Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

6 May 2021 *

(Reference for a preliminary ruling – Approximation of laws – Regulation (EC) No 765/2008 – Requirements for accreditation and market surveillance relating to the marketing of products – Single national accreditation body – Issuing of the accreditation certificate to conformity assessment bodies – Accreditation body having its seat in a third State – Article 56 TFEU – Article 102 TFEU – Articles 20 and 21 of the Charter of Fundamental Rights of the European Union – Validity)

In Case C-142/20,

REQUEST for a preliminary ruling under Article 267 TFEU from the Consiglio di Giustizia amministrativa per la Regione Siciliana (Council of Administrative Justice, Region of Sicily, Italy), made by decision of 26 February 2020, received at the Court on 26 March 2020, in the proceedings

Analisi G. Caracciolo Srl

v

Regione Siciliana – Assessorato regionale della salute – Dipartimento regionale per la pianificazione,

Regione Sicilia – Assessorato della salute – Dipartimento per le attività sanitarie e osservatorio,

Accredia – Ente Italiano di Accreditamento,

Azienda sanitaria provinciale di Palermo,

intervening parties:

Perry Johnson Laboratory Accreditation Inc.,

THE COURT (First Chamber),

composed of J.-C. Bonichot, President of the Chamber, L. Bay Larsen, C. Toader (Rapporteur), M. Safjan and N. Jääskinen, Judges,

Advocate General: J. Richard de la Tour,

* Language of the case: Italian.

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Analisi G. Caracciolo Srl and Perry Johnson Laboratory Accreditation Inc., by S. Pensabene Lionti, avvocato,

– Accredia – Ente Italiano di Accreditamento, by L. Grisostomi Travaglini and G. Poli, avvocati,

– the Italian Government, by G. Palmieri, acting as Agent, M. Russo and E. Feola, avvocati dello Stato,

– the Czech Government, by M. Smolek, T. Müller, J. Vláčil and T. Machovičová, acting as Agents,

– the Spanish Government, by L. Aguilera Ruiz and M.J. Ruiz Sánchez, acting as Agents,

– the Austrian Government, by A. Posch, acting as Agent,

– the Polish Government, by B. Majczyna, acting as Agent,

– the European Parliament, by L. Visaggio and L. Stefani, acting as Agents,

– the Council of the European Union, by A.-L. Meyer and E. Ambrosini, acting as Agents,

– the European Commission, by G. Gattinara, L. Malferrari, F. Thiran and P. Rossi, acting as Agents,

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

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation and validity of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ 2008 L 218, p. 30).

2 The request has been made in proceedings between Analisi G. Caracciolo Srl, a laboratory conducting analyses and operating as the conformity assessment body of food businesses and carrying out its activity in Italy ('Laboratory Caracciolo'), and the Regione Siciliana (Region of Sicily, Italy) concerning the validity of the accreditation certificate issued to that laboratory by Perry Johnson Laboratory Accreditation Inc. ('PJLA'), a body having its seat in the United States.

Legal context

Regulation No 765/2008

3 Recitals 1, 9, 12, 13, 15, 19 and 20 of Regulation No 765/2008 state:

‘(1) It is necessary to ensure that products benefiting from the free movement of goods within the Community fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety at the workplace, protection of consumers, protection of the environment and security, while ensuring that the free movement of products is not restricted to any extent greater than that which is allowed under Community harmonisation legislation or any other relevant Community rules. Provision should, therefore, be made for rules on accreditation, market surveillance, controls of products from third countries and the CE marking.

…

(9) The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements.

…

(12) Where Community harmonisation legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation, as provided for in this Regulation, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the Community the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(13) A system of accreditation which functions by reference to binding rules helps to strengthen mutual confidence between Member States as regards the competence of conformity assessment bodies and consequently the certificates and test reports issued by them. It thereby enhances the principle of mutual recognition and therefore the provisions of this Regulation on accreditation should apply in relation to bodies carrying out conformity assessments in both the regulated and the non-regulated areas. The issue at stake is the quality of certificates and test reports irrespective of whether they fall within the regulated or the non-regulated area, and no distinction should therefore be made between those areas.

