Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

19 January 2017*

(Reference for a preliminary ruling — Free movement of goods — Articles 34 to 36 TFEU — Purely domestic situation — Food safety — Regulation (EC) No 178/2002 — Article 6 — Principle of risk analysis — Article 7 — Precautionary principle — Regulation (EC) No 1925/2006 — Member State legislation prohibiting the manufacture and sale of food supplements containing amino acids — Situation in which a temporary derogation to that prohibition is at the discretion of the national authority)

In Case C-282/15,

REQUEST for a preliminary ruling under Article 267 TFEU from the Verwaltungsgericht Braunschweig (Administrative Court, Brunswick, Germany), made by decision of 27 May 2015, received at the Court on 11 June 2015, in the proceedings

Queisser Pharma GmbH & Co. KG

v

Bundesrepublik Deutschland,

THE COURT (Fourth Chamber),

composed of T. von Danwitz, President of the Chamber, E. Juhász, C. Vajda, K. Jürimäe and C. Lycourgos (Rapporteur), Judges,

Advocate General: M. Bobek,

Registrar: K. Malacek, Administrator,

having regard to the written procedure and further to the hearing on 12 May 2016,

after considering the observations submitted on behalf of:

— Queisser Pharma GmbH & Co. KG, by A. Meisterernst, Rechtsanwalt,

— the German Government, by T. Henze and B. Beutler, acting as Agents,

— the European Commission, by S. Grünheid and E. Manhaeve, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 21 July 2016,

gives the following

* Language of the case: German.

Judgment

1 This request for a preliminary ruling concerns the interpretation of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ 2006 L 404, p. 26), as amended by Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 (OJ 2008 L 39, p. 11) ('Regulation No 1925/2006'), and Articles 34 to 36 TFEU.

2 The request has been made in proceedings between Queisser Pharma GmbH & Co. KG ('Queisser Pharma') and the Bundesrepublik Deutschland (the Federal Republic of Germany), in respect of an application for derogation from the prohibition on the manufacture and marketing of a food supplement containing the L-histidine amino acid.

Legal context

EU law

Regulation No 178/2002

3 Article 1 of Regulation No 178/2002 defines its subject matter and scope of application as follows:

'1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.

…'

4 Article 3 of that regulation provides:

'For the purposes of this Regulation:

…

(11) "risk assessment" means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

…'

5 Chapter II of that regulation, headed 'General Food Law', contains Articles 4 to 21. Article 4, itself headed 'Scope', provides in paragraphs 2 and 3:

'2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.

3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.'

6 Article 6 of Regulation No 178/2002, headed 'Risk Analysis', provides:

'1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.'

7 Article 7 of that regulation, headed 'Precautionary principle', states:

'1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.'

8 Article 14 of Regulation No 178/2002, headed 'Food safety requirements', provides:

'1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health;

(b) unfit for human consumption.

…

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe in so far as the aspects covered by the specific Community provisions are concerned.

…

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the [TFEU], in particular Articles [34 and 36] thereof.'

9 Article 53 of that regulation concerns emergency measures for food and feed of Community origin or imported from a third country. Article 55 of Regulation No 178/2002 concerns the general plan for crisis management.

Regulation No 1925/2006

10 Recitals 1 and 2 of Regulation No 1925/2006 state:

‘(1) There is a wide range of nutrients and other ingredients that might be used in food manufacturing, including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre, various plants and herbal extracts. Their addition to foods is regulated in Member States by differing national rules that impede the free movement of these products, create unequal conditions of competition and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules harmonising national provisions relating to the addition of vitamins and minerals and of certain other substances to foods.

(2) This Regulation aims to regulate the addition of vitamins and minerals to foods and the use of certain other substances or ingredients containing substances other than vitamins or minerals that are added to foods or used in the manufacture of foods under conditions that result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers. In the absence of specific Community rules regarding prohibition or restriction of use of substances or ingredients containing substances other than vitamins or minerals under this Regulation or under other specific Community provisions, relevant national rules may apply without prejudice to the provisions of the Treaty.’

