

Product: Duck cells from cell culture
Novel food category: Foods consisting of, isolated from or
produced from cell culture or tissue culture derived from
animals, plants, fungi or algae

Applicant: Suprême SAS (Gourmey)
EFSA-ID-2022-001096; NF-2024-
22222
Date of submission: July 2024

Application for the authorisation of Duck cells from cell culture as a novel food in under Regulation (EU) 2015/2283

Public Summary

Suprême SAS (Gourmey)
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July 2024

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Public summary of the dossier

Suprême SAS (Gourmey) is seeking novel food approval for duck cells from cell culture (*Anas platyrhynchos* (Pekin duck)) as a novel food in the European Union (EU) in accordance with Article 10 of Regulation (EU) 2015/2283. Duck cells from cell culture does not have a history of consumption in the EU as a food or food ingredient and falls under Category VI, 'Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi and algae as outlined in Article 3 of Regulation (EU) 2015/2283.

The novel food dossier has been prepared in accordance with the current EFSA guidance on novel foods (EFSA Panel on Dietetic Products et al., 2021).

Duck cells from cell culture is intended for the general population. The proposed uses include meat imitates, spreadable-textured specialities, fats, oils and derivatives, and duck meat and pâté analogues at an inclusion rate of 5 to 80% by weight of the finished food.

The novel food is a duck cell culture biomass of *A. platyrhynchos* (Pekin duck) cells. The production process consists of creating a master cell bank and working cell banks under sterile conditions using non genetically modified cells from fertilised eggs that are stable and free from microbial contamination and adventitious agents. The biomass is produced under sterile cell culture conditions in a bioreactor in which the cells are grown in a fully defined food safe medium that does not contain antibiotics or foetal bovine serum. The harvested cells are separated from the culture media by centrifugation and washed with saline solution.

Duck cells from cell culture contains a minimum of 10% protein (70% on a dry weight basis).

The production process has been sufficiently characterised, and an extensive assessment has been carried out at each phase of the process to identify and characterise potential food safety risks that could be inherent in the cultured cells or introduced during the production process.

The applicant has demonstrated that five independent batches of the novel food meet the specifications outlined in Regulation (EU) 2023/915 on contaminants in food and Regulation (EC) 2073/2005 on microbiological criteria of foodstuffs. Extensive testing has been performed to show that the novel food is nutritionally adequate and free from microbial contamination, pathogens and harmful chemical contaminants.

Although cultured foods are novel, the cell culture process itself aligns well with established food safety principles as underscored by a recent report published by the Food and Agriculture Organization (FAO, 2023). This highlights the integration of this innovative process within existing food safety frameworks. Preventative controls to mitigate any potential hazards have been addressed with the design of quality assurance programs to ensure the alignment of the Hazard Analysis and Critical Control Points (HACCP) principles. No significant safety concerns are considered to derive from the manufacturing process that are not manageable with established good manufacturing practices, prerequisite programs, and critical control points within a food safety plan.

The novel food has been fully characterised, and no safety concerns were observed from the compositional data. The cell culture media used to produce the cell cultivated duck is fully defined and composed of food-safe components that do not introduce toxicological risks.

Based on the evidence and supportive data herein this dossier, duck cells from cell culture is concluded to be safe for human consumption under the proposed conditions of use.

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