…

(15) Since the purpose of accreditation is to provide an authoritative statement of the competence of a body to perform conformity assessment activities, Member States should not maintain more than one national accreditation body and should ensure that that body is organised in such a way as to safeguard the objectivity and impartiality of its activities. Such national accreditation bodies should operate independently of commercial conformity assessment activities. It is therefore appropriate to provide that Member States ensure that, in the performance of their tasks, national accreditation bodies are deemed to exercise public authority, irrespective of their legal status.

…

(19) Competition between national accreditation bodies could lead to the commercialisation of their activity, which would be incompatible with their role as the last level of control in the conformity assessment chain. The objective of this Regulation is to ensure that, within the European Union, one accreditation certificate is sufficient for the whole territory of the Union, and to avoid multiple accreditation, which is added cost without added value. National accreditation bodies may find themselves in competition on the markets of third countries, but that must have no effect on their activities inside the Community, or on the cooperation and peer evaluation activities organised by the body recognised under this Regulation.

(20) In order to avoid multiple accreditation, to enhance acceptance and recognition of accreditation certificates and to carry out effective monitoring of accredited conformity assessment bodies, conformity assessment bodies should request accreditation by the national accreditation body of the Member State in which they are established. Nevertheless, it is necessary to ensure that a conformity assessment body is able to request accreditation in another Member State in the event that there is no national accreditation body in its own Member State or where the national accreditation body is not competent to provide the accreditation services requested. In such cases, appropriate cooperation and exchange of information between national accreditation bodies should be established.'

4 Under Article 1(1) and (2) of that regulation:

'1. This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities.

2. This Regulation provides a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security.'

5 Article 2(10) of that regulation defines 'accreditation' as meaning 'an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity'.

6 Article 2(11) of the same regulation defines the 'national accreditation body' as meaning 'the sole body in a Member State that performs accreditation with authority derived from the State'.

7 Article 4 of Regulation No 765/2008, entitled 'General principles', provides in paragraphs 1, 2, 5 and 7 thereof:

'1. Each Member State shall appoint a single national accreditation body.

2. Where a Member State considers that it is not economically meaningful or sustainable to have a national accreditation body or to provide certain accreditation services, it shall, as far as possible, have recourse to the national accreditation body of another Member State.

…

5. Where accreditation is not operated directly by the public authorities themselves, a Member State shall entrust its national accreditation body with the operation of accreditation as a public authority activity and grant it formal recognition.

…

7. The national accreditation body shall operate on a not-for-profit basis.'

8 Article 5 of that regulation, entitled 'Operation of accreditation', provides in paragraphs 1 and 3 to 5 thereof:

'1. A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect.

…

3. National accreditation bodies shall monitor the conformity assessment bodies to which they have issued an accreditation certificate.

4. Where a national accreditation body ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or has committed a serious breach of its obligations, that accreditation body shall take all appropriate measures within a reasonable timeframe to restrict, suspend or withdraw the accreditation certificate.

5. Member States shall establish procedures for the resolution of appeals, including, where appropriate, legal remedies against accreditation decisions or the absence thereof.'

9 Under Article 6 of the said regulation, which is entitled 'Principle of non-competition':

'1. National accreditation bodies shall not compete with conformity assessment bodies.

2. National accreditation bodies shall not compete with other national accreditation bodies.

3. National accreditation bodies shall be permitted to operate across national borders, within the territory of another Member State, either at the request of a conformity assessment body in the circumstances set out in Article 7(1), or, if they are asked to do so by a national accreditation

body in accordance with Article 7(3), in cooperation with the national accreditation body of that Member State.'

10 Article 7 of the same regulation, entitled 'Cross-border accreditation', provides:

'1. Where a conformity assessment body requests accreditation it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse in accordance with Article 4(2).

