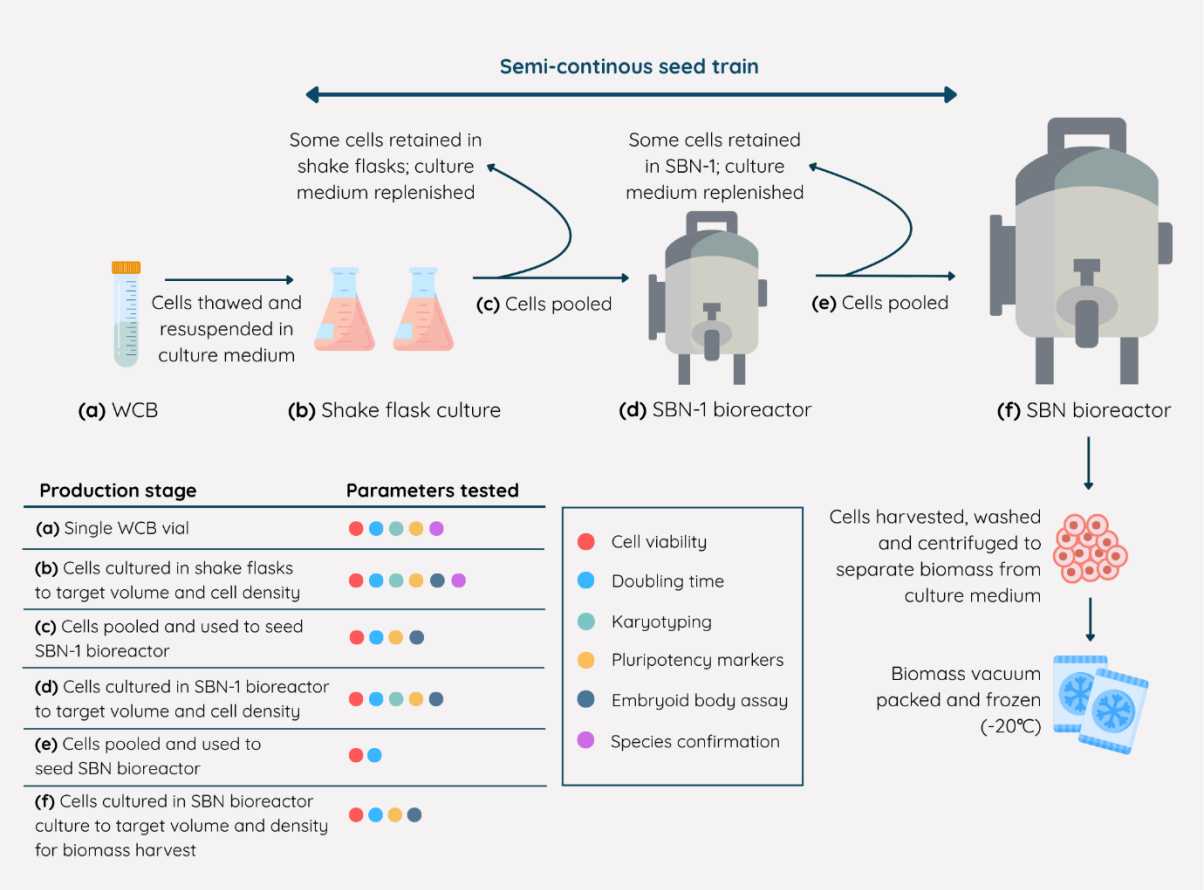

Figure 3 *A schematic overview of biomass production process and the parameters tested to monitor cell stability.*

3.2 Cell culture media and inputs, including safety data

The application includes, on a confidential basis, a comprehensive list of media and inputs, and ranks the cell culture media and inputs into three categories, as follows:

- **Category A** - ingredients that have traditionally been used in food, are authorised food substances, nutrients or have been used in food with no limitations (or limited by Good Manufacturing Practice - GMP).

- **Category B** - ingredients that have traditionally been used in food, are authorised food substances or commonly used substances but for which a toxicological or safety threshold has been established.

- **Category C** - ingredients with no history of safe use in food.

These classifications are consistent with the current risk assessment approach used by FSANZ for the assessment of cell culture media inputs.

3.2.1 Category A substances

FSANZ has reviewed the list of substances that are classified as Category A in the application and has determined that the classification is appropriate for all of them. They do not require risk assessment.

Classes of substance that are found in Category A include amino acids, trace metals, and vitamins. They are normal constituents of the diet and/or are part of endogenous mammalian metabolic pathways and are required to maintain the viability of the cells in culture. Some vitamins and trace elements are considered further in the nutrition risk assessment in relation to their potential contribution to dietary intake.

3.2.2 Category B substances

Category B substances are further classified in the application into those used only during the early stage of isolation and adaptation of the cells, but which are highly unlikely to be present in the final biomass due to cell passaging and adaptation steps, and those which may plausibly be present in the final biomass. The only Category B substance that may plausibly be present in the final biomass is 4-Aminobenzoic Acid or P-aminobenzoic acid (PABA), which is discussed further in Section 4.1.

3.2.3 Category C substances

Substances classified in the application as being in Category C have no history of safe use in food and require a full safety assessment:

- Recombinant proteins
- Beta-mercaptoethanol
- Antibiotics: penicillin and streptomycin
- Dimethyl sulfoxide
- Poloxamer 188
- Ethanolamine.

Of the Category C substances used in the early stages of cell isolation, up to the creation of the cell banks are heavily diluted in the later process of biomass production meaning there is a negligible likelihood of their presence in the final product. These include beta-mercaptoethanol and the antibiotics penicillin and streptomycin.

The Category C media components that are used in the process from MCB creation until biomass harvest, and may plausibly be present in the final biomass, are discussed further in Section 4.1. They include dimethyl sulfoxide, Poloxamer 188 (pluronic acid), recombinant bovine insulin, and ethanolamine. Further dilution of these substances occurs when the biomass is incorporated with other ingredients at inclusion rates ranging from 5% to 80%, depending on the intended application, to produce the final food. The biomass itself is not a final food. Recombinant proteins

Six recombinant growth factors were used during the early establishment of the cell line. The dilution factor of these growth factors between the early isolation stage and the point at which the MCB was created means that there is a negligible likelihood of these growth factors being present in the final biomass at harvest.[7] Therefore, no risk assessment was required for these growth factors.

Recombinant human insulin was also used in the culture medium to support cell function and growth prior to the creation of the MCB. The culture medium used for MCB production and subsequently for WCB production, cell expansion and biomass production contained recombinant bovine insulin in place of recombinant human insulin. The dilution of the recombinant human insulin between creation of the MCB and biomass harvest means it will not be present in the biomass at harvest. As such, it was not assessed further.

[7] The application specifies a dilution factor of 1.76E+77 at the MCB and 1.26E+94 at the time of harvesting.

3.3 Cell identity and stability

The phenotype and genotype of the cells were monitored to ensure they maintained the characteristics of ESCs during creation of the MCB and WCB and during the production of the cell-cultured duck biomass. Monitoring was conducted at stages that were representative of the production process described in section 3.1. The parameters monitored at each stage of the production process are depicted in Figure 3.

3.3.1 Genetic stability

Genetic stability was evaluated by karyotyping of cells sampled from the MCB, WCB, shake flask culture and SBN-1 bioreactor. For each sample, metaphase chromosome karyotyping of 50 metaphases was performed. The Pekin duck karyotype is diploid and consists of 80 chromosomes: 9 pairs of macrochromosomes and 31 pairs of microchromosomes (Li et al. 2021). Karyotyping results showed a normal diploid karyotype for all samples, and a modal number of chromosomes of 78-79. These results indicate that prolonged culture conditions did not lead to any gross chromosomal changes that would be reflective of genetic instability.

3.3.2 Phenotypic stability and pluripotency

The phenotypic stability of the cells throughout production was monitored by measuring the doubling time, viable cell density, cell viability, cumulative population doubling level, and cell morphology. All measured growth parameters remained within expected ranges for this cell line at different culture scales and throughout the course of a representative production run. Cell morphology was also consistent with that expected for ESCs and remained stable at each point it was monitored. Full details were provided as CCI.

The expression of the key pluripotency markers POU5F3, NANOG, DNMT-3B, and TERT is associated with maintenance of ESC pluripotency, as described in Section 2.6.2. A reverse transcription qPCR (RT-qPCR) assay was used to quantify the expression of each of these genes in cells sampled from the MCB and WCB, as well as during the growth of cells in the seed train and prior to final biomass harvest from the SBN bioreactor (Figure 3). A non-pluripotent cell line was used as a negative control. All four pluripotency genes were expressed at consistent levels in all samples and were highly expressed relative to the non-pluripotent control, indicating that the cells retained their pluripotency during the production phase.

To further demonstrate pluripotency, the capacity of the cells to form embryoid bodies (see Section 2.6.2) was assessed. Cells sampled from multiple production stages between the WCB and biomass harvest (see Figure 3) were placed in culture medium containing components to trigger embryoid body formation (i.e. differentiation). For this assay, the same core pluripotency markers used for the pluripotency assay above were monitored, as well as markers related to early-stage differentiation of stem cells into germ layer cells. Cells from each stage of production maintained the ability to form embryoid bodies, as measured by a decrease in the expression of pluripotency genes alongside increased expression of the early development-associated genes over time.

3.3.3 Conclusion

From cell bank to harvest, cells maintained the expected karyotype for diploid duck cells, as well as consistent growth characteristics. Cells from each stage of production were also shown to maintain their pluripotency and ability to form embryoid bodies, indicating the cells did not differentiate during the production process and the final harvested cells are equivalent to the source cell line. Taken together, the data support the conclusion that the cells in Gourmey's production process are genetically and phenotypically stable.

3.4 Microbiological considerations during production

The production of cell cultured duck biomass involves cell expansion under controlled culture conditions followed by harvesting, washing and freezing of the cell biomass (Figure 3). FSANZ considered microbiological hazards that could plausibly be introduced during these stages, including bacteria or fungi associated with personnel, handling, equipment or transfer steps. The microbiological hazards considered during the production stage are summarised in Appendix-3.

Gourmey have developed a food safety management plan for the production phase, based on an assessment of the biological hazards associated with each of the production stages. This is a HACCP-based plan that incorporates GHP, GMP and GCCP and includes the whole of the production process, cleaning, sanitization and maintenance. In their application, Gourmey have identified a series of Preventative Controls they have implemented to ensure the safety of inputs to the product, which assist in ensuring the safety of the cell biomass. Assessment of food safety management systems, process controls, or post-market operational practices was outside the scope of this assessment.

3.4.1 Cell expansion

During the cell expansion phase, cells undergo a series of proliferation steps resulting in an increased cell density and volume. From a hazard identification perspective, microbiological contamination during cell expansion may come from culture inputs or during transfer between vessels (shake flasks to bioreactor and bioreactor to bioreactor) (Figure 3).

