Reports of Cases

OPINION OF ADVOCATE GENERAL
SZPUNAR
delivered on 21 January 2016[1]

Case C-448/14

Davitas GmbH
v
Stadt Aschaffenburg

(Request for a preliminary ruling from the Bayerischer Verwaltungsgerichtshof (Higher Administrative Court of Bavaria, Germany))

(Protection of public health — Placing on the market of novel foods — Regulation (EC) No 258/97 — Article 1(2)(c) — Scope — Concept of a food or food ingredient with a new molecular structure))

Introduction

1. The present case provides the Court with the opportunity to clarify the scope of the rules on the placing on the market within the European Union of novel foods, laid down in Regulation (EC) No 258/97.[2]

2. The Bayerischer Verwaltungsgerichtshof (Higher Administrative Court of Bavaria, Germany) has before it an action brought by Davitas GmbH ('Davitas') against the German authorities following the ban imposed by them on the marketing of the product 'De Tox Forte', a food consisting of clinoptilolite, a mineral substance of volcanic origin.

3. The dispute in the main proceedings is concerned with whether such a substance, which is naturally occurring and not the product of human intervention, but which has not been used for human consumption, constitutes a novel food within the meaning of Article 1 of Regulation No 258/97 and should therefore be subjected to the safety assessment provided for in that regulation prior to marketing.

1 — Original language: French.

2 — Regulation of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 1), as last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ 2009 L 188, p. 14).

Legal context

EU law

4. Article 1 of Regulation (EC) No 258/97 reads as follows:

'1. This Regulation concerns the placing on the market within the [European Union] of novel foods or novel food ingredients.

2. This Regulation shall apply to the placing on the market within the [European Union] of foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the [EU] and which fall under the following categories:

(c) [[3]] foods and food ingredients with a new or intentionally modified primary molecular structure;

(d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;

(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;

(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.'

German law

5. Paragraph 39(2) of the Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (German Code on foodstuffs, consumer items and animal feed), in the version published on 3 June 2013 (BGBl. I, p. 1426), as last amended by the Law of 7 August 2013 (BGBl. I, p. 3154), provides:

'The competent authorities shall give the instructions and take the measures necessary to confirm or dispel a sufficient suspicion of infringement, to eliminate infringements which have been established, to prevent future infringements and to protect against health risks and deception. They may in particular

…

3. prohibit or restrict the production, treatment or placing on the market of products,

…'

3 — The categories referred to in points (a) and (b), namely foods containing or consisting of genetically modified organisms and foods produced from, but not containing, genetically modified organisms, were deleted by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1).

6. Under Paragraph 3(1) of the Verordnung zur Durchführung gemeinschaftsrechtlicher Vorschriften über neuartige Lebensmittel und Lebensmittelzutaten (Regulation on the implementation of the provisions of Community law on novel foods and novel food ingredients), in the version published on 14 February 2000 (BGBl. I, p. 123), as last amended by the notice of 27 May 2008 (BGBl. I, p. 919):

'Foods and food ingredients within the meaning of Article 1(2) of Regulation (EC) No 258/97 shall not, subject to subparagraph 2, be placed on the market by the person responsible for placing on the market without an authorisation granted in accordance with the procedures referred to in Article 3(2) of Regulation (EC) No 258/97.'

The dispute in the main proceedings

7. From 1 August 2012 Davitas marketed De Tox Forte, a foodstuff with clinoptilolite as its sole ingredient, in Germany.

8. In January 2013 Stadt Aschaffenburg (municipality of Aschaffenburg, Germany) asked the Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit (Office of the State of Bavaria for Health and Food Safety) to analyse a sample of that product.

9. On the basis of that Office's expert report, Stadt Aschaffenburg, by decision of 6 June 2013, classified the product as a 'novel food' within the meaning of Regulation No 258/97 and banned Davitas from marketing it until the company obtained a marketing authorisation in accordance with the provisions of that regulation.