However, a conformity assessment body may request accreditation by a national accreditation body other than those referred to in the first subparagraph in any one of the following situations:

(a) where the Member State in which it is established has decided not to establish a national accreditation body and has not had recourse to the national accreditation body of another Member State in accordance with Article 4(2);

(b) where the national accreditation bodies referred to in the first subparagraph do not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;

(c) where the national accreditation bodies referred to in the first subparagraph have not successfully undergone peer evaluation under Article 10 in respect of the conformity assessment activities for which accreditation is sought.

2. Where a national accreditation body receives a request pursuant to paragraph 1(b) or (c), it shall inform the national accreditation body of the Member State in which the requesting conformity assessment body is established. In such cases, the national accreditation body of the Member State in which the requesting conformity assessment body is established may participate as an observer.

3. A national accreditation body may request another national accreditation body to carry out part of the assessment activity. In such a case, the accreditation certificate shall be issued by the requesting body.'

11 Article 10 of Regulation No 765/2008, entitled 'Peer evaluation', provides in paragraph 1 thereof:

'National accreditation bodies shall subject themselves to peer evaluation organised by the body recognised under Article 14.'

12 Article 11 of Regulation No 765/2008, entitled 'Presumption of conformity for national accreditation bodies', provides:

'1. National accreditation bodies that demonstrate conformity with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the *Official Journal of the European Union*, by having successfully undergone peer evaluation under Article 10 shall be presumed to fulfil the requirements laid down in Article 8.

2. National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation under Article 10, and thereby accept, on the basis of the presumption referred to in paragraph 1 of this Article, the

accreditation certificates of those bodies and the attestations issued by the conformity assessment bodies accredited by them.'

Italian law

13 Article 40 of legge n 88, Disposizioni per l'adempimento di obblighi derivanti dall'appartenenza dell'Italia alle Comunità europee, Legge comunitaria per il 2008 (Law No 88 laying down provisions for the fulfilment of obligations deriving from Italy's membership of the European Communities, Community Law 2008) of 7 July 2009 (GURI No 161 of 14 July 2009 and GURI Ordinary Supplement No 110) ('Law No 88/2009'), provides in paragraphs 1 and 2:

'1. The provisions of this article shall apply to:

(a) laboratories not attached to food businesses, which carry out analyses in connection with self-testing procedures for food businesses;

(b) laboratories attached to food businesses, which carry out analyses for self-testing purposes on behalf of other food businesses owned by different legal persons.

2. The laboratories designated in paragraph 1(a) and (b) ("the laboratories") must be accredited, in accordance with standard UNI CEI EN ISO/IEC 17025, for individual tests or group tests, by an accreditation body recognised and operating in accordance with standard UNI CEI EN ISO/IEC 17011.'

14 On 8 July 2010 the agreement on the document concerning the criteria and methods for the listing, updating and delisting of laboratories in the regional lists of laboratories, and the uniform procedures for inspections regarding compliance by laboratories (GURI No 176 of 30 July 2010 and GURI Ordinary Supplement No 175), concluded pursuant to Article 40(3) of Law No 88/2009, was signed between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano. Under Article 1 thereof:

'This Agreement shall apply to:

(a) laboratories not attached to food businesses, which carry out analyses in connection with self-testing procedures for food businesses;

(b) laboratories attached to food businesses, which carry out analyses for self-testing purposes on behalf of other food businesses owned by different legal persons.'

15 Article 3 of that agreement, entitled 'Regional lists of laboratories', provides:

'1. The regions and autonomous provinces of Trento and Bolzano shall register in lists drawn up for that purpose laboratories present in their territory:

(a) which fulfil the conditions set out in Article 2(1);

(b) which are not yet accredited in accordance with Article 2(1) but have provided evidence that the accreditation procedure for the tests or test groups concerned has been initiated. In that case, the accreditation must be obtained within a maximum of 18 months of submitting the application to the region or the autonomous province.

2. The registration provided for in paragraph 1 shall enable the activity referred to in this Agreement to be carried out throughout the national territory and shall be valid for as long as the conditions on the basis of which it was made continue.

