

## Cellular Agriculture Europe's comments on TRIS notification 2023/0469/IT (Italy)

**Brussels, 6<sup>th</sup> September 2023:** Cellular Agriculture Europe brings together producers of cultivated meat, seafood, ingredients, and products with stakeholders to find common ground and speak with a shared voice for the good of the industry, consumers, and regulators. The purpose of our association is to represent and enhance the new cellular agriculture industry in Europe.

We therefore wish to submit comments on Italy's Draft Law with *Provisions relating to the prohibition on the production and marketing of food and feed consisting of, isolated from or produced from cell cultures or tissues derived from vertebrate animals, as well as the prohibition on the designation of processed products containing vegetable proteins as meat.*

First of all, we wish to react to the statement mentioned in paragraph 9 of the notification text according to which *"Given the absence, presently, of specific legislation at the European level (...)".* Here, as it was repeatedly said by the European Commission and the European Food Safety Authority (EFSA), the European Union does have an appropriate regulatory system in place for the safety assessment and approval of cell-cultured products with the Novel Foods Regulation<sup>1</sup>. To illustrate our statement, we wish to refer to:

- The European Commission's answers to multiple parliamentary questions. More precisely:
  - Executive Vice-President Vestager answer<sup>2</sup> to parliamentary question E-001778/2023, according to which *"The novel foods Regulation has been designed to support innovation and aims to address possible safety concerns in a number of innovative food or food production techniques, including for cell-based products. Such products can eventually be placed on the EU market only after an authorisation has been granted by the Commission on the basis of applications submitted by economic operators under the novel foods Regulation and following a thorough pre-market safety assessment by the European Food Safety Authority. The legislation also foresees that other legitimate factors relevant to the application under consideration may be taken into account for the authorisation. Moreover, the whole acquis of the EU food law, when relevant, would apply to these products. The Commission thus considers that the current rules are sufficient to make well-informed decisions on the authorisation of lab-grown meat production"*

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<sup>1</sup> See [Regulation \(EU\) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation \(EU\) No 1169/2011 of the European Parliament and of the Council and repealing Regulation \(EC\) No 258/97 of the European Parliament and of the Council and Commission Regulation \(EC\) No 1852/2001.](#)

<sup>2</sup> See [https://www.europarl.europa.eu/doceo/document/E-9-2023-001778-ASW\\_EN.html](https://www.europarl.europa.eu/doceo/document/E-9-2023-001778-ASW_EN.html).

- Former Commissioner Gabriel's answer to parliamentary question E-004038/2022<sup>3</sup>: "*Before any EU pre-market authorisation can be granted by the Commission to cell-based product as a novel food, the European Food Safety Authority (EFSA) will give its opinion on its safety, on the basis of an application dossier*".
- Statements made by Guilhem De Seze, Head of the Risk Assessment Production department at EFSA, and Bruno Gautrais, Head of the European Commission's DG SANTE Unit E2 "Food processing technologies and novel foods", at EFSA's 11<sup>th</sup> and 12<sup>th</sup> May Scientific Colloquium 27 "Cell culture-derived foods and food ingredients"<sup>4</sup>.
- EFSA's recent assessment of the safety of apple fruit cell culture biomass as a novel food pursuant to Regulation (EU) 2015/2283<sup>5</sup>.

In addition, with regard to Article 2 of the Draft Law, entitled *Prohibition on the production and marketing of food and feed consisting of, isolated from or produced from cell cultures or tissues derived from vertebrate animals*, we wish to stress that, as responsible food business operators, our members strictly adhere to the EU food legislation. Novel foods being subject to a pre-market authorisation, our members must seek regulatory approval before placing their products on the EU market.

With regard to Article 3, entitled *Prohibition on the designation of processed products containing vegetable proteins as meat*: Cellular agriculture is the process of producing animal-based foods and other products directly from animal cells. Cellular agriculture offers a wide range of products from cultivated meat, poultry, fish and seafood, to other animal-based products e.g., cultivated foie gras, eggs, dairy and other non-food products. In our view, it is meat, made in a different way. This is why we generally refer to "cultivated meat". Moreover, we would like to remind that, as part of the Novel Foods process, the labelling of the novel food shall be decided at risk management step of the procedure, in accordance with Article 9 of Regulation 2015/2283<sup>6</sup>.

We thank you for your consideration and remain accessible for any further information.

Yours sincerely,



Caroline Rey

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<sup>3</sup> See [https://www.europarl.europa.eu/doceo/document/E-9-2022-004038-ASW\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/E-9-2022-004038-ASW_EN.pdf).

<sup>4</sup> See <https://www.efsa.europa.eu/en/events/efsas-scientific-colloquium-27-cell-culture-derived-foods-and-food-ingredients>.

<sup>5</sup> See <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.8065>.

<sup>6</sup> See Footnote 1.