Message 115

Communication from the Commission - TRIS/(2024) 0198

Directive (EU) 2015/1535

Notification: 2023/0675/IT

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 04-06-2024.

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 04-06-2024. - Prolonge le délai de statu quo jusqu'au 04-06-2024.- Die Laufzeit des Status quo wird verlängert bis 04-06-2024.- Удължаване на крайния срок на статуквото до 04-06-2024. - Prodlužuje lhůtu současného stavu do 04-06-2024. - Fristen for status quo forlænges til 04-06-2024. - Παρατείνει την προθεσμία του status quo 04-06-2024. - Amplía el plazo de statu quo hasta 04-06-2024. - Praeguse olukorra tähtaega pikendatakse kuni 04-06-2024. - Jatkaa status quon määräaikaa 04-06-2024 asti. - Produžuje se vremensko ograničenje statusa quo do 04-06-2024. - Meghosszabbítja a korábbi állapot határidejét 04-06-2024-ig. - Proroga il termine dello status quo fino al 04-06-2024. - Status quo terminas pratęsiamas iki 04-06-2024. - Pagarina “status quo” laika periodu līdz 04-06-2024. - Jestendi t-terminu tal-istatus quo sa 04-06-2024. - De status-quoperiode wordt verlengd tot 04-06-2024. - Przedłużenie status quo do 04-06-2024. - Prolonga o prazo do statu quo até 04-06-2024. - Prelungește termenul status quo-ului până la 04-06-2024. - Predlžuje sa lehota súčasného stavu do 04-06-2024. - Podaljša rok nespremenjenega stanja do 04-06-2024. - Förlänger tiden för status quo fram till 04-06-2024.

The Commission received this detailed opinion on the 23-01-2024. - La Commission a reçu cet avis circonstancié le 23-01-2024. - Die Kommission hat diese ausführliche Stellungnahme am 23-01-2024 empfangen. - Комисията получи настоящото подробно становище относно 23-01-2024. - Komise obdržela toto podrobné stanovisko dne 23-01-2024. - Kommissionen modtog denne udførlige udtalelse den 23-01-2024. - Η Επιτροπή έλαβε αυτή την εμπεριστατωμένη γνώμη στις 23-01-2024. - La Comisión recibió el dictamen circunstanciado el 23-01-2024. - Komisjon sai üksikasjaliku arvamuse 23-01-2024. - Komissio sai tämän yksityiskohtaisen lausunnon 23-01-2024. - Komisija je zaprimila ovo detaljno mišljenje dana 23-01-2024. - A Bizottság 23-01-2024-án/-én kapta meg ezt a részletes véleményt. - La Commissione ha ricevuto il parere circostanziato il 23-01-2024. - Komisija gavo šią išsamiai išdėstytą nuomonę 23-01-2024. - Komisija saņēma šo sīki izstrādāto atzinumu 23-01-2024. - Il-Kummissjoni rċeviet din l-opinjoni dettaljata dwar il-23-01-2024. - De Commissie heeft deze uitvoerig gemotiveerde mening op 23-01-2024 ontvangen. - Komisja otrzymała tę opinię szczegółową w dniu 23-01-2024. - A Comissão recebeu o presente parecer circunstanciado em 23-01-2024. - Comisia a primit avizul detaliat privind 23-01-2024. - Komisia dostala toto podrobné stanovisko dňa 23-01-2024. - Komisija je to podrobno mnenje prejela dne 23-01-2024. - Kommissionen mottog detta detaljerade yttrande om 23-01-2024. - Fuair an Coimisiún an tuairim mhionsonraithe sin maidir le 23-01-2024.

MSG: 20240198.EN

1. MSG 115 IND 2023 0675 IT EN 04-06-2024 23-01-2024 LT DO 6.2(2) 04-06-2024

2. Lithuania

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4. 2023/0675/IT - 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 THE ITALIAN REPUBLIC (NOTE 2023/0675/IT)