The regions and autonomous provinces shall ensure publication, at least once a year, of the lists provided for in this article, as updated, and shall forward a copy thereof to the Ministry of Health for publication in the national list on the site of that Ministry.'

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

16 Since 2014, Laboratory Caracciolo has carried out in Italy the activities entrusted to the conformity assessment bodies in the field of self-testing procedures for food businesses, on the basis of an accreditation issued by PJLA.

17 Following an application for accreditation submitted in 2012 to Accredia – Ente Italiano di Accreditamento ('Accredia'), the single national accreditation body in Italy, Laboratory Caracciolo was included provisionally in the list of accredited laboratories of the Region of Sicily for the assessment and analysis activities carried out by those undertakings. Since the accreditation procedure with Accredia was unsuccessful, that laboratory was removed from the regional list of accredited laboratories in 2017, by decision of the Region of Sicily updating that list.

18 Laboratory Caracciolo brought an action against that decision before the Tribunale amministrativo regionale per la Sicilia (Regional Administrative Court, Region of Sicily, Italy), claiming that it holds an accreditation issued by PJLA in accordance with standard UNI CEI EN ISO/IEC 17011, as required by Article 40(1) and (2) of Law No 88/2009. According to the laboratory, PJLA's accreditation activity must be regarded as equivalent to that carried out by Accredia.

19 By interim order of 10 July 2017, that court ordered the temporary inclusion of Laboratory Caracciolo in the regional list.

20 Accredia brought an appeal against that order before the Consiglio di Giustizia amministrativa per la Regione Siciliana (Council of Administrative Justice, Region of Sicily, Italy) which, by order of 29 September 2017, set aside the interim order.

21 The Tribunale amministrativo regionale per la Sicilia (Regional Administrative Court, Sicily), before which the dispute was brought once again, dismissed the action brought by Laboratory Caracciolo on the ground that, having regard to the objectives of safeguarding public health pursued by EU legislation and the Italian legislation which transposed it, laboratories are required, in order to obtain accreditation, to submit their application to the national accreditation body. According to that court, since the Italian legislation appointed Accredia as the single national accreditation body within the meaning of Regulation No 765/2008, that body has exclusive competence to issue accreditation certificates in Italy.

22 Laboratory Caracciolo brought an appeal against that judgment before the referring court. It argued that conferring such competence on Accredia infringed Article 56 TFEU relating to the freedom to provide services and Article 102 TFEU concerning the principle of free competition, as well as the principles of equality and non-discrimination, enshrined in Articles 20 and 21 of the Charter of Fundamental Rights of the European Union ('the Charter').

23 Laboratory Caracciolo also submits that PJLA and Accredia are, in their capacity as members of the International Laboratory Accreditation Cooperation (ILAC), within which they signed a mutual recognition arrangement, subject to the same technical regulations. Consequently, in its view, since Regulation No 765/2008 does not, according to that laboratory, preclude the application of the Italian *lex specialis*, namely Article 40 of Law No 88/2009, which allows laboratories to turn, for their accreditation, to a body other than Accredia, PJLA carries out an activity equivalent to that of Accredia and has validly accredited Laboratory Caracciolo.

24 The referring court does not share the interpretation proposed by Laboratory Caracciolo. That court considers that Italian law complies with Regulation No 765/2008, in that it provides that only Accredia may issue accreditation. However, it considers that a request for a preliminary ruling is necessary in order to ascertain, in particular, whether an interpretation of the national provisions which would allow a body other than Accredia to perform accreditation would be compatible with Regulation No 765/2008 and whether that regulation allows bodies established in third countries, in so far as they offer appropriate professional safeguards, to carry out the accreditation activity at issue in the main proceedings. If not, that court is uncertain as to the validity of that regulation in the light of Articles 56 and 102 TFEU as well as Articles 20 and 21 of the Charter, in that it allows only a single national body to perform accreditation.

