

Case C-745/22**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 December 2022

Referring court:

Symvoulio tis Epikrateias (Greece)

Date of the decision to refer:

8 November 2022

Applicant:

Micreos Food Safety BV

Defendant:

Eniaios Foreas Elegchou Trofimon (EFET)

Subject matter of the main proceedings

Application for annulment of the act of the president of the management board of the Eniaios Foreas Elegchou Trofimon (Hellenic Food Authority) rejecting the applicant's application for authorisation to distribute its product Listex™ P100 on the Greek market as a processing aid in animal-derived ready-to-eat products.

Subject matter and legal basis of the request

The request for a preliminary ruling has been referred pursuant to Article 267 TFEU, specifically because doubts have arisen as to the interpretation of Article 3(2) of Regulation (EC) No 853/2004.

Questions referred for a preliminary ruling

1) Must Regulation (EC) No 853/2004 be interpreted as meaning that a product such as Listex™ P100 manufactured by the applicant, which has the characteristics described in the opinion of 7 July 2016 of the European Food

Safety Authority (EFSA) and, moreover, according to the applicant's submissions, is applied outside of slaughterhouses during the final stages of the production process and is intended to prevent rather than to remove surface contamination on products of animal origin, comes within the scope of Article 3(2) of the regulation (and its distribution on the European market is therefore subject to prior approval by the Commission in accordance with Article 11a of the regulation)?

If the answer to Question 1 is in the negative:

2) Must Regulation (EC) No 1333/2008 be interpreted as meaning that the applicant's product referred to above is a food additive or a processing aid (Article 3(2)(a) and (b) of Regulation (EC) No 1333/2008)?

Provisions of European Union law and case-law relied on

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 (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, corrigendum OJ 2004 L 226, p. 3), Articles 1(1) and 2(1)(a) and (f)

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ 2004 L 139, p. 55, corrigendum OJ 2004 L 226, p. 22), as amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 (OJ 2019 L 198, p. 241), recitals 2, 9, 10, 11, 12, 14, 18, 27, 28 and 30 and Articles 2, 3(2) and 11a(1)

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ 2005 L 338, p. 1)

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ 2008 L 354, p. 16), Articles 1(1), 2(1)(a), 3(2)(a) and (b) and 4(1) and (2)

Judgment of 28 January 2010, *Commission v France*, C-333/08, EU:C:2010:44

Provisions of national law relied on

Kodikas Trofimon kai Poton (Decision 1100/87 of the Anotato Chimiko Symvoulio (Supreme Chemical Council) of the Geniko Chimeio tou Kratous (General Chemical State Laboratory) approved by the Minister for Finance, FEK B' 788/31.12.1987, 'the Food and Drinks Code'), as amended, Articles 2(3)(l) and (m), 12a(5), 29(3), 36a, 44, 80b, 83 and 144(8)

Law 2741/1999, Eniaios Foreas Elegchou Trofimon, alles rythmiseis thematon armodiotitas tou Ypourgeiou Anaptyxis kai loipes diataxeis (Hellenic Food Authority, other matters falling within the jurisdiction of the Ministry of Development and other provisions, FEK A' 199/28.9.1999), Article 1(1), (2), (3) and (5)

Succinct presentation of the facts and procedure in the main proceedings

- 1 In 2015, the applicant applied to the European Commission for authorisation to use the product Listex™ P100 as a decontaminant to reduce the listeria bacterium in animal-derived ready-to-eat products.
- 2 The application was examined in accordance with the provisions of Regulation No 853/2004. A scientific opinion was adopted by the European Food Safety Authority (EFSA) on 7 July 2016 and a draft regulation was prepared and submitted for consultation. Ultimately, however, by its letter of 19 February 2018, the Commission informed the applicant that it did not intend to assess its application further, as the necessary political support did not exist.
- 3 On 26 February 2018, the applicant replied with the argument that, as its product at issue is a processing aid rather than a decontaminant, it does not come within the scope of Regulation No 853/2004.
- 4 By two letters to the applicant dated 17 June 2019, the Commission again rejected the application filed by the applicant and reminded the applicant that it had already informed the applicant by its previous letter that it would not pursue its assessment of the application for approval of its product as a decontaminant, stating that, even if the product in question were classed as a processing aid which, in principle, does not come within the scope of Regulation No 853/2004, the provisions of that regulation would continue to apply inasmuch as the product is used for decontamination purposes. The Commission further noted that the issue pertains to EU law, the interpretation of which comes within the exclusive jurisdiction of the Court of Justice of the European Union.
- 5 On 16 August 2019, the applicant lodged an action for annulment of the Commission's letters referred to above and an application for interim measures before the General Court, by which it submitted that the Commission had rejected its initial application for approval of its product as a decontaminant and its alternative application for recognition of the product as a non-decontaminating processing aid, and had prohibited its placing on the EU market as a processing aid for animal-derived ready-to-eat products.
- 6 By order of 26 September 2019 (T-568/19 R, EU:T:2019:694), the President of the General Court dismissed the application for interim measures, reasoning that the contested letters were not a decision with the content attributed to them by the applicant and did not, moreover, prohibit the marketing of its product. At the same time, that order mentioned that the applicant was free to seek legal remedies

against acts adopted by the authorities of Member States (the applicant had relied on harmful acts of the Estonian and Belgian authorities), thereby allowing the national courts to make an order for reference to the Court of Justice of the European Union.

