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Contents

I *Legislative acts*

REGULATIONS

- ★ **Regulation (EU) 2020/558 of the European Parliament and of the Council of 23 April 2020 amending Regulations (EU) No 1301/2013 and (EU) No 1303/2013 as regards specific measures to provide exceptional flexibility for the use of the European Structural and Investments Funds in response to the COVID-19 outbreak** 1
- ★ **Regulation (EU) 2020/559 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) No 223/2014 as regards the introduction of specific measures for addressing the outbreak of COVID-19** 7
- ★ **Regulation (EU) 2020/560 of the European Parliament and of the Council of 23 April 2020 amending Regulations (EU) No 508/2014 and (EU) No 1379/2013 as regards specific measures to mitigate the impact of the COVID-19 outbreak in the fishery and aquaculture sector** 11
- ★ **Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions ⁽¹⁾** 18

II *Non-legislative acts*

REGULATIONS

- ★ **Council Implementing Regulation (EU) 2020/562 of 23 April 2020 implementing Regulation (EU) No 401/2013 concerning restrictive measures in respect of Myanmar/Burma** 23

DECISIONS

- ★ **Council Decision (CFSP) 2020/563 of 23 April 2020 amending Decision 2013/184/CFSP concerning restrictive measures against Myanmar/Burma** 25

⁽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.

★ Council Decision (CFSP) 2020/564 of 23 April 2020 amending Decision (CFSP) 2018/298 on Union support for the activities of the Preparatory Commission for the Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO) in order to strengthen its monitoring and verification capabilities and in the framework of the implementation of the EU Strategy against Proliferation of Weapons of Mass Destruction	27
---	----

RULES OF PROCEDURE

★ Decision of the Management Board of the Agency for Support for BEREC (BEREC Office) of 10 September 2019 laying down internal rules concerning restrictions of certain rights of data subjects in relation to the processing of personal data in the framework of activities carried out by the BEREC Office	28
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I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2020/558 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 April 2020

amending Regulations (EU) No 1301/2013 and (EU) No 1303/2013 as regards specific measures to provide exceptional flexibility for the use of the European Structural and Investments Funds in response to 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 Articles 177, 178 and point (a) of Article 322(1) 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 Court of Auditors ⁽¹⁾,

After consulting the European Economic and Social Committee,

After consulting the Committee of the Regions,

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

Whereas:

- (1) Member States have been affected by the consequences of the COVID-19 outbreak in an unprecedented manner. The current public health crisis hampers growth in Member States, which in turn aggravates the serious liquidity shortages due to the sudden and significant increase in public investments needed in their healthcare systems and other sectors of their economies. That has created an exceptional situation which needs to be addressed with specific measures.
- (2) In order to respond to the impact of the public health crisis, Regulations (EU) No 1301/2013 ⁽³⁾ and (EU) No 1303/2013 ⁽⁴⁾ of the European Parliament and of the Council have already been amended, by Regulation (EU) 2020/460 of the European Parliament and of the Council ⁽⁵⁾, to allow for more flexibility in the implementation of

⁽¹⁾ Opinion of 14 April 2020 (not yet published in the Official Journal).

⁽²⁾ Position of the European Parliament of 17 April 2020 (not yet published in the Official Journal) and decision of the Council of 22 April 2020.

⁽³⁾ Regulation (EU) No 1301/2013 of the European Parliament and of the Council of 17 December 2013 on the European Regional Development Fund and on specific provisions concerning the Investment for growth and jobs goal and repealing Regulation (EC) No 1080/2006 (OJ L 347, 20.12.2013, p. 289).

⁽⁴⁾ 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).

