EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 115

Communication from the Commission - TRIS/(2024) 2750

Directive (EU) 2015/1535

Notification: 2024/0394/HU

Forwarding of a detailed opinion received by a Member State (Lithuania) (article 6, paragraph 2, second indent of Directive (EU) 2015/1535). This detailed opinion extends the standstill period until 13-01-2025.

Detailed opinion - Avis circonstancié - Ausführliche Stellungnahme - Подробно становище - Podrobné stanovisko - Udførlig udtalelse - Εμπεριστατωμένη γνώμη - Dictamen circunstanciado - Üksikasjalik arvamus - Yksityiskohtainen lausunto - Detaljno mišljenje - Részletes vélemény - Parere circostanziato - Išsamiai išdėstyta nuomonė - Sīki izstrādāts atzinums - Opinjoni dettaljata - Uitvoerig gemotiveerde mening - Opinia szczegółowa - Parecer circunstanciado - Aviz detaliat - Podrobné stanovisko - Podrobno mnenje - Detaljerat yttrande

Extends the time limit of the status quo until 13-01-2025. - Prolonge le délai de statu quo jusqu'au 13-01-2025.- Die Laufzeit des Status quo wird verlängert bis 13-01-2025.- Удължаване на крайния срок на статуквото до 13-01-2025. - Prodlužuje lhůtu současného stavu do 13-01-2025. - Fristen for status quo forlænges til 13-01-2025. - Παρατείνει την προθεσμία του status quo 13-01-2025. - Amplía el plazo de statu quo hasta 13-01-2025. - Praeguse olukorra tähtaega pikendatakse kuni 13-01-2025. - Jatkaa status quon määräaikaa 13-01-2025 asti. - Produžuje se vremensko ograničenje statusa quo do 13-01-2025. - Meghosszabbítja a korábbi állapot határidejét 13-01-2025-ig. - Proroga il termine dello status quo fino al 13-01-2025. - Status quo terminas pratęsiamas iki 13-01-2025. - Pagarina “status quo” laika periodu līdz 13-01-2025. - Jestendi t-terminu tal-istatus quo sa 13-01-2025. - De status-quoperiode wordt verlengd tot 13-01-2025. - Przedłużenie status quo do 13-01-2025. - Prolonga o prazo do statu quo até 13-01-2025. - Prelungește termenul status quo-ului până la 13-01-2025. - Predlžuje sa lehota súčasného stavu do 13-01-2025. - Podaljša rok nespremenjenega stanja do 13-01-2025. - Förlänger tiden för status quo fram till 13-01-2025.

The Commission received this detailed opinion on the 07-10-2024. - La Commission a reçu cet avis circonstancié le 07-10-2024. - Die Kommission hat diese ausführliche Stellungnahme am 07-10-2024 empfangen. - Комисията получи настоящото подробно становище относно 07-10-2024. - Komise obdržela toto podrobné stanovisko dne 07-10-2024. - Kommissionen modtog denne udførlige udtalelse den 07-10-2024. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 07-10-2024. - La Comisión recibió el dictamen circunstanciado el 07-10-2024. - Komisjon sai üksikasjaliku arvamuse 07-10-2024. - Komissio sai tämän yksityiskohtaisen lausunnon 07-10-2024. - Komisija je zaprimila ovo detaljno mišljenje dana 07-10-2024. - A Bizottság 07-10-2024-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 07-10-2024. - Komisija gavo šią išsamiai išdėstytą nuomonę 07-10-2024. - Komisija saņēma šo sīki izstrādāto atzinumu 07-10-2024. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-07-10-2024. - De Commissie heeft deze uitvoerig gemotiveerde mening op 07-10-2024 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 07-10-2024. - A Comissão recebeu o presente parecer circunstanciado em 07-10-2024. - Comisia a primit avizul detaliat privind 07-10-2024. - Komisia dostala toto podrobné stanovisko dňa 07-10-2024. - Komisija je to podrobno mnenje prejela dne 07-10-2024. - Kommissionen mottog detta detaljerade yttrande om 07-10-2024. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 07-10-2024.

