Reports of Cases

JUDGMENT OF THE COURT (Seventh Chamber)

25 May 2023 *

(Reference for a preliminary ruling – Food safety – Novel food – Regulation (EU) 2015/2283 – Sprouted buckwheat flour with a high spermidine content – Germination of buckwheat seeds in a nutrient solution containing spermidine)

In Case C-141/22,

REQUEST for a preliminary ruling under Article 267 TFEU from the Landesgericht für Zivilrechtssachen Graz (Regional Civil Court, Graz, Austria), made by decision of 17 February 2022, received at the Court on 28 February 2022, in the proceedings

TLL The Longevity Labs GmbH

v

Optimize Health Solutions mi GmbH,

BM,

THE COURT (Seventh Chamber),

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

Advocate General: M. Campos Sánchez-Bordona,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– TLL The Longevity Labs GmbH, by J. Hütthaler-Brandauer, Rechtsanwalt,

– Optimize Health Solutions mi GmbH, by M. Kasper, Rechtsanwalt,

– BM, by M. Grube and M. Kasper, Rechtsanwälte,

– the Greek Government, by K. Konsta and E. Leftheriotou, acting as Agents,

* Language of the case: German.

– the European Commission, by B.-R. Killmann and B. Rous Demiri, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 19 January 2023,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 3(2)(a)(iv) and (vii) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ 2015 L 327, p. 1), and of Article 2(c) 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).

2 The request has been made in proceedings between TLL The Longevity Labs GmbH ('TLL') and Optimize Health Solutions mi GmbH ('Optimize Health') and its manager, BM, concerning allegations of unfair competition.

Legal context

Regulation No 178/2002

3 Article 2 of Regulation No 178/2002, headed 'Definition of "food"', is worded as follows:

'For the purposes of this Regulation, "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. …

"Food" shall not include:

…

(c) plants prior to harvesting;

…'

Regulation 2015/2283

4 As set out in Article 3 of Regulation 2015/2283, headed 'Definitions', paragraph 2:

'The following definitions … apply:

(a) "novel food" means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories:

…

(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

– traditional propagating practices which have been used for food production within the Union before 15 May 1997; or

– non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

…

(vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;

…

(b) "history of safe food use in a third country" means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification referred to in Article 14;

…'

5 Article 6 of that regulation, headed 'Union list of authorised novel foods', states:

'1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 7, 8 and 9 ("the Union list").

2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein.'

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

6 TLL and Optimize Health are competing businesses which distribute food supplements. Optimize Health produces a food supplement containing sprouted buckwheat flour with a high spermidine content ('the product at issue'). Spermidine is a biogenic polyamine found in varying concentrations in the cells of all organisms. The product at issue does not have an authorisation from the European Commission as a novel food under Regulation 2015/2283. Its production is the result of a process by which buckwheat seeds are germinated in a solution containing synthetic spermidine in order to obtain seedlings. After harvesting, the seedlings are washed with water, dried and ground into a flour in accordance with a process which does not produce more seedlings than seed grains used.

7 TLL produces food with a high spermidine content, but in accordance with a different process, consisting in extracting spermidine from ungerminated wheat germ. TLL brought an action before the referring court in order to prohibit Optimize Health from distributing the product at issue, claiming that it was a novel food which, in accordance with Article 6(2) of Regulation 2015/2283, must be authorised and included in the Union list of authorised novel foods. According to TLL, by placing the product at issue on the EU market without an authorisation and without that product being included in the Union list of authorised novel foods, Optimize Health has engaged in unfair competition.

8 Optimize Health contends, in essence, that the product at issue is not a novel food. It states, first of all, that germination is a stage of primary production for the purposes of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ 2004 L 139, p. 1). Next, since, under Article 2 of Regulation No 178/2002, a plant is not a food prior to its harvesting, Regulation 2015/2283 is inapplicable. Lastly, spermidine has been available in the European Union for more than 25 years.

9 In those circumstances, the Landesgericht für Zivilrechtssachen Graz (Regional Civil Court, Graz, Austria) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is Article 3(2)(a)(iv) of Regulation [2015/2283] to be interpreted as meaning that "sprouted buckwheat flour with a high spermidine content" is a novel food, inasmuch as only sprouted buckwheat flour without a raised spermidine content was used for human consumption to a significant degree within the European Union before 15 May 1997 or has a history of safe food use thereafter, irrespective of how the spermidine comes to be in the sprouted buckwheat flour?

