Case C-652/23

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:

2 November 2023

Referring court:

Landesverwaltungsgericht Steiermark (Austria)

Date of the decision to refer:

17 October 2023

Applicant:

pro medico Handels GmbH

Defendant:

Bürgermeisterin der Stadt Graz

Subject matter of the main proceedings

Interpretation of Regulation (EC) No 178/2002 with regard to the legality of the prohibition on the placing on the market of a foodstuff which, when consumed as intended, significantly exceeds the acceptable daily intake indicated by the EFSA.

Subject matter and legal basis of the request

Interpretation of EU law, Article 267 TFEU, in particular

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 No 178/2002’).

Questions referred for a preliminary ruling

1. Must Article 14(2)(b) of Regulation No 178/2002, read in conjunction with Article 14(5) thereof, be interpreted as precluding legislation of a Member State or an interpretation of that legislation whereby a food is to be regarded as unfit for human consumption if its usability in accordance with its intended purpose is not guaranteed, without any of the reasons set out in Article 14(5) of Regulation No 178/2002 for food being unacceptable for human consumption (contamination by extraneous matter or otherwise, or putrefaction, deterioration or decay) having to be present?

2. If Question 1 is answered in the negative:

Must Article 14(2)(b) of Regulation No 178/2002, read in conjunction with Article 14(5) thereof, be interpreted as meaning that a food must be considered to be unfit for human consumption if, when consumed as intended, it (significantly) exceeds a level regarded by the European Food Safety Authority (EFSA), in its evaluation of a mineral substance contained in the food, as the Tolerable Upper Intake Level (UL)?

3. If Question 2 is answered in the affirmative:

Is the limit value for zinc set by the EFSA binding or is it permissible for the limit value to be exceeded to a certain degree if, in accordance with Article 14(3)(b) of Regulation No 178/2002, information is affixed to the product stating that the product is suitable only for a certain group of persons, that no other preparations containing zinc may be taken alongside it and that the intake must be limited in time?

Provisions of European Union law relied on

Regulation No 178/2002, in particular Article 14(2)(b), Article 14(5) and Article 14(3)(b)

Provisions of national law relied on

Bundesgesetz über Sicherheitsanforderungen und weitere Anforderungen an Lebensmittel, Gebrauchsgegenstände und kosmetische Mittel zum Schutz der Verbraucherinnen und Verbraucher (Lebensmittelsicherheits- und Verbraucherschutzgesetz) (Federal Law on safety and other requirements for foodstuffs, commodities and cosmetics with a view to ensuring consumer protection (Law on food safety and consumer protection) (‘the LMSVG’)

Succinct presentation of the facts and procedure in the main proceedings

1 In a decision dated 23 May 2022, the Bürgermeisterin der Stadt Graz (Mayor of the City of Graz) prohibited pro medico Handels GmbH, established in Graz (Austria), from placing the unsafe food ‘zinc – zinc citrate’ (‘the product at issue’) on the market in accordance with point 1 of Paragraph 39(1) of the LMSVG. It also ordered the withdrawal from the market and recall from consumers in accordance with point 9 of Paragraph 39(1) of the LMSVG.

2 The prohibition on placing the product on the market remains in place until the causes for the product being unfit for human consumption have been eliminated.

3 That decision was essentially based on the expert opinion of Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH dated 29 November 2021.

4 That expert opinion states that a capsule of ‘zinc – zinc citrate’ contains 30 mg zinc per capsule according to the labelling and thus a zinc content of 37 mg/daily dose. In 2016, a maximum recommended level for vitamins, minerals and food supplements was published by the Österreichisches Lebensmittelbuch (Austrian Food Code; ‘the ÖLB’), which amounted to 15 mg/day for zinc.

5 The European Food Safety Authority (EFSA) has set a Tolerable Upper Intake Level (UL) of 25 mg/day for zinc.

6 Since consumption of the product at issue clearly exceeds the EFSA limit value by 25 mg, it is unsuitable and unsafe for human consumption and it is therefore prohibited to place that product on the market pursuant to point 1 of Paragraph 5(1) of the LMSVG.

7 In the complaint lodged against that decision, it was argued, inter alia, that there are no binding maximum levels of vitamins and minerals in food supplements in Austria or anywhere else in Europe. The UL set by the EFSA is not relevant. The EFSA itself concluded that the highest intake dose at which no side effects had been observed was around 50 mg/day.

8 The product at issue is not suitable for long-term use without restrictions due to its zinc content. However, food safety is guaranteed if no other products containing zinc are used. Furthermore, as provided for in the product instructions, the use of the food supplement must be limited to eight weeks and no other products containing zinc may be used at the same time.

Succinct presentation of the reasoning in the request for a preliminary ruling

9 Since the correct application of EU law does not appear so obvious that there is no room for reasonable doubt, the questions set out above are referred for a preliminary ruling pursuant to Article 267 TFEU.

10 According to Article 14 of Regulation No 178/2002, food that is unsafe is not to be placed on the market. Accordingly, national law stipulates in Paragraph 5 of the LMSVG that it is prohibited to place food on the market that is unsafe in accordance with Article 14 of Regulation No 178/2002.