⁽⁵⁾ Regulation (EU) 2020/460 of the European Parliament and of the Council of 30 March 2020 amending Regulations (EU) No 1301/2013, (EU) No 1303/2013 and (EU) No 508/2014 as regards specific measures to mobilise investments in the healthcare systems of Member States and in other sectors of their economies in response to the COVID-19 outbreak (Coronavirus Response Investment Initiative) (OJ L 99, 31.3.2020, p. 5).

the programmes supported by the European Regional Development Fund (the 'ERDF'), the European Social Fund (the 'ESF') and the Cohesion Fund (collectively 'the Funds') and the European Maritime and Fisheries Fund (the 'EMFF'). In order to contribute to an effective response to the current public health crisis, the scope of support from the ERDF was considerably expanded.

- (3) However, the serious negative effects on Union economies and societies are becoming worse. It is therefore necessary to provide for exceptional additional flexibility to Member States to enable them to respond to this unprecedented public health crisis by enhancing the possibility to mobilise all non-utilised support from the Funds.
- (4) With a view to alleviating the burden on public budgets responding to the public health crisis, Member States should be given the exceptional possibility to request, for cohesion policy programmes, a co-financing rate of 100 % to be applied for the accounting year 2020-2021, in accordance with budget appropriations and subject to available funding. Based on an assessment of the application of that exceptional co-financing rate, the Commission could propose an extension of this measure.
- (5) In order to provide additional flexibility to Member States for the reallocation of resources with a view to providing tailor-made responses to the public health crisis, possibilities for financial transfers under the Investment for growth and jobs goal between the ERDF, the ESF and the Cohesion Fund should be introduced or enhanced. Furthermore, transfer possibilities between categories of regions should also be exceptionally increased for Member States given the widespread impact of the public health crisis, while respecting Treaty objectives for cohesion policy. Such transfers should not affect the resources under the European territorial cooperation goal, the additional allocations to outermost regions, support to the Youth Employment Initiative (YEI) or the Fund for European Aid to the Most Deprived.
- (6) In order to enable Member States to deploy quickly available resources to respond to the COVID-19 outbreak and taking into account that, given the advanced stage of implementation of the 2014-2020 programming period, the reallocation of resources can only concern resources available for programming for the year 2020, it is justified to exempt, on an exceptional basis, Member States from the need to comply with thematic concentration requirements for the remainder of the programming period.
- (7) In order to enable Member States to concentrate on the necessary response to the COVID-19 outbreak and to reduce administrative burdens, certain procedural requirements linked to programme implementation and audits should be simplified. In particular, Partnership Agreements should no longer be amended for the remainder of the programming period, whether to reflect prior changes in operational programmes or to introduce any other changes. The deadlines for the submission of the annual implementation reports for the year 2019 and for the transmission of the Commission's summary report based on those annual implementation reports should be postponed. As regards the Funds and the EMFF, an extended possibility for audit authorities to make use of a non-statistical sampling method should also be explicitly provided for in respect of the accounting year 2019-2020.
- (8) It is appropriate to specify that eligibility of expenditure should be exceptionally allowed for completed or fully implemented operations that foster crisis response capacities in the context of the COVID-19 outbreak. It should be possible for such operations to be selected even before the necessary programme amendment is approved by the Commission. Specific arrangements for invoking the COVID-19 outbreak as a reason of *force majeure* in the context of decommitment should be provided.
- (9) In order to reduce administrative burdens and delays in implementation where changes in financial instruments are necessary to provide for an effective response to a public health crisis, the review and update of the *ex ante* assessment and updated business plans or equivalent documents, as part of the supporting documents demonstrating that support provided was used for its intended purpose, should no longer be required for the remainder of the programming period. The possibilities for the support for working capital through financial instruments under the European Agricultural Fund for Rural Development (EAFRD) should be extended.
- (10) In order to ensure that Member States can make full use of support from the Funds and the EMFF, additional flexibility should be provided for the calculation of the payment of the final balance at the end of the programming period.

