



Brussels, 8.11.2023  
C(2023) 7599 final

**COMMISSION IMPLEMENTING DECISION**

**of 8.11.2023**

**on the request for registration, pursuant to Regulation (EU) 2019/788 of the European Parliament and of the Council, of the European citizens' initiative entitled 'Trust and Freedom'**

(Only the English text is authentic)

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**on the request for registration, pursuant to Regulation (EU) 2019/788 of the European Parliament and of the Council, of the European citizens' initiative entitled 'Trust and Freedom'**

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative<sup>1</sup>, and in particular Article 6(2) and (3) thereof,

Whereas:

- (1) A request for registration of a European citizens' initiative entitled 'Trust and Freedom' was submitted to the Commission on 9 October 2023.
- (2) That request follows the request for registration of a European citizens' initiative entitled 'Trust and Freedom' which was submitted to the Commission on 24 July 2023.
- (3) By letter of 23 August 2023 (C(2023) 5630 final), pursuant to Article 6(4) of Regulation (EU) 2019/788, the Commission informed the group of organisers that as regards the request for registration submitted on 24 July 2023, the requirements for registration set out in Article 6(3), first subparagraph, points (a), (d) and (e), of that Regulation were fulfilled and that Article 6(3), first subparagraph, point (b), thereof was not applicable. However, the Commission also explained that the initiative did not fulfil the requirement set out in Article 6(3), first subparagraph, point (c), of Regulation (EU) 2019/788. In particular, the Commission explained that as regards the third of the three objectives of the initiative ('Safeguarding Fundamental Rights in EU Legislation via a Mechanism of Nullification'), the Commission is not empowered to propose any legislation that would allow the establishment of an independent judicial review 'activated by citizens, local, and national parliaments, prior to their adoption, to review and nullify any EU legal act draft that violates the fundamental rights enshrined in the Charter of Fundamental Rights' and that judicial remedies are exhaustively established in the Treaties.
- (4) The Commission therefore informed the organisers pursuant to Article 6(4), first subparagraph, of Regulation (EU) 2019/788 that they could either amend the initiative to take into account the Commission's assessment, or maintain, or withdraw, the initial initiative in accordance with Article 6(4), second subparagraph, of Regulation (EU) 2019/788.

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<sup>1</sup> OJ L 130, 17.5.2019, p. 55. , ELI: <http://data.europa.eu/eli/reg/2019/788/oj>.

- (5) On 9 October 2023, the group of organisers resubmitted the initiative without the third objective.
- (6) The aims of the amended initiative as expressed by the organisers are for the Commission to propose legislation ‘that fosters freedom, transparency, accountability and individual engagement within the EU’ and ‘to establish and strengthen checks and balances, ensuring that EU institutions are responsive to the needs and interests of the individuals while upholding our human rights as enshrined in the Charter of Fundamental Rights of the EU’. These aims are further defined by the organisers, through two objectives. The first objective, ‘Upholding Human Dignity and the Recognition of Informed Consent’, calls for measures addressed to the Member States regarding ‘the definition of informed consent, promoting the primacy of human dignity, freedom, and bodily autonomy within the European Union’. The second objective, ‘Enhancing Transparency and Empowering Citizens’, calls on the Commission to propose a legal act ‘that enhances transparency and access to information in EU decision-making processes’.
- (7) An annex to the amended initiative provides further details on the subject matter, objectives and background to the initiative. It refers to fundamental rights and urges the Commission ‘to uphold the moral and spiritual heritage enshrined in the preamble’ of the Charter of Fundamental Rights of the European Union ‘by promoting indivisible, universal values of human dignity, freedom, equality, and solidarity, fostering democracy, the rule of law, and prioritizing the individual through Union citizenship and a zone of freedom, security, and justice.’
- (8) As regards the first objective of the initiative on human dignity and the recognition of informed consent, the annex lists five principles: (i) ‘Respect for Individual Autonomy and Integrity’ by recognising that ‘informed consent means that every individual has the right to make informed decisions regarding their healthcare and treatment options’; (ii) ‘Preservation of Free Consent in all Circumstances’, as free consent ‘is crucial both in research (clinical trials) and treatment contexts’; (iii) ‘Provision of Accurate, Understandable, and Accessible Information’ with respect to communication between healthcare professionals and patients; (iv) ‘Comprehensive Understanding of Clinical Trials and Medical Procedures’, meaning that patients ‘should fully understand the nature, purpose, risks, and potential risks’; (v) ‘Recognising the Right to Refuse or Withdraw Consent’.
- (9) Concerning the second objective of the initiative on transparency, the annex lists five actions: (i) ‘Mandating greater transparency by calling for the publication of agendas, meeting minutes, internal reports, e-mails, and SMS’; (ii) ‘Disclosing lobbying activities by establishing a public register of lobbyists’ and ‘their interactions with EU officials’; (iii) ‘Prohibiting secretive meetings’ by EU officials; (iv) ‘Evaluating public interest over private interest’; (v) ‘Establishing sanctions for violations’.
- (10) An additional document attached to the initiative with a general indication of the legal bases and proposed instruments has also been submitted by the organisers as part of their registration request.
- (11) The Commission considers that as regards the measures called for by the first objective of the initiative on human dignity and informed consent, while the Commission lacks competence for proposing a legislative act regulating the issue of consent extensively and in a general manner, across all different areas of health law, it could, in principle, propose relevant measures based on specific provisions of the

