TO THE PRESIDENT AND MEMBERS
OF THE GENERAL COURT OF THE EUROPEAN UNION

OBSERVATIONS ON THE PLEA OF INADMISSIBILITY SUBMITTED BY THE COUNCIL OF THE EUROPEAN UNION ON 30 MAY 2023

IN CASE T-138/23
SEMMELWEIS EGYETEM V. COUNCIL OF THE EUROPEAN UNION

Lodged on 18 July 2023, pursuant to Article 130(5) of the Rules of Procedure of the General Court, by

SEMMELWEIS EGYETEM

Applicant

of 26 Üllői út, Budapest 1085, Hungary, represented by Dr. Péter P. Nagy ügyvéd of the Budapest Bar and by Dr. Balázs Karsai ügyvéd of the Budapest Bar, both of the law firm Nagy és Trócsányi registered with the Budapest Bar Association at 217, with an address at 4/B Ugocsa utca, Budapest 1126, telephone: +36 1 487-8700, email: nagy.peter@nt.hu (with service to be effected in these proceedings at the eCuria account associated with that email address)

v.

COUNCIL OF THE EUROPEAN UNION

Defendant

in proceedings brought for partial annulment in respect of Council Implementing Decision (EU) 2022/2506 of 15 December 2022 on measures for the protection of the Union Budget against breaches of the principles of the rule of law in Hungary, insofar as it concerns the Applicant.

I. Introduction

1. Applicant Semmelweis Egyetem (misspelled by Defendant in its Plea of Inadmissibility as *"University of Semmelweis"*[1]) lodged an application against the Council of the European Union for the partial annulment of Article 2(2) of Council Implementing Decision (EU) 2022/2506 on measures for the protection of the Union budget against breaches of the principles of the rule of law in Hungary (the "**contested Decision**").

2. In its Plea of Inadmissibility dated 30 May 2023, Defendant preliminarily objected to the application arguing that **(i)** the contested Decision does not concern the Applicant directly and individually and, **(ii)** the contested Decision does entail implementing measures and, **(iii)** Semmelweis Egyetem may or may not qualify as being 'maintained' by a so-called public interest trust (in fact: foundation). Neither of these arguments are supported by facts.

3. Applicant, in response to the Plea of Inadmissibility, submits these observations pursuant to Article 130(5) of the Rules of Procedure of the General Court:

4. F i r s t, the contested Decision made the prohibition crystal clear: *"[…] no legal commitment shall be entered into with […] any entity maintained by such a public interest trust"* (Art. 2(2) contested Decision). Being such an entity, it is Semmelweis Egyetem itself which is being excluded from European programs and so from the overall fabric of European higher education. While it is true that the indirect and ultimate casualties of the prohibition are the students and researchers of the Applicant, the unavoidable consequence of the measures have resulted in market distortion (the Fifth Plea), directly impacting the Applicant itself thereby negatively impinging its ability to continue with its business of providing medical education.

5. S e c o n d, as the Commission candidly revealed to the European Parliament[2], the contested Decision, without any further or implementing measures, have already resulted in effective sanctions which – unless lifted by mid-July 2023 – prevent the students of the Applicant from participating in the Erasmus+ programs.

6. T h i r d, it is a matter of legal fact that the ownership of Semmelweis Egyetem has been restructured making it an entity maintained by a public interest trust (i.e., foundation) by Annex 1/A of Act 2021:IX[3]. In this relationship the term 'maintained'

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[1] See e.g. pp. 1-2 Plea of Inadmissibility.

[2] *"On public interest trusts, the Commission services have already informed Hungary that in order to proceed with the agreements to be signed under the Erasmus+ call for 2023, the cut-off date is fast approaching. The awards should, in principle, be done by mid-July."* As Commissioner J. Hahn addressed the European Parliament on 31 May 2023 (see transcript attached as Annex A.11 or at https://www.europarl.europa.eu/doceo/document/CRE-9-2023-05-31-INT-1-123-0000_EN.html).

[3] See in more details at ¶11 Application.

as applied in Art. 2(2) contested Decision is not a word to be placed in EU parlance, it is the translation of the Hungarian word ‘fenntartó’. The purpose of the foundation as enshrined in law[4] is *"to exercise the right of founder, owner and maintainer"*.