25 It is in that context that the Consiglio di Giustizia amministrativa per la Regione Siciliana (Council of Administrative Justice, Region of Sicily) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Does Regulation (EC) No 765/2008 preclude a provision of national law (such as Article 40 of Law No 88/2009) being interpreted as allowing accreditation to be carried out by bodies not established in a Member State of the European Union – and therefore without the party concerned being required to apply to the single accreditation body – where such bodies in any event ensure that standards UNI CEI EN ISO/IEC 17025 and UNI CEI EN ISO/IEC 17011 are complied with and demonstrate (by means of mutual recognition [arrangements], for example) possession of a qualification which is essentially the same as that of the single bodies referred to in Regulation (EC) No 765/2008?

(2) In the light of Article 56 TFEU, Articles 20 and 21 of the [Charter] and Article 102 TFEU – in so far as it establishes essentially a national monopoly in respect of accreditation by the "single body" system – does Regulation (EC) No 765/2008 infringe the principles of primary EU law and, in particular, the principles of freedom to provide services and non-discrimination, the prohibition of unequal treatment and competition rules that prohibit monopoly situations?'

Consideration of the questions referred

Preliminary observations

26 It should be noted that even if, formally, the questions referred do not concern the interpretation of any specific provision of Regulation No 765/2008, that does not prevent the Court from providing all the elements of interpretation of EU law that may be of assistance in adjudicating in the case in the main proceedings. In that regard, it is for the Court to extract from all the information provided by the national court, in particular from the grounds of the order for reference, the points of EU law which require interpretation, in view of the subject matter of the main dispute (see, to that effect, judgment of 7 November 2019, *K.H.K. (Account preservation)*, C-555/18, EU:C:2019:937, paragraph 29 and the case-law cited).

27 In that regard, it is apparent from the request for a preliminary ruling that the referring court's doubts relate essentially to the interpretation and validity of the provisions of Chapter II of that regulation, that chapter being entitled 'Accreditation', and in particular of Article 4(1) and (5) and of Article 7(1) thereof. Consequently, it is necessary to reformulate the questions referred so as to reflect those considerations.

The first question

28 By its first question, the referring court asks, in essence, whether Article 4(1) and (5) and Article 7(1) of Regulation No 765/2008 must be interpreted as precluding the interpretation of national legislation according to which accreditation may be performed by bodies other than the single national accreditation body, within the meaning of that regulation, which have their seat in a third State, where those bodies ensure compliance with international standards and demonstrate, in particular by means of mutual recognition arrangements, that they have a qualification equivalent to that of the said single accreditation body.

29 It should be noted, as a preliminary point, that Article 2(11) of Regulation No 765/2008 defines a 'national accreditation body' as 'the sole body in a Member State that performs accreditation with authority derived from the State'.

30 Under Article 4(1) of that regulation, each Member State is to appoint a single national accreditation body. Article 4(5) provides that, where accreditation is not operated directly by the public authorities themselves, the Member State is to entrust its national body with that public authority activity and grant it formal recognition.

31 Article 7 of Regulation No 765/2008 sets out the detailed rules for cross-border accreditation. Paragraph 1 of that provision states that conformity assessment bodies are to request accreditation from the national accreditation body appointed by the Member State in which they are established. Under subparagraphs (a) to (c) of Article 7(1) it is possible to depart from that rule where no national accreditation body has been established in the Member State in which the conformity assessment body is established or where activities in respect of which the national accreditation body cannot perform accreditation in accordance with the provisions of that regulation are involved.

32 It follows from a combined reading of those provisions that each Member State is required to appoint a single national accreditation body and that conformity assessment bodies are in principle required to request accreditation by that body. Apart from the exceptions provided for in Article 7(1)(a) to (c) of Regulation No 765/2008, those provisions therefore do not allow a conformity assessment body to submit an application for accreditation to a national accreditation body other than that of the Member State in which it is established. Nor do those provisions allow a conformity assessment body to obtain accreditation from a body established in a third State for the purpose of carrying out its activity in the European Union.

33 It should be noted that the interpretation set out in the preceding paragraph is corroborated by the context of Article 4(1) and (5) and Article 7(1) of Regulation No 765/2008.

