



## Reports of Cases

### JUDGMENT OF THE COURT (Seventh Chamber)

21 March 2024\*

(Reference for a preliminary ruling – Food safety – Hygiene rules for food of animal origin – Regulation (EC) No 853/2004 – Scope – Exceptions – Supply of food between retail establishments constituting a marginal, localised and restricted activity – Concept of ‘marginal, localised and restricted activity’ – National legislation departing from the definition of that concept provided by that regulation)

In Case C-10/23,

REQUEST for a preliminary ruling under Article 267 TFEU from the Înalta Curte de Casație și Justiție (High Court of Cassation and Justice, Romania), made by decision of 19 October 2022, received at the Court on 11 January 2023, in the proceedings

**Remia Com Impex SRL**

v

**Autoritatea Națională Sanitară Veterinară și pentru Siguranța Alimentelor (ANSVSA),**

**Direcția Sanitară Veterinară și pentru Siguranța Alimentelor Dolj,**

THE COURT (Seventh Chamber),

composed of F. Biltgen, President of the Chamber, N. Wahl and M.L. Arastey Sahún (Rapporteur), Judges,

Advocate General: N. Emiliou,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- the Romanian Government, by E. Gane, L. Ghiță and A. Wellman, acting as Agents,
- the European Commission, by F. Le Bot and L. Radu Bouyon, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

\* Language of the case: Romanian.

gives the following

### **Judgment**

- 1 This request for a preliminary ruling concerns the interpretation of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ 2004 L 139, p. 55, and corrigendum OJ 2004 L 226, p. 22), in particular Article 1(3), (4) and (5) of that regulation, read in the light of recital 13 thereof, as well as the principle of equivalence.
- 2 The request has been made in proceedings between Remia Com Impex SRL ('Remia'), on the one hand, and the Autoritatea Națională Sanitară Veterinară și pentru Siguranța Alimentelor (ANSVSA) (National Veterinary Health and Food Safety Authority, Romania) and the Direcția Sanitară Veterinară și pentru Siguranța Alimentelor Dolj (Dolj Directorate for Veterinary Health and Food Safety, Romania), on the other, concerning the legality of an order, adopted by ANSVSA, establishing the procedure for veterinary health and food safety registration of the activities of establishments directly selling primary products or carrying out retail sales.

### **Legal context**

#### ***European Union law***

- 3 Under recitals 2, 3, 4 and 13 of Regulation No 853/2004:
  - '(2) Certain foodstuffs may present specific hazards to human health, requiring the setting of specific hygiene rules. This is particularly the case for food of animal origin, in which microbiological and chemical hazards have frequently been reported.
  - (3) In the context of the common agricultural policy, many Directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.
  - (4) With regard to public health, these rules contain common principles, in particular in relation to the manufacturers' and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.
- ...
- (13) Member States should have some discretion to extend or to limit the application of the requirements of this Regulation to retail under national law. However, they may limit their application only if they consider that the requirements of [Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ 2004 L 139, p. 1, and corrigendum OJ 2004 L 226, p. 3)] are sufficient to achieve food hygiene objectives and when the supply of food of animal origin from a retail establishment to another establishment is a marginal, localised and restricted activity.

Such supply should therefore be only a small part of the establishment's business; the establishments supplied should be situated in its immediate vicinity; and the supply should concern only certain types of products or establishments.'

4 Article 1 of Regulation No 853/2004, entitled 'Scope', provides:

'1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 853/2004. They shall apply to unprocessed and processed products of animal origin.

...

3. This Regulation shall not apply in relation to:

- (a) primary production for private domestic use;
- (b) the domestic preparation, handling or storage of food for private domestic consumption;
- (c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;
- (d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;
- (e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

4. Member States shall establish, under national law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such national rules shall ensure the achievement of the objectives of this Regulation.

5. (a) Unless expressly indicated to the contrary, this Regulation shall not apply to retail.

- (b) However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:
  - (i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply;

or

- (ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.
- (c) Member States may adopt national measures to apply the requirements of this Regulation to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs (a) or (b).

...'