II. Background

7. Semmelweis Egyetem is not charged with any wrongdoing or offence of any kind. Neither in connection with the Union budget as protected by Regulation (EU) 2022/2092 (the "**Conditionality Regulation**") nor otherwise.

8. [The same applies to the *National Foundation for Healthcare and Medical Education* (an entity referred to as 'public interest trust' in the contested Decision), the entity in charge for maintaining Semmelweis Egyetem.]

9. Despite a striking absence of any act or failure to have acted in the context of the rule of law, indeed with no indication to any act or omission on the part of Applicant to *"affect or seriously risk affecting the sound financial management of the Union budget or the protection of the financial interests of the Union in a sufficiently direct way"* (Art. 4(1) Conditionality Regulation), the Defendant had adopted Art. 2(2) of the contested Decision which in turn has directly affected the businesses of the Applicant, making Applicant the victim of market distortion (¶¶197-207, The Fifth plea: Distortion of market, Application).

10. Semmelweis Egyetem understands that Defendant believes that by the adoption of the contested Decision it only attempted to act within the framework of Art. 4 Conditionality Regulation. Nevertheless, it developed – if even unintentionally – into a campaign for the removal of Semmelweis Egyetem from European academic life which is an essential part of its business. This measure suits only the Applicant's competitors in the academic market, to the detriment of Applicant's business.

11. All the more bizarre, that by acting in the good name of the rule of law, Defendant infringed Applicant's right to be heard, a fundamental right within the European Union’s legal order, enshrined in the first indent of Article 41(2) of the Charter of Fundamental Rights of the European Union (The Second Plea, Application). The Application herein serves also to remedy this infringement of the Charter while the statement of inadmissibility continues to object to Applicant's right to be heard.

12. While the contested Decision may have attempted to provide a *“general and systemic protection of the Union budget”*[5], Applicant reiterates its position that having not been approached to provide any information whatsoever regarding its governance structure or otherwise, the supposed *“conflict of interest”*[6] and *“lack of*

[4] See Section 1, row 18 of Annex 1/A of Act 2021:IX.
[5] See ¶10 Plea of Inadmissibility.
[6] See ¶10, ¶¶30-32 and ¶52 Plea of Inadmissibility.

transparency"[7] as posited by Defendant are somewhat farfetched. Indeed, attempting to argue that *"although not yet proven, can nevertheless be reasonably foreseen"*[8] in this specific instance makes a mockery of their own process, and that of the Court. Such a process mirrors the respectful request of the Council that the General Court rule on the inadmissibility of the action itself *"without adjudicating on its substance"*[9] and silencing parties affected by the contested Decision.

13. Applicant further attests that given the extent of the irrefutable detriment to its international offer through Erasmus+ and other programmes, the Commission has failed to *"ensure that the legitimate interests of the final recipients and beneficiaries are properly safeguarded"*[10]. Indeed, the assertion by Defendant that the Member State simply "*provides beneficiary universities with national funding*"[11] starkly demonstrates that Defendant did not in fact interrogate the processes involved in the complex implementation of consortium selections and decisions, otherwise it would know that such an assertion is far too simplistic and would not in fact be sufficient. Furthermore, it's assurance that the current situation can be *"swiftly"*[12] assessed highlights its lack of understanding of the years such projects take to design and execute as well as of the consequences of being removed from existing longstanding projects, and the membership of future ones.

14. By the time of filing the present Observations, Applicant has been excluded from at least six further projects with explicit reference to the contested Decision (see the rejection letters and the notification on protection measures attached hereto as Annex A.12, A.13, A.14, A.15, A.16 and A.17), in addition to those other projects that the Applicant has been excluded from earlier (see the rejection letters and the notification on protection measures attached to the Application as Annex A.2, A.3, A.4 and A.5.).

15. Some of these rejections have not been limited to the Applicant's participation as a beneficiary in the given project, but instead cut all ties with the Applicant, including the suspension of private individual professionals and researchers from certain positions (see, for example, in Annex A.15, *"[…] Management Committee and Working Group participants affiliated to Hungarian legal entities implied by the Council Decision are suspended from this role […]"*).

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[7] See ¶10 Plea of Inadmissibility.
[8] See ¶11 Plea of Inadmissibility.
[9] See ¶3 Plea of Inadmissibility.
[10] See ¶13 Plea of Inadmissibility.
[11] See ¶39 Plea of Inadmissibility.
[12] See ¶13 Plea of Inadmissibility.