(2) If Question 1 is answered in the negative: Is Article 3(2)(a)(vii) of Regulation [2015/2283] to be interpreted as meaning that the term "production process" for food includes primary production processes?

(3) If Question 2 is answered in the affirmative: Does the novelty of a production process within the meaning of Article 3(2)(a)(vii) of Regulation [2015/2283] depend on whether the production process itself has never before been used for any food or whether it has not been used for the food under assessment?

(4) If Question 2 is answered in the negative: Does the germination of buckwheat seed in a nutrient solution containing spermidine qualify as a primary production process for a plant to which food legislation, including Regulation [2015/2283], does not apply, as the plant is not a food prior to harvesting (Article 2(c) of Regulation [No 178/2002])?

(5) Does it make a difference if the nutrient solution contains natural or synthetic spermidine?'

The requests that the oral part of the procedure be reopened

10 By letters lodged at the Court Registry on 23 and 29 March 2023 respectively, Optimize Health and BM requested the reopening of the oral part of the procedure, pursuant to Article 83 of the Rules of Procedure of the Court of Justice, claiming, in essence, that relevant new facts had emerged following a decision of the Oberlandesgericht Wien (Higher Regional Court, Vienna, Austria) of 14 March 2023 in which that court stated, as regards sprouted buckwheat flour with a high spermidine content, that TLL had initiated a consultation process for a similar but fictitious product, with the result that that process was, to all intents and purposes, an artificial construct. The Commission and the Greek Government relied on that process in their written observations and, in his Opinion, the Advocate General referred to a notification from the Republic of Austria to the Commission concerning the same process.

11 By letter lodged at the Court Registry on 27 April 2023, Optimize Health made a new request for the reopening of the oral part of the procedure, pursuant to Article 83 of the Rules of Procedure, arguing, in essence, that relevant new facts had emerged following an order of the Oberlandesgericht Wien (Higher Regional Court, Vienna) of 30 March 2023 in which that court stated, as regards an almost identical product to the product at issue, that it cannot be regarded as a novel food.

12 As the Advocate General observed in point 29 of his Opinion, the notification from the Republic of Austria to the Commission is not such as to affect the outcome of the reference for a preliminary ruling, since the referring court was unable to take it into account for the purposes of its request.

13 Furthermore, it should be borne in mind that the Statute of the Court of Justice of the European Union and the Rules of Procedure make no provision for the parties to submit observations in response to the Advocate General's Opinion (judgment of 31 January 2023, *Puig Gordi and Others*, C-158/21, EU:C:2023:57, paragraph 37).

14 It is true that, under Article 83 of its Rules of Procedure, the Court may at any time, after hearing the Advocate General, order the reopening of the oral part of the procedure, in particular if it considers that it lacks sufficient information or where the case must be decided on the basis of an argument which has not been debated between the parties.

15 However, the Court, after hearing the Advocate General, considers that the requests submitted to it for the reopening of the oral part of the procedure do not disclose any new fact which is of such a nature as to be a decisive factor for the decision that it is called upon to deliver in the present case and that it has all the information necessary for it to answer the questions referred.

16 Accordingly, there is no need to order the reopening of the oral part of the procedure.

Consideration of the questions referred

The first question

17 By its first question, the referring court asks, in essence, whether Article 3(2)(a)(iv) of Regulation 2015/2283 must be interpreted as meaning that a food, such as sprouted buckwheat flour with a high spermidine content, which was not used for human consumption to a significant degree within the European Union before 15 May 1997 is a 'novel food', within the meaning of that provision.

18 It should be recalled that it follows from Article 3(2)(a)(iv) of Regulation 2015/2283 that any food that was not used for consumption to a significant degree within the European Union before 15 May 1997 constitutes, in principle, 'novel food' within the meaning of that regulation, if it is food 'consisting of, isolated from or produced from plants or their parts'. That provision nevertheless provides that, as an exception to that principle, the classification of 'novel food' does not apply to this type of food consisting of or produced from plants, provided that two cumulative conditions are met. According to the first of those conditions, the food concerned must have 'a history of safe food use within the Union'. The second condition requires that the food 'is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:

– traditional propagating practices which have been used for food production within the Union before 15 May 1997; or

– non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances'.