Gourmey confirmed that all the materials used in the production of the cell cultured duck are either food or pharmaceutical grade, minimising the microbial risk associated with culture inputs. Since mesophilic bacteria, yeast or fungi contamination is likely to be visually observable in the shake flasks and thus disposed of before entering the final expansion phase in sealed bioreactors, the cell biomass inside bioreactors can be considered to be “microbiologically sterile” (FSA 2023).

Culture transfer between vessels is therefore a point in the process where microbiological contamination could occur. During cell expansion, the controlled culture environment is conducive to the growth of most foodborne bacterial pathogens should a contamination event occur. However, it is reasonable to expect that this would be detected due to changes in physical parameters monitored during outgrowth. Bacterial and fungal contamination would also be visible microscopically, however, any cell-associated mycoplasmas or viruses would not. Using GCCP and GHP will minimise the risk of microbial contamination during culture transfer.

3.4.2 Harvesting and washing

Once the target cell density is reached, cells are harvested via centrifugation and washed in a saline solution. Removal of cells from the closed bioreactors increases the potential for microbiological hazards from ingredients, personnel, equipment, and the environment to contaminate the cell biomass. *L. monocytogenes* should be considered a significant microbiological hazard which must be managed during harvesting, packaging, and product storage.

Several microbiological risk factors were identified during this stage of production: 1) at the point of harvest, the cell biomass does not have a natural background microflora: 2) presence of residual nutrients and moisture associated with the cell biomass; and 3) neutral pH would support microbial growth. Temperature is the only potential limiting factor for growth of most foodborne bacterial pathogens and is the final critical control point in the

production of the duck cell biomass. The major foodborne pathogen associated with food processing environments is *L. monocytogenes,* while *Salmonella* spp. are considered a hazard associated with product handling. In 2019, the European Commission stated the following criteria for *L. monocytogenes* of <100 cfu/g for RTE products during their shelf life, whether they support growth; and, for RTE foods that support growth, absence in 5 x 25g samples at the point they leave control of the food producer.

Gourmey use a positive release testing programme which has been aligned to the specifications (Section 4.5.2).

3.4.3 Packaging and storage

Following harvesting and washing, the cell biomass is centrifuged and vacuum packaged into food safe packaging and blast frozen for storage at -20°C or less. Freezing prevents microbial growth but does not eliminate viable microorganisms which may be present, including *L. monocytogenes,* and *Salmonella* spp. Contaminating microorganisms may remain viable during frozen storage and can resume growth upon thawing. Although not under consideration in this application, Gourmey stated that the frozen cell biomass will be further processed into final food products which potentially will undergo minimal cooking. FAO/WHO guidance states that cells should be harvested in a manner that maintains the cell/tissue integrity and avoids microbial contamination.

The final harvested cell biomass should be considered a potentially hazardous food (PHF) as defined in Standard 3.2.2. Managing this product as a PHF will ensure the product is kept under temperature control throughout the supply chain to final consumption.

3.5 Production conclusions

The production process produces cell-cultured duck biomass by expanding cells from the WCB through a staged seed train of shake flasks and bioreactors, followed by harvesting, washing, and freezing. From cell bank to harvest, the cells remain genetically and phenotypically stable.

The applicant has identified all cell-culture media and inputs used during the production process. Substances that may plausibly be present in the final biomass are assessed in Section 4.

As there is no specific step within the production process that will reduce or eliminate microbiological contaminants, most critical control points were identified as being points where microbiological hazards can be prevented from entering or increasing during production. Adherence to a HACCP-based food safety system underpinned by good practices that accurately identified critical controls is important in reducing the microbiological risk for cell-cultured food production. In-process monitoring and temperature control as well as final product testing can be used to manage the potential microbiological risk.

4 Biomass assessment

This section covers the harvested cell biomass. The subsequent handling of biomass following harvest, as well as the processing of the finished food product, falls outside the scope of this application and has not been included in the microbiological hazard identification.

FSANZ notes further processing of the cell biomass is considered food handling under Chapter 3 of the Code; food business will need to comply with relevant food safety standards. The toxicology, microbiological, nutrition and dietary exposure assessments and specifications below apply to the harvested cell biomass, not the final mixed food.

4.1 Toxicology assessment

4.1.1 Duck cells

The domestic duck, *Anas platyrhynchos domesticus*, has a long history of safe human consumption, as summarised in Section 2.5.

Allergy to duck meat is rare and typically causes less severe reactions when compared to chicken meat or turkey meat. The allergens that have been characterised in poultry meat are low molecular weight proteins of 5–25 kDa (Hemmer et al. 2016). It is not known whether embryonic stem cells express the allergenic proteins, but in the interests of consumer safety it should be assumed they do.

4.1.2 Media inputs

FSANZ provided the applicant with information on the classification of media inputs into the categories described in Section 3.2. On receipt of the finalised application, FSANZ reviewed the categorisation and concluded that it had been applied correctly. As explained in Section 3.2, Category 1 substances do not require hazard assessment.

4.1.2.1 Category 2 substances

4.1.2.1.1 4-Aminobenzoic Acid or P-aminobenzoic acid (PABA) –

This is an organic compound essential for the synthesis of folic acid in fungi, bacteria and plants, but it is not an essential nutrient for vertebrates. PABA is naturally present in the diet and is also synthesised by the normal microbial flora of the human gastrointestinal tract. Consumption of PABA at 3 g/qid[8] for four weeks was associated with adverse effects in humans, including hepatic injury (EC 2006).

PABA is used as a nutrient in the culture media during the proliferation and expansion phase of production of cell-cultured duck biomass, and is consumed by the cells, so levels in the final product are very low. Exposure to PABA through consumption of the final product is likely to be negligible compared to normal dietary exposure. The levels of PABA were provided as CCI, therefore cannot be included in this report, however, due to the PABA being at very low levels, FSANZ concluded that PABA in the cell-cultured duck biomass is not considered to be a food safety risk.

[8] *Quater in die* (L.), or four times a day

4.1.2.2 Category 3 substances

4.1.2.2.1 Dimethyl sulfoxide (DMSO)

Dimethyl sulfoxide is of low oral toxicity. Small quantities are used during cryopreservation in the production of the biomass.

Mice

Caujolle et al. (1967) reported that mice tolerated an oral dose of 5 g/kg bw/d for 20 days with no adverse effects beyond a transient weight loss at the beginning of the in-life phase. The same authors identified a NOAEL of 2 g/kg bw/d in a 45-day study in rats, with hepatic necrosis observed at a higher dose of 5 g/kg bw/d in the same study.

Rats

Caujolle et al. (1967) identified a NOAEL of 2 g/kg bw/d in a 45-day study in rats, with some necrosis of hepatocytes observed at a higher dose of 5 g/kg bw/d in the same study. In contrast, Smith et al. (1967a) gave doses of 1, 3 and 10 g/kg BW/day by gavage to rats for 59 days and observed only a slight and reversible weight reduction.

Dogs

A NOAEL was not established in repeat-dose oral studies of DMSO in dogs conducted by Smith et al. (1967a), but they did not use doses lower than 2.5 g/kg bw/d.

Non-human primates

The oral NOAEL for DMSO in non-human primates is 2970 mg/kg BW/day (ECHA, 2023).

Developmental and reproductive studies

Caujolle et al (1967) did not observe any no teratogenic effects were observed at doses up t0 12 g DMSO/kg bw/d in mice. In rats, malformed pups were slightly more frequent in treated rats than controls, but there was no increase in incidence of malformed pups between maternal doses of 5 or 10 g/kg bw/d.

Special studies

Rubin and Mattis (1966) conducted an oral toxicity study of DMSO in Beagle dogs (6/sex/group), with treatment lasting for 23 weeks, followed by up to 31 weeks of recovery. Initially dogs were dosed by gavage with 0, 2.5, 5, 10, 20 or 40 g DMSO/kg bw/d for five days per week, although the highest two doses were not tolerated. The dogs in those groups were transferred to the 10 g/kg bw/d group. Response to the mydriatic effect of tropicamide was lost in all groups from Week 4. Changes in lens translucency were recorded from Week 9 in dogs dosed with ≥5 g/kg bw/d, and from Week 13 in dogs dosed with ≥2.5 g/kg bw/d. The lens changes were only partially reversible. The authors added a brief note at the end of their publication to state that no lens changes had been observed in Rhesus monkeys dosed with 5 g DMSO/kg bw/d for 100 days.

The eye was identified as the most sensitive target organ in subchronic and chronic oral toxicity studies conducted by Noel et al. (1975) in dogs and pigs. Dogs were more sensitive than pigs to this toxic effect. Doses of 1, 3 and 9 mL/kg bw/d (1.1, 3.3 and 9.9 g/kg bw/d) were administered to dogs for five days every week for up to two years, with regular ophthalmological examinations. Ocular lesions were first observed after 5 to 10 weeks of

dosing. Progressive loss of transparency of the lens was observed in all dose groups, and changes in the vitreous humour were observed after 9 months of dosing in dogs in the 3 and 9 mL/kg bw/day groups.

The ocular toxicity reported in non-primate species, with the dog the most sensitive species, does not appear to be relevant to human health risk assessment. Gordon and Kleberger (1968) summarised numerous protracted human exposures to DMSO that were not associated with any ocular lesions. These included several cohorts who were treated topically with at least 30 grams DMSO per day for between 158 days and 30 months. Another cohort were treated with ocular DMSO at up to 66%/d for up to 19 months, with no ocular lesions resulting. Review of 9521 patients, treated with DMSO for up to 21 months, did not identify a single case of exposure leading to ocular lesions.

Human studies

A systematic review of adverse effects of DMSO in humans was conducted by Kollerup Madsen et al. (2019). DMSO has been used for medical treatment and as a pharmacological agent in humans since the 1960s. Currently DMSO is used for treatment of interstitial cystitis, and as a penetrating vehicle for various drugs. Adverse reactions are generally mild and transient, and DMSO is safe for human use in small doses.

In the production of cell-cultured duck biomass, only small quantities of DMSO are used during cryopreservation, and there is a dilution effect through subsequent cell expansion. The likelihood of exposure to DMSO through consumption of cell-cultured duck biomass is therefore negligible.

4.1.2.2.2 Poloxamer 188 (pluronic acid; Pluronic® F-68)

This is a non-ionic detergent used in the culture medium to protect cells from hydrodynamic damage. It is a triblock copolymer of the form polyethylene oxide-polypropylene oxide-polyethylene oxide with an average molecular mass is 8,400 g/mol. The applicant proposes a specification stating a maximum level of poloxamer 188 of 500 ppm (0.05%).

. Singh-Joy and McLain (2008) cited a 1967 study that found that the oral LD50 in rats is >15 g/kg bw. The US FDA (2017) cited oral NOAELs of 2500 mg/kg bw/d for rats and 100 mg/kg bw/d for dogs.

Most animal or human studies submitted in the application or located by literature search concern intravenous use of poloxamer 188.

Existing regulations

The US FDA permits the use of poloxamer 188 as an excipient in oral pharmaceuticals. An assessment of a pharmaceutical delivered with poloxamer 188 noted the daily dose was greater than the FDA Inactive Ingredients Guide maximum oral dose of 18 mg/day, but that toxic effects are not expected at <5000 mg/day poloxamer 188 (US FDA 2007).