III. Admissibility

16. In its Plea of Inadmissibility, the Defendant submitted that, in its view, Semmelweis Egyetem does not have legal standing to bring the present proceedings for the following reasons:

    i. Art. 2(2) of the contested Decision is not of direct concern to the Applicant[13],

    ii. Art. 2(2) of the contested Decision is not of individual concern to the Applicant[14],

    iii. Art. 2(2) of the contested Decision entails implementing measures[15].

17. Semmelweis Egyetem refutes these arguments, as follows.

A. Article 2(2) of the contested Decision is of direct concern to the Applicant

18. In its Plea of Inadmissibility, the Defendant explicitly admitted that *"Article 2(2) of the contested Decision lays down the obligation for the Commission and Hungary […] not to enter into legal commitments with certain entities"*[16]. Still, according to the Defendant, Article 2(2) of the contested Decision is not of 'direct concern' to the Applicant within the meaning of Article 263(4) TFEU for the following reasons:

    i. the determination of the scope of application of the contested Decision requires an individual assessment[17],

    ii. the effects of the contested Decision on the Applicant depend on the *"concurring obligation"*[18] to protect recipients and final beneficiaries of EU funds[19],

    iii. the effects of the contested Decision on the Applicant depend on the adoption of implementing measures which apply to individual situations[20].

19. These three objections are discussed in turn below.

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[13] See ¶¶18-47 Plea of Inadmissibility.
[14] See ¶¶48-59 Plea of Inadmissibility.
[15] See ¶¶60-68 Plea of Inadmissibility.
[16] See the first sentence of ¶21 Plea of Inadmissibility.
[17] See ¶¶24-35 Plea of Inadmissibility.
[18] See ¶14 and ¶41 Plea of Inadmissibility.
[19] See ¶¶36-41 Plea of Inadmissibility.
[20] See ¶¶42-47 Plea of Inadmissibility.

(1) the determination of the scope of application of the contested Decision <u>does not</u> require an individual assessment

20. The entirety of Defendant's arguments set out in ¶¶24-35 of the Plea of Inadmissibility are based on its interpretation of the word 'maintained' (set out in Article 2(2) of the contested Decision) as allegedly being an *"autonomous concept of EU law"*[21] or *"autonomous notion of EU law"*[22]. In this context, the Defendant goes as far as to submit that *"this notion was introduced by the Council"*[23].

21. The Defendant's arguments are fundamentally misguided, particularly considering that at the same time Defendant acknowledges – correctly –, that the notion of 'public interest trusts' within the meaning of Article 2(2) of the contested Decision is to be established on the basis of Hungarian law, and not on the basis of EU law (see the first sentence of ¶26 Plea of Inadmissibility: *"**<u>Unlike</u>** the notion of 'public interest trust established on the basis of the Hungarian Act IX of 2021, the notion of entity 'maintained' by a PIT has to be considered as an autonomous concept of EU law."*, emphasis ours).

22. The notion of entities being 'maintained' by a public interest trust (in fact, foundation) was <u>not</u> introduced by the Council, but by Act 2021:IX referred to by the Defendant itself (see ¶21 above). Indeed, the expression 'maintained' is used at some 50 places in Act 2021:IX, including Annex 1/A of Act 2021:IX that explicitly makes Semmelweis Egyetem an entity maintained by a public interest trust (foundation), the Foundation for National Health Care and Medical Education. As such, the notion of 'entities maintained by a public interest trust' is organically embedded in Act 2021:IX. This notion is also reflected in Section II. (titled *"Maintainer of the University"*) of the deed of foundation of Semmelweis Egyetem.[24]

23. Act 2021:IX was published in the Official Gazette of Hungary in <u>April 2021.</u> The Commission sent its very first request for information to Hungary ca. 6 months later, in <u>November 2021</u>.[25] This chronology supports the given understanding that 'maintained' was introduced by the Hungarian legislator and then accordingly used by the Commission and the Council, and not the other way around.

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[21] See, in particular, ¶¶26-27 Plea of Inadmissibility.
[22] See, in particular, ¶¶28-29 and ¶35 Plea of Inadmissibility.
[23] See ¶30 Plea of Inadmissibility.
[24] See Annex A.7 of the Application.
[25] See preamble (1) of the contested Decision.