11 Article 2 of that regulation, headed ‘Definitions’, provides:

‘For the purposes of this Regulation:

…

(2) “other substance” means a substance other than a vitamin or a mineral that has a nutritional or physiological effect.’

12 Article 8 of that regulation, headed ‘Substances prohibited, restricted or under Community scrutiny’, provides:

‘1. The procedure provided for in this Article shall be followed where a substance other than vitamins or minerals, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods under conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

2. On its own initiative or on the basis of information provided by Member States, the Commission may take a decision designed to amend non-essential elements of this Regulation, following in each case an assessment of available information by the Authority, in accordance with the regulatory procedure with scrutiny referred to in Article 14(3), to include, if necessary, the substance or ingredient in Annex III. In particular:

(a) if a harmful effect on health has been identified, the substance and/or the ingredient containing the substance shall:
   (i) be placed in Annex III, Part A, and its addition to foods or its use in the manufacture of foods shall be prohibited; or
   (ii) be placed in Annex III, Part B, and its addition to foods or its use in the manufacture of foods shall only be allowed under the conditions specified therein;

(b) if the possibility of harmful effects on health is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C.

…'

13 Article 11(2) of that regulation, headed 'National provisions', provides:

'If a Member State, in the absence of Community provisions, considers it necessary to adopt new legislation:

(a) on the mandatory addition of vitamins and minerals to specified foods or categories of foods; or

(b) on the prohibition or restriction on the use of certain other substances in the manufacture of specified foods,

it shall notify the Commission in accordance with the procedure laid down in Article 12.'

German law

14 The Lebensmittel- und Futtermittelgesetzbuch (German Code on foodstuffs and animal feed) BGB1. 2005 I, p. 2618) aims to protect human health by prevention measures in the private national field or to prevent a risk that these products present or may present. The referring court refers to the version of the Code published on 3 June 2013 (BGBl. 2013 I, p. 1426), as amended by Paragraph 2 of the Law of 5 December 2014 (BGBl. 2014 I, p. 1975) ('the LFGB').

15 In accordance with Paragraph 1(3) of the LFGB, the Code aims to transpose and implement legal acts of the European Union concerning fields covered by the latter, such as Regulation No 178/2002.

16 Paragraph 2 of the LFGB, headed 'Definitions', provides:

'…

2. "Food" means food as defined in Article 2 of Regulation [No 178/2002].

3. “Food additives” means food additives as defined in Article 3(2)(a) in conjunction with Article 2(2) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [(OJ 2008 L 354, p. 16)], last amended by Commission Regulation (EU) No 298/2014 of 21 March 2014 [(OJ 2014 L 89, p. 36)]. Additives include:

(1) Substances with or without nutritional value which are not usually consumed as a food on their own or as the characteristic ingredient of a food and which are intentionally added to a food for other than technological reasons during manufacturing or processing, as a result of which they themselves or their breakdown or reaction products become or can become, directly or indirectly, a component of the food; this does not include substances of natural origin or those chemically identical to substances of natural origin and which in accordance with custom are predominantly used for their nutritional value, aroma or taste or as a stimulant.

…

(3) Amino acids and their derivatives,

…’

17 Paragraph 4(1) of the LFGB, headed ‘Scope’, provides:

‘The provisions of this law

…

(2) for food additives also apply for substances equated with them in accordance with Paragraph 2(3), sentence 2 or on the basis of Paragraph 2(3), number 2,

…’

18 Paragraph 5(1) of the LFGB, headed ‘Prohibitions for the protection of health’ provides:

‘It is prohibited to manufacture or process foods for others such that their consumption is injurious to health within the meaning of Article 14(2)(a) of Regulation [No 178/2002]. This is without prejudice to

(1) the prohibition on placing on the market of food which is unsafe for health in accordance with Article 14(1) in conjunction with Article 14(2)(a) of Regulation (EC) No 178/2002, …

…’

19 Paragraph 6(1) of the LFGB, on prohibitions on food additives, stipulates:

‘It is forbidden,

(1) in the manufacture or processing of foods intended to be placed on the market,
(a) to use non-approved food additives, either unmixed or in mixtures with other substances,

…

(2) to market by way of trade foodstuffs manufactured or processed in contravention of the prohibition laid down in subparagraph 1 or not conforming with a regulation issued pursuant to Paragraph 7(1) or (2) number 1 or 5,

…’

20 Pursuant to Paragraph 7 of the LFGB, the Bundesministerium (Federal Ministry, Germany) is authorised to grant, by means of an order, derogations to the prohibitions laid down in Paragraph 6(1) of the LFGB.