19 In the present case, it is apparent, in essence, from the order for reference that the product at issue, which was not used for human consumption to a significant degree within the European Union before 15 May 1997, is a flour enriched with spermidine, and which is obtained from a plant, namely buckwheat, that is to say, from a 'plant', within the meaning of Article 3(2)(a)(iv) of Regulation 2015/2283. The seedlings of that plant, after drying and milling, are used to produce that flour, with the result that, in the light of those factors and subject to the matters to be verified by the referring court, the product at issue should, in principle, be regarded as falling within the concept of 'novel food', within the meaning of that provision.

20 It is necessary, however, to examine whether the exception provided for in that provision – which allows a food to be excluded from the concept of novel food, subject to the two cumulative conditions referred to in paragraph 18 above – is applicable to a product such as the product at issue.

21 As regards the first of those conditions, relating to the existence of a 'history of safe food use within the Union', it should be noted that its content is not defined by Regulation 2015/2283. Nevertheless, Article 3(2)(b) of that regulation specifies, with regard to the concept of a 'history of safe food use in a third country', that that applies where 'the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country'.

22 As the Advocate General observed in point 34 of his Opinion, the concept of a 'history of safe food use in a third country', as defined in Article 3(2)(b) of that regulation, may be transposed to the concept of a 'history of safe food use within the Union', within the meaning of Article 3(2)(a)(iv) of that regulation. There is nothing to support a finding that the concept of 'history of safe food use' should have a different meaning depending on whether it is used with reference to a third country in the context of Article 3(2)(b) of Regulation 2015/2283 or to a country of the European Union in the context of Article 3(2)(a)(iv) of that regulation.

23 In the present case, subject to the matters to be verified by the referring court, it is not apparent that the safety of the product at issue has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one country of the European Union, with the result that the product at issue would not satisfy the first of the two cumulative conditions required in order to avoid classification as a novel food under Article 3(2)(a)(iv) of Regulation 2015/2283.

24 Given the cumulative nature of those conditions and the finding made in the preceding paragraph, it is not necessary, in principle, for the referring court to examine the second of those conditions.

25 However, should the referring court reach the conclusion that the product at issue satisfies the first of those conditions, it should be recalled that the second condition requires that the food concerned consist of or be produced from plants obtained by propagating practices which either have been used for food production within the European Union before 15 May 1997 or have not been used for such purposes before that date, in which case it is also necessary that those practices do not give rise to 'significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances'.

26 As the Advocate General observed, in essence, in point 36 of his Opinion, propagating practices for the production of new plants by reproduction are to be distinguished from practices covering the entire production process of a food.

27 It is apparent from the information in the file sent to the Court that the use of an aqueous solution of spermidine for the cultivation of buckwheat seedlings is not a plant propagation technique within the meaning of the preceding paragraph and Article 3(2)(a)(iv) of Regulation 2015/2283, but a production process for enriching the seedlings in order to achieve a high spermidine content. In such a scenario, which it is for the referring court to ascertain, such a production process would be irrelevant for the purpose of examining the second of the cumulative conditions.

28 In the light of the foregoing considerations, the answer to the first question is that Article 3(2)(a)(iv) of Regulation 2015/2283 must be interpreted as meaning that a food, such as sprouted buckwheat flour with a high spermidine content, which was not used for human consumption to a significant degree within the European Union before 15 May 1997, constitutes a 'novel food' within the meaning of that provision given that, first, it is obtained from a plant, secondly, it is not apparent that its safety has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one country of the European Union, and, thirdly and in any event, it is not obtained by propagating practices, within the meaning of that provision.

The second to fifth questions

29 In view of the answer given to the first question, there is no need to answer the second to fifth questions.

Costs

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

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

Article 3(2)(a)(iv) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

must be interpreted as meaning that a food, such as sprouted buckwheat flour with a high spermidine content, which was not used for human consumption to a significant degree within the European Union before 15 May 1997, constitutes a 'novel food' within the meaning of that provision given that, first, it is obtained from a plant, secondly, it is not apparent that its safety has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one country of the European Union, and, thirdly and in any event, it is not obtained by propagating practices, within the meaning of that provision.

[Signatures]