Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

9 November 2016*

(Reference for a preliminary ruling — Novel foods and novel food ingredients — Regulation (EC) No 258/97 — Article 1(2)(c) — Concept of foods and food ingredients with a new primary molecular structure)

In Case C-448/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the Bayerischer Verwaltungsgerichtshof (Higher Administrative Court of Bavaria, Germany), made by decision of 15 September 2014, received at the Court on 26 September 2014, in the proceedings

Davitas GmbH

v

Stadt Aschaffenburg,

intervener:

Landesanwaltschaft Bayern,

THE COURT (Fifth Chamber),

composed of J.L. da Cruz Vilaça, President of the Chamber, A. Tizzano (Rapporteur), Vice-President of the Court, A. Borg Barthet, E. Levits and F. Biltgen, Judges,

Advocate General: M. Szpunar,

Registrar: K. Malacek, Administrator,

having regard to the written procedure and further to the hearing on 29 October 2015,

after considering the observations submitted on behalf of:

— Davitas GmbH, by C. Sachs, Rechtsanwältin,

— Stadt Aschaffenburg, by A. Schellenberg, Rechtsanwältin,

— Landesanwaltschaft Bayern, by R. Käß, acting as Agent,

— the Greek Government, by I. Chalkias, O. Tsirkinidou and A. Vasilopoulou, acting as Agents,

* Language of the case: German.

— the European Commission, by S. Grünheid and K.A. Herbout-Borczak, acting as Agents,

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

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of 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 novel food ingredients (OJ 1997 L 43, p. 1), as 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) ('Regulation No 258/97').

2 The request has been made in proceedings between Davitas GmbH and Stadt Aschaffenburg (municipality of Aschaffenburg, Germany) concerning a decision of Stadt Aschaffenburg prohibiting the marketing of a food product called 'De Tox Forte'.

Legal context

EU law

3 According to recitals 1 and 2 of Regulation No 258/97:

'(1) [D]ifferences between national laws relating to novel foods or food ingredients may hinder the free movement of foodstuffs; … they may create conditions of unfair competition, thereby directly affecting the functioning of the internal market;

(2) [I]n order to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the [European Union] …'

4 Article 1 of Regulation No 258/97 reads as follows:

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

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

(c) 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 (Code on foodstuffs, consumer items and animal feed), in the version published on 3 June 2013 (BGBl 2013 I, p. 1426), as amended by the Law of 7 August 2013 (BGBl 2013 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, handling or placing on the market of products …’

6 In accordance with 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. 2000 I, p. 123), as amended by the notice of 27 May 2008 (BGBl. 2008 I, p. 919):

‘Foods and food ingredients within the meaning of Article 1 of Regulation 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 No 258/97.’

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

7 From 1 August 2012 Davitas marketed De Tox Forte, a food product whose sole ingredient is clinoptilolite, a mineral substance of volcanic origin, in Germany.

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

9 In its expert report of 1 March 2013 that office found that clinoptilolite should be regarded as a ‘novel food ingredient’ within the meaning of Regulation No 258/97, as no evidence had been produced of significant consumption of that ingredient within the EU before 15 May 1997.

10 On the basis of the expert report, by decision of 6 June 2013 the municipality of Aschaffenburg classified De Tox Forte as a ‘novel food’ within the meaning of that regulation, in that it consisted solely of clinoptilolite. On that ground, it prohibited Davitas from marketing it until the grant of an authorisation to place it on the market pursuant to the provisions of the regulation.

11 Davitas brought an action for the annulment of that decision before the Bayerisches Verwaltungsgericht Würzburg (Bavarian Administrative Court, Würzburg, Germany). In that action, Davitas conceded that clinoptilolite had not been used for human consumption 'to a significant degree' in the EU before 15 May 1997. It nonetheless submitted that, in any event, that ingredient could not be categorised as 'novel', because it did not satisfy the second condition in Article 1(2) of Regulation No 258/97 in that it did not fall under any of the categories defined in Article 1(2)(c) to (f).

12 In particular, as regards the category referred to in Article 1(2)(c), Davitas argued that clinoptilolite did not have a 'new primary molecular structure' within the meaning of that provision, since that ingredient was present in nature before 15 May 1997 with the same molecular structure as that used for the preparation of De Tox Forte.

13 By judgment of 23 April 2014, the Bayerisches Verwaltungsgericht Würzburg (Bavarian Administrative Court, Würzburg) dismissed Davitas's action on the ground that, for the purposes of the application of Article 1(2)(c) of Regulation No 258/97, it was immaterial that clinoptilolite existed in nature before 15 May 1997 with a similar molecular structure to that used for the preparation of De Tox Forte, since it had been shown that that ingredient was not at that time consumed as a food.

14 The Bayerischer Verwaltungsgerichtshof (Higher Administrative Court of Bavaria, Germany), to which Davitas appealed against that judgment, entertains doubts as to the interpretation of Article 1(2)(c) of that regulation.

15 In those circumstances, the Bayerischer Verwaltungsgerichtshof (Higher Administrative Court of Bavaria) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. 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?

2. 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?'

Consideration of the questions referred

16 By its questions, which should be considered together, the referring court essentially asks whether Article 1(2)(c) of Regulation No 258/97 must be interpreted as meaning that the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the EU before 15 May 1997, or to those whose molecular structure did not exist as such in nature before that date.

17 To answer that question, it should be noted as a preliminary point that the subject of the regulation is the placing on the market of novel foods and novel food ingredients (judgment of 9 June 2005, *HLH Warenvertrieb and Orthica*, C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraph 81).

18 Article 1(2) of the regulation seeks to delimit the scope of the regulation, in particular by defining what is to be understood by novel foods and food ingredients (judgments of 9 June 2005, *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 15 January 2009, *M-K Europa*, C-383/07, EU:C:2009:8, paragraph 15).