- (11) In order to facilitate the transfers authorised under this Regulation, the condition laid down in point (f) of Article 30(1) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽⁹⁾ regarding use of appropriations for the same objective should not apply in respect of transfers proposed under this Regulation.
- (12) In order to ensure consistency between the approach taken under the Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak and *de minimis* aid, on the one hand, and the conditions for providing support to undertakings in difficulty under the ERDF, on the other, Regulation (EU) No 1301/2013 should be amended to allow for the grant of support to such undertakings in those specific circumstances.
- (13) Since the objectives of this Regulation, namely to respond to the impact of the public health crisis by introducing flexibility measures in the field of providing support from the European Structural and Investment Funds ('ESI Funds'), cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the proposed action, 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 to achieve those objectives.
- (14) Given the urgency of the situation related to the COVID-19 outbreak, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*.
- (15) In view of the COVID-19 outbreak and the urgent need to address the associated public health crisis and its social and economic consequences, 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.
- (16) Regulations (EU) No 1301/2013 and (EU) No 1303/2013 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EU) No 1301/2013

In Article 3(3) of Regulation (EU) No 1301/2013, point (d) is replaced by the following:

‘(d) undertakings in difficulty as defined in Union State aid rules; undertakings receiving support complying with Temporary Framework for State aid measures (*) or Commission Regulations (EU) No 1407/2013 (**), (EU) No 1408/2013 (***) and (EU) No 717/2014 (****) shall not be regarded as undertakings in difficulty for the purpose of this point;

(*) OJ C 91 I, 20.3.2020, p. 1.

(**) Commission Regulation (EU) No 1407/2013 of 18 December 2013 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to *de minimis* aid (OJ L 352, 24.12.2013, p. 1).

(***) Commission Regulation (EU) No 1408/2013 of 18 December 2013 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to *de minimis* aid in the agriculture sector (OJ L 352, 24.12.2013, p. 9).

(****) Commission Regulation (EU) No 717/2014 of 27 June 2014 on the application of Articles 107 and 108 of the Treaty on the Functioning of the European Union to *de minimis* aid in the fishery and aquaculture sector (OJ L 190, 28.6.2014, p. 45).’.

⁽⁹⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

Article 2

Amendments to Regulation (EU) No 1303/2013

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

- (1) in Part Two, Title II, the following Chapter is added:

*‘CHAPTER V****Exceptional measures for the use of the ESI Funds in response to the COVID-19 outbreak****Article 25a***Exceptional measures for the use of the ESI Funds in response to the COVID-19 outbreak**

1. By way of derogation from Article 60(1) and the first and fourth subparagraphs of Article 120(3), at the request of a Member State, a co-financing rate of 100 % may be applied to expenditure declared in payment applications during the accounting year starting 1 July 2020 and ending 30 June 2021 for one or more priority axes in a programme supported by the ERDF, the ESF or the Cohesion Fund.

Requests for modification of the co-financing rate shall be submitted in accordance with the procedure for the amendment of programmes set out in Article 30 and shall be accompanied by a revised programme or programmes. The co-financing rate of 100 % shall apply only if the relevant amendment of the operational programme is approved by the Commission before the submission of the final application for an interim payment in accordance with Article 135(2).

Before submitting the first payment application for the accounting year starting 1 July 2021, Member States shall notify the table referred to in point (d)(ii) of Article 96(2) confirming the co-financing rate which was applicable during the accounting year ending 30 June 2020 for the priorities concerned by the temporary increase to 100 %.

2. In response to the COVID-19 outbreak, the resources available for programming for the year 2020 for the Investment for growth and jobs goal may, at the request of a Member State, be transferred between the ERDF, the ESF and the Cohesion Fund, irrespective of the percentages referred to in points (a) to (d) of Article 92(1).

For the purpose of those transfers, the requirements laid down in Article 92(4) shall not apply.

Transfers shall not affect resources allocated to the YEI in accordance with Article 92(5) or to the aid for the most deprived under the Investment for growth and jobs goal in accordance with Article 92(7).

Resources transferred between the ERDF, the ESF and the Cohesion Fund under this paragraph shall be implemented in accordance with the rules of the Fund to which the resources are transferred.

3. By way of derogation from Article 93(1) and in addition to the possibility provided for in Article 93(2), resources available for programming for the year 2020 may, at the request of a Member State, be transferred between categories of regions in response to the COVID-19 outbreak.

