Date of acceptance : 26/09/2019

ОБЩ СЪД НА ЕВРОПЕЙСКИЯ СЪЮЗ
TRIBUNAL GENERAL DE LA UNIÓN EUROPEA
TRIBUNÁL EVROPSKÉ UNIE
DEN EUROPÆISKE UNIONS RET
GERICHT DER EUROPÄISCHEN UNION
EUROOPA LIIDU ÜLDKOHUS
ΓΕΝΙΚΟ ΔΙΚΑΣΤΗΡΙΟ ΤΗΣ ΕΥΡΩΠΑΪΚΗΣ ΕΝΩΣΗΣ
GENERAL COURT OF THE EUROPEAN UNION
TRIBUNAL DE L'UNION EUROPÉENNE
CÚIRT GHINEARÁLTA AN AONTAIS EORPAIGH
OPĆI SUD EUROPSKE UNIJE
TRIBUNALE DELL'UNIONE EUROPEA
EIROPAS SAVIENĪBAS VISPĀRĒJĀ TIESA
EUROPOS SĄJUNGOS BENDRASIS TEISMAS
AZ EURÓPAI UNIÓ TÖRVÉNYSZÉKE
IL-QORTI ĠENERALI TAL-UNJONI EWROPEA
GERECHT VAN DE EUROPESE UNIE
SĄD UNII EUROPEJSKIEJ
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TRIBUNALUL UNIUNII EUROPENE
VŠEOBECNÝ SÚD EURÓPSKEJ ÚNIE
SPLOŠNO SODIŠČE EVROPSKE UNIJE
EUROOPAN UNIONIN YLEINEN TUOMIOISTUIN
EUROPEISKA UNIONENS TRIBUNAL

LUXEMBOURG

ORDER OF THE PRESIDENT OF THE GENERAL COURT

26 September 2019 *

(Application for interim measures — Bacteriophage — Listeria — Listex™ P100 — Inadmissibility)

– 908816 –

In Case T-568/19 R,

Micreos Food Safety BV, established in Wageningen (Netherlands), represented by S. Pappas, lawyer,

applicant,

v

European Commission, represented by B. Eggers, W. Farrell and I. Galindo Martín, acting as Agents,

defendant,

APPLICATION pursuant to Articles 278 and 279 TFEU seeking the suspension of the alleged decision by the European Commission of 17 June 2019 by which it allegedly prohibited the placing on the market of Listex™ P100 for use as a processing aid on animal derived Ready-To-Eat-Food,

THE PRESIDENT OF THE GENERAL COURT

makes the following

Order

* Language of the case: English.

Background to the dispute, procedure and forms of order sought

1 The applicant, Micreos Food Safety BV, is the producer of a number of phage products both for pharmaceutical and food safety use.

2 The product Listex™ P100 is used to reduce the pathogenic bacterium *Listeria monocytogenes* from Ready-To-Eat-Food ('RTE-Food').

3 According to the applicant, its product Listex™ P100 has been marketed in the European Union since 2006 as a non-decontamination processing aid without having been formally classified as such. Furthermore, according to the applicant, it is 'recognised in the EU' as a processing aid for use on fruits and vegetables.

4 In 2007, the applicant approached the European Commission seeking confirmation of the use of Listex™ P100 as a non-decontaminating processing aid on animal-derived RTE-Food on the basis of 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). However, the Commission took the view that the use of Listex™ P100 on animal-derived RTE-Food should be addressed as a 'decontaminant' requiring approval in accordance with Article 3(2) of 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).

5 In 2009, the Netherlands approved its use as a processing aid on animal derived RTE-Food such as cheese.

6 On 19 June 2015, the applicant, despite its objections that Listex™ P100 should not be considered as a 'decontaminant', submitted a file for approval of the use of the product under Regulation No 853/2004.

7 On 19 February 2018, the Commission informed the applicant that, due to the absence of sufficient 'political support' for approval of Listex™ P100 under Regulation No 853/2004, it intended not to pursue the approval process further.

8 On 25 April 2019, PA International, acting on behalf of the applicant, approached the Commission and requested, among other things, the recognition of Listex™ P100 as a non-decontaminating processing aid.

9 Similarly, by letter of 9 May 2019, the applicant requested the Commission to approve the use of Listex™ P100 on animal-derived RTE-Food as a non-decontaminating processing aid.

