Official Journal of the European Union

L 231

English edition

Legislation

Volume 63

17 July 2020

Contents

([1]) Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2020/1040 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 July 2020

amending Regulation (EU) 2016/1628 as regards its transitional provisions in order to address the impact of the COVID-19 crisis

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Regulation (EU) 2016/1628 of the European Parliament and of the Council ([3]) lays down requirements relating to emission limits for gaseous and particulate pollutants and EU type-approval procedures for various categories of engines for non-road mobile machinery.

(2) The dates applicable to the new emission limit values, referred to as 'Stage V' in Regulation (EU) 2016/1628, are set out in order to provide manufacturers with clear and comprehensive information and an appropriate period of time for the transition to Stage V, whilst at the same time substantially reducing the administrative burden for approval authorities.

(3) The COVID-19 outbreak has caused a disruption in the supply chain of critical parts and components, which has led to delays for engines and machinery fitted with those engines that comply with less stringent emission limit values than those of Stage V and that need to be placed on the market before the dates set out in Regulation (EU) 2016/1628.

(4) As a result of the disruption caused by the COVID-19 outbreak, it is very likely that non-road mobile machinery manufacturers, referred to as 'original equipment manufacturers' or 'OEMs' in Regulation (EU) 2016/1628, will not be able to ensure that engines and the machinery fitted with those engines benefiting from the transition period under Regulation (EU) 2016/1628 meet the deadlines set out in that Regulation without these manufacturers sustaining serious economic damage.

([1]) Opinion of 11 June 2020 (not yet published in the Official Journal).

([2]) Position of the European Parliament of 10 July 2020 (not yet published in the Official Journal) and decision of the Council of 14 July 2020.

([3]) Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

(5) Given the current circumstances, and in order to ensure the smooth functioning of the internal market, to provide legal certainty, and to avoid potential market disruption, it is necessary to prolong certain transitional provisions of Regulation (EU) 2016/1628.

(6) Given that the prolongation of the transitional provisions will have no environmental impact, as the transition engines concerned have already been produced, coupled with the fact that it is difficult to predict the exact duration of the delays caused by the COVID-19 disruption, the extension of the relevant periods should be 12 months.

(7) Since the objective of this Regulation, namely to prolong certain transitional provisions of Regulation (EU) 2016/1628, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union ('TEU'). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(8) In view of the urgency entailed by the exceptional circumstances caused by the COVID-19 outbreak, it was considered to be appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.

(9) Regulation (EU) 2016/1628 should therefore be amended accordingly.

(10) In view of the fact that the transition period provided for in Regulation (EU) 2016/1628 for certain engine sub-categories is to expire on 31 December 2020 and that OEMs had until 30 June 2020 to produce non-road mobile machinery fitted with transition engines of those sub-categories, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union* and should apply from 1 July 2020. Such an application is warranted by the unforeseeable and sudden nature of the COVID-19 outbreak as well as by the need to ensure legal certainty and equal treatment of OEMs regardless of whether they produce non-road mobile machinery before or after the date of entry into force of this Regulation,

HAVE ADOPTED THIS REGULATION:

Article 1

Article 58 of Regulation (EU) 2016/1628 is amended as follows:

(1) paragraph 5 is amended as follows:

(a) the second subparagraph is replaced by the following:

'For engines of sub-categories of category NRE for which the date set out in Annex III for the placing on the market of Stage V engines is 1 January 2020, Member States shall authorise the extension of the transition period and of the 18-month period referred to in the first subparagraph by an additional 12 months for OEMs with a total yearly production of less than 100 units of non-road mobile machinery equipped with internal combustion engines. For the purposes of the calculation of that total yearly production, all OEMs under the control of the same natural or legal person shall be considered to be a single OEM.';

(b) the third subparagraph is replaced by the following:

'For engines of sub-categories of category NRE for which the date set out in Annex III for the placing on the market of Stage V engines is 1 January 2020, used in mobile cranes, the transition period and the 18-month period referred to in the first subparagraph shall be extended by 12 months.';

(c) the following subparagraph is added:

'For engines of all sub-categories for which the date set out in Annex III for the placing on the market of Stage V engines is 1 January 2019, except for the engines referred to in the fourth subparagraph, the transition period and the 18-month period referred to in the first subparagraph shall be extended by 12 months.';

(2) in paragraph 7, the following point is added:

'(d) 36 months from the applicable date for the placing on the market of engines set out in Annex III, in the case set out in the fifth subparagraph of paragraph 5.'.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 July 2020.