21 Paragraph 54(2) and (3) of the LFGB is worded as follows:

‘2. Decisions of general application shall be adopted by the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office of Consumer Protection and Food Safety, Germany) provided that there are no compelling health protection reasons not to do so. They shall be applied for by the person who first intends to import the products into the country. When assessing the risks that a product poses to health, regard shall be had to international research findings and, in the case of foodstuffs, nutritional habits in the Federal Republic of Germany. The decisions of general application referred to in the first sentence are to operate for the benefit of all importers of the products concerned coming from EU Member States or other States party to the Agreement on the European Economic Area.

3. An exact description of the product and the available documents that are required for the decision shall be attached to the application. The application shall be dealt with within a reasonable time. If a final decision on the application has not been made within 90 days, the applicant shall be informed of the reasons for the delay.’

22 Paragraph 68 of the LFGB states:

‘1. ... derogations from the provisions of this law … may be issued upon application in accordance with subparagraphs 2 and 3.

2. Derogations may only be authorised

(1) for the manufacture, processing and marketing of specific foods …, in so far as results are expected which could be of significance to the modification or supplementation of the regulations applying to the food … under official supervision or in so far as harmonisation of the regulations with legal acts of … the European Union has not yet occurred; the legitimate interests of the individual as well as all factors which could influence the general competitive situation in the branch of industry affected must be given appropriate consideration,

…

(4) in other cases where, due to particular circumstances, especially the impending spoilage of food …, it appears necessary to avoid undue hardship; …

3. Derogations may only be issued if the facts justify the assumption that there is no risk posed to human or animal health …

4. The grant of the derogations referred to in subparagraph 2, numbers 1 and 3, fall within the competence of the Federal Office of Consumer Protection and Food Safety … Conditions may be attached to the authorisation.

5. The derogation under subparagraph 2 may be issued for a maximum of three years. In the cases under subparagraph 2, number 1, it can, on request, be extended three times … each time for a maximum period of three years in so far as the conditions of the grant are still fulfilled.

6. Authorisation for a derogation may be revoked at any time for an important reason. Reference to that reason will be made in the authorisation.

…’

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

23 Queisser Pharma, a company established in Germany, manufactures a food supplement called ‘Doppelherz aktiv + Iron + Vitamin C + Histidine + Folic Acid’, the recommended dose of which provides, daily, in particular, 100 mg of amino acid L-histidine and 10 mg of iron.

24 On 27 March 2006, Queisser Pharma submitted to the Federal Office for Consumer Protection and Food Safety (‘the Office’) an application for derogation under Paragraph 68 of the LFGB to manufacture and market that product as a food supplement in the territory of the Federal Republic of Germany.

25 By decision of 2 November 2012, the Office rejected that application, on the grounds that the conditions for granting a derogation under Paragraph 68 of the LFGB were not met. According to the Office, in accordance with Paragraph 68(3) of the LFGB, the derogation could only have been issued where the facts justified the assumption that there was no risk posed to human or animal health. Although the Office considered that the L-histidine contained in the product at issue in the main proceedings did not present any risk for health, it nevertheless expressed doubts concerning the safety of that product because of the fact that it contributed 10 mg of iron to the metabolism daily.

26 Following the rejection of the complaint it made against that decision, Queisser Pharma brought an action before the Verwaltungsgericht Braunschweig (Administrative Court, Brunswick, Germany) seeking to establish that a derogation under the first sentence of Paragraph 68(1) of the LFGB is not necessary to manufacture and market the product at issue.