- 5 Article 4 of Regulation No 853/2004, entitled ‘Registration and approval of establishments’, provides, in paragraph 2 thereof:

‘Without prejudice to Article 6(3) of Regulation (EC) No 852/2004, establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only:

- (a) primary production;
- (b) transport operations;
- (c) the storage of products not requiring temperature-controlled storage conditions; or
- (d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b).’

***Romanian law***

- 6 Ordinul nr. 111/2008 privind aprobarea Normei sanitare veterinare și pentru siguranța alimentelor privind procedura de înregistrare sanitară veterinară și pentru siguranța alimentelor a activităților de obținere și de vânzare directă și/sau cu amănuntul a produselor alimentare de origine animală sau nonanimală, precum și a activităților de producție, procesare, depozitare, transport și comercializare a produselor alimentare de origine nonanimală (Order No 111/2008 approving the veterinary health and food safety rules relating to the procedure for veterinary health and food safety registration of the direct and/or retail obtaining and sale of food of animal or non-animal origin, as well as the production, processing, storage, transport and marketing of foodstuffs of non-animal origin; ‘Order No 111/2008’) of 16 December 2008 (*Monitorul Oficial al României*, Part I, No 895 of 30 December 2008) was adopted by ANSVSA.

- 7 Article 2 of Order No 111/2008 provides:

‘The veterinary health and food safety rules referred to in Article 1 were drawn up to establish the procedure for veterinary health and food safety registration of the activities of establishments directly selling primary products or carrying out retail sales, in accordance with ... Article 1(4) of [Regulation No 853/2004].’

- 8 Those veterinary health and food safety rules (‘the veterinary health rules’) are set out in Annex 1 to Order No 111/2008.

- 9 Article 16 of the veterinary health rules provides:

‘This Chapter establishes the procedure for veterinary health and food safety registration of the retail sale of food of animal or non-animal origin.’

10 Article 17 of those rules provides:

‘For the purposes of this Chapter, the following definitions shall apply:

- (a) “retail” ... – the supply of food of animal and non-animal origin obtained in establishments registered for veterinary health and food safety purposes/approved for veterinary health purposes or/and the restricted, localised and limited supply of food of animal and non-animal origin obtained in small quantities in retail establishments and sold:
1. to the final consumer at the place of production;
  2. to other retail establishments registered for veterinary health and food safety purposes throughout the national territory;
  3. to catering establishments registered for veterinary health and food safety purposes;
  4. to the final consumer at agri-food markets as well as at markets, exhibitions, events organised during religious festivities or other similar public events, organised periodically by local/district authorities throughout the national territory, with the exception of fresh meat from porcine animals;

...

- (d) “restricted supply” – adding value to small quantities of food of animal and non-animal origin for the final consumer through other retail establishments;
- (e) “localised supply” – adding value to food of animal origin throughout the national territory, in compliance with the conditions on transport, the cold chain and traceability;
- (f) “limited supply” – obtaining at the point of sale restricted categories of food of animal origin intended for adding value for the final consumer through other retail establishments;

...’

11 Article 18(1) of the veterinary health rules states:

‘The activities of the retail establishments referred to in Annex 1 shall be carried out on the basis of the certificate of good standing or, as the case may be, the certificate of incorporation issued by the trade register office at the Tribunalul (Regional Court, Romania) of the place where the activities are carried out and on the basis of a veterinary health and food safety registration document issued by the District Directorate for Veterinary Health and Food Safety or the Directorate for Veterinary Health and Food Safety of the Municipality of Bucharest in accordance with the template set out in Annex 3.’

12 Under Article 19(1) of those rules:

‘In order to obtain a veterinary health and food safety registration document for the activities of the retail establishments referred to in Annex 1, food business operators or their legal representatives must submit a file to the District Directorate for Veterinary Health and Food Safety or the Directorate for Veterinary Health and Food Safety of the Municipality of Bucharest containing the following documents: ...’