10 The Commission responded by letters of 17 June 2019, sent to the applicant and to its representative, PA International ('the contested acts').

11 By application lodged at the Court Registry on 16 August 2019, the applicant brought an action against the Commission for annulment of the contested acts.

12 It appears, prima facie, that the applicant interprets the contested acts as 'forming a unity', by which the Commission '(a) definitively refrained from the pursuance of the relevant Comitology procedure in relation to the Commission Draft Regulation "permitting the use of Listex™ P100 for the reduction of *Listeria monocytogenes* on Ready-To-Eat products of animal origin" as a decontaminant under Regulation (EC) 853/2004, (b) refused to examine such use of Listex™ P100 as a non-decontaminating processing aid and (c) prohibited for the first time the further placing on the market of Listex™ P100 being on the market since 2006 for use as a processing aid on animal-derived Ready-To-Eat food'.

13 By separate document lodged at the Court Registry on the same day, the applicant brought the present application for interim measures, in which it claims that the President of the General Court should:

- 'order the suspension of the application of all the provisions of the [contested acts] until the Court has ruled on the application for annulment submitted by the applicant';
- order, pursuant to Article 157(2) of the Rules of Procedure of the General Court, the immediate suspension of the 'operation of the contested regulation pending the adoption of an order which will bring the interim proceedings to an end';
- order the Commission to pay the costs.

14 The President of the General Court, taking the view that there was no scope for the immediate adoption of the requested measures, invited the Commission to submit its observations by 4 September 2019.

15 In its observations on the application for interim measures, lodged at the Court Registry on 3 September 2019, the Commission contends that the President of the General Court should:

- dismiss the application for interim measures;
- reserve the costs.

Law

16 It is apparent from reading Articles 278 and 279 TFEU together with Article 256(1) TFEU that the judge hearing an application for interim measures may, if he considers that the circumstances so require, order that the operation of a measure challenged before the General Court be suspended or prescribe any necessary interim measures, pursuant to Article 156 of the Rules of Procedure of the General Court. Nevertheless, Article 278 TFEU establishes the principle that actions do not have suspensory effect, since acts adopted by the institutions of the European Union are presumed to be lawful. It is therefore only exceptionally that

the judge hearing an application for interim measures may order the suspension of operation of an act challenged before the General Court or prescribe any interim measures (order of 19 July 2016, *Belgium* v *Commission*, T-131/16 R, EU:T:2016:427, paragraph 12).

17 The first sentence of Article 156(4) of the Rules of Procedure requires applications for interim measures to state 'the subject matter of the proceedings, the circumstances giving rise to urgency and the pleas of fact and law establishing a prima facie case for the interim measure applied for'.

18 Accordingly, the judge hearing an application for interim relief may order suspension of operation of an act and other interim measures if it is established that such an order is justified, prima facie, in fact and in law, and that it is urgent in so far as, in order to avoid serious and irreparable harm to the applicant's interests, it must be made and produce its effects before a decision is reached in the main action. Those conditions are cumulative and, consequently, an application for interim measures must be dismissed if any one of them is not satisfied. The judge hearing an application for interim relief is also required, when appropriate, to weigh up the competing interests involved (see order of 2 March 2016, *Evonik Degussa* v *Commission*, C-162/15 P-R, EU:C:2016:142, paragraph 21 and the case-law cited).

19 In the context of that overall examination, the judge hearing the application has a wide discretion and is free to determine, having regard to the specific circumstances of the case, the manner and order in which those various conditions are to be examined, there being no rule of law imposing a pre-established scheme of analysis within which the need to order interim measures must be assessed (see order of 19 July 2012, *Akhras* v *Council*, Case C-110/12 P(R), not published, EU:C:2012:507, paragraph 23 and the case-law cited).

20 Having regard to the material in the case file, the judge hearing the application considers that he has all the information needed to rule on the present application for interim measures, without there being any need first to hear oral argument from the parties.

21 Since the Commission has contested the admissibility of the application for interim measures, it is appropriate to examine first whether the present application is admissible.

22 According to the form of order sought, as formulated by the applicant, it asks the Court to 'order the suspension of the application of all the provisions' of the contested acts.

23 The contested acts, to which the applicant refers, are composed of two letters by the Commission of 17 June 2019 that do not clearly identify the various 'provisions' alleged to have been adopted by the Commission.

