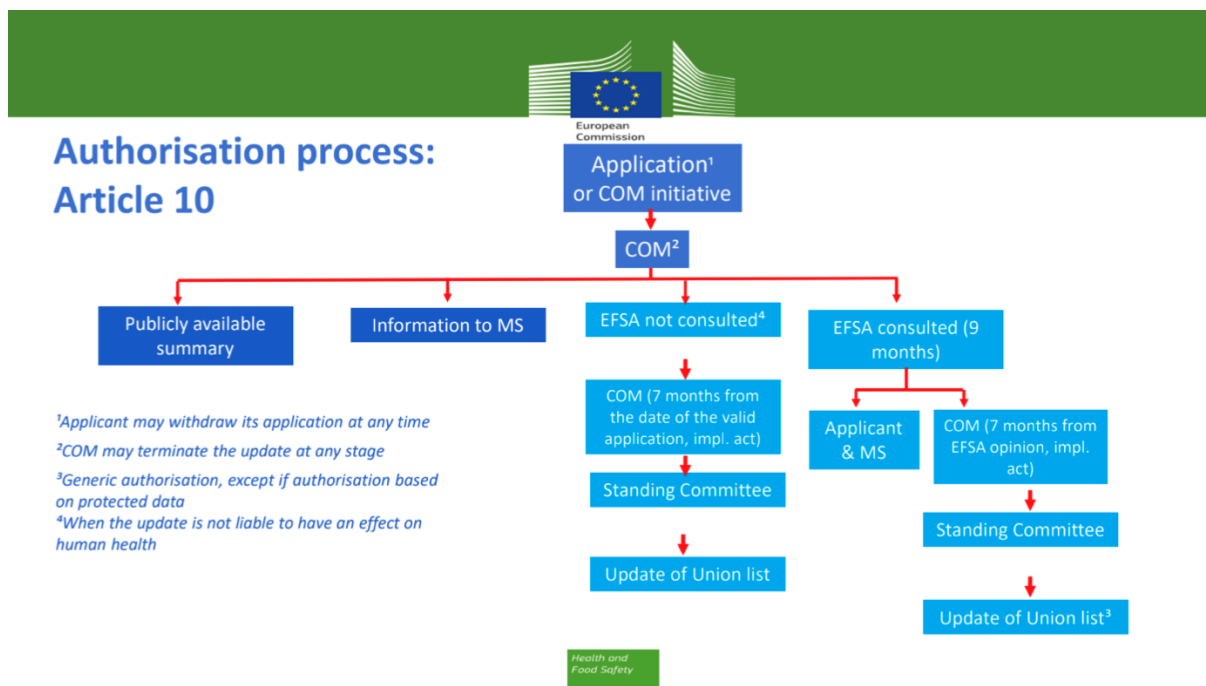


Synthetic imitation of food: regulatory framework

The EU policy framework

In the EU, imitation of animal products grown in a lab can either fall under the ‘Novel Food’ regulation ([EU/2015/2283](#)), or under the genetically modified food and feed regulation No 1829/2003¹. EU law defines a novel food as “any food that was not used for human consumption to a significant degree within the Union before 15 May 1997”, the date when the regulation on novel food came into force. The regulation further specifies that novel food can be newly developed, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally eaten outside the EU.

According to Art. 10 of the Regulation, the approval process for marketing a novel food within the EU foresees the involvement of the EU Commission and, possibly, of the European Food Safety Authority (EFSA) which allows or not the product to be sold to EU consumers: the initiative is presented either by the European Commission or any applicant. It is shared with Member States with no delay. Then, the Commission might involve the EFSA for its opinion on safety assessment (to be delivered within 9 months from the request). After consideration, the Commission decides to update the EU list of novel foods with an implementing act, allowing the new food to be sold in the EU market (within seven months from the reception of the application if EFSA is not involved, or within sixteen months -to be extended in case of further information is required- if the Authority’s opinion is asked). If EFSA is involved, the Commission has to send the draft implementing draft act to the Standing Committee on Plants, Animals, Food and Feed after receiving EFSA’s assessment. All along the process, both the Commission and the applicant can decide to withdraw the application.



¹ If the technique that is used to produce the product falls under the GMO regulation.

Figure 9: Authorization process of a novel food. Source: European Commission

GMO regulation is applied to the product if the techniques that are used to produce it fall under its scope. To be underlined that **producers argue that, even if the production process involves genetic modifications, the final outcome itself shall not be considered as a GMO.**

According to interviews done by Ketelings et al (2021), when asked about the legislative framework, **experts said that lab-grown imitation of meat should comply with the GMO legislation under European law.** Such a conclusion can be drawn from the fact that one possibility to harvest the initial cells can include gene modification or, a modification to avoid the use of antibiotics. However, during a public intervention at an event hosted by the European Parliament (on July 13, 2022), a **representative of the European Commission's DG Sante, while talking about lab-grown replacement of meat, considered the Novel food regulation as the reference legislative framework.**

Key regulations in other countries include:

- **USA:** the United States Department of Agriculture (USDA) and its Food and Drug Administration (FDA) jointly regulate cultivated protein food production and marketing. The FDA regulates the collection and growth of cultured cells, while the USDA oversees cell harvesting, processing, and labeling. These agencies appear to be early in the process of establishing regulatory frameworks and have only established initial committees to develop processes and guidelines.
- **Singapore** is the first and only country to consent the commercialization of a single cultivated meat product. The Singapore Food Agency (SFA) granted approval to the company Eat Just for its cultivated chicken bites. Despite Eat Just's permit, there is no clear path to market for other providers.
- **China:** imitation of food grown in a lab is mentioned as one of the sector on which the Chinese government's 14th five-years plan is investing on, marking the first-time alt-protein has been specifically mentioned in relation to top-level economic development guidelines issued by the country's government. **20 million Yans** (almost €3 million) are supposed to be earmarked to finance alternative proteins in publicly funded R&D projects.

At the same time, in 2021 the government announced that it will finance the three-year project called 'High-efficiency biological manufacturing Technology of artificial meat', led by Jiangnan University.