The applicant proposes a maximum of 500 ppm (0.05%) w/w poloxamer 188, as a specification in cell-cultured duck biomass. At this maximum, a serving size of 145 g cell-cultured duck biomass (see sections 4.3.2 and 4.4.5.2 for details on this serve size) exposure to poloxamer 188 through consumption of cell-cultured duck biomass is therefore very low.

4.1.2.2.3 Recombinant bovine insulin

No recombinant bovine insulin was found in five batches of cell-cultured duck biomass (LOD 0.5 µg/g). FSANZ also notes that insulin is a peptide hormone that is broken down to amino acids by digestive processes and is not endocrinologically active by the oral route. Recombinant bovine insulin is not considered to pose a risk to consumers of cell-cultured duck biomass.

4.1.2.2.4 Ethanolamine

Ethanolamine is essential for the formation of cell membranes and is naturally present in food. It is abundant in the human body, found in every cell as the head group of phosphatidylethanolamine, and as free ethanolamine in body fluids such as blood and breastmilk (Patel and Witt 2017).

The toxicology of mono-, di-. and triethanolamine was reviewed by Knaak et al. (1997). Acute toxicity of monoethanolamine is low, with oral LD50 values ≥ 0.7 g/kg in the mouse, 1.1 g/kg in the female rat, and 1.2 g/kg in the male rat. When repeat-dose dietary studies in rats were summarised, the lowest dose at which toxic effects were observed was 80 mg/kg bw/d. Most oral studies in rats were via drinking water. The lowest dose at which an adverse effect was observed in rats dosed via drinking water was 160 mg/kg bw/d. Target organs included liver, kidneys, and blood (anaemia).

Many genotoxicity assays have been conducted and the great majority showed negative results. Ethanolamine was not considered to be carcinogenic in 2-year rodent assays (Knaak et al. 1997).

Pereira et al. (1987) found that a maternal dose of 850 mg/kg bw/day caused a maternal mortality rate of 16% in mice, but had no effect on litter size, pup birthweight, pup survival or postnatal weight gain of pups. Hellwig and Liberacki (1997) observed no adverse effects on fetuses in a developmental toxicity study of ethanolamine in Wistar rats, even at doses at which there was maternal toxicity. Rats were dosed by gavage with 0, 40, 120 or 450 mg/kg bw/d from gestation days 6 through 15 inclusive. No maternal toxicity was observed at ≤120 mg/kg bw/d. At 450 mg/kg bw/d, decreases in feed consumption, body weight and body weight gain were observed in dams. These results contrast with those of an earlier study by Mankes (1986) who conducted a developmental study of ethanolamine in Long-Evans rats. Timed-pregnant rats were dosed by gavage with 0, 50, 300 or 500 mg ethanolamine/kg bw/d from gestation day 6 to 15 inclusive. Adverse effects were observed at all doses and included decreased mean value for pup bodyweight, and increased incidences of dead or resorbed pups and malformed pups. FSANZ notes several drawbacks with the Mankes (1986) study, which was not conducted according to any guideline. There is a lack of dose-response relationship for some adverse effects including *in utero* dead pups, resorbed pups, and malformed pups. In addition, some findings in pups were recorded as deformities which are now recognized to be developmental delays (e.g. wavy ribs, degree of vertebral ossification). The weight of evidence supports the conclusion that ethanolamine is not a developmental or reproductive toxicant.

The proposed specification for ethanolamine in cell-cultured duck biomass is < 30 µg/g, and analytical data from five independent batches found levels of ethanolamine well below that level, ranging between 3.0 and 13.3 µg/g (average: 6.94 µg/g). A serving size of 145 g cell-cultured duck biomass, and a maximum ethanolamine content of 13.3 µg/g, this would result in a total exposure of 1.929 µg, or 27.6 µg/kg bw for a 70 kg individual. The margin of exposure between the maternal NOAEL of 120 mg/kg bw/d identified by Hellwig and Liberacki (1997) and this exposure level is 436.

4.1.3 Conclusion

The domestic duck has a long history of safe human consumption. Allergy to duck meat is rare.

Media inputs used in production and potentially present in the finished product are PABA, DMSO, poloxamer 188, recombinant bovine insulin and ethanolamine.

PABA is naturally present in the diet and is also synthesised by the normal microbial flora of the human gastrointestinal tract. Human exposure to PABA through consumption of the final product is likely to be negligible compared to normal dietary exposure and it is not considered to be a food safety risk.

Dimethyl sulfoxide is of low oral toxicity. It has a long history of pharmaceutical and medical use in humans, and adverse reactions are generally mild and transient. Small quantities are used during cryopreservation in the production of the biomass, but DMSO is unlikely to be present in the final product due to a dilution effect.

Recombinant bovine insulin has not been detected in the final product. Insulin is a peptide hormone that is broken down to amino acids by digestive processes. It is therefore not endocrinologically active by the oral route.

Ethanolamine is naturally present in food, and abundant in the human body. Comparison of the maternal NOAEL identified in a rat study (Pereira et al. 1987) and the highest level determined in cell-cultured duck biomass produces a large MOE of 436.

4.2 Microbiology assessment

FSANZ assessed microbiological data provided for multiple batches of harvested cell cultured duck biomass. Testing included relevant contamination indicator organisms and selected foodborne pathogens. Across the batches assessed, those pathogens were reported as not detected at the stated limits of detection.

Microbiological testing data of the cell biomass were considered as supporting information within the overall risk assessment and were not relied upon to establish validation, verification or compliance outcomes. The microbiological risk assessment was constrained primarily by limited production history and the absence of detailed information on the final stages of production (Section 3.4). Additional uncertainty arose from the downstream processing and the intended use of the cell biomass in food. The relationship between identified hazards and available microbiological evidence is summarised in Appendix-3.

4.2.1 The cell biomass structure

The harvested cells are a homogeneous uniform cell biomass, with the potential for a microbial hazard to be evenly distributed throughout the product during harvesting process. This is different to comminuted or ground meats where the distribution of microorganisms is heterogeneous. The cell biomass is therefore not equivalent in structure or risk to that of comminuted meat products and would require a thorough cook step to ensure any microorganisms, if present, are adequately mitigated.

The harvested biomass has intrinsic properties, including pH and water activity, that do not inherently restrict microbial growth. Accordingly, microbiological testing results were interpreted in the context of the described production and handling steps prior to further processing. Potential hazards identified in the microbiological assessment of the cell cultured

duck are discussed below.

4.2.2 Listeria monocytogenes

L. monocytogenes is ubiquitous in the environment and can become established in food processing environments. *L. monocytogenes* has been isolated from domestic and wild animals, birds, soil, vegetation, fodder and water; as well as from the floors, drains and wet areas of food processing factories (FSANZ 2013). While *L. monocytogenes* generally does not affect healthy people, for susceptible populations, *L. monocytogenes* can cause severe disease that is potentially life threatening, with a case fatality rate of 15-30%. Published data indicate that contaminated foods responsible for foodborne listeriosis usually contain levels of *L. monocytogenes* >100 cfu/g (Ryser and Buchanan 2013).

Microbiological contamination can occur through poor hygienic practices of food handlers; or by exposure of food ingredient to contaminated air, water, raw materials or food-contact surfaces (Codex 2007). *Listeria* has been identified as a potential hazard that could be introduced during the harvesting and washing stages of production of the cell cultured duck biomass.

4.2.3 Other foodborne pathogens

Foodborne pathogens, including faecal-associated pathogens such as *Salmonella* and *E. coli* are potential hazards that could contaminate the cell biomass during further processing either from personnel or the equipment. Given there is no critical control point beyond this point to manage this risk, maintaining temperature control is essential, and a recognised microbiological control step (e.g. cooking) should be applied before consumption.

4.2.4 Other hazards

Gourmey have indicated that production will be scaled up to a level of 2500 litre bioreactor. Based on the current data available, FSANZ notes it is not possible to characterise the microbial risk at this production scale, particularly during harvesting and washing of the cell biomass. However, evaluation of changes in production using HACCP, as well as demonstration of meeting the microbial specifications and process monitoring will enable effective microbial risk management at increased production levels.

4.3 Nutrition assessment

4.3.1 Objectives of the nutrition risk assessment

The objectives of the nutrition risk assessment were to:

- Compare the nutritional composition of cell-cultured duck to comparator foods and assess whether its consumption would result in nutritional imbalance in the diet.
- Evaluate whether any antinutritional factors present in cell-cultured duck affect the bioavailability of other nutrients.

4.3.2 Approach for the nutrition risk assessment

Gourmey expects cell-cultured duck biomass to be used as an ingredient in the manufacture of cell cultured pan-seared foie gras and other cell-cultured duck meat analogues to be consumed in the same or similar patterns as conventional counterpart foods. The applicant has advised that cell-cultured duck is not intended to fully replace conventional duck meat products but to provide an alternative to conventional products. Results from the 2011-12 Australian National Nutrition and Physical Activity Survey (NNPAS) reported that less than 1% of respondents consumed duck (extracted by FSANZ based on ABS 2015a).

Depending on the intended use, portion sizes of cell-cultured duck products are expected to range from 28–80 g, with cell-cultured duck comprising 5–80% of the product by weight. For this assessment, a portion of duck of 181 g was used (see Section 4.4.5.2 for derivation) and was modelled at the applicant-suggested inclusion rates of 40% (72 g) and 80% (145 g). The 40% inclusion scenario was used primarily to assess nutrient adequacy as it represents a realistic midpoint formulation, while the 80% inclusion scenario represents a conservative, high consumption scenario for assessing potential excessive intakes.

Compositional data for 5 batches of cell-cultured duck were provided by Gourmey. Details of the composition of the cell-cultured duck are in Appendix-1. The nutrient content of cell-cultured duck was compared to conventional duck (duck, breast, lean, raw) and chicken breast (chicken, breast, lean flesh, raw) using data from the Australian Food Composition Database (FSANZ 2025) and assessed against the Nutrient Reference Values for Australia and New Zealand (NRV) (NHMRC and MoH 2006).

As cell-cultured duck is expected to be used as an ingredient in a range of food matrices, duck breast was used as a generic comparator food. However, given the low consumption of duck breast in the general population, chicken breast was also used as a comparator to reflect a higher potential consumption scenario. Breast meat was selected as a comparator as it is the primary muscle tissue consumed from poultry and is widely used as a reference food in dietary surveys, food composition databases and exposure assessments. A portion size of 142 g was used for chicken breast (see Table 2; extracted by FSANZ based on ABS 2015a). Nutrient comparisons were undertaken on both a per portion and per 100 g basis. A discussion of how the serving sizes for comparator foods were determined is provided in Section 4.4.5.2.