For the European Parliament	*For the Council*
The President	*The President*
D. M. SASSOLI	J. KLOECKNER

REGULATION (EU) 2020/1041 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 July 2020

amending Regulation (EU) No 1303/2013 as regards the resources for the specific allocation for the Youth Employment Initiative

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 177 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Regulation (EU) No 1303/2013 of the European Parliament and of the Council ([3]) lays down the common and general rules applicable to the European Structural and Investment Funds.

(2) The general budget of the European Union for the financial year 2020 ([4]) amended the total amount of resources for the Youth Employment Initiative ('YEI') by increasing commitment appropriations for the specific allocation for the YEI in 2020 by EUR 28 333 334 in current prices and increasing the total amount of commitment appropriations for the specific allocation for the YEI for the entire programming period to EUR 4 556 215 406 in current prices.

(3) For 2020, the additional resources of EUR 23,7 million in 2011 prices are funded by the Global Margin for Commitments within the margin of the multiannual financial framework for the years 2014–2020.

(4) In view of the urgency to amend the programmes which support the YEI in order to include the additional resources for the specific allocation for the YEI before the end of 2020, it was considered to be appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.

(5) Regulation (EU) No 1303/2013 should therefore be amended accordingly.

(6) This Regulation should enter into force as a matter of urgency on the day following that of its publication in the *Official Journal of the European Union*,

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([1]) Opinion of 10 June 2020 (not yet published in the Official Journal).

([2]) Position of the European Parliament of 8 July 2020 (not yet published in the Official Journal) and decision of the Council of 14 July 2020.

([3]) Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006 (OJ L 347, 20.12.2013, p. 320).

([4]) OJ L 57, 27.2.2020, p. 1.

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1303/2013 is amended as follows:

(1) in Article 91, paragraph 1 is replaced by the following:

'1. The resources for economic, social and territorial cohesion available for budgetary commitment for the period 2014–2020 shall be EUR 330 105 627 309 in 2011 prices, in accordance with the annual breakdown set out in Annex VI, of which EUR 325 938 694 233 represents the global resources allocated to the ERDF, the ESF and the Cohesion Fund, and EUR 4 166 933 076 represents a specific allocation for the YEI. For the purposes of programming and subsequent inclusion in the budget of the Union, the amount of resources for economic, social and territorial cohesion shall be indexed at 2 % per year.';

(2) in Article 92, paragraph 5 is replaced by the following:

'5. Resources for the YEI shall amount to EUR 4 166 933 076, of which EUR 23,7 million constitutes the additional resources for 2020. Those resources shall be complemented by ESF targeted investment in accordance with Article 22 of the ESF Regulation.

Member States that benefit from the additional resources for the specific allocation for the YEI may request the transfer of up to 50 % of these additional resources to the ESF in order to constitute the corresponding ESF targeted investment as required by Article 22(1) of the ESF Regulation. Such a transfer shall be made to the respective categories of region corresponding to the categorisation of the regions eligible for the increase of the specific allocation for the YEI. Member States shall request the transfer in the request for amendment of the programme in accordance with Article 30(1) of this Regulation. Resources allocated to past years may not be transferred.

The second subparagraph of this paragraph shall apply to any additional resources for specific allocation for the YEI allocated in 2019 and 2020.';

(3) Annex VI is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 July 2020.

For the European Parliament	*For the Council*
The President	*The President*
D. M. SASSOLI	J. KLOECKNER

ANNEX

'ANNEX VI

ANNUAL BREAKDOWN OF COMMITMENT APPROPRIATIONS FOR THE YEARS 2014 TO 2020

Adjusted annual profile (including the YEI top-up)

	2014	2015	2016	2017	2018	2019	2020	Total
EUR, 2011 prices	34 108 069 924	55 725 174 682	46 044 910 736	48 027 317 164	48 341 984 652	48 811 933 191	49 046 236 960	330 105 627 309'

REGULATION (EU) 2020/1042 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 July 2020

laying down temporary measures concerning the time limits for the collection, the verification and the examination stages provided for in Regulation (EU) 2019/788 on the European citizens' initiative in view of the COVID-19 outbreak

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 24 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure ([1]),

Whereas:

(1) On 11 March 2020, the World Health Organization announced that the COVID-19 outbreak had become a worldwide pandemic. The Member States have been affected in a dramatic and exceptional way by the consequences of that pandemic. They have taken a series of restrictive measures to stop or slow down the transmission of COVID-19, including lockdown measures to restrict the free movement of their citizens, the prohibition of public events, and the closure of shops, restaurants and schools. Those measures have led to a standstill of public life in almost all Member States.