In accordance with 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 a detailed opinion of the Republic of Lithuania on the draft technical regulation prepared by the Italian competent authority proposing to lay down provisions on the prohibition of the production and marketing of food and feed consisting of, isolated from or produced from cell cultures or tissues derived from Vertebrate animals and on the prohibition of the designation as meat, the provisions of which concern the prohibition of the manufacture and sale of food and feed consisting of, isolated from, or produced from cell cultures or tissues derived from vertebrate animals, as well as the prohibition of the classification of processed products containing plant proteins as meat (Technical Regulation Information System (hereinafter 'TRIS') notification No. 2023/0469/IT (hereinafter 'Draft Technical Regulation').
In the opinion of the Republic of Lithuania:
In this detailed opinion, we set out the arguments and reasons in support of the above opinion and, on that basis, we ask Italy to lift disproportionate and unjustified prohibitions restricting the free movement of goods within 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.
1.1. Article 2 of the draft Technical Regulation sets out 'the prohibition on the production and marketing of food and feed consisting, isolated or produced from cell cultures or tissues derived from vertebrate animals'. Italy states that 'Food business operators and feed business operators shall be prohibited from using food business operators and feed business operators to prepare, sell, store for sale, import, manufacture, administer or distribute food or feed or to promote food or feed consisting of cell cultures or tissues derived from vertebrates' ('cultivated meat') in accordance with the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002. Penalties are provided in Article 5 of the draft Technical Regulation for non-compliance with this prohibition
Italy points out that, in view of the current absence of specific legislation at European level, it has been decided to take precautionary measures at national level in order to protect health and cultural heritage interests. The Technical Report and Impact Analysis accompanying the draft Technical Regulation states that 'In view of the current absence of specific legislation at European level, Italy has decided to take precautionary measures at national level to protect health and cultural heritage interests and the draft Technical Regulation aims to protect human health by imposing a ban on the production and marketing of synthetic food products in implementation and in accordance with the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002 of the European Parliament of 28 January 2002'.
It should be noted that Article 7(1) of the above-mentioned Regulation (EC) No 178/2002 of the European Parliament and

of the Council 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 (hereinafter 'Regulation (EC) No 178/2002') provides that 'in particular circumstances where, following an evaluation of the available information, the possibility of harmful effects on health is identified, but scientific uncertainty persists, provisional risk management measures may be adopted to ensure the high level of health protection chosen by the Community, pending further scientific information for a more detailed risk assessment.'
Article 7(2) of Regulation (EC) No 178/2002 states that 'measures adopted on the basis of paragraph 1 of this Article shall be proportionate and not restrictive of trade beyond what is necessary to achieve the high level of health protection chosen by the Community, taking into account technical and economic feasibility and other factors considered legitimate in this field. These measures shall be re-examined within a reasonable time, taking into account the nature of the risk of life or health identified and the type of scientific information necessary to dispel scientific uncertainty and to carry out a more comprehensive risk assessment.'
The impact assessment of the draft Technical Regulation in Italy does not provide data on the proportionality of the chosen prohibition and that there are no less restrictive measures than necessary to achieve the same objectives. The draft Technical Regulation does not specify that it is a temporary risk management measure, does not specify the insurance period and when the measures set out in Article 2 of the draft Technical Regulation (insurance) will be re-examined and repealed. Nor does it specify what level of Community health protection will be guaranteed by this insurance, which is limited to Italian territory.
It should be noted that cultured 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 a novel food and to ensure the effective functioning of the internal market and a high level of protection of human health and consumer interests.
Lithuania considers that farmed meat meets the definition of novel food in Article 3(2)(a) of the Novel Food Regulation and should therefore be subject to the general conditions for inclusion in the Union list of novel foods, i.e. to allow the use of a novel food provided that:
on the basis of the available scientific evidence, the food does not endanger the safety of human health;
the intended use of the food does not mislead the consumer, in particular if the food is intended to replace another food and is significantly replaced by a nutritional value;
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 authorisation of a novel food producer in accordance with the procedure laid down in the Novel Food Regulation, which seeks to obtain an authorisation for the supply of new food from the market following an application to the European Commission. Such food shall be subject to a scientific assessment prior to authorisation in order to ensure its 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 a novel food and the Commission manages the files of each applicant and makes proposals for the authorisation of a novel food once it has been found to be safe.
In the opinion of the Republic of Lithuania, the harmonised authorisation measures laid down in the Novel Food Regulation mean that if a food is authorised to be placed on the EU market, it can be marketed in any EU Member State, including Italy, and therefore the provisions of Articles 2 and 6 of the draft Technical Regulation are not compatible with the above-mentioned EU regulation.
It should be noted that it is intended that Article 2 of the draft Technical Regulation should apply to operators, both in third countries and in EU Member States, who wish to sell, hold for sale, import, manufacture for export, administer or distribute in Italy, or to promote for that purpose, food or feed consisting of cell cultures or tissues derived from vertebrate animals. Such legal regulation introduced by the Technical Regulation will have a direct negative impact on the development of the new sector and on the movement of cultivated meat production in the internal market. Nor does

the draft Technical Regulation provide for the application of the principle of mutual recognition to cultivated 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, in breach of the provisions of Article 34 TFEU.