10. Davitas brought an action for the annulment of that decision before the Bayerisches Verwaltungsgericht Würzburg (Bavarian Administrative Court, Würzburg).

11. In that action, Davitas did not dispute the fact that clinoptilolite had not been used for human consumption to a significant degree within the European Union before 15 May 1997, the reference date for the application of Regulation No 258/97, but maintained that the substance concerned could not be classified as a 'novel food' since it did not fall under any of the categories referred to in Article 1(2)(c) to (f) of Regulation No 258/97.

12. As regards, more specifically, the category referred to in Article 1(2)(c) of that provision, Davitas submitted that clinopltilolite did not have a 'new primary molecular structure' because the molecular structure of the substance used in the preparation of De Tox Forte had existed naturally long before 15 May 1997.

13. By judgment of 23 April 2014, the Bayerisches Verwaltungsgericht Würzburg (Bavarian Administrative Court, Würzburg) dismissed the action brought by Davitas on the ground, in particular, that, for the purposes of applying Article 1(2)(c) of Regulation No 258/97, it was sufficient that clinoptilolite had not been used as a food before 15 May 1997. The existence of that substance prior to that date was not relevant.

14. Davitas appealed against that judgment to the Bayerischer Verwaltungsgerichtshof (Higher Administrative Court of Bavaria), which is unsure how to interpret Article 1(2)(c) of Regulation No 258/97.

The questions referred for a preliminary ruling and the procedure before the Court of Justice

15. It was against that background that the Bayerischer Verwaltungsgerichtshof (Higher Administrative Court of Bavaria) decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'Is the product "De Tox Forte" marketed by the appellant a food or food ingredient with a new molecular structure within the meaning of Article 1(2)(c) of Regulation No 258/97?

In particular, does it suffice, in order to be able to answer this question in the affirmative, that that product, which contains the substance clinoptilolite in its particular primary molecular structure, was not yet being used as a food prior to 15 May 1997, or is it also necessary that that product is produced by means of a production process which results in a new or intentionally modified molecular structure, that is, it must be a substance which did not previously exist in nature in that form?'

16. The order for reference, dated 15 September 2014, was lodged at the Court Registry on 26 September 2014. Written observations were submitted by the parties to the main proceedings, the Landesanwaltschaft Bayern (Bavarian Legal Service), which participated in the main proceedings in the role conferred upon it by German public law, the Greek Government and the European Commission.

17. Those parties and interested parties, with the exception of the Greek Government, also participated in the hearing held on 29 October 2015.

Analysis

18. By the questions it has referred for a preliminary ruling, which I propose to examine together, the referring court seeks, in essence, to ascertain whether the concept of a food or food ingredient with a new or intentionally modified primary molecular structure, within the meaning of Article 1(2)(c) of Regulation No 258/97, includes a substance of mineral origin which exists naturally and has not undergone a production process capable of modifying its molecular structure, where that structure was not used in the composition of a food consumed in the territory of the European Union before 15 May 1997.

19. Those questions will require the Court to interpret Article 1(2)(c) of Regulation No 258/97 for the first time.[4]

20. It is settled case-law that, in interpreting a provision of EU law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part.[5] The origins of a provision of EU law may also provide information relevant to its interpretation.[6]

21. I would observe that the provision in Article 1(2) of Regulation No 258/97 is central to the scheme of that regulation inasmuch as it determines the regulation's scope by defining the concept of 'novel food and novel food ingredient'.[7]

4 — The Court has already had occasion to examine other provisions of Article 1 in the cases which gave rise to the judgments in *HLH Warenvertrieb and Orthica* (C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370) and *M-K Europa* (C-383/07, EU:C:2009:8).

5 — See, in particular, judgments in *Merck* (292/82, EU:C:1983:335, paragraph 12) and *Koushkaki* (C-84/12, EU:C:2013:862, paragraph 34).

6 — Judgment in *Inuit Tapiriit Kanatami and Others v Parliament and Council* (C-583/11 P, EU:C:2013:625, paragraph 50).