34 It is thus apparent from recital 15 of that regulation that Member States should not maintain more than one national accreditation body and should ensure that that body is organised in such a way as to safeguard the objectivity and impartiality of its activities. Furthermore, according to that same recital, those bodies, in the performance of their tasks, are deemed to exercise public authority, irrespective of their legal status.

35 Article 6 of Regulation No 765/2008, relating to accreditation, provides, moreover, that the principle of non-competition is to apply to assessment bodies and accreditation bodies. The latter are, moreover, subject to compliance with the requirements laid down in Article 8 of that regulation, which include independence, objectivity, impartiality and the absence of commercial pressures and of conflicts of interests.

36 The interpretation referred to in paragraph 32 above is also supported by a teleological interpretation of the regulation.

37 It is apparent from Article 1(1) and (2) of Regulation No 765/2008, read in the light of recital 1 thereof, that that regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities in order to ensure that products benefiting from the free movement of goods within the European Union fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, the protection of the environment and public security.

38 According to recital 9 of Regulation No 765/2008, the particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is to ensure conformity with the applicable requirements.

39 Recitals 12 and 13 of that regulation also state that accreditation, organised in a transparent manner to ensure the necessary level of confidence in conformity certificates, should be considered by the national public authorities of the European Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. The binding rules on which the system of accreditation is based are intended to strengthen mutual confidence between Member States as regards the competence of their respective conformity assessment bodies and consequently the certificates and test reports issued by those bodies, thus enhancing the principle of mutual recognition.

40 As is apparent from recital 20 of that regulation, that system is intended to avoid multiple accreditation, to enhance acceptance and recognition of accreditation certificates and to carry out effective monitoring of accredited conformity assessment bodies.

41 In order to achieve the objectives pursued by Regulation No 765/2008, namely that products fulfil requirements providing a high level of protection of public interests, the EU legislature thus laid down provisions governing accreditation, relating in particular to the nature and operation of the body performing that task or to the issue of certificates of conformity and their mutual recognition, intended to ensure the necessary level of confidence in the latter. In that regard, the requirement of a single national accreditation body appointed in each Member State is intended to ensure compliance with the objectives set out above, in particular that of the effective monitoring of accredited conformity assessment bodies, pursued by that regulation.

42 That interpretation of Article 4(1) and (5) and of Article 7(1) of Regulation No 765/2008 cannot be called into question by the fact, pointed out by the referring court, that an accreditation body of a third State may have a qualification certifying compliance with international standards to perform accreditation and conclude mutual recognition arrangements, within the framework of international associations such as, in the present case, ILAC.

43 As the Spanish Government, in essence, and the Polish Government point out, adherence to such a mutual recognition arrangement does not ensure that the accreditation body meets the requirements laid down by Regulation No 765/2008. It is true that the signatories to the ILAC mutual recognition arrangement must demonstrate that they meet ISO international standards concerning the requirements addressed to the bodies responsible for the accreditation of conformity assessment bodies as well as additional requirements, in particular in terms of experience. Nevertheless, those requirements do not correspond to those laid down by the regulation, given in particular that, under Article 4(5) thereof, those national accreditation bodies carry out a public authority activity in compliance with the requirements of independence, impartiality and competence, inter alia, set out in Article 8 of the regulation.

44 Furthermore, the ILAC mutual recognition arrangement concerns the recognition of conformity certificates issued by entities accredited by signatories to the arrangement, in order to promote international trade, and not that of the equivalence of the qualifications of national accreditation bodies, under Article 11(2) of Regulation No 765/2008.

45 In the light of the foregoing, the answer to the first question is that Article 4(1) and (5) as well as Article 7(1) of Regulation No 765/2008 must be interpreted as precluding the interpretation of national legislation according to which accreditation may be performed by bodies other than the single national accreditation body, within the meaning of that regulation, which have their seat in a third State, even where those bodies ensure compliance with international standards and demonstrate, inter alia by means of mutual recognition arrangements, that they have a qualification equivalent to that of the said single accreditation body.