- 7 Subsequently, the Commission contacted the competent services of the Member States by letter dated 8 November 2019, by which it observed, in response to the submission that the product should be regarded as a processing aid exempt from Regulation No 853/2004, that Listex™ P100 comes within the scope of Article 3(2) of that regulation, as it is intended to reduce contamination from the listeria bacterium in animal-derived ready-to-eat products and therefore, even if it were classed as a processing aid for decontamination purposes, it would still be subject to approval under Regulation No 853/2004. By that letter, the Commission also recalled that the product had not been approved for placing on the market in accordance with Article 3(2) of the regulation for use in food of animal origin and noted that, in its opinion, the Member States had no discretion to approve it as a processing aid for food of animal origin.
- 8 By its application of 27 April 2020 to the Yfypourgos Ygeias (Deputy Minister for Health), which was forwarded for jurisdictional reasons to the Hellenic Food Authority by letter of 21 May 2020 of the Ypourgeio Agrotikis Anaptyxis kai Trofimou (Ministry of Rural Development and Food), the applicant then asked if its product Listex™ P100 could be approved for placing on the Greek market as a processing aid for animal-derived ready-to-eat products and, if so, for the necessary approval to be granted. It also mentioned that the product in question had already been recognised as a processing aid in other countries (USA, Canada, Australia, Switzerland and Israel).
- 9 By act of 24 June 2020 adopted in response to that application, that is, the act contested in the main proceedings, the president of the management board of the Hellenic Food Authority dismissed that application for recognition of the product at issue as a processing aid, finding that, as it is a decontaminant, it is subject to prior approval by the Commission. He also explained in that act why, in the opinion of the competent authority, the product could not be approved for use as a processing aid (absence of the necessary regulatory framework, and reservations expressed in the EFSA opinion referred to above regarding the classification of the product as a food additive or processing aid and the potential for its effective and safe use) and expressed certain reservations as to the ability of the authority to comment on the issue of the classification of the product at issue pending final judgment by the Court in the matter.
- 10 In light of the foregoing, the applicant lodged its application for annulment of the above act of 28 September 2020 before the Symvoulío tis Epikrateias (Council of State), the referring court.
- 11 The applicant submits that its product does not come within the scope of Article 3(2) of Regulation No 853/2004 for the following reasons. First, that

provision relates exclusively to the decontamination of products of animal origin in slaughterhouses, a precondition that does not apply in the case of Listex™ P100. Second, its product is intended for use in the very final stages of the production process, even after thermal processing of the food, specifically once it has already been decontaminated and is ready for cutting and packaging. Third, its product is not intended to ‘remove surface contamination from products of animal origin’ within the meaning of that provision; it presupposes that the products to which it is applied are not contaminated and aims to prevent contamination in the event that listeria bacteria exceed permitted limits during the period of storage up to the sale and consumption of the food. The applicant relies in that regard on Regulation No 2073/2005 on microbiological criteria for foodstuffs in support of its submissions.

- 12 Meanwhile, after the application for annulment had been lodged in the main proceedings, the General Court handed down the order of 18 December 2020 on the applicant’s application (T-568/19, EU:T:2020:647), in which it held that, contrary to the applicant’s submissions, the Commission’s contested letters, first, are not acts that are open to challenge and, second, are not a decision prohibiting the placing of the product on the EU market. The order made on the main action for annulment and the previous order made on the application for interim measures both note that the applicant is not deprived of the right to judicial protection, as it is free to challenge the relevant acts of the authorities of the Member States before the national courts, thereby allowing them to make an order for reference to the Court of Justice.
- 13 Moreover, by letter of 7 February 2022, the president of the Hellenic Food Authority explained to the referring court why it was not possible, in the opinion of that authority, to class the product as a processing aid intended for purposes other than decontamination, the reasons being that the applicant had failed to produce relevant data, the preconditions of Regulation No 1333/2008 to the use of the product as a processing aid were not fulfilled, including in light of the findings of the EFSA, and there were doubts as to its safety and effectiveness.

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

- 14 As a preliminary point, the referring court notes that the statement of reasons in the contested act, by which it was found that the product which the applicant wished to be approved for placing on the market is a decontaminant or is, in any event, used for decontamination purposes and therefore comes within the scope of Regulation No 853/2004, is, prima facie, lawful and adequate, as it is corroborated by the evidence in the case file of the main proceedings and is based on Articles 3(2) and 11a of that regulation.
- 15 That being said, the referring court finds that the applicant’s arguments to the contrary must be dismissed for the following reasons:

- 16 First, in response to the applicant's submission that its product does not come within the scope of Article 3(2) of Regulation No 853/2004, the referring court holds that that provision, in the light of the intended purpose of Regulation No 853/2004 as stated in recital 9, which is to provide consumer protection with regard to food safety, encompasses the decontamination of products of animal origin in all types of establishments (as follows from recital 18), therefore including outside of slaughterhouses, irrespective of the stage in the production process.
- 17 Second, even assuming that it is true, the applicant's submission that the product at issue is intended to prevent rather than to remove surface contamination from products of animal origin does not affect the case in the main proceedings, as it is still used to 'remove surface contamination from products of animal origin' within the meaning of the provision of Article 3(2) of Regulation No 853/2004.
- 18 Nevertheless, the referring court notes that, as doubts have arisen as to the meaning of Article 3(2) of Regulation No 853/2004 and bearing in mind that the judgment delivered in the main proceedings will not be open to legal remedy under national law, it is necessary to refer the questions set out above to the Court for a preliminary ruling.