27 By decision of 17 February 2015, adopted in the course of the proceedings before the referring court, the Office withdrew its decision of 2 November 2012 and granted Queisser Pharma a derogation under Paragraph 68 of the LFGB for a period of three years. The Office indicated in this respect that, contrary to what it had held in that earlier decision, there was no need to take into account iron contained in the product at issue in the main proceedings in the course of the assessment of the conditions required in Paragraph 68 of the LFGB. Queisser Pharma, nevertheless, maintained its action before the referring court.

28 In that regard, that court states that, under German law on administrative litigation, the action brought on 22 March 2013 by Queisser Pharma remains admissible as long as that company demonstrates a legitimate interest in seeking a declaration that it was not necessary to request such a derogation.

29 The referring court, relying inter alia on national case-law, in particular that identified by the Bundesgerichtshof (Federal Court of Justice, Germany) asks whether the derogation system laid down by the LFGB complies with EU law. Indeed, according to that case-law, national provisions on food safety must comply with primary EU law, in particular Articles 34 and 36 TFEU, those articles not being restricted merely to cross-border situations, which is apparent from the specific reference to them in Article 14(9) of Regulation No 178/2002. The referring court questions the compatibility of the national legislation at issue in the main proceedings with Articles 34 to 36 TFEU because of the failure to respect the principle of proportionality.

30 Moreover, the referring court questions the compatibility of national legislation, such as that at issue in the main proceedings, with Regulation No 178/2002 and Regulation No 1925/2006. According to that court, Articles 6, 7 and 14 of Regulation No 178/2002 may be considered as governing the area of food safety conclusively so that national prohibitions on individual foodstuffs or food ingredients may only be issued under the conditions specified therein. Similarly, it may be considered that the procedure

laid down in Article 8 of Regulation No 1925/2006 governs conclusively the possibility of adding amino acids to food supplements, with the effect of impairing the adoption of conflicting national provisions.

31 Thus, the referring court asks whether the national legislation at issue in the main proceedings is in breach of EU law in that it, first, prohibits the use of amino acids in food in general, regardless of whether there are reasons to suspect that there is a risk to health and, second, imposes conditions on the possibility of obtaining a derogation.

32 In those circumstances, the Verwaltungsgericht Braunschweig (Administrative Court, Brunswick) decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

‘(1) Are Articles 34, 35 and 36 of the Treaty on the Functioning of the European Union in conjunction with Article 14 of Regulation [No 178/2002] to be interpreted as precluding national statutory provisions which prohibit the manufacture or processing and/or marketing of a food supplement with amino acids (here: L-histidine), unless a temporary derogation has been issued at the discretion of the national authority and subject to specific additional factual requirements?

(2) Does the scheme of Articles 14, 6, 7, 53 and 55 of Regulation [No 178/2002] mean that national bans on individual foods or food ingredients may only be issued under the conditions set out therein, and does this preclude a national statutory provision as set out at 1 above?

(3) Is Article 8 of Regulation [No 1925/2006] to be interpreted as precluding a national statutory provision as set out at 1 above?’

Consideration of the questions referred

33 By its questions, which it is appropriate to consider together, the referring court asks, in essence, whether Articles 6, 7, 14, 53 and 55 of Regulation No 178/2002, Article 8 of Regulation No 1925/2006 and Articles 34 to 36 TFEU must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which prohibits the manufacture, processing or marketing of any food supplement containing amino acids, unless a derogation has been issued, for a specific period, by a national authority with discretion in that respect.

34 It must be observed, as a preliminary point, that certain provisions of EU law covered by the questions referred for a preliminary ruling do not apply in the context of the dispute in the main proceedings.

35 First, as regards Regulation No 1925/2006, it is apparent from reading recital (1) together with Article 1(1) and Article 2(2) of that regulation that amino acids, in so far as they have a nutritional or physiological effect and are added to foods or used in the manufacture of foods, are within the scope of application of that regulation as ‘other substances’, as defined in Article 2(2).

