

Case C-13/23

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:

16 January 2023

Referring court:

Verwaltungsgericht Osnabrück (Germany)

Date of the decision to refer:

15 December 2022

Applicant:

cdVet Naturprodukte GmbH

Defendant:

Niedersächsisches Landesamt für Verbraucherschutz und
Lebensmittelsicherheit (LA-VES)

Subject matter of the main proceedings

Animal feed – Authorisation and marketability of a feed additive – Grapefruit seed extract – Regulation No 1831/2003 – Charter of Fundamental Rights

Subject matter and legal basis of the request

Interpretation of EU law, Article 267 TFEU

Questions referred for a preliminary ruling

1. Is Regulation (EC) No 1831/2003, in particular Article 3(1)(a), Article 4(1), Article 7(1) and Article 10(1)(a), (2) and (5) thereof, which provide that, in the case where no authorisation has been granted, a blanket ban on placing on the market, using and processing feed additives is to be ordered, with no account taken of the circumstances of the particular case in question, compatible with the principle of proportionality enshrined in Article 52(1) of

the Charter, in the light of the freedom to conduct a business protected by Article 16 of the Charter and the right to property provided for in Article 17(1) of the Charter?

2. In the event that the Court answers the first question in the affirmative, with the result that Regulation (EC) No 1831/2003, in particular Article 3(1)(a), Article 4(1), Article 7(1) and Article 10(1)(a), (2) and (5) thereof, is to be interpreted without restriction, does the extract used by the applicant as a feed additive, which, according to the distributor's product specification sheet, is produced from grapefruit seeds and grapefruit peel and is described in that sheet as grapefruit seed extract (more specifically, grapefruit seed extract S), (also) constitute (in any event) the substance listed in Article 2, point 3, of Implementing Regulation (EU) No 2021/758, in conjunction with Part 1 of Chapter I.A of Annex I thereto, as 'Grapefruit extract CoE 140'?

Provisions of European Union law relied on

Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation): Article 138(1) and (2)(d)

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition: Article 1(1), Article 3(1), Article 4(1), Article 7(1), Article 10(1)(a), (2) and (5)

Commission Implementing Regulation (EU) No 230/2013 of 14 March 2013 on the withdrawal from the market of certain feed additives belonging to the group of flavouring and appetising substances: Article 1, Annex to Article 1

Commission Implementing Regulation (EU) 2021/758 of 7 May 2021 on the status of certain products as feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council and on the withdrawal from the market of certain feed additives: Article 1, Article 2, Part 1 of Chapter I.A of Annex I, pursuant to Article 1

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: Article 15(1) and (2)

Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC: Article 17(1)(e)

Provisions of national law relied on

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Food, Commodities and Feed Code ('the LFGB'): Paragraph 17(2), point 1(a) and point 2(a), Paragraph 21(3), point 1(b), Paragraph 39(1) and (4)

Succinct presentation of the facts and procedure in the main proceedings

- 1 The applicant is an undertaking which produces and sells animal feed. The applicant's product range includes, inter alia, the product 'DarmRein Pulver/GutClean Powder', a complementary feed for dogs, cats and other domestic animals which the applicant describes on its product label, in accordance with Article 17(1)(e) of Regulation No 767/2009, as being composed of 'brewer's yeast, willow bark and elm bark'. According to the labelling, the product contains other additives including, inter alia, grapefruit seed extract. The product is further labelled as follows: 'For intestinal cleansing, powder, particularly suitable for cats. For on-demand feeding in diet-related digestive and intestinal problems'. The label also includes a feeding recommendation.
- 2 On 24 February 2022, employees of the defendant carried out at the applicant's premises an official inspection as provided for in Article 137(2) of Regulation 2017/625. At that point, there were a number of complaints relating, inter alia, to the product 'DarmRein Pulver/GutClean Powder'. According to the distributor's product specification sheet examined as part of that inspection, the substance listed under sensory additives on the product label as grapefruit seed extract is – as stated – grapefruit seed extract (more specifically, grapefruit seed extract S). The extract, which was produced by extraction with vegetable glycerine from grapefruit seeds and grapefruit peel, consists of glycerine-containing extract (83%), water and vitamin C. The most important ingredients (active substances) are, in particular, ascorbic acid (vitamin C) and a 'grapefruit-bioflavonoid complex'.
- 3 Following a hearing, the defendant, by decision of 30 March 2022 adopted under Article 138(1) and (2) of Regulation 2017/625 in conjunction with Paragraph 39(1) and (4) of the LFGB, prohibited the applicant from offering and placing on the market the product in question, on the ground of failure to obtain