MSG: 20242750.EN

1. MSG 115 IND 2024 0394 HU EN 13-01-2025 07-10-2024 LT DO 6.2(2) 13-01-2025

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4. 2024/0394/HU - C50A - Foodstuffs

5. article 6, paragraph 2, second indent of Directive (EU) 2015/1535

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DETAILED OPINION OF THE REPUBLIC OF LITHUANIA ON THE TECHNICAL REGULATION PREPARED BY HUNGARY (NOTIFICATION No 2024/0394/HU)

Pursuant to Article 6(2) of 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, we hereby submit the detailed opinion of the Republic of Lithuania on a draft technical regulation prepared by the competent authority of Hungary proposing to lay down provisions relating to the prohibition on the production and placing on the market of laboratory-grown meat (Draft act prohibiting the production and placing on the market of laboratory-grown meat, notified in the Technical Regulations Information System ('TRIS') under reference No 2024/0394/HU ('Draft Technical Regulation')).

In this detailed opinion, we set out the arguments and grounds on which our opinion is based and, on these grounds, we request Hungary to lift the disproportionate and unjustified prohibitions restricting the free movement of goods in the internal market of the European Union.

1. THE TECHNICAL REGULATION INFRINGES ARTICLE 34 TFEU.
In the opinion of the Republic of Lithuania, the draft Technical Regulation infringes Article 34 of the Treaty on the Functioning of the European Union (TFEU) by restricting the free movement of goods between the Member States of the European Union (EU) and the obstacles to the free movement of goods between EU Member States created by this draft are not justified under Article 36 TFEU.

Article 34 TFEU establishes a rule that quantitative restrictions on imports and all measures having equivalent effect are prohibited between EU Member States.

Article 2 of the draft Technical Regulation states that 'with the exception of medical and veterinary use, the production and placing on the market of laboratory-grown meat and products containing laboratory-grown meat as an ingredient shall be prohibited'. Article 3 also provides that 'In the event of a breach of the provisions of Article 2, the food chain supervisory body may apply the legal consequences under Chapter VI of Law No. 6 of 2008 on the food chain and its official supervision (hereinafter: Food Act), in accordance with the provisions of the Food Act and the decree issued for the implementation thereof'.

In the opinion of the Republic of Lithuania, the prohibition on the production and placing on the market of laboratory-grown meat and products constitutes a measure having equivalent effect to a quantitative restriction on imports/exports within the meaning of Article 34 TFEU. We emphasize that, in this case, the draft Technical Regulation proposed by Hungary is to be regarded as a restriction on both exports and imports. Exports – since the absolute prohibition on the production and placing on the market of laboratory-grown meat will result in persons operating in Hungary being unable

to produce and therefore unable to export to other European Economic Area (EEA) countries. Imports – since the ban on placing on the market will also apply to suppliers from other EEA States, preventing them from placing their products on the Hungarian market. This creates significant obstacles to the free movement of goods, which are prohibited by Article 34 TFEU.

Article 2 of the draft Technical Regulation stating that 'with the exception of medical and veterinary use, the production and placing on the market of laboratory-grown meat and products containing laboratory-grown meat as an ingredient shall be prohibited', refers to placing on the market in general and thus suggests that it will apply to all operators, irrespective of their country of origin, seeking to place products on Hungarian territory. It is important to point out that such legal regulation established by the Technical Regulation will have a direct negative impact both on the movement of cultivated meat production in the internal market and on the overall development of this new sector. Nor does the draft Technical Regulation provide for the application of the principle of mutual recognition to laboratory-grown meat products which are/will be lawfully marketed in other Member States of the European Union or Turkey or originating in a country of the European Free Trade Association which is a signatory to the Agreement on the European Economic Area.

In Lithuania's view, such a situation must be regarded as restricting the free movement of goods between EU Member States and, consequently, being in breach of the provisions of Article 34 TFEU.

In that regard, it should be recalled that, according to the settled case-law of the Court of Justice of the European Union, any measure of an EU Member State which is capable of hindering, directly or indirectly, actually or potentially, intra-EU trade must be regarded as a measure having equivalent effect to quantitative restrictions within the meaning of Article 34 TFEU (Judgement of 11 July 1974, Dassonville, 8/74, EU:C:1974:82, paragraph 5); Judgement of 23 December 2015, Scotch Whisky Association and Others, C-333/14, EU:C:2015:845, paragraph 31.

2. THE OBSTACLES TO THE FREE MOVEMENT OF GOODS BETWEEN MEMBER STATES CREATED BY THE TECHNICAL REGULATION ARE NOT JUSTIFIED UNDER ARTICLE 36 TFEU.
Article 36 TFEU allows prohibitions or restrictions on the import, export or transit of goods 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 of art, history or archaeology and 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.