NRVs used included the Estimated Average requirement (EAR), Adequate Intake (AI), and where relevant, Upper Level of Intake (UL). EAR and UL are to be used for comparisons with usual (long term) intakes from the whole diet, and AI are based on population intakes. Therefore, any comparisons of nutrient intakes from single portions of a food are outside the context of intakes from the whole diet and are for indicative or comparative purposes only, not to assess adequacy or excess. For this assessment, the EAR for men aged 19-30 and the AI for men aged 19 and over was considered most appropriate reference point as it represents a standard adult sub-group used in nutrient requirement assessments and provides a suitable benchmark for comparison with usual dietary intakes in a generally healthy adult population. The UL for children aged 1-3 years was used as a conservative approach to account for the most vulnerable population group.

4.3.3 Macronutrients

Gourmey provided data on the macronutrient composition of cell-cultured duck, including energy, protein, amino acids and fatty acids. Compared with conventional duck and chicken breast, cell-cultured duck is lower in energy, protein and essential amino acids on both a per 100 g and per portion basis, has a similar total fat content per portion, contains no detectable carbohydrate (consistent with conventional duck and chicken breast), and has a higher moisture content (Table A1.1). FSANZ has also assessed CCI provided by the applicant on saturated, unsaturated and trans-fat levels in cell-cultured duck, these nutrients were not considered a nutritional concern.

Although protein and amino acids are lower than those of conventional duck and chicken, given the current low consumption of duck and duck-based products, the low likelihood that cell-cultured duck will fully replace other protein foods in the diet, and evidence that protein intakes in Australia and New Zealand are generally adequate (ABS 2026; University of Otago and Ministry of Health 2011), these differences are not considered a nutritional concern.

There are no nutritional concerns related to the macronutrient composition of cell-cultured duck.

4.3.4 Micronutrients

Gourmey provided data on the vitamin and mineral composition of cell-cultured duck. Compared with conventional duck and chicken breast on a per portion basis, cell-cultured duck contains lower levels of several vitamins (niacin, pyridoxine, cobalamin, vitamin D, pantothenic acid) (Table A1.2), with riboflavin present at levels lower than conventional duck but higher than chicken breast.

Cell-cultured duck also contains lower levels of some minerals (phosphorus, potassium and magnesium) per portion (Table A1.3). Per portion, cell-cultured duck contains higher levels of biotin, iron and zinc, similarly low levels of calcium and manganese compared to conventional duck and chicken breast and sodium at levels comparable to conventional duck and chicken breast.

For vitamins and minerals present at lower levels than comparator foods, cell-cultured duck generally makes a modest contribution to the EAR or AI per portion, furthermore duck-based products are consumed infrequently in Australia and New Zealand. Where micronutrients were present at higher levels, estimated intakes under conservative consumption scenarios remained below established UL, where these have been set, or were otherwise not associated with adverse effects. On this basis, FSANZ has no nutritional concerns related to the overall micronutrient composition of cell-cultured duck.

4.3.4.1 Thiamin

The level of thiamin in cell-cultured duck has been considered using data accepted as CCI. The assessment concluded the level of thiamin in cell-cultured duck is not considered a nutritional concern.

4.3.4.2 Biotin

Cell-cultured duck contains higher levels of biotin than conventional duck or chicken breast, providing approximately the AI for biotin per portion (Table A1.2). No UL has been established for biotin and no adverse effects have been observed at high intakes. At the estimated inclusion rates assessed (i.e. 40% and 80% cell-cultured duck in the final product) the level of biotin present in cell-cultured duck is not considered a nutritional concern.

4.3.4.3 Folate

Cell-cultured duck contains 67 µg folate per portion. Neither conventional duck nor chicken breast contain folate. The amount of folate in one portion of cell-cultured duck equates to 21% of the EAR (as dietary folate equivalents). The application does not specify the form of folate present in the final cell-cultured duck product. As the UL applies only to folic acid, a conservative assumption was made that all folate present is in the form of folic acid. At the maximum suggested inclusion rate of 80%, the level of folate in a portion of cell-cultured duck would remain below the UL (Table A1.4). The level of folate in cell-cultured duck is not considered a nutritional concern.

4.3.4.4 Vitamin D

Cell-cultured duck contains lower levels of vitamin D than conventional duck and chicken. A portion of cell-cultured duck provides 7% of the AI, which is lower than that provided by conventional duck (218%) and chicken (105%) (Table A1.2). Population intake data

indicates that average vitamin D intakes in Australia for people aged 2 years and over are close to the AI, with major dietary contributors including cereal-based mixed dishes, eggs, and poultry and feathered game (ABS 2025).

Given the low consumption of duck and duck-based products and the likelihood that cell-cultured duck would minimally displace other poultry foods, the level of vitamin D in cell-cultured duck is not considered a nutritional concern.

4.3.4.5 Vitamins A, E and K

Retinol (vitamin A), vitamin E and vitamin K were present in cell-cultured duck at levels below reported analytical limits (Table A1.2). Conventional duck does not contain retinol and chicken breast provides only a small contribution to the EAR for retinol. Conventional duck and chicken breast contribute only modestly to dietary vitamin E and vitamin K intake.

As these fat-soluble vitamins are not major contributors to dietary intake from duck or chicken products and given the expected low frequency of consumption of cell-cultured duck-containing products, the low levels present in cell-cultured duck are not considered a nutritional concern.

4.3.4.6 Iron

Cell-cultured duck contains higher levels of iron than conventional duck and chicken breast. A portion of cell-cultured duck provides 163% of the EAR, compared with 97% from conventional duck and 6% from chicken breast (Table A1.3).

At the maximum suggested inclusion rate of 80%, iron intake from a portion of cell-cultured duck would remain below the UL for adults (43%) and all age groups of children, including infants and children aged 1-3 years (20 mg/day; approximately 98% under a conservative, single-portion scenario).

Given the expected low frequency of consumption of cell-cultured duck, including by young children, FSANZ does not consider the iron content of cell-cultured duck to be a nutritional concern.

Population intake data indicate that inadequate intake of iron remains more prevalent than excess intake in Australia and New Zealand. The 2023 NNPAS found that 17.3% of Australians aged 2 years and over had inadequate iron intake from food and beverages, while intakes above the UL were reported in less than 5% of all age and sex groups (ABS 2026). The 2008/09 New Zealand Adult Nutrition Survey similarly did not identify excess iron intake as a population-level risk and reported an iron deficiency prevalence of 4.2% for respondents 15 years and above (University of Otago and Ministry of Health 2011).

Given its higher iron content relative to comparator foods, iron intake from cell-cultured duck was further assessed in the dietary intake assessment (Section 4.4).

4.3.4.7 Selenium

The selenium content of cell-cultured duck was below 0.2 mg/100 g. By comparison, the selenium content of conventional duck and chicken breast is substantially higher (Table A1.3). Population intake data indicate that a small proportion of Australians have inadequate selenium intake (5.3% aged 2 years and above) (ABS 2026), with poultry and feathered game being one of several contributing food groups (ABS 2025). While conventional duck and chicken contribute to dietary selenium intake, cell-cultured duck is expected to be consumed infrequently and would only partially displace other poultry foods.

The selenium content of cell-cultured duck is not considered a nutritional concern.

4.3.4.8 Sodium

Cell-cultured duck contains lower levels of sodium than conventional duck and higher levels than chicken breast per portion (Table A1.3). At the maximum suggested inclusion rate of 80%, the level of sodium in a portion of cell-cultured duck provides 156 mg of sodium. This level is below the UL for children aged 1 –3 years (1000 mg/day) and suggested dietary target for adults (2000 mg/day). The sodium content of cell-cultured duck is therefore not considered a nutritional concern.

4.3.4.9 Zinc

Cell-cultured duck contains higher levels of zinc than chicken breast and similar levels to conventional duck on a per portion basis (Table A1.3). At the maximum suggested inclusion rate of 80%, zinc intake from a portion of cell-cultured duck remains below the UL. The zinc content of cell-cultured duck is therefore not considered a nutritional concern.

4.3.4.10 Other vitamins and minerals assessed

Gourmey provided compositional information for certain vitamins and minerals that may be present at low levels in the final food, including vitamin C, choline, chromium, copper, molybdenum and iodine. These nutrients were assessed by FSANZ however due to their low levels and limited contribution to dietary intake from comparator foods, they were not considered further as they are not expected to pose a nutritional or public health concern.

4.3.5 Effect of cell-cultured cells on absorption of nutrients

FSANZ considered whether cell-cultured duck could affect the absorption of other nutrients. FSANZ undertook a literature search in PubMed[9] on 12 November 2025 to identify any relevant literature. No relevant studies were identified. The applicant advised that no antinutrients are used in the cell culture media. Antinutrients are generally associated with foods of plant origin (Gemede and Ratta 2014).

4.3.6 Conclusion

FSANZ did not identify any nutritional concerns associated with the consumption of cell-cultured duck, noting the low expected frequency of consumption and the use of conservative scenarios in the assessment.

The macronutrient composition of cell-cultured duck was generally similar to or lower than comparator foods. Although protein levels were lower than those of conventional duck and chicken breast, this is not expected to result in a nutritional imbalance given that most Australians and New Zealanders consume sufficient protein in their diet and the low expected frequency of consumption of cell-cultured duck-containing products.

The micronutrient composition of cell-cultured duck was assessed in comparison with comparator foods, and estimated nutrient intakes were compared with relevant NRVs. While

[9] Search terms: ("cultured duck" or "in vitro duck" or "in-vitro duck" or "lab-grown duck" or "cell-based duck" or "cultivated duck" or "cultured quail" or "in vitro quail" or "in-vitro quail" or "lab-grown quail" or "cell-based quail" or "cultivated quail" or "cultured chicken" or "in vitro chicken" or "in-vitro chicken" or "lab-grown chicken" or "artificial chicken" or "cell-based chicken" or "cultivated chicken" or "cultured meat" or "in vitro meat" or "in-vitro meat" or "lab-grown meat" or "artificial meat" or "cell-based meat" or "cultivated meat") AND ("antinutrient" or "antinutritional" or "anti-nutrient" or "anti-nutritional" or "bioactive" or "biologically active" or "absorbed" or "absorption")

cell-cultured duck contained lower levels of several vitamins and minerals compared with comparator foods, it is expected to only partially displace these foods in the diet and is therefore not expected to result in a nutritional imbalance. Where cell-cultured duck contained higher levels of micronutrients including iron, zinc, folate and biotin, estimated intakes remained below relevant UL, where established. On this basis, no micronutrient-related nutritional concerns were identified.

FSANZ did not identify evidence that cell-cultured duck would affect the bioavailability of other nutrients.

4.4 Dietary intake/exposure assessment

Dietary intake/exposure assessment provides an estimate of the magnitude, frequency and duration (where appropriate) of intake/exposure to the risk factors identified in this assessment.

4.4.1 Objectives

- Estimate potential consumption of cell-cultured duck, with comparisons to the substitute food where appropriate.
- Estimate the dietary intake of certain nutrients in cell-cultured duck, considering both adequacy and safety of intake as identified as relevant in the nutrition risk assessment.
- Estimate the dietary exposure to any production input that may remain in harvested cells; however, the hazard assessment did not identify any substances that required a detailed dietary exposure assessment.