36 Nevertheless, as is apparent from recital (2) of Regulation No 1925/2006, in the absence of specific EU law rules regarding prohibition or restriction of the use of other substances or ingredients containing those ‘other substances’, relevant national rules may apply without prejudice to the provisions of the Treaty. In the current state of EU law, amino acids have not been the object of any specific prohibition or restriction, under Article 8 of Regulation No 1925/2006, which sets out the procedure for the prohibition of ‘other substances’ at EU level.

37 Therefore, although, under Article 11(2)(b) of Regulation No 1925/2006, relevant national rules adopted after the entry into force of that regulation must be notified to the Commission, Member States are, in principle, entitled to continue to apply, inter alia, national rules on the prohibition of the use of amino acids in food supplements in existence at the time of the entry into force of that

regulation. Consequently, Regulation No 1925/2006 is not intended to apply in the context of the case in the main proceedings. That regulation nevertheless does not exclude the application of other specific provisions laid down by the Union legislature concerning those 'other substances' or provisions of the Treaty.

38 Then, regarding Articles 34 to 36 TFEU, according to the order for reference, all the elements of this case are confined within the Federal Republic of Germany.

39 As noted by the Advocate General in points 98 to 100 of his Opinion, Articles 34 to 36 TFEU do not apply to the main proceedings because, first, all the elements are confined within a single Member State (see, to that effect, judgments of 30 November 1995, *Esso Española*, C-134/94, EU:C:1995:414, paragraph 13, and of 15 November 2016, *Ullens de Schooten*, C-268/15, EU:C:2016:874, paragraph 47) and, second, the provisions of the LFGB, at issue in the main proceedings, do not have as object or effect disadvantaging exports vis-à-vis internal commerce (see, to that effect, judgment of 16 December 2008, *Gysbrechts and Santurel Inter*, C-205/07, EU:C:2008:730, paragraph 40).

40 The referring court considers nevertheless that, despite the finding that this case has no cross-border aspect, Articles 34 to 36 TFEU could apply, on the ground that, according to Article 14(9) of Regulation No 178/2002, where there are no specific EU law provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the FEU Treaty, in particular Articles 34 and 36 thereof.

41 It must be noted, however, as stated in essence by the German Government in its written observations, that an express reference to Articles 34 to 36 TFEU, such as that in Article 14(9) of Regulation No 178/2002, cannot extend the scope of application of Articles 34 to 36 TFEU to a situation, such as that at issue in the main proceedings, which does not include any other element allowing it to be found that those articles apply.

42 Finally, as regards Regulation No 178/2002, the documents submitted to the Court make it possible to establish that Articles 53 and 55 of that regulation, which cover situations in which urgent measures must be taken and crisis management situations respectively, cannot apply in the context of the present case.

43 It follows that Article 8 of Regulation No 1925/2006, Articles 34 to 36 TFEU and Articles 53 and 55 of Regulation No 178/2002 do not apply in the context of the dispute in the main proceedings and do not preclude national legislation such as that at issue in the main proceedings.

44 As regards Articles 6, 7 and 14 of Regulation No 178/2002, it must be stated that, according to Article 14(1) and (2) of that regulation, food is not to be placed on the market if it is unsafe, namely if it is injurious to health or unfit for human consumption. Consequently, the placing on the market of any food injurious to health or unfit for human consumption must be prohibited.

45 In that regard, it follows from Article 14(7) and (9) of that regulation that, in the absence of specific EU law provisions governing food safety, food is considered safe if it complies with the specific provisions of national food law of the Member State in the territory of which it is marketed. In such a situation, that provision enables that Member State to lay down rules governing food safety.

46 It must be stated, in that context, that, in the absence of harmonisation and in so far as uncertainty persists in the current state of scientific research, it is for the Member States to decide at which level they intend to ensure the protection of the health and life of persons (see, to that effect, judgments of 14 July 1983, *Sandoz*, 174/82, EU:C:1983:213, paragraph 16; of 23 September 2003, *Commission* v *Denmark*, C-192/01, EU:C:2003:492, paragraph 42; and of 28 January 2010, *Commission* v *France*, C-333/08, EU:C:2010:44, paragraph 85).