(2) The measures taken by the Member States have inevitably also had a serious impact on the European citizens' initiative. For European citizens' initiatives ('initiatives') to be valid, Regulation (EU) 2019/788 of the European Parliament and of the Council ([2]) requires the organisers to collect at least 1 million statements of support in at least one quarter of the Member States within a period of 12 months. The collection of statements of support in paper form, local campaigning and the organisation of public events, which are of significant importance for a successful initiative, have become substantially more difficult because of the measures taken in response to the COVID-19 pandemic.

(3) Member States and the Union institutions also have certain legal obligations under Regulation (EU) 2019/788. Those obligations are subject to strict time limits from which Regulation (EU) 2019/788 does not allow any derogations.

(4) The Treaty on European Union grants citizens of the Union the right to approach the Commission with a request inviting it to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties. The European citizens' initiative is one of the main instruments for citizens of the Union to engage in an easy and accessible way in the democratic and political debate about the Union and to put issues that matter to them on the agenda of the Union.

(5) In the current exceptional circumstances and in particular because of the measures taken by the Member States in response to the COVID-19 pandemic, temporary measures are necessary to preserve the effectiveness of the European citizens' initiative as an instrument, and to provide legal certainty regarding possible extensions of the applicable time limits.

(6) Member States have indicated that, in order to be able to continue to monitor and control the public health situation, they will only gradually reduce the level of restrictions introduced by the measures taken in response to the COVID-19 pandemic. It is therefore appropriate to extend the period for the collection of statements of support by six months, covering the period from 11 March 2020, when the World Health Organization announced that the COVID-19 outbreak had become a pandemic. That extension is based on the assumption that at least during the first six months from 11 March 2020 at least a quarter of Member States or a number of Member States representing more than 35 % of the Union population will have measures in place that will substantially hamper the organisers' ability to collect statements of support in paper form and to carry out local campaigning. The maximum collection period for statements of support for initiatives in respect of which the collection period was ongoing on 11 March 2020 should therefore be extended by six months. Moreover, for initiatives in respect of which the collection period started between 11 March and 11 September 2020, the collection period should be extended until 11 September 2021.

([1]) Position of the European Parliament of 9 July 2020 (not yet published in the Official Journal) and decision of the Council of 14 July 2020.

([2]) Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative (OJ L 130, 17.5.2019, p. 55).

(7) In order to ensure uniform conditions for the implementation of this Regulation and given that the end of the pandemic in the Union is difficult to predict, implementing powers should be conferred on the Commission to further extend the collection period in respect of initiatives for which the collection period is still ongoing on 11 September 2020 where measures in response to the COVID-19 pandemic which substantially hamper the ability of organisers to collect statements of support in paper form and to inform the public of their ongoing initiatives continue to exist after that date in at least a quarter of Member States or a number of Member States representing more than 35 % of the Union population. The six-month extension of the collection period provided for by this Regulation should give the Commission sufficient time to decide whether a further extension of the collection period is justified. Those implementing powers should also allow the Commission to adopt implementing acts to extend the collection period in the event of a new public health crisis linked to a new outbreak of COVID-19, provided that at least a quarter of Member States or a number of Member States representing more than 35 % of the Union population have taken measures that are likely to have the same effect. When adopting those implementing acts, the Commission should indicate the initiatives concerned, with the new end date of their collection periods following any extensions granted, as well as the factual circumstances justifying the granting of such extensions. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([3]).

(8) In its assessment before adopting implementing acts that extend the collection period, the Commission should take into account whether the measures taken by Member States in response to the COVID-19 pandemic or in response to a new COVID-19 outbreak substantially hamper the ability of organisers to collect statements of support in paper form and carry out local campaigning.

(9) The Commission should inform the organisers of the initiatives concerned and the Member States of any extension of the collection period together with the new end date of the collection period in respect of each initiative concerned. In accordance with the Commission's obligation to inform under Article 4(3) of Regulation (EU) 2019/788, those new end dates should also be indicated in the online register and on the public website on the European citizens' initiative.

(10) The measures taken by the Member States in response to the COVID-19 pandemic may significantly affect the ability of competent authorities to complete the verification of statements of support for a given initiative within the time limit of three months laid down in Regulation (EU) 2019/788. For example, there may be fewer staff available, or the competent authorities may have additional tasks and responsibilities as a consequence of the pandemic.