24 In that regard, it must be held that, in proceedings for interim measures, the Union judicature's responsibility is to assess the admissibility and, where appropriate, the merits of the form of order sought by the applicant and not to formulate the form of order. Asking the judge hearing the application for interim measures to 'order the suspension of the application of all the provisions' of the contested acts, without specifying in what these various provisions might consist, amounts to asking the judge himself to draw up the form of order which he is subsequently supposed to assess (see, to that effect, the order of 13 December 2004, *Sumitomo Chemical* v *Commission*, C-381/04 P(R), not published, EU:C:2004:796, paragraph 20).

25 However, the text of the application allows the tenor of the alleged decision that the applicant seeks to have suspended to be identified. It can be deduced from paragraphs 17, 18 and 36 of the application for interim measures that the applicant seeks the suspension of operation of an alleged decision by the Commission of 17 June 2019 by which it purportedly prohibited the placing on the EU market of the applicant's product Listex™ P100 as a non-contaminating processing aid for use on animal-derived RTE-Food ('the alleged decision').

26 According to the applicant, the refusal by the Commission to authorise Listex™ P100 as a decontaminant under Regulation No 853/2004 and the refusal to recognise it as a non-decontaminating processing aid combined with the stance taken by the Commission as to the relevance of an authorisation under Regulation No 853/2004 as regards national authorisations as a processing aid amounts to a decision by which the further placing on the market of Listex™ P100 as a processing aid for animal-derived RTE-Food is 'prohibited for the first time'.

27 The Commission contends that the present application is inadmissible due to the non-existence of the alleged decision, attacked in the main proceedings.

28 It is settled case-law that the admissibility of the main action must not, in principle, be examined in proceedings for interim measures (see order of 20 June 2014, *Wilders* v *Parliament and Council*, T-410/14 R, not published, EU:T:2014:564, paragraph 19 and the case-law cited).

29 However, according to Article 156(1) of the Rules of Procedure, an application to suspend the operation of any measure adopted by an institution shall be admissible only if the applicant has challenged that measure in an action before the General Court. This rule is not a mere formality but presupposes that the main action, on which the application for interim relief is based, can actually be examined by the judge in the main proceedings (see order of 20 June 2014, *Wilders* v *Parliament and Council*, T-410/14 R, not published, EU:T:2014:564, paragraph 18 and the case-law cited).

30 Furthermore, in order for that application for suspension of operation to be held admissible, the applicant must establish that there are grounds for concluding prima facie that the main application to which the application for interim measures

relates is admissible, in order to prevent a situation where that person is able, by means of an application for interim measures, to obtain suspension of the operation of a measure which the Court subsequently refuses to declare void because, on examination of the substance of the case, the application is declared inadmissible (see, to that effect, order of 18 November 1999, *Pfizer Animal Health* v *Council*, C-329/99 P(R), EU:C:1999:572, paragraph 89).

31 Those requirements follow from the fact that the purpose of proceedings for interim relief is solely to ensure that interim protection is available to individuals, if it is necessary in order for the definitive future decision to be fully effective, in order to ensure that there is no lacuna in the legal protection provided by the EU judicature (see, to that effect, order of 18 November 1999, *Pfizer Animal Health* v *Council*, C-329/99 P(R), EU:C:1999:572, paragraph 90).

32 Such examination of the admissibility of the main action is necessarily summary because proceedings for interim measures are by nature urgent (see, order of 4 December 2007, *Cheminova and Others* v *Commission*, T-326/07 R, EU:T:2007:364, paragraph 44 and the case-law cited).

33 In the context of an application for interim measures, the admissibility of the main action can be assessed only on a prima facie basis, the aim being to examine whether the applicant has adduced sufficient evidence or arguments justifying the prima facie conclusion that the admissibility of the main action cannot be excluded (see, order of 4 December 2007, *Cheminova and Others* v *Commission*, T-326/07 R, EU:T:2007:364, paragraph 45 and the case-law cited).

34 Accordingly, and given that the Commission contests the existence of the alleged decision, in the present proceedings for interim relief it must be examined whether the applicant adduces sufficient evidence or arguments for concluding, prima facie, that there was a decision as alleged, namely, a decision by which the Commission purportedly prohibited the placing on the EU market of the product Listex™ P100 as a non-contaminating processing aid for the use on animal-derived RTE-Food.