4. Requests for transfers under paragraphs 2 and 3 of this Article shall be submitted in accordance with the procedure for amendment of programmes set out in Article 30, shall be duly justified and shall be accompanied by the revised programme or programmes identifying the amounts transferred by Fund and by category of region, where relevant.

5. By way of derogation from Article 18 of this Regulation and the Fund-specific Regulations, financial allocations set out in requests for programme amendments submitted or transfers notified pursuant to Article 30(5) of this Regulation, on or after 24 April 2020, shall not be subject to the requirements on thematic concentration set out in this Regulation or the Fund-specific Regulations.

6. By way of derogation from Article 16, as from 24 April 2020, Partnership Agreements shall not be amended and programme amendments shall not entail the amendment of Partnership Agreements.

By way of derogation from Articles 26(1), 27(1), 30(1) and 30(2), as from 24 April 2020 the consistency of programmes and of their implementation with the Partnership Agreement shall not be verified.

7. For operations that foster crisis response capacities in the context of the COVID-19 outbreak as referred to in the second subparagraph of Article 65(10), Article 65(6) shall not apply.

By way of derogation from point (b) of Article 125(3), such operations may be selected for support by the ERDF or the ESF prior to the approval of the amended programme.

8. For the purposes of point (b) of Article 87(1), where the COVID-19 outbreak is invoked as a reason of *force majeure*, information on the amounts for which it has not been possible to make a payment application shall be provided at an aggregate level by priority for operations whose total eligible cost is less than EUR 1 000 000.

9. The annual report on implementation of the programme referred to in Article 50(1) for the year 2019 shall be submitted by 30 September 2020 for all ESI Funds, by way of derogation from the deadlines set out in the Fund-specific Regulations. The transmission of the summary report to be prepared by the Commission in 2020, in accordance with Article 53(1), may be postponed accordingly.

10. By way of derogation from point (g) of Article 37(2), no review or update of the *ex ante* assessments shall be required where changes in financial instruments are necessary to provide an effective response to the COVID-19 outbreak.

11. Where financial instruments provide support in the form of working capital to SMEs pursuant to the second subparagraph of Article 37(4) of this Regulation, new or updated business plans, or equivalent documents, and evidence allowing verification that the support provided through the financial instruments has been used for its intended purpose as part of the supporting documents, shall not be required.

By way of derogation from Regulation (EU) No 1305/2013, such support may also be provided by the EAFRD under measures referred to in Regulation (EU) No 1305/2013 and relevant to the implementation of financial instruments. Such eligible expenditure shall not exceed EUR 200 000.

12. For the purposes of the second subparagraph of Article 127(1), the COVID-19 outbreak shall constitute a duly justified case that audit authorities may invoke, based on their professional judgement, to use a non-statistical sampling method for the accounting year starting 1 July 2019 and ending 30 June 2020.

13. For the purposes of application of point (f) of Article 30(1) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (*), the condition that appropriations are for the same objective shall not apply in respect of transfers under paragraphs 2 and 3 of this Article.

(*) Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).;

(2) in Article 130, the following paragraph is added:

‘3. By way of derogation from paragraph 2, the contribution from the Funds or the EMFF through payments of the final balance for each priority per Fund and per category of regions in the final accounting year shall not exceed, by more than 10 %, the contribution from the Funds or the EMFF for each priority per Fund and per category of regions as laid down in the decision of the Commission approving the operational programme.

The contribution from the Funds or the EMFF through payments of the final balance in the final accounting year shall not exceed the eligible public expenditure declared or the contribution from each Fund and category of regions to each operational programme as laid down in the decision of the Commission approving the operational programme, whichever is the lower.’.

Article 3

Entry into force

This Regulation shall enter into force on the day 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, 23 April 2020.