The second question

46 By its second question, the referring court asks the Court, in essence, to assess the validity of the provisions of Chapter II of Regulation No 765/2008 in the light of Articles 56 and 102 TFEU as well as Articles 20 and 21 of the Charter, in so far as they provide that accreditation is performed exclusively by the single national body, within the meaning of that regulation.

47 First of all, as regards the provisions relating to the freedom to provide services, it should be noted, in the first place, that Article 56 TFEU requires not only the elimination of all discrimination on grounds of nationality against providers of services who are established in another Member State, but also the abolition of any restriction on the freedom to provide services, even if it applies without distinction to national providers of services and to those of other Member States, which is liable to prohibit, impede or render less advantageous the activities of a provider of services established in another Member State where it lawfully provides similar services (judgment of 11 December 2019, *TV Play Baltic*, C-87/19, EU:C:2019:1063, paragraph 35 and the case-law cited).

48 In the second place, in accordance with the Court's case-law, such a restriction may nevertheless be allowed as a derogation, on grounds of public policy, public security or public health, as expressly provided for in Articles 51 and 52 TFEU, which are also applicable in the area of freedom to provide services by virtue of Article 62 TFEU, or justified, where it is applied without discrimination, by overriding reasons in the public interest (judgment of 28 January 2016, *Laezza*, C-375/14, EU:C:2016:60, paragraph 31 and the case-law cited). Furthermore, as provided in Article 51 TFEU, the provisions on the freedom to provide services do not apply, so far as any given Member State is concerned, to activities which in that State are connected with the exercise of official authority.

49 In that regard, it is necessary to note that, in accordance with Article 4(1) and (5) of Regulation No 765/2008, each Member State is to appoint a single national body for the purpose of performing accreditation, as a public authority activity, and grants it formal recognition. Article 2(11) of that regulation specifies in that regard that the body that performs accreditation derives its authority from the Member State which appointed it.

50 It is apparent from Article 4(7) and from Articles 6 and 8 of Regulation No 765/2008 that accreditation bodies may not engage in commercial activities or compete with other conformity assessment bodies or accreditation bodies and must operate on a not-for-profit basis. They must act independently and impartially and have exclusive competence in the territory of the Member State in which they are established to carry out the accreditation activity entrusted to them by that State, except in the circumstances, strictly defined by Article 7 of that regulation, in which accreditation by another national accreditation body may be requested.

51 Similarly, it should be noted that national accreditation bodies have, as follows from Article 5 of Regulation No 765/2008, a decision-making power and a power to monitor and to impose penalties, which are among the factors to be taken into consideration in order to determine whether an activity is connected with the exercise of public powers (see, to that effect, judgment of 7 May 2020, *Rina*, C-641/18, EU:C:2020:349, paragraphs 45 to 49 and the case-law cited).

52 Thus, accreditation is directly and specifically connected with the exercise of official authority within the meaning of Article 51 TFEU, which is not covered by the scope of the provisions of the treaty in the field of freedom of establishment (see, to that effect, judgment of 12 December 2013, *SOA Nazionale Costruttori*, C-327/12, EU:C:2013:827, paragraphs 50 and 51).

53 It follows from paragraphs 47 to 52 above that the provisions of Chapter II of Regulation No 765/2008 relating to accreditation cannot be contrary to Article 56 TFEU, since the accreditation performed under Regulation No 765/2008 is connected with the exercise of public powers.

54 Next, under the first paragraph of Article 102 TFEU, any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it is to be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Thus, it is necessary to determine whether national accreditation bodies may be classified as 'undertakings' within the meaning of that provision.

55 In that regard, the Court has held that the concept of an undertaking covers any entity engaged in an economic activity and that any activity consisting in offering goods or services on a given market is an economic activity (judgment of 19 December 2012, *Mitteldeutsche Flughafen and Flughafen Leipzig-Halle* v *Commission*, C-288/11 P, EU:C:2012:821, paragraph 50 and the case-law cited).