In that regard, it should be noted that it is for a Member State which prohibits the marketing in its territory of a specific product or substance, which may be regarded as the placing on the market, to prove that that measure is necessary and, where appropriate, that the marketing of those products poses a serious risk, for example, to public health, and that those rules comply with the principle of proportionality (judgement of 9 December 2010 in case C421/09 Humanplasma, EU:C:2010:760, paragraph 45). The Member State must also provide all relevant evidence, such as technical, scientific, statistical or nutritional data (judgement of 5 February 2004 in Case C-270/02 Commission v Italy, EU:C:2004:78). Furthermore, it is the responsibility of the Member State to demonstrate that the objective pursued cannot be attained by other means having a less restrictive effect on intra-Union trade (judgement of 20 May 1976 in Case C-104/75 De Peijper, EU:C: 1976: 67). In other words, such restrictions should be justified and proportionate. In this context, it should be noted that the draft Technical Regulation submitted by Hungary is not accompanied by an impact assessment, nor does it refer to the scientific studies and data on which the decision to take precautionary measures is based, so the appropriateness and proportionality of the chosen measures in relation to the objectives pursued by the draft Technical Regulation are currently not reasonably assessed.

Hungary justifies the need for the provisions of the draft Technical Regulation by stating that there are a number of concerns regarding the production and placing on the market of laboratory-grown meat. The answers to the questions raised will only be available after a full impact assessment has been carried out, but the adverse effects that can be anticipated in advance are such as to justify a ban on the production and placing on the market of laboratory-grown meat. Hungary points out, however, that the uses which may be exempted from the general prohibition (such scenarios include medical and veterinary use, given that they could directly or indirectly protect human health) should be specified.

In addition, Hungary submits that, apart from the protection of human health and the environment, sustainable agricultural production and the preservation of traditional rural lifestyles justify the introduction of regulation. It is not clear how the safety of cell technologies can be ensured in order to avoid potential health risks for consumers; therefore, regulation is necessary. Traditional livestock-based meat production is crucial for the future of the country's food economy, in particular for the sustainability of food production and the preservation of rural areas. Increased production of laboratory-grown meat can have a negative impact on the agricultural sector and overall rural living conditions. In addition, representative population surveys show that consumers are more opposed to laboratory-grown meat than to foods containing insect proteins.

In the opinion of the Republic of Lithuania, the obstacles to the free movement of goods created by the draft Technical Regulation are not justified on grounds of the protection of any of the public interests referred to in Article 36 TFEU. Furthermore, the draft Technical Regulation is not accompanied by technical, scientific, statistical, or other data substantiating the negative impact of cultivated meat on public safety and health, nor the positive impact of the ban on consumer protection in Hungary. Additionally, no evidence has been provided that the objective indicated by the legislative drafter cannot be achieved by other effective and less trade-restrictive measures in the internal market.

In this context, it should first be noted that we support the need to ensure food safety; however, such controls cannot be an end in themselves, disproportionate or excessive, and apply to food entering Hungary from other EU Member States. Accordingly, the prohibition in Article 2 of the draft Technical Regulation does not constitute a justified measure to restrict the free movement of goods within the EU internal market and potentially infringes Article 36 TFEU, which states, inter alia, that the 'prohibitions [...] shall not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.
The preamble to the draft Technical Regulation also states that the Technical Regulation is intended to be adopted in 'recognising the indisputable positive impact of traditional food production on agriculture and rural living conditions as a whole, and the threats to our fundamental values posed by technologies and production methods other than traditional food production'. In the opinion of the Republic of Lithuania, this statement in the Technical Regulation, in the absence of an impact assessment accompanying the draft Technical Regulation, remains subjective/declaratory/evaluative and should therefore not form the basis of the mandatory restrictions on the free movement of goods in question. It should be noted that the draft Technical Regulation is not accompanied by an assessment of the impact on competition in the EU internal market that reasons the extent to which the legal regulation proposed by Hungary will have a direct negative impact on the development of a new sector or on the movement of cultivated meat products within the EU internal market and the extent to which the proposed regulation is proportionate to protect traditional food production by limiting new food industry models. Finally, there is no assessment of the impact it will have in the long term, for example, considering climate change and the EU's foreign trade policy with third countries (with apparent trends towards tightening the import of agricultural products into the EU), in terms of securing quality and affordable food for the European population.