1.2. In addition to the provisions of Article 2 of the draft Technical Regulation, which constitute a direct obstacle to the free movement of goods between Member States, the technical regulation also introduces indirect measures restricting the movement of goods between Member States. Article 3 of the draft Technical Regulation prohibits the labelling of processed products containing vegetable protein as a product, i.e. in the production and marketing of processed products containing only vegetable proteins in the Italian national territory, the use of: names relating to meat, meat production, references to animal species or groups of animal species or animal morphology or animal anatomy, specific terms for butchers, salted meat or fisheries, etc. Article 5 of the draft Technical Regulation provides for penalties for non-compliance with this prohibition.
According to Lithuania, products containing plant protein and their labelling are regulated by Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers ('Regulation 1169/2011').
Article 38 of Regulation No 1169/2011 provides: '1. In matters specifically harmonised by this Regulation, Member States may not adopt or maintain national measures unless Union law so permits. Those national measures shall not create obstacles to the free movement of goods, including discrimination against foodstuffs from other Member States. 2. Without prejudice to Article 39, Member States may adopt national measures in the field of matters not specifically harmonised by this Regulation, provided that they do not prohibit, impede or restrict the free movement of goods complying with this Regulation.' Article 1(1) of Regulation No 1169/2011 provides: '1. This Regulation lays down a framework for ensuring a high level of consumer protection in relation to food information, taking into account the different perceptions of consumers and their information needs, while ensuring the smooth functioning of the internal market.' Annex VI to Regulation No 1169/2011 lays down specific provisions on the name of the food and the accompanying particulars on the label where a food containing one of the ingredients or one of the ingredients that is normally used or naturally present, as expected by consumers, is replaced by a different component or other ingredient; 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.
In the opinion of Lithuania, specific labelling bans in Article 3 of the draft Technical Regulation apply to products containing plant protein and impose penalties for non-compliance with this requirement on Italian territory will affect operators from both third countries and other EU Member States seeking to sell, import or distribute food in Italy or promote it. The draft Technical Regulation does not provide for the application of the principle of mutual recognition to products containing plant protein 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. Accordingly, the proposed regulation in Articles 3 and 5 of the draft Technical Regulation is to be regarded as restricting the free movement of goods between EU Member States and thus in breach of the provisions of Article 34 TFEU.

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.
2.1. In that regard, it should be noted that a Member State that imposes a prohibition on the marketing of a particular

product or substance in its territory must demonstrate that the measure is necessary and, where appropriate, that trade in those products poses a serious risk to public health, such as public health and that those rules comply with the principle of proportionality (Judgement of 9 December 2010, Humanplasma, C 421/09, 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. We would point out that the impact assessment submitted by Italy does not qualify as meeting the above criteria.
In Lithuania's view, the obstacles to the free movement of goods created by the draft Technical Regulation are not justified on the grounds of the protection of the public interest referred to in Article 36 TFEU, nor has the draft Technical Regulation provided any technical, scientific, statistical or other data substantiating the positive impact of the ban on the protection of Italian consumers, nor has it provided any evidence that the objective stated by the legislator cannot be achieved by other effective and less restrictive measures on the internal market.
We would also point out that Article 2 of the draft Technical Regulation refers to Article 7 paragraph of Regulation (EC) No 178/2002 and therefore the regulation of this article is temporary in a temporary risk management measure. Among other things, the draft Technical Regulation is not accompanied by the justification referred to in Article 7(2) of Regulation (EC) No 178/2002 for proportionality and justification that trade restrictions will not go beyond what is necessary to achieve the objective and assess less restrictive measures.
In this context, it should be noted, first of all, that we support the need to ensure food security, but that such controls cannot be an end in itself or superfluous and are implemented for foodstuffs imported into Italy from other Member States. Accordingly, the prohibition laid down in Article 2 of the draft Technical Regulation does not justify a measure restricting the free movement of goods within the EU internal market.
2.2. No impact assessment has been carried out on the prohibition of labelling of processed products containing plant protein laid down in Article 3 of the draft Technical Regulation. The objectives of the draft Technical Regulation (Article 1) state that 'this law shall lay down provisions designed to ensure the protection of human health and interests of citizens and the preservation of the agri-food heritage as products expressing the socio-economic and cultural development of Italy which are of strategic importance to national interests'.
In Lithuania's view, this ban on labelling is contrary to Article 38 of Regulation No 1169/2011, since the national measures adopted by Italy with regard to products containing plant protein constitute an obstacle to the free movement of goods, including discrimination against products from other Member States containing plant protein.
We also consider that the objective of protecting the national animal husbandry heritage, recognising its high cultural, social, economic and environmental value, as well as providing adequate support for its promotion, does not fall within the justifiable areas referred to in Article 36 TFEU (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 artistic, historic or archaeological value, and the protection of industrial and commercial property) and therefore does not justify restricting the free movement of goods within the EU internal market.
In the light of the above, we consider that the provisions of Article 2 of the draft Technical Regulation should be clarified and abolished, while Article 3 of the draft Technical Regulation excludes other requirements restricting the free movement of goods that are incompatible with EU law.

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