

## Cellular Agriculture Europe's comments on TRIS notification: 2024/0394/HU<sup>1</sup> (Hungary)

**Brussels, 23<sup>rd</sup> August 2024:** 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 the following comments on the Hungarian *Draft act prohibiting the production and placing on the market of laboratory-grown meat*.

- ❖ **Compliance with EU law:** The EU authorities have indicated on multiple occasions that the Novel Foods Regulation<sup>2</sup> applies to cell-based foods. Placing novel foods on the EU market falls under the competence of the Commission, which is, according to Articles 6 and 9 of EU Regulation 2015/2283 on novel foods, responsible for authorising the marketing of novel foods and updating the Union list accordingly. Besides, before adopting its implementing act allowing the novel food for sale on the EU market, the Europe Commission calls upon the member states brought together in the Standing Committee on Plants, Animals, Food and Feed (PAFF) to either approve or reject its draft text, which means that the Member States do have a say in the approval process. Once a novel food has been authorised on the EU market, the trade of that novel food shall be governed by the principle of free movement of goods, set by Article 26 and 28 to 37 of the Treaty on the Functioning of the EU (TFEU), insofar as the Union list is binding in its entirety and is directly applicable in all Member States.

Takeaway 1: Member States are bound to comply with the Union list of approved novel foods and to approve free trade of novel foods authorised in the EU single market by the Commission after a positive vote by the Member States.

Then, we wish to react to the statements made in paragraphs 8 and 9 of the notification text according to which *“There are a number of concerns about the production and placing on the market of laboratory-grown meat. Answers to the questions raised will only be possible on the basis of a comprehensive impact assessment. However, the adverse effects that can be presumed in advance are such as to justify a ban on the production and placing on the market*

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<sup>1</sup> See <https://technical-regulation-information-system.ec.europa.eu/en/notification/26066>

<sup>2</sup> [Regulation \(EU\) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods](#).

*of laboratory-grown meat” or “It is not clear how the safety of cell-based technology can be guaranteed in order to avoid potential health risks for consumers and it is therefore necessary to introduce regulation”:*

- ❖ **Risk assessment under the Novel Food authorisation procedure:** as pointed out by Commissioner Stella Kyriakides<sup>3</sup> at the 23<sup>rd</sup> January AGRIFISH Council Meeting where a note<sup>4</sup> on cell-based foods was discussed: *“On food safety, we are on very solid ground. The Novel Food Regulation makes sure of that in two key ways. Firstly, it makes sure that human health and consumer interests are very well protected in a properly functioning internal market. **Novel foods undergo a demanding pre-market safety and nutritional assessment by independent scientists from the European Food Safety Authority (EFSA)**”.*

Indeed, considering the evolution of scientific knowledge and the investment of food business operators, the EU has repealed the old Novel Foods Regulation (258/97) with the adoption of Regulation EU 2015/2283 on novel foods. The definition of “*novel food*” has been updated as “*any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union and that falls under at least one of the [ten] categories*”, including now “*food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae*”. According to the Novel Food authorisation procedure, once the European Commission receives an application, it conducts an initial assessment of the application to ensure it contains all necessary information. The Commission may then request the European Food Safety Authority (EFSA) to give its opinion as to whether the update of the Union list is liable to have an effect on human health, and in order to set its opinion, the EFSA is entitled to request additional information to the applicant.

While Europe can pride itself for having one of the safest foods in the world, this is most certainly due to its stringent risk assessment procedure, which is among the strictest in the world. This should alleviate any doubt on the safety of cell-based foods.

Takeaway 2: A thorough assessment of the potential impact of cell-based food on human health or the environment is already foreseen in the Novel Food authorisation procedure which applies to these innovative products.

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<sup>3</sup> See [https://ec.europa.eu/commission/presscorner/detail/en/SPEECH\\_24\\_384](https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_24_384)

<sup>4</sup> See <https://data.consilium.europa.eu/doc/document/ST-5469-2024-INIT/en/pdf>

- ❖ **Presumption of risk and precautionary principle:** the principle of free movement of goods enshrined in the EU Treaty and in Article 5 of the General Food Law<sup>5</sup> for food products. In this context, Member States wishing to implement provisional measures restricting the commercialisation of a food product have the authority to do so when they inform the Commission of the need for such measures but the Commission has not taken any actions<sup>6</sup>. In such cases, Member States need to demonstrate the urgent need for such measures and the existence of a risk to human health, animal health, or the environment, based on new and reliable scientific data<sup>7</sup>. It is true that Member States have the power to protect public health when it is threatened by a food product, by restricting its marketing. Furthermore, according to the precautionary principle defined in Article 7 of the General Food Law, these restrictions may be anticipatory.