24. Indeed, the limb *"any public interest trust and any entity maintained by them"* has consistently been used by the Commission[26] and the Defendant[27] without any indication that these two sets of entities should be identified in different, separate contexts of interpretation (let alone, the former one on the basis of Hungarian law, and the latter one on the basis of EU law, as the Defendant now suggests).

25. In its Plea of Inadmissibility, the Defendant failed to identify a single reference in either the contested Decision, or in any of the documents that lead to the adoption of the contested Decision, where any sort of EU law context is tied to the notion 'maintained' within the meaning of Article 2(2) of the contested Decision. This comes as no surprise as there is no such reference, and the sole reason why EU institutions have used the expression 'maintained' is that it is the English translation of the Hungarian word 'fenntartó' (see ¶6 and ¶22 above).

26. It follows that the notion of 'any public interest trust' (in fact, foundation) and the notion of 'any entity maintained by such a public interest trust' are inextricably linked to each other, and their interpretation has never been made subject to EU law but, indeed, has always been subject to Hungarian law.

27. Even if the Defendant were to be correct in thinking that the notion of 'maintained' by public interest trusts is open for interpretation under EU law (*quod non*), the Defendant's arguments would still be unsuitable for asserting that the contested Decision is not of direct concern to Semmelweis Egyetem.

28. It is settled case law that the test of direct concern was interpreted by the Court *"to mean that a natural or legal person would be directly concerned by an EU act where* ***the addressee of the measure had either no discretion in its implementation or, if it had some, the discretion was entirely theoretical"***[28] (emphasis ours).

29. As such, according to the judicial practice of the Court, the existence or absence of direct concern is explicitly tied to whether the addressee enjoys discretion in the implementation of the given measure, and **not** to whether the applicant falls within the scope of the given measure. If the addressee enjoys no discretion (or, enjoys

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[26] See, in particular, ¶133, ¶135, ¶¶140-142, ¶147 of the Proposal for a Council Implementing Decision on measures for the protection of the Union budget against breaches of the principles of the rule of law in Hungary, dated 18 September 2022, and ¶7, ¶65 and ¶69 of the Communication for the Commission to the Council on the remedial measures notified by Hungary under Regulation (EU, Euratom) 2020/2092 for the protection of the Union budget, dated 30 November 2022, and the transcript of Commissioner J. Hahn's speech delivered to the European Parliament on 31 May 2023, attached hereto as Annex A.11.

[27] See preamble (22) and (62) of the contested Decision.

[28] See the Judgment of 17 January 1985, *SA Piraiki-Patraiki and Others v Commission of the European Communities*, C-11/82, EU:C:1985:18, paragraphs 6 to 10. See also Albors-Llorens, Albertina (2012) *"Sealing the Fate of Private Parties in Annulment Proceedings? The General Court and the New Standing Test in Article 263(4) TFEU"*, The Cambridge Law Journal, March 2012, Vol. 71, No. 1 (March 2012), p. 52.

some, but that is only theoretical), then the condition of direct concern is met. If the addressee enjoys discretion that is more than theoretical, then the condition of direct concern is not met.

30. By contrast, direct concern is not more established if the measure in question actually identifies the given applicant, and the direct concern is not less established if the measure in question does not actually identify the given applicant. What indeed depends on the applicability of the measure to the given applicant is *the relevance of* the matter of direct concern. Simply, if the measure is not applicable to the given applicant, then the matter of direct concern cannot have legal relevance. If the measure is applicable to the given applicant, then the matter of direct concern has legal relevance.

31. In other words, the existence of direct concern cannot possibly be undermined by – alleged – uncertainties around whether the given measure applies to the applicant. If a given measure does not apply to the given applicant, then the matter of direct concern does not even come up, because in such a case the given applicant is not concerned by the given measure *at all*. If a given measure applies to the given applicant, then the matter of direct concern indeed comes up, and shall be assessed in accordance with the judicial practice referred to in ¶28 above.

32. The assessment of the existence or absence of direct concern thus necessarily presupposes that the measure in question applies to the given applicant, otherwise the assessment would be pointless. This is why the existence or absence of the addressee's discretion cannot be made dependent on whether Semmelweis Egyetem qualifies as an entity 'maintained' by a public interest trust within the meaning of Article 2(2) of the contested Decision, and hence this is why the Defendant's argument to the opposite is fundamentally wrong and is against the judicial practice of the Court.

