Identification of hazards in meat products manufactured from cultured animal cells: Annex A

Criteria for novel food suitability assessment

Any food that meets the definition of ‘novel food’ is subject to the assessment process and requirements of the Novel Foods Regulation (EU Regulation number 2015/2283) and meat products manufactured from cultured animal cells would be regulated as such. The following discusses the key criteria for novel food suitability assessment to ensure that the product under application for authorisation is safe for consumption.

Production process concerns

- The main concerns with the production process include chemicals or biological contaminants that could occur during the cell culturing process. Demonstration of adequate control of the process, correct differentiation and maturation and end-to-end safety management is required with an understanding of how the chemicals used interact with the product and whether any of these are toxic, non-food grade and safe for consumers. Although there is a general sequence of events that will be followed to produce the final cultured meat, there might be great variety across all the cell culture production. It might therefore be necessary for risk assessors to broaden their horizons in understanding how robust these production processes are for consistency in a safe product.

Compositional concerns

- Differences in the final composition of the product can arise through the production process (footnote 1) (footnote 2) resulting in a different final composition compared to meat. This can be from changes induced from not having all the extra material that is found in muscle e.g. no vascularate/stromal cells, not veins, no fat, as well as having a nutritional contribution from the scaffold material (footnote 3) (footnote 4).
- When considering this product, the composition will not just focus on one end product, but on how a cell line develops into the final product, whether it matures correctly, as well as considering the safety of the scaffold material used to support the cells, the chemicals included in the process, and the medium that the cells have also been grown in. Therefore, depending on the product type and the process involved, the assessment will need to consider this.

Stability/microbiological safety

- There are claims made in the literature that the product will have a better stability profile than that of conventional meat due to the sterile conditions in production resulting in lower microbiological load in the product at its inception, consequently leading to a lower spoilage risk (footnote 5) (footnote 6). Whilst this is a logical hypothesis, without undertaking a stability assessment on the cultured meat at production scale, the actual microbiological safety of

the product is not understood. At present, there was not data returned in the literature pool that gave any indication to the final stability/shelf-life of the product.

Allergenicity, toxicology, ADME (and protein analysis)

- One of the main issues with the scientific literature with the reference to understanding the risk profile and potential hazards of culture meet is that there is a very limited amount or product focus or product specific data, especially with regards to the final composition, allergenicity, toxicology and ADME of the product. Only a few papers provided some useful data on these factors, such as the paper on insect cultured meat completing a proximate analysis, but in general most papers review cultured meat conceptually, from the perspective of cell culture, or from improving a specific aspect of cultured meat such as improving the scaffold material There are many quantitative and qualitative measures used to check the extent of proliferation and differentiation e.g. use of genetic biomarkers, florescent imaging, genetic analysis, as well as studies on the impact of stretch and strain. However, the literature on risk assessment on cultured meat is lacking.
- One area that could be of concern is the change to the protein structure and protein sequences off the cells, which could be more dependent on the media formulation (footnote 7) and production process, which could change the protein quality of the final product potentially lowering the product and presenting a nutritional risk to the consumer through being a source lower quality protein (footnote 8) (footnote 9). It is also possible with that changes may lead to unintended consequences such as inducing an allergic reaction or changing the digestibility of the protein due to changes in the structure and composition of the final product (footnote 10).
- When a new product comes to market and it is a food that meets the definition of a novel food all the sections of a novel food should be completed however as the nature of the product may mean, toxicology studies and ADME studies do not provide much information in understanding how these react in the body. However, a detailed composition and protein analysis such as understanding the protein sequences, the protein quality and fractions of this product may be needed to alleviate any concerns alongside allergy studies to ensure that any changes in protein structures from this novel production process does not have any unintended consequences for consumer.

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