

EuropaBio response to TRIS Notification 2024/0394/HU

Brussels, 12 September 2024

EuropaBio, the European Association for Bioindustries, is the recognised voice of the European biotech industry championing world-class solutions for society's challenges, including ensuring the competitiveness of the agrifood sector and food resilience for Europe.

We wish to submit the following comments on the Hungarian *Draft Act prohibiting the production and placing on the market of laboratory-grown meat*.

- **Risk of Single Market distortion**

In the EU, cultivated meat is regulated by the [Novel Foods Regulation 2015/2283](#), which requires a thorough risk assessment for all products submitted for application by the European Food Safety Authority (EFSA). Once considered safe and approved, a novel food is subject to the free movement of goods across all 27 EU member states.

By introducing a specific national requirement, this Hungarian draft law would present an unreasonable barrier to the functioning of the single market by interfering with the free movement of goods (article 36, Treaty on the Functioning of the European Union). Differentiating requirements for cultivated meat would undermine European and national competitiveness and ultimately prove a disservice to consumers and producers.

Member State restrictions on the free movement of products cannot pertain to economic interest and must be justified by specific conditions, such as demonstrable threat to public health¹. The EFSA will consider the risks for public health, and specific concerns can be submitted during the public consultation stage of each risk assessment.

- **Presumption of risk and proportionality principle**

In the accompanying message to the draft law, Hungarian authorities state that a ban on cultivated meat would be justified due to “adverse effects that can be presumed in advance”. According to the General Food Law, a pre-emptive ban on specific products is allowed under the precautionary principle². However, the precautionary principle applies only when risk to human health can be

¹ “The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.”, Article 36, TFEU

² “1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a

demonstrated through a scientific assessment, but scientific uncertainty remains. This principle is meant as a provisional measure before further data and research can be provided.

In the case of cultivated meat, such a risk to human health has not been demonstrated. On the contrary, cultivated meat applications have been approved by relevant food safety authorities, in Singapore and the United States, for example. In 2023, the FAO and WHO published an extensive joint report on safety aspects of cultivated meat, concluding that the hazards associated to cultivated meat products “are already well known and existing equally as well in conventionally produced food”³.

Furthermore, the application of the precautionary principle necessitates risk management measures that are proportionate to existing threats. Member States must therefore implement the measures that cause the least possible harm to the free movement of goods across the Union. In this case, a pre-emptive ban is not justified in light of the risks.

- **The EU’s approval process for Novel Foods**

The Hungarian draft law presupposes that cultivated meat products pose a threat to human health and the environment. However, the authorisation procedure for Novel Foods under EU law addresses these safety concerns through a detailed and science-based risk assessment process. The risk assessment is done by EFSA, which includes, among other analyses, an analysis of nutritional, toxicological and allergenic properties of the novel food and its production process. EFSA provides the European Commission with a scientific opinion on the novel food, with the Commission implementing relevant risk management measures as part of the product approval carried out together with Member States. The EU has one of the most robust risk assessment processes in the world, with Europeans benefitting from this high standard of food safety. Therefore, a pre-emptive ban is unnecessary as a thorough and detailed risk assessment by EFSA is already foreseen in the Novel Food Regulation. Furthermore, a ban would dismiss the work done based on presumptions. Regulation of food and feed products on the European Market should be based on scientific research and risk assessment rather than political agendas, to ensure that consumers benefit from a high degree of safety and transparency.

This risk assessment process also foresees other factors: as per the General Food Law, “Economic, traditional, ethical and environmental factors” are also considered when approving a product for placement on the market, therefore addressing the concerns expressed by Hungarian authorities that cultivated meat presents a threat to traditional products. Member States are also fully involved in the approval process for novel foods, through the risk management phase, as they are represented in the Standing Committee on Plants, Animals, Food and Feed (PAFF). A national ban is therefore unnecessary, as Hungarian authorities will have multiple occasions to express and discuss their concerns for any authorization of a novel food under the existing EU legal framework, during the risk assessment as well as the risk management phase.

reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.”, Article 7, Regulation (EC) No 178/2002

³ FAO & WHO. 2023. Food safety aspects of cell-based food. Rome. <https://doi.org/10.4060/cc4855en>

- **Consumer concerns**

The Hungarian draft law also mentions consumer scepticism towards cultivated meat. This undermines the competitiveness of the Single Market by presuming that consumers would not want to consume it, which is particularly difficult for products that have so far not even been available to consumers. Furthermore, several surveys conducted on the topic of novel foods show that consumers are open to cultivated meat products being placed on the market. Recently, a YouGov survey⁴ found that over half of the respondents, including in Hungary, believe cultivated meat should be made available if a safety assessment has been conducted.

The voice of consumers is also taken into consideration during the risk assessment process, through the open consultation phase of EFSA's risk assessment.

- **Complementarity of traditional agriculture and novel foods**

This Hungarian draft law considers cultivated meat to be a threat to traditional agriculture and foods. However, the agricultural sector is set to benefit from an uptake in novel food production, as it would support diversity of protein production and ease land use pressures.

In July 2024, Europe's first application for cultivated meat product as a Novel Food was made by Gourmey⁵, for foie gras, which is part of France's gastronomic tradition. Cultivated meat can be complementary to national and regional traditions, and work in synergy with existing agricultural practices.

⁴ <https://gfi-europe.org/wp-content/uploads/2024/07/YouGov-survey-of-attitudes-to-cultivated-meat-in-15-countries.pdf>

⁵ <https://www.gourmey.com/post/seeking-approval-in-five-key-markets-confirming-global-ambitions>