7 — Judgments in *HLH Warenvertrieb and Orthica* (C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraph 82) and *M-K Europa* (C-383/07, EU:C:2009:8, paragraph 15). I shall use only the term 'food', since the distinction between foods and food ingredients is irrelevant in the present case.

22. It is clear from the very wording of that provision that the definition comprises two cumulative elements.

23. First, foods are considered to be novel if they were not used for human consumption to a significant degree in the territory of the European Union on the date when Regulation No 258/97 entered into force, 15 May 1997.[8]

24. Secondly, the food in question must also fall under one of the four categories referred to in Article 1(2)(c) to (f) of that regulation.

25. The category referred to in Article 1(2)(c), the official EU language versions of which are broadly the same, concerns foods 'with a new or intentionally modified primary molecular structure'.[9]

26. The questions raised by the referring court relate more specifically to the interpretation of the expression 'new primary molecular structure'.

27. In that regard, the appellant in the main proceedings maintains that the term 'new' refers to a molecular structure which did not exist as such naturally but is the product of human intervention, and that that term therefore describes a substance whose molecules have been created or modified by man. It submits that De Tox Forte consists of volcanic rock in its natural state which has simply been subjected to an ancient process by which the rock is ground while its molecules remain unaltered.

28. The other parties and interested parties,[10] on the other hand, consider that, in order for the primary molecular structure to be considered new, it is sufficient that it was not used in a food within the European Union before 15 May 1997.

29. I would recall that, according to settled case-law, the meaning and scope of a term for which EU law provides no definition must be determined by reference to its usual meaning in everyday language, while account is also taken of the context in which it occurs and the purposes of the rules of which it forms part.[11]

30. In that regard, the usual meaning of the term 'new' used in Regulation No 258/97 does not help to dispel the uncertainty at issue in the present case. When applied to a molecular structure, the adjective 'new' can denote both a newly created molecule and a molecule newly used in human food.

31. I would observe that the interpretation of 'new' as meaning a molecule newly used in human food may, at first sight, seem debatable in the light of the binary structure of the definition of a 'novel food'.

32. As I have said, that definition refers not only to the criterion of non-consumption in the European Union but also to the categories of food referred to in Article 1(2)(c) to (f) of Regulation No 258/97. The reference to those categories is intended to make that definition exhaustive, in the interests of legal certainty on the part of economic operators.

33. If the expression 'new primary molecular structure' were understood as referring to a substance with a molecular structure which was not used in human food within the European Union before 15 May 1997, it would largely overlap with the first element of the definition, namely the fact that the food itself was not consumed within the European Union before that date.

8 — Judgments in *HLH Warenvertrieb and Orthica* (C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraph 87) and *M-K Europa* (C-383/07, EU:C:2009:8, paragraph 15).

9 — See, in particular, the versions in German ('Lebensmittel und Lebensmittelzutaten mit neuer oder gezielt modifizierter primärer Molekularstruktur'), [French ('présentant une structure moléculaire primaire nouvelle ou délibérément modifiée')] or Polish ('żywność i składniki żywności o nowej lub celowo zmodyfikowanej podstawowej strukturze molekularnej').

10 — Stadt Aschaffenburg, the Landesanwaltschaft Bayern, the Greek Government and the Commission.

11 — See, in particular, judgment in *Hotel Sava Rogaška* (C-207/14, EU:C:2015:414, paragraph 25).

34. However, the only foods affected by that overlap between the two defining criteria are those which are not classifiable under the categories referred to in Article 1(2)(d) and (e) of Regulation No 258/97 and which have not been subjected to a new production process giving rise to significant changes within the meaning of paragraph (f) of that provision. Essentially, therefore, these are foods consisting of substances of mineral origin.

35. That overlap arises from the fact that the EU legislature did not provide a specific category for new foods consisting of substances of mineral origin.