For the European Parliament
The President
D.M. SASSOLI

For the Council
The President
G. GRLIĆ RADMAN

REGULATION (EU) 2020/559 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 23 April 2020****amending Regulation (EU) No 223/2014 as regards the introduction of specific measures for addressing the outbreak of COVID-19**

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 175(3) 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) Regulation (EU) No 223/2014 of the European Parliament and of the Council ⁽²⁾ lays down rules applicable to the Fund for European Aid to the Most Deprived (the 'Fund').
- (2) Member States have been affected by the outbreak of COVID-19 in an unprecedented manner. The crisis entails higher risks for the most vulnerable, such as the most deprived persons, in particular by disrupting the support provided by the Fund.
- (3) In order to provide for an immediate response to the impact of the crisis on the most deprived persons, expenditure for operations fostering crisis response capacities to address the outbreak of COVID-19 should be eligible as from 1 February 2020.
- (4) With a view to alleviating the burden on public budgets responding to the outbreak of COVID-19, Member States should be given the possibility, on an exceptional basis, to request for a co-financing rate of 100 % to be applied for the accounting year 2020 to 2021 in accordance with budget appropriations and subject to available funding. Based on an assessment of the application of that exceptional co-financing rate, the Commission may propose an extension thereof.
- (5) In order to ensure that the most deprived persons can continue to receive assistance under the Fund in a safe environment, it is necessary to provide for sufficient flexibility for Member States to adjust their support schemes to the current context based on consultations with partner organisations, including by allowing alternative schemes of delivery, such as through vouchers or cards in electronic or other form, and by allowing Member States to amend certain elements of the operational programme without requiring the adoption of a Commission decision. In order to ensure safe assistance to the most vulnerable persons, it should also be possible to provide the necessary protective materials and equipment to partner organisations outside the technical assistance budget.
- (6) It is appropriate to establish specific rules for determining the eligible costs borne by beneficiaries where operations are delayed, suspended or not fully implemented as a result of the outbreak of COVID-19.
- (7) In order to enable Member States to focus on introducing measures to respond to the outbreak of COVID-19 and avoid the disruption of the delivery of support to the most deprived persons because of the risk of contamination, it is appropriate to provide for specific measures that reduce the administrative burden on authorities and provide flexibility with regard to compliance with certain legislative requirements, in particular those relating to monitoring, control and audit.

⁽¹⁾ Position of the European Parliament of 17 April 2020 (not yet published in the Official Journal) and decision of the Council of 22 April 2020.

⁽²⁾ Regulation (EU) No 223/2014 of the European Parliament and of the Council of 11 March 2014 on the Fund for European Aid to the Most Deprived (OJ L 72, 12.3.2014, p. 1).

- (8) Since the objective of this Regulation, namely to introduce specific measures to ensure the effective implementation of the Fund during the outbreak of COVID-19, cannot be sufficiently achieved by the Member States but can rather, by reason of its 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 to achieve that objective.
- (9) Given the urgency of the support needed, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.
- (10) In view of the urgency entailed by the exceptional circumstances caused by the outbreak of COVID-19, the associated public health crisis and its social and economic consequences, 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.
- (11) Regulation (EU) No 223/2014 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 223/2014 is amended as follows:

- (1) in Article 9, the first subparagraph of paragraph 4 is replaced by the following:

‘4. Paragraphs 1, 2 and 3 do not apply for the purposes of modifying elements of an operational programme falling under sub-sections 3.5 and 3.6 and section 4, respectively, of the operational programme templates set out in Annex I, or the elements set out in points (a) to (e) and (g) of Article 7(2) in the event that they are modified as a result of the crisis response to the outbreak of COVID-19.’;

- (2) in Article 13(1), the following subparagraph is added:

‘By way of derogation from the first subparagraph, the deadline for the submission of the annual implementation report for the year 2019 shall be 30 September 2020.’;

- (3) in Article 20, the following paragraph is inserted:

‘1a. By way of derogation from paragraph 1, at the request of a Member State, a co-financing rate of 100 % may be applied to the public expenditure declared in payment applications during the accounting year starting 1 July 2020 and ending 30 June 2021.