(2) the effects of the contested Decision on the Applicant <u>do not</u> depend on a *"concurring obligation"*[29] to protect recipients and final beneficiaries of EU funds

33. In ¶¶36-41 of the Plea of Inadmissibility, the Defendant attempts to undermine the existence of direct concern to Semmelweis Egyetem by conflating the contested measure (that is, Article 2(2) of the contested Decision) with things that fall outside the contested measure itself and hence are not relevant for the purposes of assessing whether the contested measure itself is of direct concern to the Applicant.

34. Semmelweis Egyetem reiterates that, according to the settled case law of the Court, the condition that a legal person *"must be directly <u>concerned</u> **<u>by the decision</u>** against which the action is brought, laid down in the fourth paragraph of Article 263 TFEU, requires two cumulative criteria to be met, namely, first, **<u>the contested measure</u>** <u>must</u> directly affect the legal situation of the individual and, second, **<u>it</u>** must*

[29] See ¶14 and ¶41 Plea of Inadmissibility.

*leave no discretion to its addressees who are entrusted with the task of implementing **it**, such implementation being purely automatic and resulting from the EU rules alone without the application of other intermediate rules"*[30] (emphasis ours).

35. Clearly, the examination of whether a contested measure is of direct concern to the given applicant is explicitly tied to the given contested measure, and not to any further aspect or circumstance that goes beyond the contested measure itself, such as for example its *"effects"*[31] *and/or any "concurring obligation"*[32], as the Defendant wrongly suggests.

36. In the present case, the contested measure is embedded in Article 2(2) of the contested Decision: *"Where the Commission implements the Union budget in direct or indirect management pursuant to of Article 62(1) points (a) and (c), of Regulation (EU, Euratom) 2018/1046, no legal commitments shall be entered into with any public interest trust established on the basis of the Hungarian Act IX of 2021 or any entity maintained by such a public interest trust."*.

37. The Defendant, however, refers to multiple further aspects and circumstances, ones that go way beyond the contested measure itself, and thereby pretends that the wording of the contested measure continues that:

    i. *"[…], unless students do not have access to mobility grants in a way that duly protects the financial interests of the Union"*[33], or

    ii. *"[…], unless Hungary does not provide beneficiary universities with national funding to allow their continued participation in the programme"*[34], or

    iii. *"[…], unless there are no additional policy choices to protect recipients and final beneficiaries"*[35].

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[30] See the Judgments of 5 May 1998, *Société Louis Dreyfus & Cie v Commission of the European Communities*, C-386/16 P, EU:C:1998:193, paragraph 43 and the case-law cited, and of 29 June 2004, *Front National v European Parliament*, C-486/01 P, EU:C:2004:394, paragraph 34 and the case-law cited, and of 10 September 2009, *Ente per le Ville Vesuviane v Commission*, Joined Cases C-445/07 P and C-455/07 P, EU:C:2009:529, paragraph 45 and the case-law cited, and of 27 February 2014, *Stichting Woonlinie and Others* v *Commission*, C-133/12 P, EU:C:2014:105, paragraph 55 and the case-law cited, and of 6 November 2018, *Scuola Elementare Maria Montessori* v *Commission*, *Commission* v *Scuola Elementare Maria Montessori* and *Commission* v *Ferracci*, C-622/16 P to C-624/16 P, EU:C:2018:873, paragraph 42 and the case-law cited, and of 30 June 2022, *Danske Slagtermestre v European Commission*, C-99/21 P, EU:C:2022:510, paragraph 45 and the case-law cited.

[31] See the title of Section III.A.2. and III.A.3. Plea of Inadmissibility.

[32] See ¶14 and ¶41 Plea of Inadmissibility.

[33] See the first sentence in ¶39 Plea of Inadmissibility.

[34] See the second sentence in ¶39 Plea of Inadmissibility.

[35] See ¶40 Plea of Inadmissibility.

38. The contested measure, however, clearly does not include these additional aspects and circumstances.

39. What the contested measure does include is an absolute and unconditional prohibition. The Defendant attempts to turn the absolute and unconditional nature of this prohibition on its head by presenting the contested measure as if it had been conditional upon its own first limb (*"Where the Commission implements the Union budget in direct or indirect management pursuant to of Article 62(1) points (a) and (c), of Regulation (EU, Euratom) 2018/1046 […]"*), however, in reality, this first limb only sets the scope of the prohibition and does not alter its absolute and unconditional nature.

