Good Food Institute Europe

Explaining the EU regulatory framework for cultivated meat

With authorisation applications for cultivated meat potentially on the horizon in the EU, policymaker and public interest has been sparked in this emerging food production method. This note provides information on the EU's Novel Food framework for the authorisation of cultivated meat products.

What is cultivated meat?

Cultivated meat is the same as the beef, pork and chicken people eat today – but made in a different way to farming animals. Cultivating meat involves taking a small sample of animal cells and growing them in a fermentor that supports the same process that happens inside an animal by providing warmth and basic nutrients. The result is genuine meat that can be formed into products indistinguishable from conventionally produced meat.

How is cultivated meat regulated in the EU?

Before a cultivated meat product can be sold in the EU, it must be approved by the European Food Safety Authority (EFSA), the European Commission and Member States. The pre-market authorisation of cultivated meat is governed by the Novel Foods Regulation - one of the most robust food safety frameworks in the world. The process will involve a thorough and evidence-based assessment of the safety and nutritional value of each cultivated meat product.

What does the Novel Food authorisation process look like?

The Novel Food authorisation procedure consists of two stages - risk assessment and risk management. In risk assessment EFSA analyses the nutritional, toxicological and allergenic properties of the novel food and its production process. After 9 months, EFSA provides the European Commission with its scientific opinion on the safety of the product. If this opinion is positive, in risk management the Commission drafts an implementing act which is considered in the Standing Committee for Plants, Animals, Food and Feed - with representatives from the Commission and all 27 EU Member States. Approval of the implementing act is the final step in novel food authourisation.

Is the Novel Food authorisation process robust enough?

Yes. As the European Commission notes, the EU has one of the highest food safety standards in the world. Food safety is guaranteed through regulatory measures across the entire food chain and the Novel Food Regulation is an integral part of this, providing a thorough and evidence-based evaluation process. EFSA has consistently been found to deliver high quality scientific advice, and retains a high level of trust amongst stakeholders and the public, and EFSA itself has stated that the Novel Food Regulation and associated guidance are fit for purpose in the context of cultivated meat.

Do Member States have a role in authorisations?

Yes. During the risk management stage of novel food approvals, the European Commission along with the 27 representatives of each EU Member States are brought together via the Standing

Committee on Plants, Animals, Food and Feed (PAFF). PAFF Committee decision making is via qualified majority voting, providing Member States substantial input into authorisation decisions.

Can the regulatory framework also consider social and economic impacts of products?

Yes. The Novel Food authorisation process enables debate on wider considerations during product assessment. As the General Food Law states, during risk management the Commission and 27 representatives of each EU Member State can consider the economic, social and cultural aspects of decision-making, enabling product authorisations decisions to be taken in a holistic context.

Does the public have a voice in the authorisation process?

Yes. The Novel Food authorisation process includes a public consultation for products at the conclusion of the risk assessment process. The consultation - available on OpenEFSA - encourages feedback on scientific data and studies that should be considered by EFSA during risk assessment.

Does the EU precautionary principle mean cultivated meat market entry should be stopped?

No. The General Food Law Regulation outlines the precautionary principle only comes into play after an evidence-based assessment has been carried out, applying when "*...the possibility of harmful effects on health is identified, but scientific uncertainty persists*". Risk management measures must be proportionate and necessary for protecting human health, and must be provisional until more information can be analysed. As cultivated meat has not yet been approved for sale, these principles would be violated, as there is no risk for human health from a product that consumers cannot access.

Should we regulate cultivated meat as a pharmaceutical product?

No. Regulating cultivated meat as a pharmaceutical product is impractical. Cultivated meat is a food made in food production facilities, so it should be regulated as food – with the same world-leading safety and hygiene standards that apply to everything else we eat in Europe. There is no precedent for regulating a food using a pharmaceutical regulatory regime in Europe, and doing so would actually weaken the ability of regulators to answer critical questions related specifically to food safety.

How should cultivated meat be labelled?

Labelling and denominations for cultivated meat will be considered as part of the Novel Food authorisation process. During risk management, Member States and the Commission should ensure that the approach taken is consumer-driven, ensuring clear signposts such as chicken, beef and salmon are allowed on labels when qualified with terms like 'cultivated'. This is important as consumers with meat or seafood allergies must be informed these products are not safe for them.

Are there ways in which the regulatory framework for cultivated meat could be improved?

EU food safety regulations are the most robust in the world, and it's important these standards are upheld for cultivated meat. While there are opportunities to improve the Novel Food authorisation process through better application guidance and increased pre-submission support for producers, overall the regulatory framework remains fit for purpose for the assessment of cultivated meat.