Requests for modification of the co-financing rate shall be submitted in accordance with the procedure for the amendment of operational programmes set out in Article 9 and shall be accompanied by a revised programme. The co-financing rate of 100 % shall apply only if the relevant amendment of the operational programme is approved by the Commission before the submission of the final application for interim payment in accordance with Article 45(2).

Before submitting the first payment application for the accounting year starting 1 July 2021, Member States shall notify the table referred to in section 5.1 of the operational programme templates set out in Annex I, confirming the co-financing rate which was applicable during the accounting year ending 30 June 2020.’;

- (4) in Article 22(4), the following subparagraph is added:

‘By way of derogation from the first subparagraph, expenditure for operations for fostering crisis response capacity to address the outbreak of COVID-19 shall be eligible from 1 February 2020.’;

- (5) in Article 23, the following paragraph is inserted:

‘4a. Food and/or basic material assistance may be provided to the most deprived persons directly or indirectly, such as through vouchers or cards, in electronic or other form, provided that such vouchers, cards or other instruments can be exchanged only against food and/or basic material assistance.’;

(6) in Article 26, paragraph 2 is amended as follows:

(a) point (a) is replaced by the following:

‘(a) the cost of purchasing food and/or basic material assistance and the cost of purchasing personal protective materials and equipment for partner organisations;’;

(b) point (c) is replaced by the following:

‘(c) the administrative, preparation, transport and storage costs borne by the partner organisations at a flat-rate of 5 % of the costs referred to in point (a); or 5 % of the value of the food products disposed of in accordance with Article 16 of Regulation (EU) No 1308/2013;’;

(7) the following articles are inserted:

Article 26a

Eligibility of expenditure for operations supported under OP I during their suspension as a result of the outbreak of COVID-19

Delays in the delivery of food and/or basic material assistance as a result of the outbreak of COVID-19 shall not lead to a reduction of the eligible costs borne by the purchasing body or partner organisations in accordance with Article 26 (2). Such costs may be declared to the Commission in their entirety in accordance with Article 26(2) before the food and/or basic material assistance is delivered to the most deprived persons, provided that delivery is resumed after the end of the crisis associated with the outbreak of COVID-19.

Where food is spoiled because of the suspension of delivery as a result of the outbreak of COVID-19, the costs set out in point (a) of Article 26(2) shall not be reduced.

Article 26b

Eligibility of expenditure for operations supported under OP II or technical assistance during their suspension as a result of the outbreak of COVID-19

1. Where the implementation of operations is suspended as a result of the outbreak of COVID-19, a Member State may consider the expenditure during the suspension to be eligible expenditure even if no services are delivered, provided that all of the following conditions are met:

(a) the implementation of the operation is suspended after 31 January 2020;

(b) the suspension of the operation is due to the outbreak of COVID-19;

(c) the expenditure has been incurred and paid;

(d) the expenditure constitutes a genuine cost to the beneficiary and cannot be recovered or compensated for; for recoveries and compensation which are not provided by the Member State, the Member State may consider this condition to be met on the basis of a declaration by the beneficiary; recoveries and compensation shall be deducted from the expenditure;

(e) the expenditure is limited to the period of the suspension of the operation.

2. For operations for which the beneficiary is reimbursed on the basis of simplified cost options and where the implementation of the actions constituting the basis for reimbursement is suspended as a result of the outbreak of COVID-19, the Member State concerned may reimburse the beneficiary on the basis of the outputs planned for the period of the suspension, even if no actions are delivered, provided that all of the following conditions are met:

(a) the implementation of the actions is suspended after 31 January 2020;

(b) the suspension of the actions is due to the outbreak of COVID-19;

(c) the simplified cost options correspond to a genuine cost borne by the beneficiary, which shall be demonstrated by the beneficiary, and cannot be recovered or compensated for; for recoveries and compensation which are not provided by the Member State, the Member State may consider this condition to be met on the basis of a declaration by the beneficiary; recoveries and compensation shall be deducted from the amount corresponding to the simplified cost option;

- (d) the reimbursement to the beneficiary is limited to the period of the suspension of the actions.