(11) Member States should ensure that, despite the measures taken in response to the COVID-19 pandemic, their administrations function as normally as possible. However, in exceptional circumstances, a Member State should be allowed to submit a reasoned request to the Commission for an extension of the verification period. The request should be substantiated and take into account the effects of pandemic-related measures on the functioning of that Member State's competent authorities. In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to grant the requested extension. The extension should not be longer than the initial verification period.

(12) Due to the measures taken by the Member States in response to the COVID-19 pandemic, it may be difficult for Union institutions to organise meetings with organisers or public hearings in the context of the examination of valid initiatives in the Member State in which they intend to organise such meetings or hearings. In such cases, the institutions should be allowed to postpone those meetings or hearings until a date when they are possible in view of the public health situation in that Member State. Where the public hearing is postponed, the Commission should be able to delay the adoption of its communication setting out its legal and political conclusions on the initiative until three months after the public hearing has taken place, to enable the Commission to take due account of the findings at the hearing.

(13) Where the period for collection, verification or examination is extended due to the measures taken by the Member States in response to the COVID-19 pandemic, the retention periods for statements of support laid down in Regulation (EU) 2019/788 should be extended accordingly.

([3]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(14) Due to the unforeseeable and sudden nature of the COVID-19 outbreak, and the resulting measures taken by the Member States, which have been repeatedly extended, as well as the length of time required by the legislative procedures for the adoption of relevant measures, it has not been possible to adopt the temporary measures provided for in this Regulation in time as regards some individual initiatives. For that reason, the temporary measures should also cover the period before the entry into force of this Regulation.

(15) This Regulation should also apply to initiatives registered before 1 January 2020 under Regulation (EU) No 211/2011 of the European Parliament and of the Council ([4]), to which the provisions of that Regulation on the collection of statements of support and on verification and certification by Member States continue to apply pursuant to Article 27 of Regulation (EU) 2019/788.

(16) Considering the temporary nature of the Member States' measures in response to the COVID-19 pandemic, the period of application of this Regulation should also be limited.

(17) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of preserving the efficacy of the European citizens' initiative instrument during the COVID-19 pandemic to lay down temporary measures concerning the time-limits for the collection, the verification and the examination stages provided for in Regulation (EU) 2019/788. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with Article 5(4) of the Treaty on European Union.

(18) This Regulation should be adopted as a matter of urgency, so that situations of legal uncertainty affecting citizens, organisers, national administrations and the Union institutions remain as short as possible, in particular where the relevant time periods for the collection of statements of support, verification and examination in respect of a number of initiatives have already ended or are about to end.

(19) In view of the urgency entailed by the exceptional circumstances caused by the COVID-19 outbreak, it was considered to be appropriate to provide for an exception to the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.

(20) In order to allow for the prompt application of the measures provided for in this Regulation, this Regulation should enter into force as a matter of urgency on the day following that of its publication in the *Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down temporary measures applicable to the collection, the verification and the examination periods for registered European citizens' initiatives under Regulation (EU) 2019/788 and Regulation (EU) No 211/2011 ('initiatives'), in the context of the measures taken by the Member States in response to the COVID-19 pandemic.

Article 2

Extension of time limits for the collection of statements of support

1. Notwithstanding Article 8(1) of Regulation (EU) 2019/788 and Article 5(5) of Regulation (EU) No 211/2011, where the collection of statements of support for an initiative was ongoing on 11 March 2020, the maximum collection period shall be extended for a period of six months in respect of that initiative.

Where the collection of statements of support for an initiative started between 11 March 2020 and 11 September 2020, the collection period shall be extended until 11 September 2021, in respect of that initiative.

The Commission shall inform the organisers of the initiatives concerned and the Member States of the extension provided for in the first and second subparagraphs of this paragraph. It shall indicate the new end date of the collection period for each initiative in the online register referred to in Article 4(3) of Regulation (EU) 2019/788.

([4]) Regulation (EU) No 211/2011 of the European Parliament and of the Council of 16 February 2011 on the citizens' initiative (OJ L 65, 11.3.2011, p. 1).

2. The Commission may adopt implementing acts to further extend the maximum collection period for statements of support for initiatives referred to in paragraph 1, where at least a quarter of Member States or a number of Member States representing more than 35 % of the Union population continue to apply after 11 September 2020 measures in response to the COVID-19 pandemic which substantially hamper the ability of organisers to collect statements of support in paper form and to inform the public of their ongoing initiatives.