Furthermore, referring to the case-law and cases of the Court of Justice of the European Union (CJEU), it is important to emphasise that the case-law of the Court of Justice of the European Union considers restrictions on the free movement of goods, even of lesser effect than an absolute prohibition, to be prohibited and unjustified. According to the case-law of the CJEU, the free movement of goods between Member States is a fundamental principle of the TFEU, which manifests itself in the prohibition of quantitative restrictions on imports between Member States and of all measures having equivalent effect as laid down in the aforementioned Article 34 TFEU (see e.g. judgement of 15 July 2004, in case C-239/02 Egberts et al., paragraph 50). The CJEU has also clarified that an absolute prohibition on advertising the characteristics of a product is likely to impede access to the market for new products manufactured in other Member States more than for domestic products which are more familiar to the consumer (Ibid., paragraph 53). Thus, even a prohibition on advertising imposed by national law constitutes an obstacle to trade within the European Union, falling within the scope of Article 34 TFEU (Ibid., paragraph 54). For example, in the Danish vitamins case, the CJEU ruled that the Danish administrative practice of prohibiting the marketing of foods enriched with vitamins and minerals, unless it has been demonstrated that such enrichment meets the health needs of the Danish population, is in breach of Article 34 TFEU (see e.g. judgment of 23 September 2003 in case C-192/01 Commission of the European Communities v Kingdom of Denmark, paragraph 57). However, that practice may be justified, in accordance with the principle of proportionality: the

measures must be limited to what is necessary to protect public health and must be proportionate to the objective pursued, which could not have been attained by measures less restrictive of internal trade. We would point out that, in accordance with the existing case-law of the Court of Justice of the European Union, an absolute prohibition on the manufacture and placing on the market of a product could be applied only exceptionally if all the above-mentioned conditions were met.

3. PRODUCTS QUALIFYING AS NOVEL FOODS ARE SUBJECT TO 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

It should be noted that laboratory-grown meat, as a product not previously used for human consumption, is considered a novel food and is subject to Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods <...> (hereinafter 'the Novel Food Regulation'). Its purpose and application is to lay down rules for the placing on the Union market of novel foods and to ensure the effective functioning of the internal market and a high level of protection of human health and consumer interests.
In the opinion of the Republic of Lithuania, laboratory-grown meat or cultured meat meets the definition of novel food set out in Article 3(2)(a) of the Novel Food Regulation and should therefore be subject to the general conditions for inclusion of novel foods in the Union list, i.e. the use of a novel food is authorised provided that:
a) on the basis of the available scientific evidence, the food does not endanger the safety of human health;
b) the intended use of the food does not mislead the consumer, in particular if the food is intended to replace another food and there is a significant change in nutritional value;
c) where a food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

The Novel Food Regulation stipulates that only novel foods authorised and included in the EU list may be placed on the EU market or used in foodstuffs in accordance with the conditions of use and labelling requirements set out in that list.

The Novel Food Regulation stipulates that the European Commission, by means of an implementing act, draws up and updates the first EU list of novel foods, whereas the procedure for placing a novel food on the market is not regulated by national legislation, but by the procedure laid down in the Novel Food Regulation through the authorisation of a novel food producer, who seeks to obtain an authorisation for the placing on the market of a novel food following an application to the European Commission. Such foods shall be subject to a scientific assessment prior to authorisation in order to ensure their safety. The authorisation shall specify the conditions of use of the food, its name as a food/ingredient and the labelling requirements.

The European Food Safety Authority (EFSA) carries out a scientific risk assessment of applications for novel foods and the Commission manages the files of each applicant and makes proposals for the authorisation of novel foods once they have been found to be safe.

In the opinion of the Republic of Lithuania, the harmonised measures for the authorisation of novel foods laid down in the Novel Food Regulation mean that, if a foodstuff has been authorised to be placed on the EU market, it can be marketed in any EU Member State, including Hungary, and therefore the provisions of Articles 2 and 3 of the draft Technical Regulation must be regarded as incompatible with the aforementioned EU regulation.

Finally, it is important to note that global population growth also poses challenges to ensuring the supply of affordable, healthy, nutritious, safe, and sustainably produced proteins. According to the United Nations, the world population is expected to continue to grow for another 50 or 60 years, reaching a peak of 10.3 billion people in the mid-2080s, compared to 8.2 billion in 2024. This will result in a significant increase in global protein demand. Accordingly, the development of the alternative protein industry will generate new, high value-added jobs and promote the integration of businesses into international value chains and the export of high value-added food products.

In addition to the above, interest in plant-based diets and alternative protein products among consumers is growing worldwide, including in major European Union countries. However, given that countries such as the US, Israel, and Singapore already allow the sale of these products, it is important that the EU remains competitive in the development of these technologies and dictates the conditions for regulation and standards globally.

In the light of the above, we consider that the provisions of the draft Technical Regulation should be clarified and disproportionate prohibitions restricting the free movement of goods that are incompatible with EU law should be removed.

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