4.4.2 Methodology

Dietary intake/ exposure assessments require data on the concentration of the chemical/nutrient of interest in the food requested and consumption data for the foods, usually collected through a national nutrition survey.

The dietary intake assessment was conducted to estimate the levels of chronic dietary intake of nutrients in cell-cultured duck that were relevant following the nutrition risk assessment (e.g. iron). Chronic dietary intake estimates are used to represent the long term, usually life-long, dietary intake for the population from the range of foods containing the chemical of interest.

The dietary intake assessment for this application was undertaken using FSANZ's dietary modelling computer program Harvest, along with deterministic calculations outside of Harvest. The latter was done for estimating total dietary nutrient intakes including cell-cultured duck. A summary of the general FSANZ approach to conducting dietary intake assessments is on the FSANZ website. A detailed discussion of the FSANZ methodology and approach to conducting dietary intake assessments is set out in *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2024). Nutrient intakes were also determined from published information from national nutrition surveys.

The dietary intake assessment also included an estimation of serving size based on how people could eat the suggested final products containing cell-cultured duck in comparison to comparator foods.

4.4.3 Food consumption data used and population groups assessed

The food consumption data used for the dietary intake assessments were:

- 2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS), one 24-hour food recall survey of 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% of respondents (ABS 2015a).

- 2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS), one 24-hour food recall covering 3,275 New Zealand school children aged 5-14 years, with 25% of respondents also completing a second 24-hour recall (MoH 2005).

- 2008–09 New Zealand Adult Nutrition Survey (2008 NZ ANS): a 24-hour recall of 4,721 New Zealanders aged 15 years and above, with a second 24-hour recall undertaken for 25% of respondents. (MoH 2011a; MoH 2011b).

The design of these nutrition surveys and the key attributes, including survey limitations, are set out on the FSANZ website.

In this assessment, dietary intakes were estimated for 'consumers only' (e.g. consumers of conventional duck and chicken meats) where food consumption amounts were used in the assessment. Nutrition survey respondents who had no consumption of these foods were not included in the results presented. All results were weighted to make them representative of the respective populations.

For the chronic dietary intake assessment, one day of food consumption data from both of the New Zealand surveys were used, whereas the average of two days of data from the 2011-12 NNPAS was used for Australia. Two-day average intakes better reflect longer term estimates of dietary intake and therefore are a better estimate of the chronic dietary intake. Where usual intakes of nutrients are presented for Australia, these were derived using the National Cancer Institute Method (NCI Method) which uses the two days of consumption data from the survey. Where usual intakes are reported for New Zealand, these were estimated using the Iowa State University method C-SIDE. All usual intakes are derived from foods and beverages, but do not include intakes from dietary supplements.

For the nutrient intake assessments, population subgroups were used for Australia and New Zealand according to NRVs age/sex groups (NHMRC and MoH 2006). Details of the population subgroups are provided in Table A2.1. The results from the New Zealand nutrition surveys were not reported exactly according to the NRV age group cut offs. Hence, adjustments were made when presenting New Zealand results in comparison to the NRV.

Whilst data from the 2023 NNPAS (ABS 2025) has been released by the ABS, only summary nutrient intakes and food consumption statistics at the food group level and usual nutrient intakes have been published to date. At the time of this assessment the raw data from the survey that allows extraction of consumption for specific foods was not available to FSANZ, therefore the 2023 NNPAS data were not able to be used for this dietary intake assessment.

4.4.4 Iron intake assessment

The nutrition risk assessment found that cell-cultured duck contains a higher concentration of iron than conventional duck and chicken breast, and that iron intake would approach the UL for infants and children aged 1-3 years under conservative assumptions (i.e. if this age group consumed the cell-cultured duck at a consumption amount equivalent to the mean serving size estimated for the total population, with cell-cultured duck included at the

maximum suggested inclusion rate of 80%). Hence, detailed intake assessments were conducted for iron to see whether iron intakes are at a safe level (e.g. below the UL) considering the usual intake levels from food and beverages (baseline scenario) and for some cell-cultured duck consumption scenarios using respective consumption amounts for different NRV age/sex groups.

Being a new food there is no consumption data available for cultured duck cells in national dietary surveys. Due to limited consumption data on conventional duck meat in the Australian and New Zealand national dietary surveys, chicken meat consumption data was alternatively used for this assessment as the best comparator and as a proxy for an amount of cell-cultured duck that could be consumed. Use of chicken meat as the comparator is also aligned with the nutrition risk assessment.

For this assessment, chicken consumption amounts at the mean and 90th percentile (P90) were derived. These amounts differ for each of the specific population groups assessed. The chicken consumption values used to represent the cell-cultured duck consumption amounts are representative of a longer-term consumption pattern taking into account chicken meat that is eaten as a serve in its own right as well as other amounts from mixed dishes such as in main meals (e.g. stews or curries) or other uses such as in sandwiches.

4.4.4.1 Scenarios assessed

Gourmey has advised that inclusion of cell-cultured duck biomass in final foods by weight is in the rage of 5-80%. Based on this suggested inclusion level, two scenarios were tested at 80% (the upper limit representing the worst-case scenario) and at 40% as a mid-point to better represent different final foods proposed (e.g. cell-cultured foie gras, cell-cultured duck pâté, and other cell-cultured duck analogues such as cultured minced duck meat and cell-cultured duck breast).

- **Scenario 1:** Consumers choose to eat cell-cultured duck at amounts equivalent to 80% of the longer-term total consumption of chicken meat, in addition to conventional meat including chicken (the worst-case scenario).

- **Scenario 2:** Consumers choose to eat cell-cultured duck at amounts equivalent to 40% of the longer-term total consumption of chicken meat, in addition to conventional meat including chicken.

Both scenarios incorporate a very small degree of double counting as consumption of conventional chicken meat is not removed before adding in consumption of cell-cultured duck. This is a conservative assumption made as part of FSANZ's standard tiered approach to undertaking dietary intake assessments, where further, more refined assessments that may remove baseline chicken meat consumption, can be undertaken if the first tier risk assessment results indicate the need for a more refined assessment.

4.4.4.2 Concentration data used

Iron concentration data for cell-cultured duck were taken from the application (CCI data). Usual iron intake levels from food and beverages and intakes from dietary supplements[10] (e.g. vitamin and mineral tablets) were sourced from the Australian and New Zealand national nutrition surveys (ABS 2015a; ABS 2015b; MoH 2003; University of Otago and MoH 2011; MPI 2018) and were considered as the baseline intake levels.

[10] Mean nutrient intake data from dietary supplements for iron is available only for Australia, therefore it was also used as the level of intake for New Zealand.

4.4.4.3 Calculating the iron intake

The intake of iron from cell-cultured duck was estimated by multiplying the estimated mean and high (P90) consumption amounts of cell-cultured duck (using chicken consumption data for Australia and New Zealand representing a longer-term consumption amount) by iron concentration in cell-cultured duck. To estimate the total iron intake, the intake of iron from cell-cultured duck was added to baseline mean and high intakes of iron. For the high intakes of iron, the highest reported percentile from the published usual intakes of iron was used for each country: 95th percentile intakes for the Australian population (ABS 2015c) and 90th percentile intakes for the New Zealand population. The usual intakes of iron from the 2023 NNPAS (ABS 2026) were not used for this assessment because the reported age/sex groups do not exactly match with the NRV age/sex groups assessed. Despite this, there are no substantial differences in the intake levels reported between the 2011-2012 and 2023 NNPAS that would change the overall conclusions.

The dietary intake assessment was designed to calculate the most realistic estimate of dietary intakes for iron as possible. However, where significant uncertainties in the data and information exist, conservative assumptions were generally used to ensure that the estimated dietary intake is not an underestimation.

4.4.5 Results

4.4.5.1 Duck and chicken meat consumption

Consumption of conventional duck and chicken meat for Australia and New Zealand was initially estimated for comparison purposes because it was generally assumed that consumers choose to eat cell-cultured duck in the same way they eat chicken meat. For this estimation, the Harvest ‘raw commodity model’ was used that considers consumption data of duck and chicken meats eaten ‘as is’ (i.e. as a piece on a dinner plate) and from mixed dishes, such as meat in a sandwich, on a pizza, in stir fries etc. The mean and P90 consumption, along with proportion of consumers, for conventional duck and chicken meats that were included in the nutrition surveys for Australia and New Zealand are shown in Table 1. The Australia and New Zealand populations had the higher mean and P90 consumption for chicken meat with higher proportion of consumers than duck meat.

The mean and P90 chicken meat consumption for several Australian and New Zealand population subgroups (according to the NRV age group) were also estimated and provided in Table A2.2 (Appendix-2 These results were used when estimating iron intake from cell-cultured duck for the respective population subgroups for the scenarios assessed.

Table 1 *Estimated long-term duck and chicken meat consumption for Australia and New Zealand**

Meat type	Australia**			New Zealand**					
	2 years and above			5–14 years			15 years and above		
	Consumption (g/day)		% cons to resp.#	Consumption (g/day)		% cons to resp.#	Consumption (g/day)		% cons to resp.#
	Mean	P90		Mean	P90		Mean	P90	
Duck	53	101	<1	18	24	<1	91	253	<1
Chicken	94	190	61.8	90	192	41.1	127	262	38.7

* Harvest raw commodity model was used for this estimation.
** Average of two days of consumption data for Australia and one day of data for New Zealand were used.
# Consumers as a % of total respondents.

4.4.5.2 Serving size

For this assessment, day one consumption data for the three surveys were estimated using the Harvest 'nutrient intake model' that considers consumption data where respondents reported meat eaten 'as is' (i.e. as a piece on a dinner plate). It does not include consumption amounts from mixed dishes such as meat on pizzas, on sandwiches or in casseroles. Therefore, the consumption amounts derived using this method represent a portion size of meat, and the consumption amounts, which are derived from a distribution of consumption amounts from individuals, are not skewed down by the consumption of smaller amounts of meat from mixed dishes.

The estimated serving sizes for duck and chicken meat consumption for Australia and New Zealand are provided in Table 2. The mean and P90 conventional duck meat consumption for the Australian population are 181 g/day and 368 g/day respectively. The mean conventional duck meat consumption amount of 181 g was considered as the appropriate serving size for the suggested cell-cultured duck final products with the harvest cells inclusion level of 40% and/or 80% as appropriate in the nutrition risk assessment, and the higher inclusion rate to inform the serve size used for the toxicological assessment (145 g). Due to limited consumption data availability for the New Zealand population, the serving size derived for the Australian population was considered appropriate for the New Zealand population as well. Respective mean and P90 chicken meat consumption were also estimated for comparison purposes.

Table 2 *Estimated serving sizes for duck and chicken meat consumption for Australia and New Zealand**

Meat type	Australia			New Zealand					
	2 years and above			5–14 years			15 years and above		
	Consumption (g/day)		% cons to resp.#	Consumption (g/day)		% cons to resp.#	Consumption (g/day)		% cons to resp.#
	Mean	P90		Mean	P90		Mean	P90	
Duck	181	368	<1	NC	NC	NC	NR	NR	NR
Chicken	142	268	17.1	110	195	21.4	132	232	21.2

* Harvest nutrient intake model was used for this estimation. One day data from the three surveys was used.
# Consumers as a % of total respondents.
NC: no consumption has been reported in the survey.
NR: not reported due to too few consumers to derive reliable consumption values.