13 Article 20(1) of the veterinary health rules reads as follows:

‘For the retail establishments which meet the veterinary health and food safety requirements laid down by the specific legislation, the District Directorate for Veterinary Health and Food Safety or the

Directorate for Veterinary Health and Food Safety of the Municipality of Bucharest shall issue a veterinary health and food safety registration document in accordance with the template set out in Annex 3.'

### **The dispute in the main proceedings and the questions referred for a preliminary ruling**

- 14 On 9 March 2018 Remia brought an action before the Curtea de Apel Bucureşti (Court of Appeal, Bucharest, Romania) seeking (i) the annulment of Article 2 of Order No 111/2008, Articles 16 and 17 of the veterinary health rules, Article 18(1) and Article 19(1) of those rules, and the words 'in accordance with the template set out in Annex 3' which appear in Article 20(1) thereof, as well as the entirety of Annex 3 thereto, (ii) the review of the situation of the establishments registered in the district of Dolj, with a view to their classification as establishments subject to registration or approval for the purposes of Regulations No 852/2004 and No 853/2004, and (iii) the payment of compensation for the damage caused by the infringement of EU law because of, inter alia, the incorrect completion of the administrative procedures necessary to protect Remia's legitimate interest, namely the issuing of veterinary health and food safety registration documents to establishments requiring approval.
- 15 By a judgment of 4 December 2019, the Curtea de Apel Bucureşti (Court of Appeal, Bucharest) dismissed that action as unfounded.
- 16 Remia has brought an appeal against that judgment before the Înalta Curte de Casaţie şi Justiţie (High Court of Cassation and Justice, Romania) – the referring court – pleading, in essence, that Order No 111/2008 is unlawful inasmuch as it disregards the definition of the concept of 'marginal, localised and restricted activity' provided in recital 13 of Regulation No 853/2004.
- 17 According to ANSVSA, the definitions of those terms which appear in Article 17(d), (e) and (f) of the veterinary health rules are not contrary to recital 13 of that regulation.
- 18 At a hearing which took place before the referring court, Remia requested that a reference be made to the Court of Justice for a preliminary ruling, arguing, in essence, that the national legislation at issue in the main proceedings permits the scope of Regulation No 853/2004 to be limited, in breach of EU law. In its view, the effect of Order No 111/2008 is that activities are not made subject to approval when, although they constitute retail sales, they have characteristics requiring approval because they are not covered by the exceptions provided for in Article 1(5)(b) of that regulation. The word 'localised', within the meaning of that provision, designates, according to recital 13 of the regulation, establishments situated in the immediate vicinity of the establishment supplying food of animal origin, whereas Article 17(e) of the veterinary health rules refers to the supply of such food throughout the national territory.
- 19 In that regard, the referring court explains that it is required to make a reference to the Court of Justice, in accordance with the third paragraph of Article 267 TFEU, given that it is a court or tribunal of a Member State against whose decisions there is no judicial remedy under national law. The dispute in the main proceedings raises the issue of the compatibility of provisions of national law with Regulation No 853/2004. In view of the wording of recital 13 of that regulation, the definition of the concept of 'marginal, localised and restricted activity' provided by that national law gives rise, according to that court, to a difficulty in the interpretation of EU law.

- 20 In those circumstances, the Înalta Curte de Casație și Justiție (High Court of Cassation and Justice) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:
- ‘(1) Must [Regulation No 853/2004] as a whole, and the provisions of [Article 1(3), (4) and (5) thereof] in particular, be interpreted as meaning that cold stores which carry out retail sales activities to other retail establishments, but not to the final consumer, have to be approved in accordance with that regulation, when the activity concerned does not fall within the exceptions provided for in Article 1(5)(b) [of that regulation]?
  - (2) Must [Regulation No 853/2004] and EU law, in general, be interpreted as meaning that the national authorities which are responsible for ensuring the implementation of the policy which constitutes the objective to be achieved by the legislation and ensuring compliance with the corresponding obligations of the economic operators concerned are required to interpret the condition relating to marginal, localised and restricted activity, contained in Article 1(5)(b)(ii) [of that regulation], in the light of recital 13 [thereof], or may they derogate from that interpretation by means of their own definitions of the terms?
  - (3) If the answer to Question 2 is in the affirmative, must the relevant definitions, contained in a national act transposing [Regulation No 853/2004], respect the substance of the concepts, as described in recital 13 [of that regulation]?
  - (4) In view of the fact that the provisions of Article 17 of the [veterinary health rules annexed to Order No 111/2008] provide that the activity of retail sale of products of animal origin may also include activities of supply and sale of products to other retail establishments throughout the territory of Romania without the obligation to obtain a veterinary health permit, does EU law and, in particular, [Regulation No 853/2004], preclude such a provision and/or such an administrative practice?
  - (5) Does the principle of equivalence require that, where a measure of an administrative authority may be annulled on the ground that it does not comply with a national law, that administrative act may also be annulled on the ground that it does not comply with a relevant EU regulation, such as [Regulation No 853/2004]?’