36. The existence of a legislative lacuna in that regard was highlighted in the recent reform of Regulation No 258/97. Thus, Article 3(2)(a)(iii) of Regulation (EU) 2015/2283 of the Parliament and of the Council [12] now contains a separate category for 'food consisting of, isolated from or produced from material of mineral origin'.

37. So far as concerns Regulation No 258/97, that lacuna can, in my opinion, be remedied by interpreting Article 1(2)(c) in the light of the purpose and the general scheme of the regulation concerned.

38. It must be recalled here that Regulation No 258/97 has a twofold objective, which is to ensure the functioning of the internal market in new foodstuffs and to protect human health against the risks to which they may give rise. [13]

39. Regulation No 258/97 constitutes general legislation in that it covers all novel foods irrespective of their nature, with the exception of certain areas which are regulated by sector-specific legislation. [14]

40. The purpose of the provision in question is to define the scope of that legislation by stipulating the characteristics by which foods may be categorised as 'novel'.

41. It should be noted that both the general nature and the purpose of that provision make it impossible to interpret it restrictively.

42. In particular, contrary to what the appellant proposes in the main proceedings, it cannot be submitted that Regulation No 258/97 seeks to protect public health only against substances which do not exist naturally but have been created or modified by man.

43. Thus foods falling under Article 1(2)(d) and (e) of Regulation No 258/97, namely those consisting of micro-organisms, fungi, algae, plants or animals, are classified as 'novel' irrespective of whether they are the product of human intervention, for the sole reason that they were not consumed within the European Union prior to the reference date.

44. To my mind, the same approach must be taken to foods falling under the category referred to in Article 1(2)(c) of that provision, which must be classified as 'novel' where the substance with the molecular structure in question was not used in the composition of foods consumed within the European Union at the time when Regulation No 258/97 entered force.

12 — Regulation of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation No 258/97 and Commission Regulation (EC) No 1852/2001 (OJ 2015 L 327 p. 1).

13 — Judgments in Monsanto Agricoltura Italia and Others (C 236/01, EU:C:2003:431, paragraph 74) and M-K Europa (C 383/07, EU:C:2009:8, paragraph 22).

14 — Thus foods from genetically modified organisms are governed by Regulation No 1829/2003. Furthermore, foodstuffs are the subject of regulations when and in so far as they are used as food enzymes, food additives, food flavourings or extraction solvents: see Article 2(1) of Regulation No 258/97. A legislative proposal currently under examination will result in the creation of sector-specific rules on foods from animal clones (COM(2013) 893 of 18 December 2013).

45. I would observe in this regard that the category of novel foods referred to in point (c) exhibits certain features that distinguish it from the other categories set out in Article 1(2) of Regulation No 258/97.

46. Unlike points (d) and (e) of that provision, which classify organic substances on the basis of their origin, and point (f) of that provision, which concerns foods to which has been applied a new production process giving rise to significant changes in their composition or in their structure, point (c) contains a more generic reference to the 'primary molecular structure' of a food.

47. Moreover, as Stadt Aschaffenburg and the Commission rightly observe, point (c) is the only category capable of including novel foods which do not consist of the organic substances referred to in points (d) and (e) and which have not been subjected to a new production process within the meaning of point (f).

48. In the light of those considerations, if point (c) were interpreted restrictively, the scope of the concept of a 'novel food' would be significantly reduced.

49. In particular, interpreting the expression 'new molecular structure' as referring exclusively to substances created by man would have the effect of excluding from the scope of Regulation No 258/97 all substances of mineral origin, given that the latter cannot fall under the categories referred to in Article 1(2)(d) and (e) of that regulation.

50. An interpretation of the definition of a novel food which had the effect of excluding an entire generic category of foods from that definition would be contrary to the general scope of the legislation at issue and to its purpose as defined above.

51. The interpretation of the category in question as referring to substances with a molecular structure which has not yet been used in human food is, moreover, borne out by the history of the provision concerned.