40. As far as the test of direct concern, the relevance of this absoluteness and unconditionality is already obvious: the addressees of the measure enjoy no discretion whatsoever in the implementation of the measure. In this context, please see ¶¶87-90 of the Application and ¶¶28-29 above.

(3) the effects of the contested Decision on the Applicant <u>do not</u> depend on the adoption of implementing measures which apply to individual situations

41. The Defendant mixes apples and oranges by submitting ¶¶42-47 of the Plea of Inadmissibility *in the context of direct concern*.

42. In *Palirria Souliotis v Commission*, the Court made it clear that:

> *"The need for an act which does not entail implementing measures laid down in the fourth paragraph of Article 263 TFEU* ***<u>constitutes a different condition</u>*** *from the requirement that the act be of direct concern to the applicant. In particular, it must be held that the question whether or not the contested regulation leaves a margin of discretion to the national authorities responsible for the implementing measures is irrelevant in ascertaining whether the contested regulation entails implementing measures […]."*[36].

43. By contrast, in ¶¶42-47 of its Plea of Inadmissibility, apparently in the context of its arguments that the contested Decision is not of direct concern to Semmelweis Egyetem, Defendant submits argumentation regarding that the contested Decision, in the Defendant's view, entails certain implementing measures (*"[…] adoption of further implementing measures"*[37], *"[…] will have to implement the prohibition […]"*[38],

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[36] See the Judgment of 12 September 2013, *Palirria Souliotis v Commission*, T-380/11, EU:T:2013:420, paragraph 44 and the case-law cited. See also Kucko, Magdalena (2017) *"The Status of Natural and Legal Persons According to the Annulment Procedure Post-Lisbon"*, LSE Law Review, Vol 2, p. 115.
[37] See ¶42 Plea of Inadmissibility.
[38] See ¶43 Plea of Inadmissibility.

"[…] further actions of budget implementation"[39] etc.), which, however, is a separate, different element of the applicable criteria under the third limb of Article 263(4) TFEU.

44. According to the judicial practice of the Court, these arguments are not relevant in the context of the direct concern test, but only in the context of the test of 'does not entail implementing measures'. Accordingly, Semmelweis Egyetem will address these arguments in the latter context, see Section C. below.

45. What is indeed relevant in the context of the direct concern test, is ¶44 of the Plea of Inadmissibility. Here, the Defendant once against explicitly acknowledges the absolute and unconditional nature of the prohibition set out in Article 2(2) of the contested Decision (although attempts to belittle its importance): *"[…] the contested Decision does not entail a cause of exclusion from the selection procedure, but* ***only precludes the very final step of such procedures, namely the signature of a grant agreement****"*[40] (emphasis ours). This prohibition exactly substantiates the argument that Article 2(2) of the contested Decision is of direct concern to Semmelweis Egyetem within the meaning of Article 263(4) TFEU, together with the legal fact that the prohibition is absolute and unconditional, and hence its addressees enjoy no discretion whatsoever in its implementation.

B. The matter of individual concern is not relevant

46. As far as actions for annulment brought by non-privileged applicants, Art. 263(4) TFEU differentiates between two – mutually exclusive – scenarios:

    i. proceedings against an act which is of direct and individual concern to the given applicant(s)[41],

    ii. proceedings against a regulatory act which is of direct concern to the given applicant(s) and does not entail implementing measures[42].

47. These two scenarios are mutually exclusive because there is no overlap between the scope of 'acts' (see ¶46(i) above) and 'regulatory acts' (see ¶46(ii) above) within the meaning of Art. 263(4) TFEU.[43]

48. It is beyond dispute that the contested Decision is a 'regulatory act', and not an 'act', within the meaning of Art. 263(4) TFEU. *This* is not contested by the Defendant, either.

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[39] See ¶45 Plea of Inadmissibility.
[40] See ¶44 Plea of Inadmissibility.
[41] See the second limb of Art. 263(4) TFEU.
[42] See the third limb of Art. 263(4) TFEU.
[43] See ¶¶70-71 Application and the case-law cited.