In relation to consumers' insights/perception of cell-cultured meat in Australia and New

Zealand, the 2023 FSANZ Consumer Insights Tracker[11], an online survey of 1237 Australian and 810 New Zealand consumers aged 18 years and older reported that only 23.6% of consumers said they would include cell-cultured meat in their diet. Most of them (50.5%) said cell-cultured meat would partially replace traditional meat (e.g. farm-raised beef, chicken or pork), 14.3% of them said cell-cultured meat would completely replace the traditional meat and 37.5% of them said cell-cultured meat would be consumed in addition to the traditional meat. A consumers' perception survey conducted in New Zealand reported that out of 572 respondents aged 25–55 years who were meat consumers, 30% were willing to purchase (regularly, often, or always) cell-cultured meat instead of conventional meat (Giezenaar et al. 2023).

4.4.5.3 Iron intake

Estimated dietary intakes of iron for the Australian population are presented in Table A2.3 (Appendix 2). The mean and high (P95) usual intakes of iron at baseline did not exceed the UL for all the Australian population subgroups assessed. However, a high proportion (about 38–40%) of females aged from 14–50 years had inadequate iron intake (i.e. <EAR) at baseline. This proportion is about 37%–48% for females aged 12–49 years according to the 2023 NNPAS data. The results showed that the total mean intake of iron did not exceed the UL in any of the Australian population subgroups for scenario 1 (the worst-case scenario). The total high intake of iron was at or below the UL for all the Australian population subgroups for scenario 2. For scenario 1, the total high intake of iron exceeded the UL for several Australian population subgroups where the highest exceedance (130% of the UL) was estimated for the males aged 2–3 years.

Estimated usual dietary intakes of iron for the New Zealand population are shown in Table A2.4. The mean and high (P90) usual intakes of iron did not exceed the UL in any of the New Zealand population subgroups assessed. The proportion of New Zealand children with inadequate iron intake was 6.6% at baseline (based on UK Dietary Reference Values) (MoH 2005). The prevalence of inadequate iron intake was high among New Zealand females aged 15–18 years at baseline (34.2%) (MoH 2011a; MoH 2011b). The total mean intake of iron did not exceed the UL in any of the New Zealand population subgroups for scenario 1 (the worst-case scenario). The total high intake of iron was at or below the UL for all the New Zealand population subgroups for scenario 2. For scenario 1, the total high intake of iron exceeded the UL for several New Zealand population subgroups where the highest exceedance (140% of the UL) was estimated for the males aged 15–50 years.

4.4.6 Conclusion

In the longer term, the Australian and New Zealand populations consume higher mean and P90 amounts of chicken meat with a higher proportion of consumers than duck meat. The mean conventional duck meat consumption amount of 181 g for Australia, where respondents reported duck meat eaten 'as is', was considered as the appropriate serving size for the suggested cell-cultured duck final products.

The estimated total high dietary intake of iron exceeded the UL for a small number of population groups assessed due to the worst-case scenario assumptions used, including the assumption that considered consumers choose to eat cell-cultured duck in the same way they eat chicken meat. However, the consumers' insights/perceptions about cell-cultured meat indicated it is unlikely that consumers would eat cell-cultured meat in the same way they currently eat conventional meat, or that most people would eat cell-cultured meat in addition to conventional meat. Therefore, there is no concern in relation to iron intake from

[11] Consumer Insights Tracker 2023 Technical Report.pdf

cell-cultured duck.

4.5 Cell-cultured duck specification

Section 1.1.1—15 of the Code stipulates that cell-cultured foods must meet relevant identity and purity specifications outlined in Schedule 3. As Gourmey's cell-cultured duck is a new food without approval for use in other countries, there is currently no primary or secondary specification in section S3—2 or S3—3 of the Code, nor is there a Codex Standard for cell-cultured foods. FSANZ has proposed a new specification within Schedule 3 – Identity and Purity.

Gourmey submitted analytical data demonstrating consistency with the specification they provided in the application. FSANZ used this information to develop a proposed specification for inclusion in Schedule 3 (see Table 3).

The applicant set limits for cell-culture media ingredients—pluronic acid (<500 µg/g), insulin (<2 µg/g), and ethanolamine (30 µg/g)—and monitors these levels in the final product to ensure consistency with their food safety program. Batch data provided by the applicant showed the cell-cultured duck can meet the limits. Pluronic acid, insulin and ethanolamine were not however included in FSANZ's proposed specification given the safety assessment in section 4.1 did not identify risks that require management through limits in a specification.

4.5.1 Proximate values

The proximate values for protein, moisture, carbohydrate, fat and ash are derived from those provided in the application. The results provided by the applicant show cell-cultured duck can meet the proposed specification in Table 3.

4.5.2 Microbiological parameters

Microbiological specifications for cell cultured duck biomass were informed by consideration of plausible hazards, microbiological data provided by Gourmey, and the nature of the product as a cell cultured food ingredient.

Residual risk is driven predominantly by post-bioreactor contamination (e.g. *Listeria*, *Salmonella* and other environmental bacteria) and downstream time–temperature controls, rather than by persistent contamination arising during cell expansion which would be detected during production. The proposed microbiological parameters are consistent with the hazards identified for assessment, as summarised in Appendix-3, and focus on microbiological characteristics relevant to food safety within the scope of this pre-market assessment.

Gourmey's cell-cultured duck is produced through a highly controlled and hygienic biomanufacturing process, utilising rigorously tested cells sourced from fertilised eggs of flocks certified as free from avian influenza and *Salmonella* spp. The laying birds receive the basic vaccination package in the EU for *Salmonella enterica* and *Salmonella* Typhimurium, supported by standard EU vaccination protocols for laying birds.

To maintain product safety, environmental monitoring of production facilities is routinely conducted for pathogens such as *Listeria* and *Salmonella*, verifying the effectiveness of sanitation and hygienic zoning measures. Tests for *Campylobacter* and *Salmonella* are performed to confirm absence of contamination during cell expansion and harvesting, which are vital for ensuring microbiological safety and good hygiene practices. The cell-cultured duck biomass is systematically tested for contamination indicators like aerobic plate count, Enterobacteriaceae, yeasts, moulds, and for foodborne pathogens including *Salmonella* spp.

and *L. monocytogenes*, with results detailed in the application's proposed specification.

Cell-cultured duck demonstrates a unique risk profile compared to traditionally slaughtered poultry due to the nature of the cell bank sourcing, supplier controls, production processes, and stringent acceptance criteria. The final product, which is not assessed in this application, will also undergo validated thermal or non-thermal processing pathogen-reduction processing. However, it was also noted that the cell biomass will be used to manufacture duck products such as pâtés and foie gras; products that are potentially subject to minimal processing and heat-treatment.

FSANZ considers the process control measures used in the initial isolation and quality cell line development substantially mitigate the likelihood of *Campylobacter* contamination in the biomass. For this reason, FSANZ has not included *Campylobacter,* in the proposed specification in Table 3. *Listeria* and *Salmonella* spp. are bacteria that can contaminate the biomass during harvesting, washing and packaging due to increased environmental contacts which are not controlled for during these activities. Further, they would remain viable in the cell biomass during storage and would be a potential health and safety risk for consumers.

4.5.3 Metals

Gourmey has requested limits for lead, arsenic, cadmium and mercury are included in the specification for cell-cultured duck. According to test results submitted by the applicant, the concentrations detected in cell-cultured duck are lower than the maximum permissible levels (MPLs) for these metals as listed in section S3—4 of the Code. For this reason, FSANZ proposes including the limits requested by the applicant in the proposed specification – see Table 3.

4.5.4 Proposed cell cultured duck specification

FSANZ has proposed a new specification within Schedule 3 – Identity and Purity. The parameters and details are included in Table 3.

Table 3 *Proposed cell-cultured duck biomass specification*

Parameter	Proposed specification
Description	Duck cell biomass obtained from culturing embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*.
Protein	not less than 10% (not less than 70% on a dry basis)
Moisture	not less than 80%
Ash	not more than 1.7%
Fat	not more than 1.8%
Carbohydrate	not more than 0.1%
Lead	not more than 0.01 mg/kg
Arsenic	not more than 0.01 mg/kg
Cadmium	not more than 0.005 mg/kg
Mercury	not more than 0.005 mg/kg
Microbiological:	

Aerobic Plate Count	maximum 3,000 cfu/g
Listeria monocytogenes	absent in 25 g
***Salmonella* spp.**	absent in 25 g
Enterobacteriaceae	not more than 100 cfu/g
Yeasts	not more than 100 cfu/g
Moulds	not more than 100 cfu/g

4.6 Cell-cultured duck conclusions

FSANZ assessed the safety of the harvested cell-cultured duck biomass with respect to toxicological, microbiological and nutritional considerations, including dietary exposure.

The harvested cells are derived from domestic duck, a species with a history of safe consumption, and FSANZ did not identify any toxicological concerns associated with the cells or with residual production inputs, given their low toxicity and the negligible levels expected to be present in the final food.

FSANZ concludes that, based on the evidence provided, cell cultured duck biomass does not pose a microbiological safety concern due to the controlled nature of the production process, the use of defined acceptance criteria, and the application of validated pathogen-reduction steps.

Microbiological hazards considered across donor animal sourcing, cell line establishment, cell banking, production and harvesting were identified using a structured approach and are summarised in Appendix-3. While microbiological hazards arising during the proliferation stage can be readily detected through observable changes in cell growth, uncertainty in the risk assessment remains due to the limited production history and absence of an established history of safe use in food products. Based on available data, microbiological hazards associated with the harvested cell biomass are considered to be low. However, the cell biomass should be treated as a potentially hazardous food under Standard 3.2.2. Management of relevant hazards during final food production is outside the scope of this application and has not been assessed.

The nutritional assessment found that consumption of cell-cultured duck is not expected to result in nutritional imbalance. Although cell-cultured duck contains higher levels of iron than comparator foods of duck breast and chicken, dietary intake modelling indicated that iron intakes remain below the UL for most population groups, with intakes approaching or exceeding the UL identified only under conservative, high-consumption scenarios that are not expected to reflect typical or habitual consumption. As ULs are established to protect against adverse effects from chronic, sustained intakes, these modelled exceedances do not indicate a nutrition-related safety concern.

Based on the available data, FSANZ concludes that cell-cultured duck does not raise food safety or nutrition concerns when consumed at expected levels.