## **Consideration of the questions referred**

### ***Admissibility***

- 21 The Romanian Government argues that the order for reference does not set out the factual context of the dispute in the main proceedings, even though this is essential in order to classify the facts, to determine the applicable provisions of national law, and to identify the rules of EU law whose interpretation is useful for resolving the dispute in the main proceedings.
- 22 In particular, the fact that there is no description of the factual context makes it impossible to know the type of activities carried out by Remia or to understand whether that company might benefit from the procedure for the approval of its activities or whether those activities are covered by Regulation No 853/2004. That being the case, that government states that, according

to the information which is available to ANSVSA but which does not appear in the order for reference, Remia's main activity is the wholesale trade of products of animal origin and the rental of storage facilities.

- 23 The referring court has not therefore indicated, in the order for reference, (i) the reasons why it referred to the provisions of EU law relied on in the questions referred and (ii) the link between the subject matter of the dispute in the main proceedings and those questions. Consequently, the request for a preliminary ruling is inadmissible in its entirety.
- 24 Without pleading such inadmissibility, the European Commission nonetheless emphasises that there are lacunae in the order for reference as regards the first and fifth questions.
- 25 Regarding the first question, that institution considers that a reading of the order for reference does not enable the nature of Remia's activities to be clearly discerned. However, it considers that it is apparent from that order that that company carries out retail sales activities at other retail establishments.
- 26 Regarding the fifth question, which concerns the principle of equivalence, the Commission notes that the order for reference does not mention the provisions of national law under which a decision originating from an administrative authority may be annulled for failure to comply with a national law; nor does it mention any measure which the national courts could take in the event of a finding that a national administrative measure is at odds with EU law.
- 27 In that regard, it should be borne in mind that, according to settled case-law, the procedure provided for in Article 267 TFEU is an instrument of cooperation between the Court of Justice and the national courts, by means of which the Court provides the national courts with the points of interpretation of EU law which they need in order to decide the disputes before them (judgment of 26 March 2020, *Miasto Łowicz and Prokurator Generalny*, C-558/18 and C-563/18, EU:C:2020:234, paragraph 44 and the case-law cited).
- 28 According to equally settled case-law, in the context of the cooperation between the Court of Justice and the national courts, the need to provide an interpretation of EU law which will be of use to the national court means that the national court is bound to observe scrupulously the requirements concerning the content of a request for a preliminary ruling, expressly set out in Article 94 of the Rules of Procedure of the Court of Justice (judgment of 28 November 2023, *Commune d'Ans*, C-148/22, EU:C:2023:924, paragraph 44 and the case-law cited). Those requirements are, moreover, set out in paragraphs 13, 15 and 16 of the Recommendations of the Court of Justice of the European Union to national courts and tribunals in relation to the initiation of preliminary ruling proceedings (OJ 2019 C 380, p. 1).
- 29 Thus, first of all, in accordance with Article 94(a) of the Rules of Procedure, it is essential that the referring court define the factual and legislative context of the questions it is asking or, at the very least, explain the factual circumstances on which those questions are based. In the procedure established by Article 267 TFEU, the Court is empowered to give rulings on the interpretation of EU legislation only on the basis of the facts which the national court puts before it (judgment of 28 November 2023, *Commune d'Ans*, C-148/22, EU:C:2023:924, paragraph 45 and the case-law cited).