19 It is apparent from the very wording of that provision that, to be categorised as 'novel' within the meaning of Regulation No 258/97, foods or food ingredients must satisfy two cumulative conditions.

20 First, it is necessary that human consumption of those substances was not 'significant' within the EU before 15 May 1997, the date of entry into force of that regulation (see, to that effect, judgment of 9 June 2005, *HLH Warenvertrieb and Orthica*, C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraphs 82 and 87).

21 Secondly, it is necessary that the substances also fall within one of the categories expressly described in Article 1(2)(c) to (f) of the regulation.

22 In this respect, it should be noted that the category defined in Article 1(2)(c), which is the subject of the questions referred, includes in particular foods and food ingredients 'with a new … primary molecular structure'.

23 That wording shows that the category defined by that provision differs from the other categories in Article 1(2) of Regulation No 258/97 in its generic reference to the 'primary molecular structure' of a food or food ingredient, whereas Article 1(2)(d) and (e) relate more specifically to organic substances of a particular composition and Article 1(2)(f) of the regulation refers to substances to which a new production process has been applied giving rise to significant changes in their composition or structure.

24 It follows that the category mentioned in Article 1(2)(c) of the regulation may include different substances, regardless of their composition or production process, in so far as they have a 'new primary molecular structure'.

25 However, those words are not defined in Regulation No 258/97, which thus contains no indications from which it can be determined whether the category in Article 1(2)(c) of the regulation includes foods or food ingredients which were not used for human consumption in the EU before 15 May 1997, or whether it only covers foods or food ingredients whose primary molecular structure was created *ex novo* or modified compared to that already existing in nature before that date.

26 According to settled case-law, the meaning and scope of terms for which EU law provides no definition must be determined by reference to their usual meaning in everyday language, while account is also taken of the context in which they occur and the purposes of the rules of which they form part (judgment of 24 June 2015, *Hotel Sava Rogaška*, C-207/14, EU:C:2015:414, paragraph 25 and the case-law cited).

27 In the present case, the ordinary meaning of 'new primary molecular structure' does not in itself enable an unequivocal interpretation of the expression to be given. As the Advocate General observes in point 30 of his Opinion, the expression can equally well refer in ordinary language to a primary molecular structure newly used in human food or to such a structure newly created or modified by man.

28 To interpret that expression, both the context in which the words in Article 1(2)(c) of Regulation No 258/97 are used and, more broadly, the purpose of the regulation must therefore be considered.

29 As regards, first, the context of that provision, it must be stated that, as the Advocate General observes in point 39 of his Opinion, the regulation is an instrument of a general nature, in that it covers all novel foods or food ingredients irrespective of their nature, with the exception of certain areas regulated by sector-specific legislation.

30 The interpretation of Article 1(2)(c) of Regulation No 258/97 to the effect that the expression 'new primary molecular structure' relates to foods or food ingredients not used for human consumption in the EU before 15 May 1997 is the only interpretation compatible with that context. To interpret those words differently would deprive the regulation of its general nature, in that such an interpretation would amount to excluding from its scope all foods or food ingredients, in particular those of mineral origin, that already existed in nature in their primary molecular structure before 15 May 1997 and are not composed of the organic substances referred to in Article 1(2)(d) and (e) of the regulation or are not subject to a new production process within the meaning of Article 1(2)(f) of the regulation.

31 As regards, secondly, the objectives pursued by Regulation No 258/97, it should be recalled that the regulation has a twofold objective not only of ensuring the functioning of the internal market in novel foods but also of protecting public health against the risks to which they may give rise (see, to that effect, judgment of 15 January 2009, *M-K Europa*, C-383/07, EU:C:2009:8, paragraph 22 and the case-law cited).

32 For those purposes, the regulation aims to establish common standards within the EU in the field of novel foods and novel food ingredients, in particular, as stated in recital 2, by introducing a single safety assessment of those foods and food ingredients through a Community procedure before they are placed on the EU market (judgment of 15 January 2009, *M-K Europa*, C-383/07, EU:C:2009:8, paragraph 23).

33 Only an interpretation of Article 1(2)(c) of Regulation No 258/97 as meaning that the expression 'new primary molecular structure' covers foods or food ingredients which were not used for human consumption in the EU before 15 May 1997 is consistent with the pursuit of those objectives. That interpretation makes it possible to ensure the effective protection of public health against potential risks produced by novel foods and food ingredients, in that a single safety assessment will be required whenever it is proposed to use for human consumption a substance which has not hitherto been consumed by man as a food.

34 Conversely, if the concept of foods or food ingredients with a 'new primary molecular structure' covered only substances which did not exist in nature with the same primary molecular structure before 15 May 1997, any substance existing on that date which has not yet been used for human consumption and does not fall within any of the specific categories in Article 1(2)(d) to (f) of Regulation No 258/97 would be automatically exempted from the safety assessment laid down by that regulation before being put on the market in the EU, without it being possible to evaluate the possibility of a risk to health.

35 It is for the referring court to ascertain, in the light of those factors, in the main proceedings whether the competent national authorities applied Article 1(2)(c) of the regulation correctly when they categorised De Tox Forte as a 'novel food'.

36 Having regard to all the above considerations, the answer to the questions is that Article 1(2)(c) of Regulation No 258/97 must be interpreted as meaning that the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the EU before 15 May 1997.

Costs

37 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 (Fifth Chamber) hereby rules:

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 novel food ingredients, as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009, must be interpreted as meaning that the expression 'new primary molecular structure' relates to foods or food ingredients which were not used for human consumption in the territory of the European Union before 15 May 1997.

[Signatures]