For the operations referred to in the first subparagraph of this paragraph, the Member State may also reimburse the beneficiary on the basis of costs referred to in point (a) of Article 25(1), provided that the conditions set out in paragraph 1 of this Article are met.

Where a Member State reimburses the beneficiary on the basis of both the first and the second subparagraphs, it shall ensure that the same expenditure is only reimbursed once.

Article 26c

Eligibility of expenditure for operations supported under OP II or technical assistance that are not fully implemented as a result of the outbreak of COVID-19

1. A Member State may consider the expenditure for operations that are not fully implemented as a result of the outbreak of COVID-19 to be eligible expenditure, provided that all of the following conditions are met:

- (a) the implementation of the operation ceases after 31 January 2020;
- (b) the cessation of the implementation of the operation is due to the outbreak of COVID-19;
- (c) the expenditure prior to the cessation of the implementation of the operation was incurred by the beneficiary and paid.

2. For operations for which the beneficiary is reimbursed on the basis of simplified cost options, a Member State may consider the expenditure for operations that are not fully implemented as a result of the outbreak of COVID-19 to be eligible expenditure, provided that all of the following conditions are met:

- (a) the implementation of the operation ceases after 31 January 2020;
- (b) the cessation of the implementation of the operation is due to the outbreak of COVID-19;
- (c) the actions covered by the simplified cost options were at least partly delivered prior to the cessation of the implementation of the operation.

For the operations referred to in the first subparagraph of this paragraph, the Member State may also reimburse the beneficiary on the basis of costs referred to in point (a) of Article 25(1), provided that the conditions set out in paragraph 1 of this Article are met.

Where a Member State reimburses the beneficiary on the basis of both the first and the second subparagraphs, it shall ensure that the same expenditure is only reimbursed once.;

- (8) in Article 30, the following paragraph is inserted:

‘1a. Based on an analysis of potential risks, Member States may establish lighter control and audit trail requirements regarding the distribution of food and/or basic material assistance to the most deprived persons during the outbreak of COVID-19.’.

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, 23 April 2020.

For the European Parliament
The President
D.M. SASSOLI

For the Council
The President
G. GRLIĆ RADMAN

REGULATION (EU) 2020/560 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 23 April 2020****amending Regulations (EU) No 508/2014 and (EU) No 1379/2013 as regards specific measures to mitigate the impact of the COVID-19 outbreak in the fishery and aquaculture sector**

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 Articles 43(2) and 175 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) The fishery and aquaculture sector has been particularly hard hit by the market disruption generated by a significant drop in demand ensuing from the COVID-19 outbreak. The closure of sales venues, markets, outlets and distribution channels has seen prices and volumes drop substantially. The drop in demand and prices, combined with the vulnerability and complexity of the supply chain, has made the operations of fishing fleets and seafood production loss-making. Consequently, fishers have been forced to stay in port and fish farmers will have to discard or destroy products within weeks.
- (2) It should be possible for the European Maritime and Fisheries Fund (EMFF) established by Regulation (EU) No 508/2014 of the European Parliament and of the Council ⁽²⁾ to support specific measures until 31 December 2020 to mitigate the impact of the COVID-19 outbreak in the fishery and aquaculture sector. Those measures should comprise support for the temporary cessation of fishing activities, including for inland fishing and fishers on foot, and for certain economic losses for aquaculture producers and processing enterprises and in the outermost regions, provided that they are the consequence of the COVID-19 outbreak. Those measures should also comprise the provision of working capital to aquaculture producers and processing enterprises and support to producer organisations and associations of producer organisations for the storage of fishery and aquaculture products in accordance with Regulation (EU) No 1379/2013 of the European Parliament and of the Council ⁽³⁾. Expenditure for operations supported under those measures should be eligible as of 1 February 2020.
- (3) The resources available for commitments from the EMFF under shared management should be broken down in a way that ensures that fixed amounts are established for fisheries control and for the collection of scientific data, while permitting 10 % of those amounts to be used for measures related to the mitigation of the COVID-19 outbreak, and for the compensation of additional costs in the outermost regions. The other resources under shared management should be allocated by Member States on the basis of their needs.
- (4) Given the significant socio-economic consequences of the COVID-19 outbreak and the need for liquidity in the economy, it should be possible to support the temporary cessation of fishing activities caused by the COVID-19 outbreak crisis with a maximum co-financing rate of 75 % of eligible public expenditure.