47 Nevertheless, the compatibility of national legislation governing food safety, such as that at issue in the main proceedings, with the system laid down in Regulation No 178/2002 is conditional on its compliance with the general principles of food law, in particular the principle of risk analysis and the precautionary principle, laid down in Articles 6 and 7 of that regulation respectively.

48 Indeed, in accordance with Article 1(2), that regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at EU and national level.

49 Moreover, Article 4(2) of Regulation No 178/2002 provides that the general principles defined in Articles 5 to 10 of that regulation form a general framework of a horizontal nature to be followed when measures are taken. According to Article 4(3) of that regulation, food law principles and procedures in force are to be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with the provisions of Articles 5 to 10.

50 It follows that the national food legislation at issue in the main proceedings which prohibits, unless a derogation has been issued, the manufacture, processing or marketing of food supplements containing amino acids, must comply with the general framework envisaged by those provisions of Regulation No 178/2002.

51 The Court has held that Articles 6 and 7 of that regulation seek to achieve the general objective of a high level of protection of health (see, to that effect, judgment of 28 January 2010, *Commission* v *France*, C-333/08, EU:C:2010:44, paragraph 103).

52 In that regard, it follows from Article 6(1) and (2) of Regulation No 178/2002 that the risk assessment, upon which food legislation must be based, is based on available scientific evidence and is undertaken in an independent, objective and transparent manner.

53 It must be noted that Article 3(11) of that regulation defines the risk assessment as a scientifically based process and consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.

54 As for Article 7 of Regulation No 178/2002 concerning the precautionary principle, it is apparent from Article 7(1) that, in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Union may be adopted, pending further scientific information for a more comprehensive risk assessment.

55 As stated by the Advocate General in point 50 of his Opinion, provisional risk management measures, applied pursuant to Article 7 of Regulation No 178/2002, can only occur after the assessment of available information, as provided for in Article 6 of that regulation, has been carried out and has revealed scientific uncertainties regarding the possible harmful effects on health of a food or a substance added to a food.

56 In that regard, a correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the substances or foods concerned, and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research (see, to that effect, judgments of 9 September 2003, *Monsanto Agricoltura Italia and Others*, C-236/01, EU:C:2003:431, paragraph 113, and of 28 January 2010, *Commission* v *France*, C-333/08, EU:C:2010:44, paragraph 92).

57 Thus, where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the

precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective (judgment of 28 January 2010, *Commission* v *France*, C-333/08, EU:C:2010:44, paragraph 93 and the case-law cited).

58 It follows that, pursuant to Article 7(1) of Regulation No 178/2002, a Member State is, in principle, justified in adopting a scheme, such as that at issue in the main proceedings, which prohibits generally and except where a derogation has been issued, the use of amino acids in foods, where that scheme, which amounts in essence to a prior authorisation scheme, is based, in particular on the principle of risk analysis and the precautionary principle, referred to in Articles 6 and 7 of that regulation, as those principles are explained in paragraphs 51 to 57 of the present judgment.

59 Moreover, in accordance with Article 7(2) of Regulation No 178/2002, measures adopted on the basis of Article 7(1) are to be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Union, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. Furthermore, those measures are to be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

60 Such uncertainty, which is inseparable from the concept of precaution, influences the extent of the discretion of the Member State and thus has an impact on the means of applying the proportionality principle. In such circumstances, it must be accepted that a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks are fully demonstrated. However, the assessment of the risk cannot be based on purely hypothetical considerations (judgment of 28 January 2010, *Commission* v *France*, C-333/08, EU:C:2010:44, paragraph 91 and the case-law cited).

61 In the present case, the referring court does not provide sufficient information to make it possible to find that the prohibition of foods containing amino acids, laid down by the LFGB, was based on the general principles of food law stemming from Articles 6 and 7 of Regulation No 178/2002. Nevertheless, in its written observations submitted to the Court, the German Government claims that the national rules on amino acids contained in Paragraph 6(1) of the LFGB, read in conjunction with Paragraph 2(3), second sentence, number 3, of the LFGB, aim in actual fact at remedying the threat to health resulting from the addition of amino acids to foods. According to that government, the enrichment of food with amino acids presents risks for health but current scientific knowledge is incomplete and does not allow a conclusive assessment of such risks.