The Commission may also adopt implementing acts to extend the maximum collection period for statements of support for initiatives in respect of which collection is ongoing at the moment of a new COVID-19 outbreak where at least a quarter of Member States or a number of Member States representing more than 35 % of the Union population apply measures that negatively affect organisers of those initiatives to the same extent as the measures referred to in the first subparagraph.

The implementing acts provided for in the first and second subparagraphs shall identify which initiatives are concerned and the new end date of their collection period.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 6(2).

The duration of each extension under this paragraph shall be three months.

For the purpose of the assessment by the Commission of whether the requirements for the adoption of implementing acts referred to in the first and second subparagraphs are fulfilled, the Member States shall provide the Commission, upon request, with information on the measures that they have taken or intend to take in response to the COVID-19 pandemic or in response to a new COVID-19 outbreak.

The Commission shall notify its decision to the organisers and inform the Member States of any extension granted in respect of each initiative concerned. It shall publish its decision in the online register referred to in Article 4(3) of Regulation (EU) 2019/788.

3. Notwithstanding paragraphs 1 and 2, the total duration of the collection period shall not exceed 24 months.

Article 3

Extension of time limits for the verification of statements of support by the Member States

1. Notwithstanding Article 12(4) of Regulation (EU) 2019/788 and Article 8(2) of Regulation (EU) No 211/2011, where a Member State considers that due to the measures it has taken in response to the COVID-19 pandemic, it will not be possible to complete the verification of statements of support for a given initiative within the period laid down in those provisions, it may submit a reasoned request for an extension of that period. That request shall be submitted to the Commission at the latest one month before the end of the period concerned.

2. Where, upon a request submitted in accordance with paragraph 1, the Commission finds that the requirements laid down in that paragraph are fulfilled, it shall adopt an implementing act granting an extension of the period referred to in paragraph 1 to the Member State concerned. The extension shall not be less than one month or more than three months.

3. The Commission shall notify its decision to the Member State and inform the organisers of the initiative concerned of the extension. It shall publish its decision in the online register referred to in Article 4(3) of Regulation (EU) 2019/788.

Article 4

Extension of time limits for the examination of valid initiatives

1. Notwithstanding Articles 14(2) and 15(1) of Regulation (EU) 2019/788, where the Commission or the European Parliament have encountered difficulties after 11 March 2020 in organising a meeting with organisers or a public hearing, respectively, because of measures taken in response to the COVID-19 pandemic by the Member State in which those institutions intend to organise the meeting or hearing, they shall organise it as soon as the public health situation in the Member State concerned makes it possible to do so, or, in the event that the organisers agree to participate remotely in the meeting or hearing, as soon as they are able to agree with the institutions on a date for it.

2. Notwithstanding Article 15(2) of Regulation (EU) 2019/788, where the European Parliament postpones the public hearing pursuant to paragraph 1 of this Article, the Commission shall adopt its communication setting out its legal and political conclusions on the initiative within three months after the public hearing.

Article 5

Extension of time limits for retention of personal data

1. Notwithstanding Article 19(5) of Regulation (EU) 2019/788 where the maximum collection period or verification period for a given initiative is extended in accordance with Article 2 or 3 of this Regulation, the time limit of 21 months within which statements of support and copies thereof are to be destroyed shall be extended by the same period.

2. Notwithstanding Article 19(8) of Regulation (EU) 2019/788, where the maximum collection period, verification period, or examination period for a given initiative is extended in accordance with Article 2, 3 or 4 of this Regulation, the time limits within which records of email addresses are to be destroyed shall be extended by the same period.

Article 6

Committee procedure

1. The Commission shall be assisted by the committee on the European citizens' initiative established by Article 22 of Regulation (EU) 2019/788. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

Article 7

Retroactive application

Articles 2 to 5 shall have retroactive effect with regard to initiatives of which the collection period, the verification period or the examination period ended between 11 March 2020 and the date of the entry into force of this Regulation.

Article 8

Entry into force

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply until 31 December 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 July 2020.

For the European Parliament	*For the Council*
The President	*The President*
D. M. SASSOLI	J. KLOECKNER

REGULATION (EU) 2020/1043 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 July 2020

on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4)(c) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

After consulting the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([1]),

Whereas:

(1) Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus. On 30 January 2020, the World Health Organization (WHO) declared the outbreak a public health emergency of international concern. On 11 March 2020, WHO characterised COVID-19 as a pandemic.

(2) Directive 2001/83/EC ([2]) and Regulation (EC) No 726/2004 ([3]) of the European Parliament and of the Council require that applications for authorisation to place a medicinal product on the market, in a Member State or in the Union, be accompanied by a dossier containing the results of clinical trials carried out on the product.

