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Novel Food Application to Amend the Australia and New Zealand Food Standards Code for Cell Cultured Duck

Executive Summary

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Suprême SAS (Gourmey) is submitting this application to amend the Australia New Zealand Food Standards Code (referred to as the “Code”) to allow the use of cell cultured duck to be used as a food ingredient. The cell cultured duck will be mixed with other authorised ingredients to be used duck meat analogues such as “cell cultured foie gras” and “cell cultured duck pâté”.

Cell cultured duck is obtained from duck embryonic stem cells (dESC) isolated from fertilised duck eggs from the species *Anas platyrhynchos domesticus* (Pekin duck). The novel food is a pale pink/beige biomass and contains a minimum of 10% protein (70% on a dry weight basis).

The cell line used to create the Master Cell Bank (MCB), and the Working Cell Bank (WCB) has been fully characterised. The cell line has not been genetically modified. Analytical data confirm the identity, integrity, stability and sterility of the cell line and production cell banks along with the acceptance criteria for their release.

Quantitative polymerase chain reaction (qPCR) was performed on the cells confirming the identity of the cell line belongs to the species *A. platyrhynchos.* Karyotyping performed on cells from the MCB, WCB and End of Production (EOP) also confirmed that the cells were from *A. platyrhynchos* and showed normal ploidy level.

The production of cell cultured duck starts with a qualified cell bank from which an MCB is produced following the principles of Good Manufacturing Practices (GMP) in Regulation 852/2004 and Regulation 853/2004, Good Cell Culture Practice 2.0 (Pamies et al., 2022) and ICH Q5A, ICH Q5C and ICH Q5D where applicable to food production.

The production process is defined as semi-continuous as multiple independent harvests are possible from a single WCB vial due to a process referred to interchangeably by Gourmey as continuous seed train or parallel passaging. In this process, a small volume of the pooled cells is retained from the shake flasks and kept in culture in parallel to the next phases. These shake flasks can be used as a starting point for subsequent independent harvests. This semi-continuous process optimizes the production process as a new WCB vial does not need to be thawed for each harvest.

Cells from the shake flask seed train, grown in chemically defined food safe culture media, are used to inoculate the N-1 Suspension Bioreactor (SBN-1), where they are grown under controlled conditions until the desired viable cell density is reached after which, the majority of the culture volume is used to inoculate an N Suspension Bioreactor (SBN). A small volume of the cells is retained and used to maintain a continuous seed train in the SBN-1 bioreactor once it is replenished with culture media in addition to the shake flask seed train. This continuous seed train in the SBN-1, is a process optimization that allows to seed and harvest the SBN bioreactor more frequently and reduces the frequency needed to start the process from a WCB vial. Once the culture in the SBN reaches a desired viable cell density, the biomass is harvested from that bioreactor. Once the bioreactor has been harvested, it can be re-seeded from the step prior as a continuous seed train would have been maintained.

The last phase of production relates to the harvesting of the cell cultured duck biomass. The biomass is separated from the culture media by centrifugation and washed with saline solution. The biomass is packed and frozen after the wash step. The cells are kept frozen, until they are used to produce a final product, where the cells will be combined with other food-safe ingredients. A full assessment on the potential physical, microbiological, chemical and radiological hazards in the production process has been performed and adequate measures for each identified risk have been applied. In-process controls and monitoring measures have been implemented to demonstrate the

effectiveness in reducing and/or eliminating identified risks based on the HACCP and Critical Control Points principles from the Codex Alimentarius (Codex Alimentarius CXC 1-1969, Rev. 2022) and Regulation (EC) No 852/2004.

Appropriate specifications for cell cultured duck have been established which include clearly defined levels for the main nutrients, protein, along with heavy metals, microbiological parameters and media residues pluronic acid, insulin and ethanolamine in order to control the presence of undesirable substances and contamination. The nutritional and impurity profile of five batches of Cell cultured duck was analysed demonstrating compliance with the established specifications and legal limits. The presence of biogenic amines in Cell cultured duck was also assessed, however, the concentrations are present in levels comparable to those in conventional food and well within safe limits. All other tested contaminants were below the limits of detection.

It is considered that since the product will be stored frozen at -20 ºC before its use, microbiological changes will not occur during the storage period. The shelf-life will be then limited by physico-chemical reactions and undesired changes in the properties of the ingredient. Lipid oxidation is one of the main causes for quality loss during the storage of frozen meat as reported by Villegas-Cayllahua et al. (2024). Based on the low concentration of fat in the novel food, lipid oxidation is not expected to be significant in the cell biomass. It is reasonable to assume that the product will be stable when frozen for at least one year. The Cell cultured duck will be used to manufacture duck meat analogues such as “cell cultured foie gras” which are typically subject to minimal processing and heat-treatment. The cell biomass is not expected to have any detrimental impact on the shelf-life of these products. Most of the final products will be frozen, hence no changes are expected to occur during storage.

Cell cultured duck is proposed for use by the general population, without sensitivities to duck or other avian species, as a food ingredient for further processing to be used duck meat analogues at an inclusion rate of 5 to 80% by weight of the finished food.

The highest mean exposure to cell cultured duck, considering the maximum use levels for the proposed food categories, is 26.9 g/day. This exposure calculation considers that the novel food would be used in all proposed food categories at maximum use levels and hence, is an overestimation of exposure, as the real exposure is expected to be considerably lower. The intake assessment shows that the intake of nutrients is below upper tolerable intake levels, when these are available, or in line with other dietary reference values. Based on its composition, the digestibility of the novel food is expected to be comparable with the digestibility of duck liver. Therefore, the novel food is not expected to be nutritionally disadvantageous.