49. It clearly appears from the wording of Art. 263(4) TFEU – see ¶46 above – that actions for annulment brought against regulatory acts are not subject to the test of *individual* concern, but only to the test of *direct* concern. As the Court put it in *Stichting Woonpunt and Others v Commission*, *"[…]* ***the Treaty of Lisbon****, under the fourth paragraph of Article 263 TFEU,* ***relaxed the conditions of admissibility*** *of actions for annulment brought by natural and legal persons against acts of the European Union* ***by adding a third limb to that provision****. Since the effect of that limb is that the admissibility of actions for annulment brought by natural and legal persons is* ***not subject to the condition of individual concern****, it also* ***makes possible legal actions against regulatory acts which do not entail implementing measures and are of direct concern to the applicant*** *(see, to that effect, Case C-583/11 P Inuit Tapiriit Kanatami and Others v Parliament and Council [2013] ECR, paragraph 57)"*[44] (emphasis ours).

50. It follows that the Defendant's argumentation set out in ¶¶48-59 of the Plea of Inadmissibility, which is solely about the matter of *individual* concern, is not relevant for the purposes of establishing whether Semmelweis Egyetem has legal standing to bring the present proceedings. As such, the objective of this argument, beyond the desire to confuse, is once again self-evident: silencing an entity affected by the contested Decision.

C. Article 2(2) of the contested Decision does not entail implementing measures

51. According to the Defendant, the contested Decision entails implementing measures within the meaning of Article 263(4) TFEU, because *"further actions of budget implementation require the exercise of additional discretionary powers that* ***complement the prohibition*** *laid down in the contested Decision"*[45] (emphasis ours).

52. Semmelweis Egyetem respectfully reiterates that there is nothing that could possibly *"complement"* (see ¶51 above) the prohibition set out in Art. 2(2) of the contested Decision, as this prohibition is absolute and unconditional and, as such, it has the immediate and unalterable consequence of the Applicant's removal from those entities with whom legal commitments may be entered into within the meaning of Article 2(2) of the contested Decision.

53. By way of analogy, in *Microban*, a producer of antibacterial additives brought an action for annulment against a Commission decision addressed to the Member States. The decision removed triclosan (a chemical substance) from the list of additives that could be used in the manufacture of plastics intended for the packaging of food products, which had been summed up in a previous Commission

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[44] See the Judgment of 27 February 2014, *Stichting Woonpunt and Others v Commission*, C-133/12 P, EU:C:2014:105, paragraph 43 and the case-law cited.
[45] See ¶45 Plea of Inadmissibility.

directive. As far as the requirement of 'do not entail implementing measures', the Court held that:

> *"[…] Third, as regards the question whether or not the contested decision entails implementing measures within the meaning of the fourth paragraph of Article 263 TFEU, it must be repeated that, as observed at paragraphs 24 and 28 above, the subject of the contested decision is the non-inclusion of triclosan in the positive list. Consequently, pursuant to Article 4a(6)(b) of Directive 2002/72, the contested decision also removed that substance from the provisional list. […]*
>
> *In that regard, firstly, it must be observed that neither non-inclusion in the positive list nor removal from the provisional list required implementing measures on the part of the Member States. Under Article 4a(4) of Directive 2002/72, only additives appearing in the provisional list can continue to be used after 1 January 2010. Moreover, under Article 4a(6)(b) of Directive 2002/72, an additive is to be removed from the provisional list when a decision is taken by the Commission not to include it in the positive list. Accordingly,* ***the decision not to include it had the immediate consequence of*** *its removal from the provisional list and* ***a prohibition on the marketing of triclosan***, ***without the Member States needing to adopt any implementing measure****.*
>
> *[…]* ***Consequently, it cannot be considered that the prohibition on the marketing of triclosan, following its non-inclusion in the positive list and its removal from the provisional list, required the adoption of implementing measures.****"*[46].

54. This judgment of the Court clearly shows that the Defendant's argumentation that the condition of 'does not entail implementing measures' is not fulfilled in the present case because *"[…] the responsible authority either at EU or the national level will have to implement the prohibition in relation to individual cases and taking into account the specific features of the spending programme concerned"*[47] is fundamentally wrong.

55. Just like the prohibition of marketing of triclosan was a direct, automatic and unalterable consequence of the decision contested in *Microban*, the prohibition of entering into legal commitments with Semmelweis Egyetem is a direct, automatic and unalterable consequence of Article 2(2) of the contested Decision.