authorisation for additives within the European Union. At the same time, the defendant ordered immediate enforcement on the basis of point 4 of the first sentence of Paragraph 80(2) of the Verwaltungsgerichtsordnung (Rules of Procedure of the Administrative Court) (VwGO). By way of grounds for its order, the defendant stated in essence that the feed additive contained in the product, grapefruit seed extract, was affected by the market withdrawal laid down in Article 1 of Implementing Regulation No 230/2013 in conjunction with Part A of the Annex thereto and for that reason was not marketable.

- 4 Article 10(2) of Regulation 1831/2003 provides for the possibility of feed additives being re-evaluated, on condition that an application to that effect is submitted in accordance with Article 10(2) in conjunction with Article 7 of that regulation, as a means of identifying and assessing any risks associated with them, in the interests of humans, animals, the environment, users and consumers. Since the grapefruit seed extract feed additive used by the applicant had not been the subject of any such applications when the transitional period expired, there has been an infringement of Article 3(1) of Regulation No 1831/2003 and Paragraph 21(3), point 1(b), of the LFGB, according to which feed additives which have not been so authorised may not be placed on the market. Furthermore, since the grapefruit seed extract feed additive contained in it has not been authorised, the applicant's product must be regarded as 'unsafe', within the meaning of Article 15(1) of Regulation No 178/2002, and, in addition, not marketable from that point of view. Since the feed additive used is 'unsafe' within the meaning mentioned above, there is at the same time an infringement of Paragraph 17(2), point 2(a) and point 3(a), of the LFGB.
- 5 On 11 October 2022, the applicant brought an action against that decision, and at the same time applied for interim relief.
- 6 In the light of the doubts as to the compatibility of the contested rules with EU law (first question) and the interpretation of EU law (second question) respectively, forming the subject of the present request for a preliminary ruling, the applicant was granted interim relief and the suspensory effect of its action was restored.

The essential arguments of the parties in the main proceedings

- 7 In support of its position, the applicant argues that the feed additive incorporated into its product is grapefruit extract and not – as the defendant considers – grapefruit seed extract. Grapefruit extract is expressly mentioned in the European Commission's list of authorised additives in feedingstuffs (OJ 2004 C 50, p. 1) as a feed additive authorised in the European Union. In accordance with Article 1 in conjunction with Part 1 of Chapter I.A of Annex I – under the heading 'Flavouring and appetising substances' – to Implementing Regulation No 2021/758, the feed additive '*Citrus x paradisi* – Grapefruit extract CoE 140' (Grapefruit extract), for which there is no CAS number, is indeed in principle to be withdrawn from the market. However, Article 2, point 3, of that implementing

regulation contains a transitional provision which allows the applicant to continue to place on the market the product manufactured using that additive, 'Darm-Rein Pulver/GutClean Powder', until 30 May 2023.