Question 1

11 The first question referred for a preliminary ruling seeks to ascertain whether the causes referred to in Article 14(5) of Regulation No 178/2002 for food being unacceptable for human consumption (contamination, whether by extraneous matter or otherwise, putrefaction, deterioration or decomposition) must be present for a food to be regarded as unfit for human consumption within the meaning of Article 14(2)(b) of Regulation No 178/2002, read in conjunction with Article 14(5) thereof.

12 Article 14(2)(b) of Regulation No 178/2002 provides that food is to be deemed to be unsafe if it is considered to be unfit for human consumption. The wording of paragraph 5 of that article requires that, in determining whether any food is unfit for human consumption, 'regard shall be had' to the reasons stated therein for which the food is unacceptable for human consumption.

13 One view, which was also followed by the defendant in its contested decision, is that it must be concluded from that wording that the circumstances listed in the provision do not exhaustively determine whether a food is unfit for human consumption, so that other circumstances can also fulfil the criteria of Article 14(5). That understanding corresponds to the wording of point 2 of Paragraph 5(5) of the LMSVG, which defines a food as unfit for human consumption if 'the usability in accordance with its intended purpose' is not guaranteed.

14 Another view is that the reasons set out in Article 14(5) of Regulation No 178/2002 must be present for a food to be considered unfit for human consumption. This is supported by, inter alia, the wording 'regard shall be had'. The expression in the German version 'für den Verzehr durch den Menschen inakzeptabel geworden ist' suggests that the EU legislature took as a basis only a change in the composition of a food due to the reasons referred to in Article 14(5) of Regulation No 178/2002, but not other possible reasons for which a food is unfit for human consumption.

15 In its judgment of 2 September 2021 (*Toropet*, C-836/19, EU:C:2021:668), the Court of Justice of the European Union held that, under Article 14(5) of Regulation No 178/2002, a food is unfit for human consumption 'where it is unacceptable for human consumption for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay'.

Question 2

16 If the first question is answered in the negative, the question arises as to whether there are other reasons, apart from those referred to in Article 14(5) of Regulation No 178/2002, for which a food is unfit for human consumption.

17 The product at issue, a foodstuff in the form of a food supplement, leads, as explained above, to the limit value for 'zinc – zinc citrate' set by the EFSA being significantly exceeded when consumed as intended.

18 According to point 2 of Paragraph 5(5) of the LMSVG, a foodstuff is unfit for human consumption if its usability in accordance with its intended purpose is not guaranteed.

19 According to a view expressed in the legal literature, the question of when the usability of a foodstuff in accordance with its intended purpose is no longer guaranteed must be resolved in a balanced manner, taking into account all the circumstances, on the basis of a legitimate consumer expectation.

20 The Verwaltungsgerichtshof (Supreme Administrative Court, Austria) has taken the view that the expectation of an average consumer who is reasonably well informed and reasonably observant and circumspect, which is the benchmark, is arguably reflected in the ÖLB, which is in the nature of an objective expert opinion.

21 In 2016, the ÖLB set a maximum recommended level for zinc of 15 mg/day. In a recent German assessment, a maximum level of 6.5 mg zinc in food supplements was proposed. In Switzerland, a maximum level of 5.3 mg zinc per day in food supplements was recently set by regulation. In Italy, a maximum level of 15 mg zinc per day in food supplements has been established in legislation.

Question 3

22 If the answer to the second question is in the affirmative, the question arises as to whether the EFSA reference value for zinc is to be used in general or whether it is permissible for the limit value to be exceeded to a certain degree, if information within the meaning of Article 14(3)(b) of Regulation No 178/2002 is affixed to the product, stating that the product is suitable only for a certain group of people, that no other preparations containing zinc may be used alongside it and that the intake is limited to a few weeks.

23 According to an expert opinion by a nutritionist and food scientist dated 9 May 2022, submitted by the applicant, the product at issue meets the specific requirements for a food supplement.

24 The EFSA found that 50 mg/day was the highest intake dose at which no side effects were observed (No Observed Adverse Effect Level). Based on that dose and applying a safety factor, the EFSA arrived at a UL of 25 mg/day for adults.

The UL refers to the continuous total daily intake of a nutrient from all sources that are not associated with a risk of adverse effects. The UL therefore does not represent a toxicological limit value which, if exceeded, would pose a health risk.

25 In its summary, the expert opinion concludes that a product intended to place approximately 30 mg/day of zinc on the market in capsule form fulfils the requirements for a food supplement. The dose of 30 mg zinc in addition to the normal diet would lead to the UL being exceeded in people with an already very high intake of zinc from food. The product at issue is therefore not suitable for long-term use without restrictions.

26 It would therefore also be imperative to attach a notice to the product stating that the use of the food supplement should be limited to eight weeks. In addition, it would be necessary to state that the food supplement is suitable only for adults and that no other preparations containing zinc may be used at the same time.