On the other hand, the precautionary principle is also mentioned in the provisions of the Treaty on the Functioning of the EU regarding the European environmental policy<sup>8</sup>, and in national regulations as far as public health is concerned. It aims to prevent a risk that is not purely hypothetical. Jurisprudence shows that the Court of Justice requires proof of an established and serious risk for public health when the precautionary principle is invoked. A proper implementation of the precautionary principle implies the identification of potential negative consequences of a product and a risk assessment based on reliable scientific data. And risk assessment cannot be based solely on presumptions and hypothetical considerations.

Additionally, the measures that may be taken for the safeguard of public health must be necessary and strictly proportionate to the objective pursued. The proportionality principle is not applicable to EU institutions only but also to Member States<sup>9</sup>, and its objective is to ensure the substance of the fundamental economic freedoms granted by the EU Treaties. Consequently, Member States must choose, among the available measures, the one that causes the least harm to the free trade policy. Here, we would like to stress that, to date, cultivated meat or seafood is not on the European market. The European Commission received its first application for an authorisation of our member Gourmey's cultivated foie gras on 26<sup>th</sup> July 2024. One can therefore seriously question the proportionality of a ban for products that are not even allowed for sale on EU soil.

Furthermore, within this legal framework, several national measures restricting the commercialisation of food products have already been questioned. As an example, in

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<sup>5</sup> [Regulation \(EC\) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.](#)

<sup>6</sup> See Article 54 of EU Regulation 178/2002.

<sup>7</sup> CJEU, 8<sup>th</sup> September 2011, C-58/10 to C-68/10, *Monsanto SAS and Others v Ministre de l'Agriculture et de la Pêche*.

<sup>8</sup> Article 191 TFEU.

<sup>9</sup> ECJ, 20<sup>th</sup> February 1979, C-120/78, *Cassis de Dijon*.

France, the administrative judges have invalidated a Decree prohibiting genetically modified corn MON 810, because scientific data on this food product did not demonstrate any environmental risks that could justify the adoption of urgent measures for a total ban<sup>10</sup>.

Takeaway 3: the legal conditions that would permit a national, pre-emptive ban the commercialisation of cultivated meat or seafood (i.e. risk identification and assessment; proportionality) are not fulfilled.

Moreover, we would also like to react to the following statement taken from paragraph 9 of the notification text: *“Traditional livestock-based meat production is of paramount importance for the future of the domestic food economy, in particular the sustainability of food production and the retaining power of the countryside. Increased production of laboratory-grown meat can have an adverse impact on the agricultural sector and rural living conditions as a whole”*.

- ❖ **Restriction of free trade of goods for economic reasons:** The Court of Justice of the EU considered that a Member State cannot implement measures restricting free trade for purely economic reason, such as the protection of national industry<sup>11</sup>. In addition, Article 36 of the TFEU provides that *“prohibitions or restrictions [on imports, exports of goods in transit] shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States”*. In a Communication on the precautionary principle<sup>12</sup>, the Commission specified that *“measures taken under the precautionary principle should be designed to achieve an equivalent level of protection without invoking the geographical origin or the nature of the production process to apply different treatments in an arbitrary manner”*.

Takeaway 4: The EU law provides that trade restrictions between Member States cannot be based on economic grounds.

Finally, in reaction to the notification statement according to which *“representative population surveys show that consumer opposition to laboratory-grown meat exceeds the rejection of foods containing insect protein”*:

- ❖ **Consumer acceptance and appetite for cultivated meat:** According to a consumer survey recently commissioned by the Good Food Institute Europe<sup>13</sup>, 53% of Germans had heard of cultivated meat and 47% would try it, while 59% of Austrians had heard

<sup>10</sup> Conseil d'Etat 3<sup>rd</sup> and 8<sup>th</sup> ch., 15<sup>th</sup> April 2016, case 376809.

<sup>11</sup> ECJ, 6<sup>th</sup> June 2000, C-35/98, *Verkoijen*.

<sup>12</sup> COM (2000) 1 final.

<sup>13</sup> See [here](#).

of it and 42% would try it. Also, according to a cell culture-derived meat flash poll commissioned earlier this year by the European Food Safety Authority (EFSA) and presented to the member states on 23<sup>rd</sup> April 2024<sup>14</sup>, 28% of Italian respondents are in favour of cultivated meat while 36% of them are neutral; 27% of Spanish respondents are in favour while 36% are neutral and 25% of Dutch respondents are in favour and 38% of them are neutral. These figures show a raising awareness of these new products as well as European consumers' openness. Both shall necessarily grow when these products enter the EU market.

Our members are also strong supporters of consumers' informed choice when their products enter the EU market. Once the safety of cultivated meat or seafood is confirmed and their consumption allowed in the EU, the consumers should have the opportunity to choose the meat or seafood products they want to enjoy.

Takeaways 5: Although cultivated meat or seafood has not hit the shelves in the EU, European consumers' awareness and curiosity are rising.

Takeaway 6: All EU consumers shall have the freedom to purchase the food products they wish to eat wherever they are in the EU.

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

Yours sincerely,



Caroline Rey

Secretary General

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<sup>14</sup> See <https://www.efsa.europa.eu/en/events/15th-meeting-communications-experts-network>.