- 30 Next, Article 94(b) of the Rules of Procedure provides that the request for a preliminary ruling is to contain the tenor of any national provisions applicable in the case at issue in the main proceedings and, where appropriate, the relevant national case-law.
- 31 Lastly, as is stated in Article 94(c) of the Rules of Procedure, it is essential that the order for reference contain a statement of the reasons which prompted the national court to inquire about the interpretation of certain provisions of EU law, and the relationship between those provisions and the national legislation applicable to the main proceedings (judgment of 28 November 2023, *Commune d’Ans*, C-148/22, EU:C:2023:924, paragraph 46 and the case-law cited).
- 32 In this instance, it must be found that the order for reference provides only an extremely brief explanation of the subject matter of the dispute in the main proceedings, without presenting the factual context of that dispute. In addition, that order provides only an equally brief explanation of the reasons why the referring court considered that it was necessary to make a reference to the Court of Justice for a preliminary ruling.
- 33 More specifically, the first question seeks to determine whether cold stores which make retail sales to other retail establishments must be approved in accordance with Regulation No 853/2004 when that activity is not covered by the exceptions provided for in Article 1(5)(b) of that regulation.
- 34 In the absence of further details concerning the factual context of the dispute in the main proceedings, in particular as regards ascertaining the nature of Remia’s activities, the Court is not in a position to understand whether, by that question, the referring court is querying the situation of other establishments which are situated in the district of Dolj and which, according to Remia, should be subject to the obligation to obtain approval or whether it is querying Remia’s situation. In that regard, it should be noted that, although the Romanian Government argues that Remia’s main activity is wholesale trade, the Commission considers that it is apparent from the order for reference that that company carries out retail sales activities; however, it acknowledges that that order does not enable the nature of Remia’s activities to be clearly discerned.
- 35 Similarly, the reference to ‘cold stores’ in that first question – an expression which is not used anywhere else in the order for reference – is not sufficient, in the absence of any explanation as to its relevance for resolving the dispute in the main proceedings, to enable the Court to consider that it is in a position to give a useful answer to the referring court.
- 36 It follows that the first question is inadmissible.
- 37 In addition, by its fifth question, the referring court asks whether the principle of equivalence requires that, where a measure of an administrative authority may be annulled on the ground that it does not comply with a national law, that administrative measure may also be annulled on the ground that it does not comply with an EU regulation, such as Regulation No 853/2004.
- 38 In that regard, it should be borne in mind that the principle of equivalence prohibits a Member State from laying down less favourable procedural rules for actions for safeguarding rights that individuals derive from EU law than those applicable to similar domestic actions (judgment of 24 October 2018, *XC and Others*, C-234/17, EU:C:2018:853, paragraph 25 and the case-law cited).
- 39 It follows that, in order for the Court to be able to provide the referring court with a useful answer, the referring court must provide, at the very least, a minimum of information as to the procedural rules laid down by national legislation as well as the reasons why it has doubts as to whether that

legislation is in line with the principle of equivalence. However, the order for reference gives no indication as to the tenor of the relevant provisions of national law; nor does it give any indication as to the reasons why that court is questioning, in this instance, the interpretation of that principle. This is in breach of the requirements set out in Article 94(b) and (c) of the Rules of Procedure.