(3) It follows from Directive 2001/20/EC of the European Parliament and of the Council ([4]) that, before commencing any clinical trial, sponsors are required to request authorisation from the competent authority of the Member State in which the clinical trial is to be conducted. The purpose of the authorisation is to protect the rights, safety and well-being of clinical trial subjects and to ensure the reliability and robustness of the data generated by the clinical trial.

(4) Under Directive 2001/20/EC, the authorisation for a clinical trial is issued without prejudice to the application of Directives 2001/18/EC ([5]) and 2009/41/EC ([6]) of the European Parliament and of the Council.

(5) Directive 2001/18/EC provides that a deliberate release into the environment of genetically modified organisms ('GMOs') for any purpose other than for placing on the market is subject to a notification to and to written consent by the competent authority of the Member State within whose territory the release is to take place. The notification is to include an environmental risk assessment performed in accordance with Annex II to Directive 2001/18/EC and a technical dossier supplying the information specified in Annex III to that Directive.

([1]) Position of the European Parliament of 10 July 2020 (not yet published in the Official Journal) and decision of the Council of 14 July 2020.

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

([3]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

([4]) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

([5]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

([6]) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

(6) Directive 2009/41/EC provides that the risks to human health and the environment associated with the contained use of genetically modified micro-organisms are to be assessed on a case-by-case basis. To that end, that Directive provides that the user is to assess the risks to human health and the environment that the specific type of contained use may pose, using as a minimum the elements of assessment and the procedure set out in Annex III to that Directive.

(7) Clinical trials necessitate the performance of multiple operations, including the manufacture, transport and storage of the investigational medicinal products, packaging and labelling, the administration thereof to clinical trial subjects and subsequent monitoring of the subjects, and the disposal of waste and unused investigational medicinal products. Those operations may fall within the scope of Directive 2001/18/EC or 2009/41/EC in cases where the investigational medicinal product contains or consists of GMOs.

(8) Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

(9) The complexity of that procedure increases greatly in the case of multi-centre clinical trials conducted in several Member States, as sponsors of clinical trials need to submit multiple requests for authorisation to multiple competent authorities in different Member States in parallel. In addition, national requirements and procedures for the environmental risk assessment and written consent by competent authorities for the deliberate release of GMOs under Directive 2001/18/EC vary greatly from one Member State to another. Whereas in some Member States a single request for authorisation concerning the conduct of the clinical trial and the GMO aspects can be submitted to a single competent authority, in other Member States parallel requests need to be submitted to different competent authorities. Furthermore, some Member States apply Directive 2001/18/EC, others apply Directive 2009/41/EC and there are Member States that apply either Directive 2009/41/EC or 2001/18/EC depending on the specific circumstances of a clinical trial, so it is not possible to determine *a priori* the national procedure that is to be followed. Other Member States apply both Directives simultaneously to different operations within the same clinical trial. Attempts to streamline the process through informal coordination between Member States' competent authorities have been unsuccessful. There are also variations between national requirements as to the content of the technical dossier.

(10) It is therefore particularly difficult to conduct multi-centre clinical trials with investigational medicinal products that contain or consist of GMOs involving several Member States.

(11) The COVID-19 pandemic has created an unprecedented public health emergency that has claimed the life of thousands of people, affecting in particular the elderly and those with pre-existing health conditions. In addition, the very drastic measures that Member States have had to adopt to contain the spread of COVID-19 have inflicted major disruptions to national economies and the Union as a whole.

(12) COVID-19 is a complex disease that affects multiple physiological processes. Potential treatments and vaccines are in development. Some of the vaccines in development contain attenuated viruses or live vectors, which may fall within the definition of a GMO.

(13) In this situation of public health emergency, it is of major interest for the Union that safe and efficacious medicinal products intended to treat or prevent COVID-19 can be developed and be made available within the Union as soon as possible.

(14) To achieve the objective of making available safe and efficacious medicinal products intended to treat or prevent COVID-19, a range of measures have been taken at Union level by the European Medicines Agency (EMA) and by the network of national competent authorities to facilitate, support and speed up the development and marketing authorisation of treatments and vaccines.

(15) To generate the robust clinical evidence necessary to support applications for marketing authorisation of medicinal products intended to treat or prevent COVID-19 multi-centre clinical trials involving several Member States will need to be conducted.

