

Case C-142/20

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

26 March 2020

Referring court:

Consiglio di Giustizia Amministrativa per la Regione Siciliana (Italy)

Date of the decision to refer:

26 February 2020

Appellant:

Analisi G. Caracciolo s.r.l.

Respondents:

Regione Siciliana – Assessorato regionale della salute – Dipartimento regionale per la pianificazione (Sicily Regional Authority – Regional Department of Health – Regional Planning Unit)

Regione Sicilia – Assessorato della salute – Dipartimento per le attività sanitarie e osservatorio (Sicily Regional Authority – Regional Department of Health – Health Unit and Observatory)

Accredia (Italian accreditation body)

Azienda sanitaria provinciale di Palermo (Palermo Provincial Health Authority)

Subject of the action in the main proceedings

Appeal before the Consiglio di Giustizia amministrativa per la Regione siciliana (Council of Administrative Justice for Sicily) against the judgment of the Tribunale amministrativo regionale per la Sicilia (Regional Administrative Court, Sicily) by which that court rejected the action brought by Laboratorio Analisi

G. Caracciolo s.r.l. contesting its exclusion from the ‘Regional list of laboratories conducting analyses in connection with self-testing procedures for food businesses’ on the ground that it is not accredited with the single national accreditation body.

Subject-matter and legal basis of the reference

Compatibility of Article 40 of legge del 7 luglio 2009, n. 88 (Law No 88 of 7 July 2009) with Regulation (EC) No 765/2008 and, in the alternative, the validity of that regulation in the light of Articles 56 and 102 TFEU and Articles 20 and 21 of the Charter of Fundamental Rights of the European Union.

Questions referred

(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 agreements, 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 of Fundamental Rights of the European Union 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?

Provisions of EU law relied on

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 (‘Regulation No 765/2008’), and in particular Article 4(1), (5) and (7), Articles 6 and 7(1), second subparagraph, Articles 8 to 11 and recitals 1, 15, 19 and 20 thereof.

Articles 56 and 102 TFEU.

Articles 20 and 21 of the Charter of Fundamental Rights of the European Union (the ‘Charter’).

Provisions of national law cited

Law No 88 of 7 July 2009 – Provisions for the fulfilment of obligations resulting from Italy’s membership of the European Communities – Community Law 2008 (‘Law No 88/2009’). In particular, paragraphs 1 and 2 of Article 40, entitled ‘Provisions for the accreditation of laboratories for self-testing in the food industry’, state that laboratories not attached to food businesses, which carry out analyses in connection with self-testing procedures for food businesses, and laboratories attached to food businesses, which carry out those analyses on behalf of other food businesses owned by different legal entities, must be accredited, in accordance with standard UNI CEI EN ISO/IEC 17025, by an accreditation body recognised and operating in accordance with standard UNI CEI EN ISO/IEC 17011. Under paragraph 3 of that article, the criteria and methods for the listing, updating and delisting of laboratories, and the uniform procedures for inspections regarding compliance by laboratories with the abovementioned requirements, are established by a special agreement between Italy’s central government and its regions.

Legge del 23 luglio 2009, n. 99 – Disposizioni per lo sviluppo e l’internazionalizzazione delle imprese, nonché in materia di energia (Law No 99 of 23 July 2009 – Measures for the development and internationalisation of companies, including in the energy sector) (‘Law No 99/2009’). In particular, Article 4, implementing Chapter II of Regulation No 765/2008, provides, in paragraph 1 thereof, that the Ministry of Economic Development, in agreement with the ministers concerned, is to adopt by decree the requirements for the organisation and functioning of the single national entity authorised to act as an accreditation body, in accordance with the abovementioned regulation, and for the setting of accreditation fees and arrangements for the supervision of the body by the ministries concerned. Article 4(2) states that the Minister for Economic Development, in agreement with the ministers concerned, is then to appoint by decree the single Italian body authorised to perform accreditation. Moreover, it should be noted that the Ministry of Economic Development is the national authority responsible for accreditation and the national point of contact with the European Commission.