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Appendix-1 Nutrient content comparisons

Table A1.1 *Macronutrient composition of cell-cultured duck compared to conventional duck and chicken breast*

Nutritional parameter	Duck, breast, lean, raw Per 100 g *	Duck breast, lean, raw per portion (181 g)	Chicken, breast, lean flesh, raw Per 100 g *	Chicken per portion (142 g)	Cell-cultured duck Per 100 g	Cell-cultured duck per portion (72 g)
Energy (kJ)	383	693	412	383	240	174
Moisture (g)	77.5	140	75.6	107	85	61.5
Ash (g)	1.3	2.35	1.1	1.56	1.41	1.02
Protein (g)	21.2	38.4	22.5	32.0	12.1	8.74
Carbohydrate (g)	0	0	0	0	<0.1	<0.1
Total fat (g)	0.6	1.09	0.8	1.14	1.36	0.98

* Data from Australian Food Composition Database, unless otherwise stated.

Table A1.2 *Vitamin content of the cell-cultured duck compared to conventional duck and chicken breast*

Vitamin	Duck, breast, lean, raw Per 100 g *	Duck breast, lean, raw per portion (181 g)	Chicken, breast, lean flesh, raw Per 100 g *	Chicken, breast per portion (142 g)	Cell-cultured duck Per 100 g	Cell-cultured duck per portion (72 g)	EAR / AI ~	Duck breast % EAR per 100 g	Duck breast per portion % EAR	Chicken Breast % EAR per 100 g	Chicken per portion % EAR	Cell-cultured duck % EAR per 100 g	Cell-cultured duck per portion % EAR
Retinol# (µg)	0	0	4	5.68	<21	–	625	0	0	0.640	0.909	–	–
Riboflavin (mg)	0.28	0.507	0.04	0.057	0.173	0.125	1.10	25.5	46.1	3.64	5.16	15.7	11.4
Niacin (mg)	6.8	12.3	14.2	20.2	3.89	2.82	12	56.7	103	119	168	32.5	23.5
Pyridoxine (mg)	0.21	0.380	0.510	0.724	0.289	0.209	1.10	19.1	34.6	46.4	65.8	26.3	19.0
Cobalamin (µg)	2	3.62	0.100	0.142	0.512	0.371	2	100	181	5	7.10	25.6	18.5
Biotin (µg)	2.90	5.20	2.10	2.98	41.9	30.4	30	9.67	17.3	7	9.94	140	101
Total Folate (µg)	0	0	0	0	92.1	66.7	320[$]	0	0	0	0	28.8	20.8
Vitamin E (mg)	0.90	1.63	0.50	0.710	<0.08	–	10	9	16.3	5	7.10	–	–
Vitamin D3 (µg)	6	10.9	3.70	5.25	0.466	0.337	5	120	218	74	105	9	7
Pantothenic acid (B5) (mg)	1.80	3.26	1.30	1.85	0.904	0.654	6	30	54.3	21.7	30.8	15.1	10.91
Vitamin K (µg) [#]	2.8	5.07	8.4-	11.9	<0.8	–	70	4	7.24	12	17	-	-

* Data from Australian Food Composition Database, unless otherwise stated.
[#] Data taken from USDA FoodData Central (for conventional duck breast and chicken breast).
Retinol equivalents.
~ Estimated Adequate intake (EAR) for men aged 19 to 30 years from National Health and Medical Research Council Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes in New Zealand Ministry of Health editor. Australian Government, Department of Health and Ageing. Adequate intakes (AI) for men 19 years and above where an EAR is not provided.
$ Dietary folate equivalents

Table A1.3 *Mineral content of cell-cultured duck compared to conventional duck and chicken breast*

Minerals	Duck, breast, lean, raw Per 100 g *	Duck breast, lean, raw per portion (181 g)	Chicken, breast, lean flesh, raw Per 100 g *	Chicken breast per portion (142 g)	Cell-cultured duck Per 100 g	Cell-cultured duck per portion (72 g)	EAR/AI~	Duck breast % EAR per 100 g	Duck breast per portion % EAR	Chicken % EAR per 100 g	Chicken per portion % EAR	Cell-cultured duck % EAR per 100 g	Cell-cultured duck per portion % EAR
Calcium (mg)	4	7.24	4.00	5.68	1.30	0.94	840	0.48	0.86	0.48	0.68	0.16	0.11
Iron (mg)	3.2	5.79	0.26	0.37	13.5	9.76	6	53.3	96.5	4.33	6.15	225	163
Magnesium (mg)	26	47.1	31	44	22.3	16.1	330	7.88	14.3	9.39	13.3	6.76	4.89
Manganese (µg)	0.02	0.03	0.008	0.0114	0.0308	0.0223	5.50	0.309	0.559	0.145	0.207	0.56	0.41
Phosphorus (mg)	230	416	240	341	293	212	580	39.7	71.8	41.4	58.8	50.5	36.5
Potassium (mg)	380	688	390	554	364	264	3800	10	18.1	10.3	14.6	9.58	6.94
Selenium (µg)	27	48.9	17	24.1	<0.02	–	60	45	81.5	28.3	40.2	–	–
Sodium (mg)	60	109	48	68.2	108	78.2	690 ^	8.7	15.8	7	9.9	15.7	11.3
Zinc (mg)	1.1	1.99	0.52	0.74	2.83	2.05	12	9.17	16.6	4.33	6.15	23.6	17.1
Fluoride (mg)	-	-	-	-	<0.1	0.07	4	-	-	-	-	2.50	1.80

* Data from Australian Food Composition Database, unless otherwise stated.
~ Estimated Adequate intake (EAR) for men aged 19 to 30 years from National Health and Medical Research Council Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes in New Zealand Ministry of Health editor. Australian Government, Department of Health and Ageing. Adequate intakes (AI) for men 19 years and above where an EAR is not provided.
$ based on mean chicken meat Australian consumption data (g/day) for individuals age 2 years and above.
^ Based on mean AI of 460-920 mg/day for adults.

Table A1.4 *Amino acid content of the cell-cultured duck conventional duck*

Amino acid	Duck, breast, lean, raw (g/ 100 g) *	Cell-cultured duck (g/100 g) ~
Essential		
Histidine	1.77	0.26
Isoleucine	1.78	0.47
Leucine	3.22	0.88
Lysine	3.72	0.91
Methionine	1.23	0.24
Phenylalanine	1.73	0.46
Tryptophan	NR	0.14
Valine	1.85	0.58
Threonine	2.09	0.47
Non- essential		
Glutamic acid	5.61 (glutamate)	1.41
Proline	1.44	0.47
Hydroxyproline	NR	<0.2
Serine	1.76	0.49
Ornithine	NR	<0.5
Alanine	2.31	0.60
Aspartic Acid	4.0 (Asparagine)	1.02
Tyrosine	1.59	0.39
Arginine	3.53	0.76
Cystine + cysteine	NR	0.16
Glycine	1.69	0.53

* Data from Wang, R. *et al.* (2024) 'Genome-wide association analysis explores the genetic loci of amino acid content in duck's breast muscle', *BMC Genomics*, 25(1). doi:10.1186/s12864-024-10287-1.
~ Data provided by applicant.
NR = value not recorded.

Table A1.5 *Nutritional composition of cell-cultured duck compared to Upper Level (UL)*

Vitamins/Minerals	Cell-cultured duck per 100 g	Cell-cultured duck per portion (145 g) *	UL (Children aged 1-3 years) ~	Cell-cultured duck % UL per 100 g	Cell-cultured duck % UL per portion (145 g)
Total Folate (µg)	92.10	133	300	30.7	44.5
Iron (mg)	13.49	19.5	20	67.4	97.6
Magnesium (mg)	22.3	32.3	65	34.3	49.7
Phosphorus (mg)	293	424	3000	9.76	14.1
Zinc (mg)	2.83	4.10	7	40.4	58.5
Sodium (mg)	108	156	1000	10.8	15.6

* Represents conservative consumption scenario with 80% inclusion of cell-cultured duck in final food.
~ Upper Limit for children aged 1 to 3 years from National Health and Medical Research Council Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes in New Zealand Ministry of Health editor. Australian Government, Department of Health and Ageing.

Appendix-2 Additional information on the dietary intake assessment

Table A2.1 *Population groups assessed in the dietary intake assessments*

Country	Survey	Population surveyed	Age groups assessed	Sex groups assessed
Australia	2011–12 NNPAS	2 years and above	2–3 years 4–8 years 9–13 years 14–18 years 19–30 years 31–50 years 51–70 years 71 years and over	Male and Female
New Zealand	2002 NZ CNS	5–14 years	5–6 years 7–10 years 11–14 years	Male and Female
	2008 NZ ANS	15 years and above	15–18 years 19–30 years 31–50 years 51–70 years 71 years and over	Male and Female

Table A2.2 *Chicken meat consumption for Australia and New Zealand for consumers only*[#]

Country	Sex	Age group (years)	Mean consumption (g/day)	Consumption at P90 (g/day)
Australia*	Male	2–3	55	98
		4–8	61	113
		9–13	81	180
		14–18	111	182
		19–30	134	269
		31–50	112	228
		51–70	98	204
		>= 71	79	140
	Female	2–3	48	95
		4–8	50	101
		9–13	74	158
		14–18	91	186
		19–30	89	159
		31–50	89	179
		51–70	79	149
		>= 71	77	151
New Zealand^	Male	5–6	80	175
		7–10	83	192
		11–14	121	253
		15–18	159	369
		19–30	141	343
		31–50	163	326
		51–70	124	288
		>= 71	105	199
	Female	5–6	55	116
		7–10	84	169
		11–14	91	190
		15–18	106	206
		19–30	113	206
		31–50	117	243
		51–70	106	223
		>= 71	96	193

[#] As used for scenario 1 and 2: consumption amounts are representative of a longer term consumption pattern taking into account chicken meat that is eaten as a serve in its own right as well as other amounts from mixed dishes such as in main meals (e.g. stews or curries) or other uses such as in sandwiches. Harvest raw commodity model was used for this estimation.

* 2011–12 Australian National Nutrition and Physical Activity Survey. Based on consumption data from respondents with two days of data, for consumers only.

^ 2002 New Zealand National Children's Nutrition Survey and the 2008–09 New Zealand Adult Nutrition Survey. Based on day 1 consumption data from consumers only.