TFEU, such as Articles 114 and 168(4)(c). The latter provision forms a basis for specific measures in order to meet common safety concerns. The Commission could therefore submit a proposal for a legal act in those areas of public health where the Union has been given a specific competence. Beyond competence for those specific measures, the Union only has supportive competence in the field of public health in accordance with Article 6 and Article 168(1) TFEU, whereby Union action shall complement national policies and, in accordance with Article 168(7) TFEU, shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care.

- (12) As regards the measures called for by the second objective of the initiative on transparency, the Commission could submit a proposal for a legal act that enhances transparency and access to information in EU decision-making processes based on Article 15(3) TFEU.
- (13) For those reasons, the Commission considers that none of the parts of the amended initiative manifestly fall outside the framework of the Commission's powers to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties.
- (14) That conclusion is without prejudice to the assessment of whether the concrete substantive conditions required for the Commission to act, including compliance with the principles of proportionality and subsidiarity and compatibility with fundamental rights, would be met in this case.
- (15) The group of organisers has provided appropriate evidence that it fulfils the requirements laid down in Article 5(1) and (2) of Regulation (EU) 2019/788 and has designated the contact persons in accordance with Article 5(3), first subparagraph, of that Regulation.
- (16) The amended initiative is not manifestly abusive, frivolous or vexatious, nor is it manifestly contrary to the values of the Union as set out in Article 2 of the Treaty on European Union or to the rights enshrined in the Charter of Fundamental Rights of the European Union.
- (17) The initiative entitled 'Trust and Freedom' should therefore be registered.
- (18) The conclusion that the conditions for registration under Article 6(3) of Regulation (EU) 2019/788 are fulfilled does not imply that the Commission in any way confirms the factual correctness of the content of the amended initiative, which is the sole responsibility of the group of organisers of the initiative. The content of the amended initiative only expresses the views of the group of organisers, and can in no way be taken to reflect the views of the Commission,

HAS ADOPTED THIS DECISION:

*Article 1*

The European citizens' initiative entitled 'Trust and Freedom' shall be registered.

*Article 2*

This Decision is addressed to the group of organisers of the citizens' initiative 'Trust and Freedom', represented by Ms Justyna Magdalena WALKER and Ms Helena Maria TENDER DA COSTA CABRAL acting as contact persons.

Done at Brussels, 8.11.2023

*For the Commission*  
*Věra JOUROVÁ*  
*Vice-President*