- 40 Accordingly, the fifth question is also inadmissible.
- 41 However, it should be borne in mind that, in view of the spirit of judicial cooperation which governs relations between national courts and the Court of Justice in the context of preliminary ruling proceedings, the fact that the referring court did not make certain initial findings does not necessarily mean that the request for a preliminary ruling, or one of the questions contained therein, is inadmissible if the Court, in the light of the information contained in the case file, considers that it is in a position to provide a useful answer to the referring court (judgment of 22 September 2022, *Admiral Gaming Network and Others*, C-475/20 to C-482/20, EU:C:2022:714, paragraph 29 and the case-law cited).
- 42 In addition, regarding more specifically the requirement relating to the content of a request for a preliminary ruling laid down in Article 94(a) of the Rules of Procedure, the Court has held that it is sufficient that both the subject matter of the dispute in the main proceedings and the main issues raised for the EU legal order may be understood from the request for a preliminary ruling in order to enable the Member States and other interested parties to submit their observations in accordance with Article 23 of the Statute of the Court of Justice of the European Union and to participate effectively in the proceedings before the Court (judgment of 7 February 2018, *American Express*, C-643/16, EU:C:2018:67, paragraph 22 and the case-law cited).
- 43 In that regard, concerning the second, third and fourth questions, it is apparent from the statement setting out the subject matter of the dispute in the main proceedings and from the reasoning in the order for reference, which is certainly brief but is sufficiently clear, that the referring court, hearing an application for partial annulment of Order No 111/2008, essentially has doubts as to the compatibility of the concept of ‘localised supply’ as used in that order with the concept of ‘localised ... activity’ as used in Regulation No 853/2004.
- 44 Thus, the order for reference sets out to the requisite legal standard the origin and nature of the dispute in the main proceedings, the outcome of which it considers to be dependent on the interpretation to be given to that regulation. It follows that the referring court has provided sufficient information to enable the Court to give a useful answer to the second, third and fourth questions.

### ***Substance***

- 45 By its second, third and fourth questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 1(5)(b)(ii) of Regulation No 853/2004, read in the light of recital 13 thereof, is to be interpreted as precluding a piece of national legislation which departs from the definition of ‘localised ... activity’ used in those provisions and thus limits the scope of that regulation.
- 46 In that regard, first, it should be noted that it follows from Article 1(5)(a) of Regulation No 853/2004 that retail is, in principle, excluded from the scope of that regulation.

- 47 However, in accordance with the first phrase of Article 1(5)(b) of that regulation, retail is included in that scope when operations are carried out with a view to the supply of food of animal origin to another establishment.
- 48 Nevertheless, in that case, retail is excluded from the scope of that regulation in the two scenarios set out in points (i) and (ii) of that provision.
- 49 In this way, under Article 1(5)(b)(ii) of Regulation No 853/2004, that regulation does not apply to retail where the supply of food of animal origin takes place between retail establishments and where, in accordance with national law, it constitutes a marginal, localised and restricted activity.
- 50 Second, it follows from recital 13 of Regulation No 853/2004 that the Member States may limit the application of the requirements laid down by that regulation to retail only where, in particular, the supply of food of animal origin from one retail establishment to another establishment is a marginal, localised and restricted activity. Such supply should therefore be only a small part of the establishment's business; the establishments supplied should be situated in its immediate vicinity; and the supply should concern only certain types of products or establishments.
- 51 It should be borne in mind that, according to settled case-law, the preamble to an EU act may explain the content of the provisions of that act and that the recitals of such an act constitute important elements for the purposes of interpretation, which may clarify the intentions of the author of that act (judgment of 13 July 2023, *Commission v CK Telecoms UK Investments*, C-376/20 P, EU:C:2023:561, paragraph 104 and the case-law cited).
- 52 It is also settled case-law that, while the provisions of regulations, by virtue of the very nature of regulations and of their function in the system of sources of EU law, generally have immediate effect in the national legal systems without it being necessary for the national authorities to adopt measures of application, some provisions of regulations may nonetheless necessitate, for their implementation, the adoption of measures of application by the Member States. Thus, Member States may adopt implementing measures for a regulation provided that they do not thereby obstruct its direct applicability or conceal its nature as an act of EU law; that they specify that they are acting in exercise of a discretion conferred on them under that regulation; and that they adhere to the parameters laid down thereunder (judgment of 12 April 2018, *Commission v Denmark*, C-541/16, EU:C:2018:251, paragraphs 27 and 28 and the case-law cited).
- 53 The Court has also stated that the direct applicability of a regulation precludes, unless otherwise provided, the Member States from taking steps which are intended to alter the scope of the regulation itself (judgment of 15 November 2012, *Al-Aqsa v Council* and *Netherlands v Al-Aqsa*, C-539/10 P and C-550/10 P, EU:C:2012:711, paragraph 86 and the case-law cited). Accordingly, the Member States cannot, unless otherwise provided, restrict the scope of a regulation and thereby limit the scope of the obligations laid down by that regulation.
- 54 In this instance, it must be pointed out that Article 1(5)(b)(ii) of Regulation No 853/2004 expressly refers to the law of the Member States as regards the definition of the concept of 'marginal, localised and restricted activity' referred to in that provision. However, the discretion which the Member States are thus recognised as having is restricted by recital 13 of that regulation, which provides further details as to the scope of that concept.