35 In that respect, it must be recalled that the contested acts consist of two letters by the Commission of 17 June 2019.

36 The relevant part of the Commission's letter of 17 June 2019, which it sent to the applicant, states as follows:

'From the discussions with Member States, it became clear that there was too much opposition against Listex™ P100 to allow the application for its approval any possibility of obtaining political support. In that regard, by letter dated 19 February 2018, the Commission informed [the applicant] of its decision that it did not intend to pursue the evaluation of the application file.

You now claim that the product should be considered as a processing aid falling outside Regulation (EC) No 853/2004 ... Processing aids are defined in Regulation (EC) No 1333/2008 on food additives.

However, [Listex™ P100] aims at reducing the Listeria contamination in ready-to-eat food. It therefore falls under the scope of Article 3(2) of Regulation (EC) No 853/2004, which stipulates that "Food business operators shall not use any substance other than potable water ... to remove surface contamination from products of animal origin, unless use of the substance has been approved by the Commission". Therefore, a possible qualification as a processing aid for the purpose of decontamination would not remove the prevailing authorisation obligation under Regulation (EC) No 853/2004, as it was in the case of lactic acid authorised by Commission Regulation (EU) No 101/2013.

This interpretation remains that of Commission services. I would however remind you that the Court of Justice constitutes the judicial authority of the Union and it remains its exclusive competence to interpret EU law.

Furthermore, I would like to clarify that the discussion held in the Working Group of hygiene experts of Member States on 29 April 2019 was at the request of a Member State who drew the attention of the Commission to the fact that your product was advertised to companies on its territory despite not being allowed on the market and that its recognition as a processing aid in another created difficulties for competent authorities. The Commission merely recalled at this occasion that no authorisation had been given at EU level for the placing on the market of your product in accordance with Article 3(2) of Regulation (EC) No 853/2004.'

37 In respect of the preceding quote, the letter sent to PA International the same day is worded almost identically.

38 The applicant does not adduce any elements that permit the prima facie conclusion that, by the two letters referred to, the Commission had taken the alleged decision.

39 In the first place, it is noteworthy that the applicant does not describe in a clear and coherent manner the content of the alleged decision.

40 As follows from paragraph 25 above, the content of the alleged decision must be deduced from paragraphs 17, 18 and 36 of the present application for interim measures.

41 In addition, it must be observed that the present application does not allow it clearly to be identified whether, according to the applicant, the alleged decision is to be understood as a decision addressed to the Member States or to the applicant.

42 In the second place, the applicant merely affirms, in paragraphs 17, 18 and 36 of its application, that, by the two letters referred to, the Commission had taken a decision by which it purportedly prohibited the placing on the EU market of the

product Listex™ P100 as a non-contaminating processing aid for the use on animal-derived RTE-Food.

43 In particular, the applicant does not bring forward arguments supporting its claim as to the existence of the alleged decision.

44 In the third place, according to a natural reading of the two letters, the Commission recalls, prima facie, its decision not to further pursue the evaluation of the applicant's application file for approval of Listex™ P100 under Regulation No 853/2004 and a legal position regarding the interpretation of Article 3(2) of the said regulation.

45 In particular, it follows from the text of the two letters, as reproduced in paragraph 36 above, that the Commission takes a position as to the question whether Listex™ P100 falls under the scope of Article 3(2) of Regulation No 853/2004 and whether the obligation of an EU authorisation continues to apply for the marketing as a processing aid for the purpose of decontamination of RTE-Food.

46 In that respect, it must be recalled that the Commission expressly refers to the statements made as an 'interpretation' of the applicable regulatory framework by the 'Commission services'.

47 However, the applicant does not bring forward any argument as to why the two letters, despite their wording, should be understood as a decision of the alleged content rather than a mere interpretation of the regulatory framework.

48 In the fourth place, according to the Commission's view, as expressed in the two letters, Listex™ P100 falls within the scope of Article 3(2) of Regulation No 853/2004. This implies prima facie that, by virtue of that provision, the qualification as a processing aid for the purpose of decontamination cannot remove the prevailing authorisation obligation under Regulation No 853/2004.