56. It also follows from the *Microban* judgment that the legal fact that Semmelweis Egyetem is not specifically (that is, by its name) mentioned in Article 2(2) of the contested Decision does not and cannot undermine that the condition of 'does not entail implementing measures' is fulfilled in the present case. The legal situation was the same in *Microban*, none of the applicants were mentioned in the contested

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[46] See the Judgment of 25 October 2011, *Microban International and Microban (Europe) v Commission*, T-262/10, EU:T:2011:623, paragraphs 33-35.
[47] See ¶43 Plea of Inadmissibility.

decisions, yet the Court found that the condition of 'does not entail implementing measures' is fulfilled in respect of both applicants.

57. By contrast, the Defendant submitted that *"**the prohibition laid down in the contested Decision** is not of automatic application but **may only take effect through actual decisions of the Commission or of national agencies affecting the situation of the Applicant**"*[48] (emphasis ours). This statement of the Defendant is also fundamentally misguided and, in reality, the Applicant's situation is the exact opposite.

58. The prohibition laid down in the contested Decision has already affected the situation of the Applicant, without any *"implementing measures"*[49] or *"implementing decision"*[50] or *"actual decisions"*[51] taken either by the Commission or national agencies.

59. As previously mentioned at ¶14 and ¶15, the Applicant has proven that – already by the time of filing the Application – it has been excluded from multiple research projects (see the rejection letters and the notification on protection measures attached to the Application as Annex A.2, A.3, A.4 and A.5).

60. By now, the Applicant has been excluded from at least a further six projects (see the rejection letters and the notification on protection measures attached hereto as Annex A.12, A.13, A.14, A.15, A.16 and A.17).

61. As a matter of fact, all of these exclusions are such direct and automatic consequences of the prohibition set out in Article 2(2) of the contested Decision that affect the Applicant, and hence the Defendant is wrong in submitting that the contested Decision may only affect the Applicant through decisions of the Commission or of national agencies. In this context, Applicant refers to the letter of Commissioner Hahn, which also makes it clear that the prohibition is automatic and there is no room for manoeuvre to circumvent it:

> *"[…] The Decision prohibits to enter into new legal commitments with public interest trusts and entities maintained by them when implementing the EU budget directly or indirectly. […]* ***As long as the measure is in place, no award may be granted and no legal commitment involving EU budget may be signed with these entities.*** *[…]"*[52] (emphasis ours).

62. Semmelweis Egyetem respectfully points out that there is no hesitation or uncertainty whatsoever in the above statement of Commissioner Hahn, which also supports the arguments set forth by Applicant that the prohibition laid down in Article

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[48] See ¶66 Plea of Inadmissibility.
[49] See ¶42 and ¶67 Plea of Inadmissibility.
[50] See ¶46 Plea of Inadmissibility.
[51] See ¶66 Plea of Inadmissibility.
[52] See the letter of Commissioner J. Hahn attached hereto as Annex A.17.

2(2) of the contested Decision is a direct, automatic and unalterable consequence of Article 2(2) of the contested Decision.

63. It follows that Article 2(2) of the contested Decision does not entail implementing measures and, accordingly, the Applicant's legal standing may not be put into question on this basis, either.

IV. CONCLUSIONS

64. For the reasons set out above, the Applicant requests the General Court to recognize that the Applicant has legal standing to bring the present proceedings.

Budapest, 18 July 2023

Respectfully submitted,
Dr. Péter P. Nagy
Dr. Balázs Karsai

Schedule of annexes

No.	short description of the annex	page numbers of the first and last pages of the annex	number of the paragraph in which the item is mentioned for the first time
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A.12	Formal notification on budgetary protection measures	pp. 2-3.	14.
A.13	Rejection of the Applicant's participation in the EUniWell Erasmus+ project and related correspondence	pp. 4-5.	14.
A.14	Rejection of the Applicant's participation in the COST Action project and related correspondence *[email #1]*	pp. 6-8.	14.
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A.16	Rejection of the Applicant's participation in the COST Action project and related correspondence *[email #3]*	pp. 12-16.	14.
A.17	Rejection of the Applicant's participation in the HORIZON-MSCA-2022-SE-01 project and related correspondence *[email #2]*	pp. 17-18.	14.
A.18	Letter of Commissioner J. Hahn dated 1 June 2023	pp. 19-20.	61.