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Ministry of Foreign Affairs and Trade
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Subject: **Notification No 2024/0394/HU**

Draft act prohibiting the production and placing on the market of laboratory-grown meat ("a laboratóriumi hús")

Delivery of a detail opinion pursuant to Article 6(2) of Directive (EU) 2015/1535.

Dear Sir,

Within the framework of the notification procedure laid down in Directive (EU) 2015/1535[1], the Hungarian authorities notified to the Commission on 10 July 2024 the draft **act prohibiting the production and placing on the market of laboratory-grown meat ("a laboratóriumi hús"),** (hereinafter, "the notified draft").

According to the notification message, the notified draft aims to introduce a ban on the production and placing on the market of laboratory-grown meat ("a laboratóriumi hús") in order to address concerns regarding the protection of human health and the environment, sustainable agricultural production and the preservation of the traditional rural way of life.

The examination of the notified draft has prompted the Commission to issue the following detailed opinion.

Paragraph 1 of the notified draft defines laboratory grown meat ("a laboratóriumi hús") as follows:

'*For the purposes of this Act, laboratory-grown meat* ("a laboratóriumi hús") *means a product isolated or produced from animal cells or tissues under artificial conditions outside the living organism*.'

Paragraph 2 of the notified draft states that:

[1] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

'*With the exception of medical and veterinary use, the production and placing on the market of laboratory-grown meat* ("a laboratóriumi hús") *and products containing laboratory-grown meat* ("a laboratóriumi hús") *as an ingredient shall be prohibited.*'

'Novel food' is defined in Article 3(2)(a) of Regulation (EU) 2015/2283[2] 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* [one of the listed categories]'. The two conditions are to be understood as cumulative.

On cultured meat, the specific category under point (vi) of Article 3(2)(a) of that Regulation includes '*food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae*'.

Laboratory-grown meat ("a laboratóriumi hús") as defined in Paragraph 1 of the notified draft satisfies both these cumulative conditions and should therefore be considered a novel food.

In accordance with Regulation (EU) 2015/2283, any novel food is subject to a pre-market authorisation process, including a safety assessment by the European Food Safety Authority (EFSA). Once a novel food is authorised, it is included in the Union list of novel foods established by Commission Implementing Regulation (EU) 2017/2470[3] and the novel food can be marketed in the Union. No authorisation has yet been granted for any laboratory-grown meat ("a laboratóriumi hús") product, these products are therefore not allowed to be placed on the market within the Union, in line with Article 6 of Regulation (EU) 2015/2283. A ban is therefore unnecessary, as currently the prohibition to market it results from Union law and applies to all the Union territory.

In this context the Commission notes that the scientific assessment to be performed by EFSA within the procedure for the authorisation of novel foods is aimed to ensure that foods to be placed on the EU market are safe and do not present risk for human health.

A ban is therefore unjustified, since it could pre-empt the harmonised authorisation procedure for novel foods at EU level, which includes a scientific assessment by EFSA.

For the reasons stated above, the Commission delivers a detailed opinion as provided for in Article 6(2) of Directive (EU) 2015/1535 to the effect that Paragraph 2 of the notified draft does not comply with the provisions laid down in Chapters II to VI of Regulation (EU) 2015/2283 concerning the authorisation procedure for novel foods.

In this context, the Commission would like to request the Hungarian authorities to clarify whether any laboratory grown meat ("a laboratóriumi hús") product currently exists on the Hungarian market or the notified measure has been drafted to prevent their placement on the Hungarian market.

[2] 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, OJ L 327, 11.12.2015, p. 1.

[3] Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, OJ L 351, 30.12.2017, p. 72.

The Commission would remind the Hungarian authorities that under the terms of Article 6(2) of Directive (EU) 2015/1535, the delivery of a detailed opinion obliges the Member State that has drawn up the draft technical regulation concerned, to postpone its adoption for six months from the date of its notification.

This standstill period therefore comes to an end on 13 January 2025.

The Commission further draws the attention of the Hungarian authorities to the fact that under the above-mentioned provision the Member State that is the addressee of a detailed opinion is obliged to report to the Commission on the action that it proposes to take on such detailed opinion.

Should the Hungarian authorities not comply with the obligations provided in Directive (EU) 2015/1535 or should the text of the draft technical regulation under consideration be adopted without account being taken of the above-mentioned objections, or be otherwise in breach of EU law, the Commission may commence proceedings pursuant to Article 258 of the Treaty on the Functioning of the European Union.

Yours faithfully,

For the Commission

Stella KYRIAKIDES
Member of the Commission