Decreto del Ministro dello sviluppo economico del 22 dicembre 2009 (Decree of the Minister for Economic Development of 22 December 2009). This Decree names Accredia as Italy’s single national accreditation body. Article 1 of the decree governs the organisation and functioning of that body and establishes the criteria for setting accreditation fees and the arrangements for supervision of the body by the ministers concerned. Article 3 states that the Italian national accreditation body is to operate on a non-profit basis; to ensure that accreditation is carried out in the public interest; does not offer activities or services carried out by conformity assessment bodies, or provide consultancy services; does not own shares and does not have a financial or management interest in conformity assessment bodies; meets the necessary requirements to be a member of the European accreditation infrastructure referred to in Article 14 of Regulation No

765/2008; and does not compete with conformity assessment bodies or other national accreditation bodies.

Accordo Stato-Regioni dell'8 luglio 2010 (Agreement of 8 July 2010 between Italy's central government and regions). Articles 1 and 2 of that agreement reproduce the provisions of Article 40(1) and (2) of Law No 88/2009. Under Article 3 of the agreement, regional authorities are required to register in appropriate lists the laboratories in their territory accredited in accordance with Article 2(1), as well as laboratories not yet accredited but which have provided evidence that the accreditation process is under way; this must be completed within a maximum of 18 months of submitting the relevant application to the regional authority. Where a laboratory is included in the lists, the activity in question may be carried out nationwide. The regional authorities are required to publish updated lists each year.

Outline of the facts and the main proceedings

- 1 By decree of its Chief Executive of 9 April 2014, the regional authority added the appellant, Laboratorio Analisi G. Caracciolo s.r.l., to the 'Regional list of laboratories carrying out analyses in connection with self-testing procedures for food businesses' ('the regional list'), since it was accredited according to standard UNI CEI EN ISO/IEC 17025 by an accreditation body recognised and operating in accordance with standard UNI CEI EN ISO/IEC 17011.
- 2 At the time of the regional listing, the appellant was in the process of being accredited with Accredia, but later decided to obtain accreditation from Perry Johnson Laboratory Accreditation Inc. ('PJLA'), which is based in the United States. Accredia and PJLA are both accreditation bodies recognised by the abovementioned provisions.
- 3 The updated regional list was published by decree of the Chief Executive of 9 March 2017. It did not include the appellant since, according to the Palermo Provincial Health Authority's report of 4 July 2016, it was not accredited by the accreditation body Accredia.
- 4 The appellant challenged the decree and the report before the Tribunale amministrativo regionale per la Sicilia (Regional Administrative Court, Sicily), which rejected its action.
- 5 The appellant then appealed before the Council of Administrative Justice for Sicily, the referring court.

The essential arguments of the parties to the main proceedings

- 6 The appellant submits that the exclusive basis on which Accredia operates as an accreditation body infringes, inter alia, the provisions of EU competition law

(Article 102 TFEU), freedom to provide services (Article 56 TFEU), as well as the principle of non-discrimination enshrined in Articles 20 and 21 of the Charter.

- 7 The accreditation activities performed by PJLA should in fact be regarded as wholly equivalent to those performed by Accredia, since the two bodies, both members of the International Laboratory Accreditation Cooperation (ILAC), have signed a mutual recognition agreement and fully adhere to the same safety and inspection standards.
- 8 Furthermore, according to the appellant, Article 40 of Law No 88/2009 – which the applicant argues is a *lex specialis*, such that this provision may be applied independently of the provisions of Regulation No 765/2008, since Law No 88/2009 directly implements EU directives – simply requires accreditation to be carried out according to UNI CEI EN ISO/IEC 17025 and the accreditation body to be recognised and operate in accordance with UNI CEI EN ISO/IEC 17011. PJLA satisfies both of those requirements. Therefore, national legislation also allows accreditation to be carried out by bodies other than the single national body, in this case Accredia. As a result, a laboratory is permitted to apply for accreditation from PJLA.
- 9 The applicant considers that Regulation No 765/2008 must be interpreted in conformity with primary EU law, in particular Articles 56 and 102 TFEU and Articles 20 and 21 of the Charter, and that if the referring court should identify any conflict between those provisions, the question of the validity of the Regulation must be referred to the Court of Justice.
- 10 PJLA intervened in support of the appellant, submitting that Accredia's monopoly prevents it from operating in Italy and that the extraterritorial application of the provisions of EU competition law is allowed where a restrictive practice has an appreciable effect within the EU, irrespective of where the operators involved are located.
- 11 Accredia contests the merits of the appellant's grounds of appeal, first objecting to the reference for a preliminary ruling to the Court of Justice on the ground that it is apparent from Regulation No 765/2008 that the accreditation activity performed by the single body is a public function designated by the State, and not an economic activity, and second, arguing that the provisions of EU law that the appellant alleges have been infringed only apply to nationals and economic operators of the Member States, and therefore not to a body such as PJLA, which is established in a third country.
- 12 The regional authority submits that a reference for a preliminary ruling to the Court of Justice cannot be made, since in the main proceedings the need to protect public health takes precedence over the alleged infringement of the principle of EU law of guaranteeing freedom of access to the market and free competition.