49 Accordingly, the alleged prohibition on the marketing of Listex™ P100 as a decontaminant stems, prima facie, directly from Regulation No 853/2004, as interpreted by the Commission, and is not the result of the alleged decision.

50 Again, the applicant does not give any explanation as regards the regulatory framework as to why the two letters should be understood as entailing the alleged decision by the Commission rather than constituting a mere interpretation of the applicable legal framework.

51 Even if the two letters were to be understood as not merely confirming a previously adopted act but involving a decision by which the Commission definitely refused to pursue further the approval of Listex™ P100 as a decontaminant under Regulation No 853/2004, which is disputed by the Commission, it must be recalled that, in any event, the suspension of such a

decision would not serve the interest pursued by the applicant in the present application for interim measures.

52 It follows from paragraph 49 above that the alleged prohibition on the marketing of Listex™ P100 as a decontaminant stems, prima facie, directly from Regulation No 853/2004, as interpreted by the Commission. That prohibition will continue, if the Commission's interpretation is correct, until the marketing of the product is authorised under the said regulation. Accordingly, the mere suspension of a decision by which the Commission allegedly decided not to pursue the approval process further would not alter the situation as regards the marketing of Listex™ P100 as a processing aid for use on animal-derived RTE-Food.

53 In the fifth place, in so far as the applicant refers to the Belgian and Estonian authorities, which are alleged to have applied the prohibition on marketing, it must be held that these alleged circumstances also cannot support the applicant's contentions.

54 As to the alleged regulatory approach taken by the Belgian authority, it follows from the document submitted by the applicant that the Belgian authority does not refer to the alleged decision.

55 Instead, in its email of 5 June 2019, which precedes the alleged decision by almost 2 weeks, the Belgian authority refers to the 'position of the European Commission of April 2019', which, prima facie, is a reference to the discussion held at the Working Group of hygiene experts of Member States on 29 April 2019, to which the two letters also make reference.

56 As to the alleged regulatory approach taken by the Estonian authority, it is clear from the document submitted by the applicant, that the Estonian authority does not refer to the alleged decision.

57 Instead, the document is dated 13 March 2019, thus preceding the alleged decision by more than 3 months.

58 It must be concluded that the applicant has not adduced sufficient evidence or arguments for it to be concluded, prima facie, that there was a decision as alleged.

59 It follows from the foregoing that the application for interim measures must be dismissed as inadmissible, without it being necessary to rule on urgency or the condition relating to a prima facie case.

60 It should be added that this does not leave the applicant without judicial protection.

61 In that regard, it should be borne in mind that, in general, judicial review of compliance with the European Union legal order is ensured, as can be seen from Article 19(1) TEU, by the Courts of the European Union and the courts and tribunals of the Member States (see judgment of 3 October 2013, *Inuit Tapiriit*

Kanatami and Others v *Parliament and Council*, C-583/11 P, EU:C:2013:625, paragraph 90 and the case-law cited).

62 To that end, the FEU Treaty has established, by Articles 263 and 277, on the one hand, and Article 267, on the other, a complete system of legal remedies and procedures designed to ensure judicial review of the legality of European Union acts, and has entrusted such review to the Courts of the European Union (see judgment of 3 October 2013, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, C-583/11 P, EU:C:2013:625, paragraph 92 and the case-law cited).

63 As regards the role of the national courts and tribunals, it should be borne in mind that those courts and tribunals, in collaboration with the Courts of the European Union, fulfil a duty entrusted to them both of ensuring that in the interpretation and application of the Treaties the law is observed (see judgment of 3 October 2013, *Inuit Tapiriit Kanatami and Others* v *Parliament and Council*, C-583/11 P, EU:C:2013:625, paragraph 99 and the case-law cited).

64 Accordingly, if the applicant disagrees with the legal position expressed, prima facie, in the contested acts by the Commission, it is free to seek legal remedies against acts adopted by national authorities, such as the Belgian and Esthonian authorities to which the applicant refers, allowing the national courts to make an order for reference to the Court of Justice pursuant to Article 267 TFEU.

65 Pursuant to Article 158(5) of the Rules of Procedure, the costs must be reserved.

On those grounds,

THE PRESIDENT OF THE GENERAL COURT

hereby orders:

1. The application for interim measures is dismissed.

2. The costs are reserved.

Luxembourg, 26 September 2019.

E. Coulon M. Jaeger

Registrar President