- 8 The distributor's product specification sheet makes it clear that the extract used is produced from grapefruit seeds and grapefruit peel. The extract used as a feed additive is fully equivalent to other extracts which are lawfully marketed as grapefruit extract. Furthermore, the feed additive used by the applicant is not one of the other substances listed in the annexes to Implementing Regulations No 230/2013 and No 2021/758 respectively. The fact that grapefruit seeds are one, but specifically not the only, ingredient used in the manufacturing process may have informed the distributor's decision to choose the grapefruit seed extract description. This does nothing to alter the factual and legal classification of the substance as grapefruit extract in accordance with Article 1 of Implementing Regulation No 2021/758, in conjunction with Part 1 of Chapter I.A of Annex I (under the description 'grapefruit extract CoE 140') thereto. It follows that the description grapefruit seed extract is indeed inaccurate, inasmuch as it may give the false impression that grapefruit seeds alone are used during the manufacturing process. There is therefore no infringement warranting intervention as provided for in Article 138(1) and (2)(d) of Regulation 2017/625.
- 9 In any event, moreover, the order made by the defendant interferes disproportionately with its freedom to conduct a business. There is nothing whatsoever to indicate that the product in question is 'unsafe' or potentially harmful to health. The defendant, whose submissions are confined to speculation without substance, has thus failed to discharge its duty to investigate. What is more, the applicant shares the doubts expressed by the Chamber with respect to the compatibility of the provisions applied by the defendant with EU law. After all, Regulation No 1831/2003 involves, ultimately, the imposition of a blanket ban on placing on the market and using all feed additives with no account taken of the circumstances of the particular case concerned.
- 10 The defendant defends the legal order concerning feed which it made. It is clear from the distributor's product specification sheet that the product in question contains the feed additive grapefruit seed extract. Grapefruit extract and grapefruit seed extract are not identical substances for the purposes of the law concerning animal feed, and the applicant cannot therefore successfully rely on the transitional provision contained in Article 2, point 3 of Implementing Regulation No 2021/758, since that provision relates only to grapefruit extract and not to grapefruit seed extract.
- 11 That is also confirmed by the fact that the grapefruit extract covered by the Implementing Regulation ('Grapefruit extract CoE 140') comes under CAS number 8016-20-4, while the grapefruit seed extract used by the applicant in its product comes under CAS number 90045-43-5. The two terms are not therefore readily interchangeable. What is more, the composition of an extract differs both qualitatively and quantitatively depending on which parts of a fruit (for example,

seeds, peel, pulp) are extracted. The term grapefruit extract is ultimately only an imprecise, or even inadequate, characterisation of the mixture of substances which it designates; the term grapefruit seed extract, on the other hand, is a more precise description of a grapefruit extract.

- 12 Since the feed additive used, grapefruit seed extract, does not have the authorisation required under Article 10(2) in conjunction with Article 7 of Regulation No 1831/2003, it is not marketable, in accordance with Article 3(1) of that regulation. In the light of the sense and purpose of the authorisation procedure under EU law, which is to identify and assess any health risks that may be associated with a feed additive, it cannot be assumed, contrary to the view taken by the applicant, that the product sold by it is safe or harmless. The applicant is required to carry out an authorisation procedure before the European Food Safety Authority (EFSA) in order to have the feed additive ‘grapefruit seed extract’, in respect of which no reliable studies and findings are currently available, examined and assessed from the point of view of the existence of potential risks.
- 13 At the same time, it follows from the foregoing that, since the grapefruit seed extract in the feed additive is not authorised, the product is ‘unsafe’ within the meaning of Article 15(1) of Regulation No 178/2002. The applicant’s – purely economic – interests have been noted and adequately taken into account. Furthermore and finally, there are no serious doubts from the point of view of EU law as regards the proportionality of Regulation No 1831/2003, since, in accordance with the precautionary principle, it protects legal interests of paramount importance in the form of human health, animal health and the environment. The regulatory objective, described in recital 4 of Regulation No 1831/2003, of ensuring a high level of protection for humans, animals and the environment, can be achieved only by way of an authorisation procedure in which a safety assessment is carried out as part of a Community procedure for feed additives. That is the only way of taking adequate account of the complexity of the subject matter under regulation, technological progress and scientific development. The blanket authorisation of all feed additives without further assessment by an expert body poses a serious risk to the aforementioned legal interests.