- 55 It follows that, in order to adhere to the parameters laid down under Regulation No 853/2004, the Member States are required to respect the definition of ‘marginal, localised and restricted activity’ set out in that recital when they lay down, in their national legislation, the conditions for the application of Article 1(5)(b)(ii) of that regulation.
- 56 This is all the more the case when, unlike the first part of the second sentence of recital 13 of that regulation, which provides that the Member States may limit the application of the requirements laid down by that regulation to retail ‘if they consider that the requirements of Regulation (EC) No 852/2004 are sufficient to achieve food hygiene objectives’, the second part of that sentence of that recital and the third sentence thereof, which concern the concept of ‘marginal, localised and restricted activity’, are worded in mandatory terms, so that the Member States cannot derogate therefrom.
- 57 As regards the concept of ‘localised ... activity’, it follows from recital 13 of Regulation No 853/2004 that this must be a supply by a retail establishment to another establishment situated ‘in [the] immediate vicinity’.
- 58 However, it is apparent from the order for reference that the concept of ‘localised supply’ used in Article 17(e) of the veterinary health rules is defined as being supply ‘throughout the national territory’, which manifestly goes beyond a supply in the immediate vicinity. The concept of ‘the national territory’ is much broader than that of ‘[the] immediate vicinity’, especially regarding a Member State, such as Romania, whose national territory is of a considerable size.
- 59 In so doing, such a piece of national legislation has the effect of excluding, in practice, from the scope of Regulation No 853/2004 retail sales activity which does not constitute localised activity within the meaning of that regulation, thereby reducing the scope of the regulation and the obligation to obtain approval laid down in Article 4 thereof.
- 60 As can be seen from recitals 3 and 4 of Regulation No 853/2004, procedures for approval are intended to ensure a high level of protection of public health. More generally, by the adoption of that regulation, the EU legislature expressly intended to ensure, in accordance with the intention set out in recital 2 thereof, that all food of animal origin be produced and marketed in accordance with strict rules the primary objective of which is to ensure food hygiene and food safety and thereby prevent adverse effects on human health (see, to that effect, judgment of 29 May 2018, *Liga van Moskeeën en Islamitische Organisaties Provincie Antwerpen and Others*, C-426/16, EU:C:2018:335, paragraph 67).
- 61 Those objectives support the interpretation that the Member States cannot adopt provisions limiting the scope of Regulation No 853/2004.
- 62 Having regard to all the foregoing considerations, the answer to the second, third and fourth questions is that Article 1(5)(b)(ii) of Regulation No 853/2004, read in the light of recital 13 thereof, must be interpreted as precluding, given that those provisions define the concept of ‘localised ... activity’ as being a supply to establishments situated ‘in [the] immediate vicinity’, a piece of national legislation which includes in that concept supplies going beyond such a supply, such as supplies to establishments situated throughout the national territory, and thus limits the scope of that regulation.

## Costs

- 63 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Seventh Chamber) hereby rules:

**Article 1(5)(b)(ii) of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, read in the light of recital 13 thereof,**

**must be interpreted as precluding, given that those provisions define the concept of ‘localised ... activity’ as being a supply to establishments situated ‘in [the] immediate vicinity’, a piece of national legislation which includes in that concept supplies going beyond such a supply, such as supplies to establishments situated throughout the national territory, and thus limits the scope of that regulation.**

[Signatures]