(16) It is of paramount importance that clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 can be conducted within the Union, that they can begin as soon as possible and that they are not delayed due to the complexity of differing national procedures put in place by Member States in implementation of Directives 2001/18/EC and 2009/41/EC.

(17) The main objective of Union legislation on medicinal products is to safeguard public health. That legislative framework is supplemented by the rules in Directive 2001/20/EC laying down specific standards for the protection of clinical trial subjects. Directives 2001/18/EC and 2009/41/EC have as their objective to ensure a high level of protection of human health and the environment through the assessment of the risks from the deliberate release or the contained use of GMOs. In the unprecedented situation of public health emergency created by the COVID-19 pandemic, it is necessary that the protection of public health prevails. Therefore, it is necessary to grant a temporary derogation from the requirements concerning a prior environmental risk assessment and consent under Directives 2001/18/EC and 2009/41/EC for the duration of the COVID-19 pandemic or as long as COVID-19 is a public health emergency. The derogation should be limited to clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19. During the period in which the temporary derogation applies, the environmental risk assessment and consent under Directives 2001/18/EC and 2009/41/EC should not be a prerequisite for the conduct of those clinical trials.

(18) With a view to ensuring a high level of protection of the environment, sites where the genetic modification of wild-type viruses and related activities take place should continue to be required to comply with Directive 2009/41/EC. Therefore, the manufacturing of medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19, including investigational medicinal products, should be excluded from the temporary derogation. In addition, sponsors should be required to implement appropriate measures to minimise negative environmental impacts that, on the basis of the available knowledge, can be expected as a result of the intended or unintended release of investigational medicinal products into the environment.

(19) Consequently, when making an application for marketing authorisation under Directive 2001/83/EC or Regulation (EC) No 726/2004 for medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 for which the clinical trials would be covered by the derogation provided for in this Regulation, the applicant should not be required to include the written consent of the competent authority for the deliberate release into the environment of GMOs for research and development purposes as set out in Part B of Directive 2001/18/EC.

(20) This Regulation does not affect the Union rules on medicinal products for human use. As provided in Regulation (EC) No 726/2004, the environmental impact of medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 will continue to be assessed by the EMA in parallel with the evaluation of the quality, safety and efficacy of the medicinal product concerned, respecting the environmental safety requirements set out in Directive 2001/18/EC.

(21) Directive 2001/20/EC continues to apply and clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 continue to require written authorisation granted by the competent authority in each Member State in which the trial will be conducted. Compliance with ethical requirements and good clinical practice in the conduct of clinical trials continues to be mandatory as well as compliance with good manufacturing practice in the manufacture or importation of investigational medicinal products containing or consisting of GMOs.

(22) As a general rule, no medicinal product may be placed on the market in the Union or in a Member State unless a marketing authorisation has been granted by the competent authorities under Directive 2001/83/EC or Regulation (EC) No 726/2004. Nonetheless, Directive 2001/83/EC and Regulation (EC) No 726/2004 provide for exceptions from that requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, for compassionate use or in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, Article 5(1) of Directive 2001/83/EC allows Member States to fulfil special needs, to exclude from the provisions of that Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under his or her direct personal responsibility. Under Article 5(2) of Directive 2001/83/EC, Member States may also temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Under Article 83(1) of Regulation (EC) No 726/2004, Member States may make a medicinal product for human use available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorised medicinal product.

(23) Doubts have been expressed by some Member States about the interaction of those provisions of Directive 2001/83/EC and Regulation (EC) No 726/2004 with the GMO legislation. In light of the urgent need of making vaccines or treatments for COVID-19 available to the public as soon as they are ready for this purpose and to avoid delays or uncertainties as regards the status of these products in certain Member States, it is appropriate that, where Member States adopt decisions pursuant to Article 5(1) and (2) of Directive 2001/83/EC or Article 83(1) of Regulation (EC) No 726/2004 concerning medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19, an environmental risk assessment or consent in accordance with Directive 2001/18/EC or Directive 2009/41/EC are not a prerequisite.

(24) Since the objectives of this Regulation, namely to provide a temporary derogation from Union legislation on GMOs to ensure that the conduct of clinical trials in the territory of several Member States with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 is not delayed and to clarify the application of Article 5(1) and (2) of Directive 2001/83/EC and Article 83(1) of Regulation (EC) No 726/2004 as regards medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity, as set out in Article 5 of the Treaty on European Union ('TEU'). Due to the importance of ensuring a high level of protection of the environment in all policies and in accordance with the principle of proportionality as set out in that Article, this Regulation should be limited to the present situation of emergency which involves an urgent threat to human health where it is not possible to attain otherwise the objective to protect human health and does not go beyond what is necessary in order to achieve those objectives.