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

- 14 By its first question, the referring court wishes to ascertain whether Regulation No 1831/2003, in particular Article 3(1)(a), Article 4(1), Article 7(1) and Article 10(1)(a), (2) and (5) thereof, which provide that, where no authorisation has been granted, a blanket ban on placing on the market, using and processing feed additives is to be ordered, without taking into account the circumstances obtaining in the particular case, is compatible with the principle of proportionality enshrined in Article 52(1) of the Charter, in the light of the freedom to conduct a business protected by Article 16 of the Charter and the right to property provided for in Article 17(1) of the Charter.

- 15 The principle of proportionality is one of the general legal principles of EU law. As an essential structural principle, it is of fundamental importance as an objective principle of EU law in the sense that it operates as general guideline for conduct within the framework of EU law (judgment of 19 June 1980, *Testa and Others*, C-41/79, 121/79 and 796/79, EU:1980:163, paragraph 21).
- 16 The principle of proportionality is now expressly codified in Article 52(1) of the Charter. That states that any limitation on the exercise of the rights and freedoms recognised by the Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others. The rights and freedoms protected by the Charter include, inter alia, the freedom to conduct a business (Article 16) and the right to property (the first sentence of Article 17(1)), which is to say the freedom to own, use, dispose of and bequeath lawfully acquired possessions.
- 17 In that regard, it is the settled case-law of the Court of Justice that the principle of proportionality requires that acts of the EU institutions be appropriate for attaining the legitimate objectives pursued by the legislation at issue and do not exceed the limits of what is appropriate and necessary in order to achieve those objectives. With regard to judicial review of compliance with those conditions, where interferences with fundamental rights are at issue, the extent of the EU legislature's discretion may prove to be limited, depending on a number of factors, including, in particular, the area concerned, the nature of the right at issue guaranteed by the Charter, the nature and seriousness of the interference and the object pursued by the interference (judgment of 8 April 2014, *Digital Rights Ireland and Others*, C-293/12 and C-594/12, EU:2014:238, paragraphs 46 and 47).
- 18 As regards the freedom to conduct a business and the right to property, the Court of Justice has repeatedly held that these are not absolute rights, but must be considered in relation to their social function. Consequently, restrictions may be imposed on those freedoms, provided that those restrictions in fact correspond to objectives of general interest pursued by the European Union and do not constitute, with regard to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of those rights. It follows from this that the legal assessment of proportionality must be carried out in accordance with the need to reconcile the requirements of the protection of those various fundamental rights protected by the Union legal order, and striking a fair balance between them (judgment of 6 September 2012, *Deutsches Weintor*, C-544/10, EU:2012:526, paragraphs 47 and 54).
- 19 The referring court has doubts as to whether, in the present case, a fair balance consistent with the principle of proportionality (Article 52(1) of the Charter), as defined above, is struck between the freedom to conduct a business (Article 16 of the Charter) and the right to property (first sentence of Article 17(1) of the

Charter), on the one hand, and the protection of the legal interest in the health of humans, animals and the environment pursued by Regulation No 1831/2003, on the other, given that that regulation requires, where feed additives have not already been authorised, a blanket ban on placing them on the market, using them and processing them to be ordered, with no account taken of the circumstances of the particular case concerned.