From the estimated exposure calculations described above, the estimated exposure to the media residues pluronic acid, ethanolamine and insulin derived from Cell cultured duck is considered safe.

Whilst there is no history of consumption of duck cells from cell culture, duck and, therefore, duck cells, have been traditionally and historically consumed in many parts of the world. To our best knowledge, we are not aware of cases of toxicity derived from the consumption of duck meat or derived products where these events were not caused by poor hygienic handling or contamination with ubiquitous food contaminants. Duck species do not contain any poisonous or venomous species. Therefore, the cells themselves, which have been fully characterised and are stable, are not toxic. The results presented throughout this dossier support genotypic and phenotypic stability.

Cell cultured duck is adequate in their essential amino acid profile with nutritionally safe amounts of vitamins and minerals. Although not identical, the novel food nutrient composition is comparable to the composition of other conventional foods (e.g., duck liver). The amino acid profile of cell cultured duck was similar to that of conventional duck but presents a lower concentration of certain essential amino acids but has a comparable amino acid score compared to beef and chicken egg. Although comparing the nutritional profile of cell cultured duck against conventional duck meat can provide useful context for the interpretation of the nutritional profile, there are inherent differences in metabolic pathways and cellular diversity between live animals and cultured duck cells. Unlike conventional animal cells derived from whole organisms, cells derived from culture are produced under controlled conditions that do not fully replicate the complex biological processes and cellular interactions found in live animals. Cell cultivation focuses on controlled growth of specific cell types in a reproducible and scalable manner. Although the production methods and underlying biological context may differ, both Cell cultured duck and conventional duck are nutritionally safe and adequate products and Cell cultured duck are not nutritionally disadvantageous.

Analysis of the composition of Cell cultured duck has not shown any new concerning constituents outside of safe limits. The culture media used in the production process is chemically well-defined and composed of food-safe components with findings from extensive literature reviews having identified no toxicological risks on media residues. A risk assessment of each component has been performed and for media components used in the early stages of isolation and adaptation that pose a potential risk would have been diluted to below the threshold of toxicological concern (if a limit exists) in the subsequent passages taken to create the cell banks and any media components remaining in cultured duck and finished products will be below the limit of detection (LOD).

With regards to biological risks, one of the major concerns discussed in the literature is the tumorigenic potential of the cells. It should be noted that no viable cells can be reasonably expected to be present in cell cultured duck with tumorigenic potential not deemed to be a food safety concern because:

- The cell cultured duck is immediately frozen after harvest. When cells are frozen without a cryoprotectant, ice crystals form rupturing the cell membrane leading cell death (Dumont et al., 2006).
- Subsequent processing and cooking steps would serve as additional kill steps, meaning the likelihood of consuming viable cells is extremely low. The processing and storage conditions to which the cultured duck is subject are designed to maintain its physical-chemical properties but not to maintain cell viability post-harvest.
- Further, in the unlikely event that viable cells remain after freezing, processing and cooking, they would not be able to survive being ingested due to chemical digestion, where stomach acid and digestive enzymes catabolize the cells into smaller components that are either absorbed or excreted (Patricia and Dhamoon, 2023).
- The stability of the cell line is closely monitored. Any significant changes in the growth characteristics, morphology, pluripotency and the ability to form embryoid bodies would be the first indicators of undesired phenotypic and genotypic changes in the cell culture.
- Finally, the probability of all these events occurring concurrently is such that it was not possible to identify a credible pathway to harm (FAO, 2023).

The allergenicity risk assessment of duck meat protein and duck egg proteins followed a weight of evidence approach whereby a literature search and bioinformatic search was performed to identify known allergens in duck meat and eggs. Secondly, a transcriptomic analysis of cells from the WCB and cells from the end of production was performed, from which identified sequences were compared to allergen databases, and batches of the Cell cultured duck were tested for egg allergen residues. The literature indicates that allergic reactions to bird meat are rare and have been mostly associated with chicken meat. Allergy to duck meat in particular is uncommon and there is a lack of information on the specific allergenicity of duck species (*Anas platyrhynchos*). Allergic reactions to egg proteins have also been described in the literature, but mostly for chicken eggs. Little research is available on allergenicity to eggs from other bird species. Most cases of allergic reactions to duck eggs have been cases of cross-reaction in patients with known allergy to chicken eggs. Allergic reactions to duck or other bird eggs are extremely rare when these are not accompanied by allergy to chicken eggs. Data from the transcriptomic analysis revealed that there were no major allergens present in the cells, and the allergenic proteins that were identified were not a food safety concern. The results of the ELISA testing show that egg allergens were not detected in the batches of cultured duck tested indicating that cross-contamination of the cells with egg allergens has not occurred and or, the cells are not expressing egg allergens. Taken together, Cell cultured duck is considered of low allergenic risk to humans via oral consumption for the general population without sensitivities to duck and avian meats/proteins.

In conclusion, Gourmey has prepared a novel food application for cell cultured duck, for authorisation of the novel food to be used in meat imitates, spreadable-textured specialities, fats, oils and derivatives, and duck meat analogues such as “cell cultured foie gras” and “cell cultured duck pâté” at an inclusion rate of 5 to 80% by weight of the finished food. Through rigorous characterization and adherence to GMP principles, the safety and nutritional adequacy of cultured duck cells have been thoroughly established. Analytical data from multiple batches confirm compliance with specifications appropriate for the novel food, demonstrating the absence of biological, chemical and physical hazards to ensure safety for consumption.