62 It should be noted, in that regard, that it falls to the referring court to examine the compatibility of the scheme laid down by the LFGB with Regulation No 178/2002. In the context of that examination, that court must, first, satisfy itself that the assessment of the risks in using amino acids in food supplements was undertaken in a way that meets the conditions referred to in paragraphs 53 and 56 of the present judgment and is not based on purely hypothetical considerations.

63 Second, once it is shown that uncertainty persists in the current state of scientific research on the harmful effects for health of certain substances, the margin of discretion of Member States relating to the choice of the level at which they intend to guarantee the protection of public health is particularly large (see, to that effect, judgment of 29 April 2010, *Solgar Vitamin's France and Others*, C-446/08, EU:C:2010:233, paragraphs 35 and 36). Consequently, as noted by the Advocate General in point 96 of his Opinion, the fact that, in circumstances such as those at issue in the main proceedings, the competent national authority has a discretion does not in itself raise issues of compatibility with Regulation No 178/2002.

64 Third, the scheme laid down by the LFGB covers, indiscriminately, as is apparent from Paragraph 6(1), number 2, of the LFGB, read in conjunction with Paragraph 2(3), second sentence, number 3, and Paragraph 4(1), number 2, of the LFGB, all amino acids and their derivatives, without distinguishing possible categories or types of substances. While such a general prohibition scheme is not, for that reason alone, contrary to the provisions of Regulation No 178/2002, the risk analysis which the competent national authorities must carry out pursuant to Article 6 of that regulation must still clearly identify the common elements or characteristics of the substances concerned, whose real risk for human health cannot be excluded.

65 In the present case, having regard to the information provided by the German Government in its written observations, and subject to the necessary verifications which the referring court must carry out, the risk analysis and the resulting application of the precautionary principle appear to concern only certain amino acids, which would be insufficient to justify a prior authorisation scheme, such as that laid down in the LFGB, which applies without distinction to all amino acids.

66 In the context of that verification, it must be pointed out that the practical difficulties in carrying out an exhaustive assessment of the risk to health of food containing amino acids, in accordance with the case-law referred to in paragraph 56 of the present judgment, cannot justify the absence of such an exhaustive assessment prior to the adoption of a systematic and untargeted prior authorisation scheme (see, by analogy, judgment of 28 January 2010, *Commission* v *France*, C-333/08, EU:C:2010:44, paragraph 103).

67 Fourth, Paragraph 68(5) of the LFGB provides that the derogations from the prohibition referred to in Paragraph 6 of the LFGB are granted for a maximum period of three years, renewable three times only, each time for a maximum period of three years. In that regard, it must be noted that the first of those provisions, in that it lays down such temporary restrictions to the granting of those derogations, even in cases where it is established that the substance is safe, constitutes a disproportionate measure to meet the LFGB's objective of public health protection.

68 It follows from the above considerations that Articles 6 and 7 of Regulation No 178/2002 must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which prohibits the manufacture, processing or marketing of any food supplement containing amino acids, unless a derogation has been issued by a national authority with discretion in that respect, where that legislation is based on a risk analysis which concerns only certain amino acids, which it is for the referring court to verify. In any event, those articles must be interpreted as precluding such national legislation, where that legislation lays down that the derogations to the prohibition covered by it may only be granted for a specific period even in cases where the safety of a substance is established.

Costs

69 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 (Fourth Chamber) hereby rules:

Articles 6 and 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety must be interpreted as precluding national legislation, such as that at issue in the main proceedings, which prohibits the manufacture, processing or marketing of any food supplement containing amino acids, unless a derogation has been issued by a national authority with discretion in that respect, where that legislation is based on a risk analysis which concerns only certain amino

acids, which it is for the referring court to verify. In any event, those articles must be interpreted as precluding such national legislation, where that legislation lays down that the derogations to the prohibition covered by it may only be granted for a specific period even in cases where the safety of a substance is established.

[Signatures]