56 According to the Court's case-law, activities which fall within the exercise of public powers are not of an economic nature justifying the application of the competition rules of the Treaty FEU (see, to that effect, judgment of 1 July 2008, *MOTOE*, C-49/07, EU:C:2008:376, paragraph 24 and the case-law cited).

57 As regards the effect that the fact that the accreditation activity is not for profit may have on the classification of the entity in question as an undertaking, it should be noted that the Court has made clear that the decisive factor in that regard is the fact that the offer of goods or services is not in competition with that of other operators seeking to make a profit (see, to that effect, judgment of 1 July 2008, *MOTOE*, C-49/07, EU:C:2008:376, paragraph 27).

58 In the present case, it is apparent from Article 4(5) and (7) and from Article 6 of Regulation No 765/2008, read in the light of recital 15 thereof, that the national accreditation body carries out a public authority activity, outside any commercial context, that it operates on a not-for-profit basis and that that accreditation activity must comply with the principle of non-competition. In those circumstances, such a body cannot be considered to be an 'undertaking' within the meaning of EU law and cannot, therefore, be covered by the provisions relating to the prohibition of abuse of a dominant position.

59 Finally, the admissibility of the part of the second question relating to the validity of the provisions of Chapter II of Regulation No 765/2008 in the light of Articles 20 and 21 of the Charter, which enshrine the principle of equality and the principle of non-discrimination, is disputed by the Spanish and Austrian Governments in their written observations before the Court, in so far as the grounds on which the referring court considers that those provisions have been infringed are not apparent from the order for reference. The Council of the European Union shares that view, but does not challenge the admissibility of that part of the second question.

60 In the present case, it is apparent from the request for a preliminary ruling that the referring court is essentially asking whether Regulation No 765/2008 discriminates between national accreditation bodies in that it precludes a conformity assessment body from requesting accreditation by an accreditation body other than that appointed by the Member State in which it is established.

61 In that regard, it should be recalled that, in cases where national authorities are responsible for the administrative implementation of EU regulations, the legal protection guaranteed by EU law includes the right of individuals to challenge, as a preliminary issue, the legality of such regulations before national courts and to induce those courts to refer questions to the Court for a preliminary ruling (judgments of 21 February 1991, *Zuckerfabrik Süderdithmarschen and*

Zuckerfabrik Soest, C-143/88 and C-92/89, EU:C:1991:65, paragraph 16, and of 9 November 1995, *Atlanta Fruchthandelsgesellschaft and Others (I)*, C-465/93, EU:C:1995:369, paragraph 20). That part of the question referred is therefore also admissible.

62 However, in view of the grounds set out in paragraphs 47 to 59 above, justifying the validity, in the light of Articles 56 and 102 TFEU, of the provisions of Regulation No 765/2008 providing that accreditation is performed exclusively by the single national body, Articles 20 and 21 of the Charter cannot usefully be relied on to call into question the fundamental obligation for conformity assessment bodies to be accredited by that body, enjoying public powers, in the Member State in which they are established.

63 In the light of the foregoing, it must be concluded that consideration of the second question has revealed nothing capable of affecting the validity of the provisions of Chapter II of Regulation No 765/2008 in the light of Articles 56 and 102 TFEU as well as Articles 20 and 21 of the Charter.

Costs

64 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national 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 (First Chamber) hereby rules:

1. **Article 4(1) and (5) as well as Article 7(1) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Council Regulation (EEC) No 339/93 must be interpreted as precluding the interpretation of national legislation according to which accreditation may be performed by bodies other than the single national accreditation body, within the meaning of that regulation, which have their seat in a third State, even where those bodies ensure compliance with international standards and demonstrate, inter alia by means of mutual recognition arrangements, that they have a qualification equivalent to that of the said single accreditation body.**

2. **Consideration of the second question referred for a preliminary ruling has revealed nothing capable of affecting the validity of the provisions of Chapter II of Regulation No 765/2008 in the light of Articles 56 and 102 TFEU as well as Articles 20 and 21 of the Charter of Fundamental Rights of the European Union.**

[Signatures]