Table A2.3 *Estimated dietary intake of iron (mg/day) for the Australian population with additional contribution from cell-cultured duck*

Age group (years)	UL*	Mean usual intake at baseline €	High usual intake (P95) at baseline €	Mean intake from supplements Σ	Proportion with usual intake exceeding UL at baseline (%)$	Proportion with inadequate intake at baseline (% <EAR)$	Intake from cell-cultured duck for scenario 1£		Intake from cell-cultured duck for scenario 2Ω		Total intake as %UL for scenario 1¥		Total intake as %UL for scenario 2¥	
							Mean	High (P90)	Mean	High (P90)	Mean	High	Mean	High
Males														
2–3	20	8	12	3	—	8.5	6.0	10.6	3.0	5.3	85	130	70	100
4–8	40	9	13	3	—	5.9	6.6	12.2	3.3	6.1	50	70	40	55
9–13	40	12	17	4	—	3.3	8.8	19.5	4.4	9.7	65	100	50	80
14–18	45	13	19	4	—	8.3	12.0	19.7	6.0	9.8	65	95	50	75
19–30	45	13	19	8	—	2.2	14.5	29.1	7.2	14.5	80	120	60	95
31–50	45	13	19	7	—	2.2	12.1	24.6	6.1	12.3	70	110	60	85
51–70	45	12	18	4	—	2.8	10.6	22.0	5.3	11.0	60	100	45	75
71+	45	12	18	6	—	3.1	8.5	15.1	4.2	7.5	60	85	50	70
Females														
2–3	20	7	10	3	—	14.8	5.2	10.2	2.6	5.1	75	120	65	90
4–8	40	8	12	3	—	10.8	5.4	10.9	2.7	5.5	40	65	35	50
9–13	40	9	14	5	—	10.5	8.0	17.0	4.0	8.5	55	90	45	70
14–18	45	9	14	10	—	40.1	9.8	20.1	4.9	10.1	65	100	55	75
19–30	45	9	14	12	—	37.5	9.6	17.1	4.8	8.6	70	95	60	80
31–50	45	9	14	8	—	37.5	9.6	19.4	4.8	9.7	60	90	50	70
51–70	45	10	15	5	—	5	8.6	16.0	4.3	8.0	55	80	40	60
71+	45	9	14	6	—	6.7	8.3	16.3	4.2	8.1	50	80	40	60

*Upper Level for iron based on the Nutrient Reference Values for Australia and New Zealand (NHMRC and MoH 2006).

€ Mean/ high usual intakes from food and beverages from the 2011-12 NNPAS (ABS 2015c).

Σ Mean intake from supplements (ABS 2015a), day 1 data only.

$ Proportion with usual intake exceeding UL and proportion with inadequate intake at baseline (ABS 2015c). A dash '—' means zero or rounded to zero.

£ Consumers choose to eat cell-cultured duck at amounts equivalent to 80% of the total longer-term consumption of chicken meat, in addition to conventional meat including chicken.

Ω Consumers choose to eat cell-cultured duck at amounts equivalent to 40% of the total longer-term consumption of chicken meat, in addition to conventional meat including chicken.

¥Sum of mean/ high usual intake from food and beverages (baseline), dietary supplements and cell-cultured duck as a percentage of the UL. i.e. Mean = mean baseline intake + supplements + mean scenario intake; High = high baseline intake + supplements + high scenario intake.

Table A2.4 *Estimated dietary intake of iron (mg/day) for the New Zealand population with additional contribution from cell-cultured duck*

Age group (years)	UL*	Mean usual intake at baseline €	High usual intake at baseline (P90) €	Mean intake from supplements Σ	Proportion with inadequate intake at baseline (% <EAR)$	Intake from cell-cultured duck for scenario 1£		Intake from cell-cultured duck for scenario 2Ω		Total intake as %UL for scenario 1¥		Total intake as %UL for scenario 2¥	
						Mean	High (P90)	Mean	High (P90)	Mean	High	Mean	High
Males													
5–6	40	10	13	3	0	8.6	18.9	4.3	9.5	55	90	45	65
7–10	40	12	16	4	1.8	8.9	20.7	4.5	10.4	65	100	55	80
11–14	40–45**	14	19	4	2.1	13.1	27.3	6.5	13.6	80	130	65	90
15–18	45	14	19	4	5.0	17.1	39.8	8.6	19.9	80	140	60	95
19–30	45	14	20	8	0.1	15.3	37.0	7.6	18.5	85	140	65	100
31–50	45	14	20	7	0.8	17.6	35.2	8.8	17.6	85	140	65	100
51–70	45	13	19	4	1.3	13.3	31.1	6.7	15.5	70	120	55	85
71+	45	12	16	6	1.3	11.3	21.5	5.7	10.7	65	95	50	75
Females													
5–6	40	9	11	3	0.1	5.9	12.5	3.0	6.3	45	65	40	50
7–10	40	10	13	5	5.0	9.1	18.3	4.5	9.1	60	90	50	70
11–14	40–45**	10	15	10	4.2	9.9	20.5	4.9	10.3	75	110	65	90
15–18	45	9	13	10	34.2	11.5	22.2	5.7	11.1	70	100	55	75
19–30	45	10	12	12	6.0	12.1	22.3	6.1	11.1	75	100	60	80
31–50	45	10	14	8	15.4	12.6	26.2	6.3	13.1	70	110	55	80
51–70	45	10	14	5	0.7	11.5	24.1	5.7	12.0	60	95	45	70
71+	45	9	13	6	2.3	10.3	20.8	5.2	10.4	60	90	45	65

*Upper Level for iron based on the Nutrient Reference Values for Australia and New Zealand (NHMRC and MoH 2006).

**The UL for 9–13 years olds is 40 mg/day. The UL for 14 year olds is 45 mg/day.

€ Mean and high usual intake from foods and beverages derived from the 2002 NZ CNS and 2008–09 NZ ANS (MoH 2003; University of Otago and MoH 2011). The highest reported usual intake in these publications is the 90th percentile; this has been used for the estimated high intakes from food for New Zealand.

Σ Australian mean intake for supplements for day 1 only was used (ABS 2015a). For 5–6 year olds the average used is for Australians aged 4–8 years. For 7–10 years olds the mean used is for Australians aged 9-13 years. For 11–14 year olds the average used is for Australians aged 14–18 years.

$ Proportion with inadequate intake at baseline for children up to 14 years based on UK dietary reference values (1991) and for adults from 15 years and older based on NRVs for Australia and New Zealand (2006).

£ Consumers choose to eat cell-cultured duck at amounts equivalent to 80% of the total longer-term consumption of chicken meat, in addition to conventional meat including chicken.

Ω Consumers choose to eat cell-cultured duck at amounts equivalent to 40% of the total longer-term consumption of chicken meat, in addition to conventional meat including chicken.

¥Sum of mean/ high usual intake from food and beverages (baseline), dietary supplements and cell-cultured duck as a percentage of the UL. i.e. Mean = mean baseline intake + supplements + mean scenario intake; High = high baseline intake + supplements + high scenario intake.

Appendix-3 Microbiological hazard identification

Scope and purpose
This appendix summarises the identification of plausible microbiological hazards relevant to the assessment of cell cultured duck biomass produced using the assessed cell line and production process. It supports the microbiological risk assessment presented in Sections 2.5, 3.4 and 4.2 of this supporting document.

The hazard identification is based on information provided by the applicant, relevant international guidance, and scientific knowledge of microbiological hazards associated with avian species and animal cell culture systems. This appendix does not assess post market controls, food safety management systems or compliance matters.

Table A3.1 *Microbiological hazard identification across the production chain*

Production step	Hazard ID	Description and other relevant information	Contextual considerations (illustrative only)	Information considered	Assessment outcome
Donor animal sourcing	Bacterial pathogens	Ducks may harbour foodborne bacteria (e.g. *Salmonella* spp.) relevant to avian species with potential to be carried to the final product and be pathogenic; Vertical transmission and associated with reproductive organs	Sourcing from healthy animals and documented husbandry practices, consistent with Good Agricultural Practice (GAP)	Considered plausible at source; donor laying flock testing and vaccination records (vaccines as per the basic EU package)	No hazards of concern identified.
Donor animal sourcing	Viruses	Avian species may harbour endogenous or adventitious viruses (e.g. avian influenza, Newcastle disease) relevant to cell culture	Cell line provenance and history considered, consistent with principles applied to animal cell culture, consistent with GAP	Considered; noted that vaccination for Newcastle disease is mandatory in the EU so very low risk; testing for presence of potential hazards as per methods in EU Pharmacopeia	No hazards of concern identified
Donor animal sourcing	Prions	Considered due to animal origin; use of animal-derived products during cell line establishment	Species characteristics considered	Not considered a plausible hazard	NA

Production step	Hazard ID	Description and other relevant information	Contextual considerations (illustrative only)	Information considered	Assessment outcome
Cell sourcing (ESC) / early isolation	Bacteria / fungi	Environmental or handling-related contamination	Controlled laboratory handling environments; including the use of virucidal and sporicidal agents and UV light; GCCP	Considered; testing for presence of potential hazards as per methods in EU Pharmacopeia; use of antibiotics	No hazards of concern identified
Cell line establishment	Mycoplasma	Recognised contaminants of animal cell culture systems	Cell bank characterisation and testing approaches described by the Gourmey	Considered; testing for presence of potential hazards as per methods in EU Pharmacopeia	No hazards of concern identified
Cell banking (MCB / WCB)	Viruses	Contamination could affect downstream production	Cell banking principles commonly applied to animal cell cultures	Considered testing for presence of potential hazards as per methods in EU Pharmacopeia	No hazards of concern identified
Cell expansion (Shake flasks / bioreactors)	Bacteria / fungi	Introduction via materials, equipment or handling; noting that once in the bioreactors, cell culture can be considered aseptic	General good-practice cell culture (as per GCCP, HACCP and HARPC) environments	Considered; continuous monitoring of physical parameters would ensure early detection of contamination including mycoplasma and viruses, bacteria/fungi confirmed by microscopy of medium	Likelihood assessed as low given level of control of the system; any contamination would limit the growth potential of the cells resulting in the batch being discarded
Semi-continuous expansion	Bacteria/fungi	Introduction via materials, equipment or handling during transfers and inputs	General good-practice cell culture environments; sanitation managed	Considered	Increasing likelihood over time ie number of rounds per cycle
Harvesting and washing	Bacteria	Increased exposure once removed from controlled culture; Environmental or	Follow good practice guidelines (e.g. HACCP + GCCP, GHP, GMP)	Considered relevant. *L. monocytogenes* is a known environmental	Further information requested

Production step	Hazard ID	Description and other relevant information	Contextual considerations (illustrative only)	Information considered	Assessment outcome
		handling-related hazards	Training and monitoring Environmental monitoring	hazard in food production facilities	
Harvested biomass, including packaging	Indicator organisms / pathogens	Biomass does not inherently inhibit microbial growth; increased environmental and handling-related hazards	Batch test data considered as supporting information; Follow good practice guidelines (e.g. HACCP + GCCP, GHP, GMP) Training and monitoring Environmental monitoring	Considered; Potential for environmental and handling hazards;	Further information requested
Frozen storage	Bacteria	Survival of introduced organisms	General knowledge of microbial survival under freezing	Considered as contextual factor	NA
Final Products	Bacteria	Any surviving foodborne pathogens may not be killed by cooking (i.e. if minimal thermal treatments)	Accepted treatment for foods considered potentially hazardous would be sufficient to achieve a 6D reduction.	Not directedly considered but noted from the application	NA

NA – not applicable

Relationship to Appendix 4 in Application A1269

In Application A1269, Appendix 4 included examples of food safety management frameworks and good-practice programs to provide contextual background for microbiological hazard consideration. In this application, microbiological hazard identification is presented separately from post-market risk management considerations to clarify assessment scope and avoid duplication with requirements addressed elsewhere in the Code. The table therefore focuses on identifying plausible hazards and the information considered in assessing those hazards, rather than assessing or endorsing specific control programs.

Summary conclusion

No novel microbiological hazards specific to the assessed cell-cultured duck biomass were identified. Plausible hazards were identified and

carried forward into the microbiological risk assessment, with conclusions bounded to the conditions and scope of the application.