52. The definition of that category as formulated in the Commission's initial proposal referred to a 'product consisting of … a modified food molecular entity, or a molecular entity with no established history of food use'.[15] In the amended proposal, that category was reformulated to refer to foods 'with a new or intentionally modified primary molecular structure which have not normally been used hitherto as food or food ingredients'.[16] The fact that, for no particular reason, the latter element of the sentence was not retained in the Council's Common Position cannot be interpreted as indicating that the legislature wished to restrict the scope of the category at issue.[17]

53. Furthermore, as is clear from the observations of the German authorities and the Commission's written replies to the question raised by the Court, the interpretation to the effect that the category referred to in Article 1(2)(c) of Regulation No 258/97 includes substances with a molecular structure which has not been used in food before has given rise to a regular practice in the application of that regulation.

15 — See Annex 1 to the Proposal for a Council Regulation (EEC) on novel foods and novel food ingredients (COM(1992) 295 final of 7 July 1992, OJ 1992 C 190, p. 3), which lists the categories of products falling within the scope of this regulation.

16 — See Article 1(2)(c) of the Amended Proposal for a European Parliament and Council Regulation (EC) on novel foods and novel food ingredients (COM(1993) 631 final of 1 December 1993, OJ 1994 C 16, p. 10).

17 — See Article 1(2)(c) of the amended proposal for a regulation, set out in Common Position (EC) No 25/95 adopted by the Council on 23 October 1995 with a view to adopting [the Regulation] of the European Parliament and of the Council concerning novel foods and novel food ingredients (OJ 1995 C 320, p. 1).

54. In keeping with that practice, clinoptilolite has been classified as a 'novel food' when previous attempts have been made to place it on the market in the European Union. On the basis of requests from and information provided by three Member States, clinoptilolite was included as a novel food in the indicative and non-binding list published by the Commission under the name 'Novel Food Catalogue'.[18]

55. Moreover, the legislature took the same approach when defining 'novel food' in Regulation 2015/2283, repealing Regulation No 258/97. Article 3(2)(a)(i) of that regulation refers to foods 'with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997'.

56. In that regard, I would observe that it is clear both from recital 8[19] of Regulation 2015/2283 and from the fact that Article 3 of that regulation gives the same reference date (15 May 1997) as Regulation No 258/97 that it was not the legislature's intention that the scope of the new regulation should be broader than that of Regulation No 258/97.

57. For all of the foregoing reasons, I take the view that the reference to foods 'with a new … primary molecular structure' in Article 1(2)(c) of Regulation No 258/97 must be understood as denoting substances with a molecular structure which, on the date when the regulation entered into force, had not been used in human food within the European Union.

58. I would recall that a different interpretation would have the effect of excluding an entire category of foods, namely novel foods consisting of substances of mineral origin, from the scope of Regulation No 258/97, which would call into question the general nature of that legislation and could undermine its objective of ensuring a high level of human health protection. In the light of that objective, it would be unacceptable for substances of mineral origin which have never been used in human food within the European Union, unlike organic substances, not to be subjected to any kind of safety assessment before being placed on the market.

Conclusion

59. In the light of the foregoing considerations, I propose that the Court answer the questions referred for a preliminary ruling by the Bayerischer Verwaltungsgerichtshof (Higher Administrative Court of Bavaria) as follows:

The concept of a food or food ingredient with a new primary molecular structure, referred to in Article 1(2)(c) of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and food ingredients, as last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009, includes a substance of mineral origin which exists naturally and has not been subjected to a production process capable of modifying its molecular structure, where that structure was not used in the composition of a food consumed in the territory of the European Union before 15 May 1997.

18 — As the Commission states, the list in question sets out the results of discussions within the working group of experts from the competent national authorities on whether a food must be classified as 'novel' (http://ec.europa.eu/food/safety/novel_food/catalogue/index_en.htm).

19 — According to recital 8 of that regulation, its scope should, in principle, remain the same as the scope of Regulation No 258/97.