- 20 The circumstances of the particular case include, for example, the question whether the feed additive in question is also a naturally occurring (plant) substance or a synthetic one, or in what absolute amount or concentration the feed additive is added to the feed. Regulation No 1831/2003 lays down the same legal consequences for all scenarios, without assessing such circumstances. According to the distributor's product specification sheet, the feed additive used by the applicant in the product concerned is grapefruit seed extract. The components of the extract are of exclusively natural (vegetable) origin; there is not even the remotest indication that these are potentially harmful to human or animal health, particularly since the concentration of the feed additive incorporated probably falls below the range where it can be detected. The first question is relevant to the decision to be given because Regulation No 1831/2003 would not be applicable if it were contrary to EU law.
- 21 In the event that the Court of Justice answers the first question in the affirmative, the referring court wishes, by its second question, to ascertain whether the extract used by the applicant as a feed additive (also) constitutes (in any event) the substance 'Grapefruit extract CoE 140' listed in Article 2(3) of Implementing Regulation No 2021/758, read in conjunction with Part 1 of Chapter I.A of Annex I thereto..
- 22 It is true that, in accordance with Article 1 of Implementing Regulation No 2021/758, the feed additives specified in Annex I of that regulation must be withdrawn from the market in respect of the animal species or categories of animals as specified in that annex, and those feed additives include, inter alia, the substance 'Grapefruit extract CoE 140' listed in Part 1 of Chapter I.A of Annex I – under the heading 'Flavouring and appetising substances' – to that regulation. In accordance with Article 2, point 3, of Implementing Regulation No 2021/758, compound feed and feed materials produced with the additives referred to in paragraph 1, which include, inter alia, the product sold by the applicant, may continue to be placed on the market until 30 May 2023.
- 23 If the extract used by the applicant as a feed additive did indeed constitute the substance 'Grapefruit extract CoE 140' listed in Part 1 of Chapter I.A of Annex I to the aforementioned regulation – under the heading 'Flavouring and appetising substances' –, the applicant would be entitled, on the basis of the transitional provision contained in Article 2, point 3, of Implementing Regulation No 2021/758, to continue to place its product on the market on a temporary basis until 30 May 2023. At the material time, that is to say when the decision of 30 March 2022 was adopted, there would therefore have been no basis for the

defendant to take action under Article 138(1) and 2(d) of Regulation 2017/625, in its capacity as the regulatory authority, for infringement of the legal provisions on animal feed.

- 24 The referring court notes that, in its view, it has not been established that the applicant committed the alleged infringement of Article 15(1) of Regulation No 178/2002 which the defendant assumes it to have committed. In accordance with that provision, feed must not be placed on the market or fed to any food-producing animal if it is 'unsafe'. In accordance with paragraph 2 of that provision, feed must be deemed to be 'unsafe' for its intended use if it is considered to have an adverse effect on human or animal health (first indent). [German] national law contains a similar prohibition in Paragraph 17(2), point 1(a), of the LFGB. The syntax of Article 15(1) of Regulation No 178/2002 ('if it is considered to' [in the German-language version, 'if it is capable of']) shows that, while actual harm to health in a particular case is not necessary, the feed must – in the light of objective reasons for suspicion – actually have the capacity to harm health in specific circumstances, which is to say that the feed must exhibit clearly ascertainable characteristics capable of causing harm to health. The mere possibility of that feed having such effects is, however, not sufficient.
- 25 The defendant, on which the burden of making and proving a proper case in this regard falls, has not presented any specific evidence to show that the product sold by the applicant might be harmful to health given the use of the feed additive in question. A fiction to the effect that all unauthorised feed additives are to be regarded as 'unsafe' within the meaning of Article 15(1) and (2) of Regulation No 178/2002 is not – so far as it is possible to tell – provided for in EU law. That aside, the market withdrawals of the feed additives listed in the aforementioned implementing regulations, which were carried out as a result of those regulations, did not take place because of specific safety concerns, but, rather, solely because an application for their authorisation had not been submitted within the prescribed period. For the same reasons, the referring court would argue, the applicant has also not infringed Paragraph 17(2), point 2(a) and point 3(a), of the LFGB.
- 26 The aforementioned concerns, from the point of view of EU law, regarding the lawfulness of Regulation No 1831/2003 (first question) and the interpretation of the reference to the substance 'Grapefruit extract CoE 140' listed in Article 2, point 3, of Implementing Regulation No 2021/758, in conjunction with Part 1 of Chapter I.A. of Annex I thereto (second question), can be dealt with only in the context of a preliminary ruling procedure under the second paragraph of Article 267 TFEU.