Succinct presentation of the reasons for the reference for a preliminary ruling

- 13 The referring court considers that the Italian legislation in question has fully transposed Regulation No 765/2008 into national law, by providing for a single national accreditation body (Accredia), and that it is therefore not possible to extend the activity of providing accreditation to other bodies, such as PJLA.
- 14 Specifically, Law No 88/2009 and Regulation No 765/2008 must be interpreted from the perspective of integration/coordination rather than derogation/conflict, given the direct applicability of the regulation in question. In the light of that regulation, Article 40 of Law No 88/2009 must thus be understood to refer to operators acting within the 'single body' system, which is also confirmed by Article 4 of Law No 99/2009.
- 15 While the referring court considers that interpretation to be correct, it is nevertheless uncertain whether Regulation No 765/2008 precludes an interpretation of Italian legislation to the effect that accreditation may also be carried out by bodies, such as PJLA, which are not established in the European Union but have equivalent levels of qualification to those of the single body.
- 16 If so, the referring court asks, in the alternative, whether Regulation No 765/2008, by imposing a statutory monopoly on accreditation, is compatible with the EU law principles of freedom to provide services (Article 56 TFEU), protection of competition (Article 102 TFEU) equal treatment and non-discrimination (Articles 20 and 21 of the Charter), and thus whether it is valid.
- 17 As regards Article 56 TFEU in particular, the referring court refers to the case-law of the Court of Justice according to which Article 56 TFEU precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within a Member State. Article 56 TFEU requires the abolition of any restriction on the freedom to provide services imposed on the ground that the service provider is established in a Member State other than that in which the service is provided. Restrictions on the freedom to provide services are national measures which prohibit, impede or render less attractive the exercise of that freedom (judgment of 25 July 2018, *TTL*, C-553/16, EU:C:2018:604, paragraphs 45 and 46 and the case-law cited). The freedom to provide services conferred by Article 56 TFEU on Member State nationals includes 'passive' freedom to provide services, namely the freedom for recipients of services to go to another Member State in order to receive a service there, without being hindered by restrictions (judgment of 9 March 2017, *Piringer*, C-342/15, EU:C:2017:196, paragraph 35).
- 18 As to Article 102 TFEU, the referring court refers to the case-law of the Court of Justice according to which the definition of the relevant market, in the application of Article 102 TFEU, is a prerequisite of any assessment of whether the

undertaking concerned holds a dominant position (judgment of 30 January 2020, *Generics (UK) Ltd and Others v Competition and Markets Authority*, C-307/18, EU:C:2020:52, paragraphs 127, 128 and 129).

- 19 The referring court considers that the monopoly system for accreditation activities does not infringe Article 102 TFEU, since Accredia cannot be treated in the same way as an undertaking, is non-profit-making and performs an essential public function. Furthermore, PJLA, as an entity established in a third country, cannot invoke the provisions of EU law.
- 20 However, the referring court has doubts as to the compatibility with Article 102 TFEU of the monopoly established by the single body system, in relation to the freedom to provide on a competitive basis accreditation services within the EU.

WORKING DOCUMENT