(25) In view of that urgency, it was considered to be appropriate to provide for an exception from the eight-week period referred to in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.

(26) Given the objectives of this Regulation, to ensure that clinical trials with investigational medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19 can start without delay and to clarify the application of Article 5(1) and (2) of Directive 2001/83/EC and Article 83(1) of Regulation (EC) No 726/2004 as regards medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19, this Regulation should enter into force as a matter of urgency on the day following that of its publication in *the Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

Article 1

For the purposes of this Regulation, the following definitions apply:

(1) 'clinical trial' means clinical trial as defined in point (a) of Article 2 of Directive 2001/20/EC;

(2) 'sponsor' means sponsor as defined in point (e) of Article 2 of Directive 2001/20/EC;

(3) 'investigational medicinal product' means investigational medicinal product as defined in point (d) of Article 2 of Directive 2001/20/EC;

(4) 'medicinal product' means medicinal product as defined in point 2 of Article 1 of Directive 2001/83/EC;

(5) 'genetically modified organism' or 'GMO' means genetically modified organism as defined in point (2) of Article 2 of Directive 2001/18/EC.

Article 2

1. All operations related to the conduct of clinical trials, including packaging and labelling, storage, transport, destruction, disposal, distribution, supply, administration or use of investigational medicinal products for human use containing or consisting of GMOs intended to treat or prevent COVID-19, with the exception of the manufacturing of the investigational medicinal products, shall not require a prior environmental risk assessment or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC or Articles 4 to 13 of Directive 2009/41/EC when these operations relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.

2. Sponsors shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the investigational medicinal product into the environment.

3. By way of derogation from point (a) of Article 6(2) of Regulation (EC) No 726/2004 and from the second indent of the fourth paragraph of point 1.6 of Part I of Annex I to Directive 2001/83/EC, in applications for marketing authorisation for medicinal products containing or consisting of GMOs intended to treat or prevent COVID-19, the applicant shall not be required to include a copy of the competent authority's written consent to the deliberate release into the environment of GMOs for research and development purposes in accordance with Part B of Directive 2001/18/EC.

Article 3

1. Articles 6 to 11 and 13 to 24 of Directive 2001/18/EC as well as Articles 4 to 13 of Directive 2009/41/EC shall not apply to operations related to the supply and use of medicinal products containing or consisting of GMOs that are intended to treat or prevent COVID-19, including packaging and labelling, storage, transport, destruction, disposal, distribution or administration, with the exception of the manufacturing of the medicinal products, in any of the following cases:

(a) where such medicinal products have been excluded from the provisions of Directive 2001/83/EC by a Member State pursuant to Article 5(1) of that Directive;

(b) where such medicinal products have been temporarily authorised by a Member State pursuant to Article 5(2) of Directive 2001/83/EC; or

(c) where such medicinal products are made available by a Member State pursuant to Article 83(1) of Regulation (EC) No 726/2004.

2. Where feasible, Member States shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal product into the environment.

Article 4

1. This Regulation shall apply as long as WHO has declared COVID-19 to be a pandemic or as long as an implementing act by which the Commission recognises a situation of public health emergency due to COVID-19 in accordance with Article 12 of Decision No 1082/2013/EU of the European Parliament and of the Council [7] applies.

2. The Commission shall, when the conditions for the application of this Regulation referred to in paragraph 1 are no longer fulfilled, publish a notice in the *Official Journal of the European Union* to that effect.

3. Clinical trials within the scope of Article 2 of this Regulation that have been authorised under Directive 2001/20/EC prior to the publication of the notice referred to in paragraph 2 of this Article may validly continue and be used in support of an application for marketing authorisation in the absence of an environmental risk assessment or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC or Articles 4 to 13 of Directive 2009/41/EC.

Article 5

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 July 2020.

For the European Parliament	*For the Council*
The President	*The President*
D. M. SASSOLI	J. KLOECKNER

[7] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

CORRIGENDA

Corrigendum to Council Implementing Regulation (EU) 2020/510 of 7 April 2020 implementing Regulation (EU) No 359/2011 concerning restrictive measures directed against certain persons, entities and bodies in view of the situation in Iran

(Official Journal of the European Union L 113 of 8 April 2020)

On page 15, the Annex, Persons, entry 74, first column ('Name'):

for: 'REZVANMA- NESH Ali',

read: 'REZVANMA-NESH Ali'.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

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