⁽¹⁾ Position of the European Parliament of 17 April 2020 (not yet published in the Official Journal) and decision of the Council of 22 April 2020.

⁽²⁾ Regulation (EU) No 508/2014 of the European Parliament and of the Council of 15 May 2014 on the European Maritime and Fisheries Fund and repealing Council Regulations (EC) No 2328/2003, (EC) No 861/2006, (EC) No 1198/2006 and (EC) No 791/2007 and Regulation (EU) No 1255/2011 of the European Parliament and of the Council (OJ L 149, 20.5.2014, p. 1).

⁽³⁾ Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000 (OJ L 354, 28.12.2013, p. 1).

- (5) Given the need for flexibility in the reallocation of financial resources to address the consequences of the COVID-19 outbreak, the provision of support for the temporary cessation of fishing activities caused by that outbreak should not be subject to financial capping. That should be without prejudice to the existing financial capping for the other cases of temporary cessation of fishing activities. The obligation to deduct support granted for temporary cessation from support granted for the permanent cessation of fishing activities to the same vessel should continue to apply. For measures related to the mitigation of the COVID-19 outbreak, the requirement of 120 days of activity should be proportionately reduced for owners of vessels registered for less than two years and for fishermen who have started working less than two years prior to the application for support.
- (6) Given the urgency of providing the support needed, it should be possible to extend the scope of the simplified procedure to include amendments to operational programmes related to the specific measures and the reallocation of financial resources thereto to address the consequences of the COVID-19 outbreak. That simplified procedure should cover all the amendments necessary for the full implementation of the measures concerned, including their introduction and the description of the methods for calculating support.
- (7) Given the key role played by producer organisations in the management of the crisis, the ceiling for support to production and marketing plans should be increased to 12 % of the average annual value of the production placed on the market. It should also be possible for Member States to grant advances of up to 100 % of the financial support to producer organisations for that support.
- (8) The sudden disruptions of fishery and aquaculture activities ensuing from the COVID-19 outbreak, and the resulting risk of jeopardising markets for fishery and aquaculture products, make it appropriate to set up a mechanism for storing fishery and aquaculture products for human consumption. That will aim to foster greater market stability, mitigate the risk of having such products wasted or redirected to non-human food purposes, and contribute to absorbing the impact of the crisis on the return on products. That mechanism should enable fishery and aquaculture producers to make use of the same preservation or conservation techniques for similar species to ensure that fair competition between producers is maintained.
- (9) Given the suddenness and magnitude of the contraction of demand for fishery and aquaculture products resulting from the COVID-19 outbreak, it should be possible to increase the quantities eligible for storage aid to 25 % of the annual quantities of the products concerned put up for sale by the producer organisation concerned.
- (10) To enable Member States to react promptly to the suddenness and unpredictability of the COVID-19 outbreak, they should be entitled to set trigger prices for their producer organisations to trigger the storage mechanism. Those trigger prices should be set in such a way that fair competition between operators is maintained.
- (11) EMFF support should also be available for measures to compensate the economic losses resulting from the COVID-19 outbreak for operators in the fishing, farming, processing and marketing of certain fishery and aquaculture products from the outermost regions, in particular those resulting from the deterioration in the price of fish or increased storage costs. The Commission should approve, without delay, such measures proposed by Member States.
- (12) Since the objective of this Regulation, namely to mitigate the social and economic impact of the COVID-19 outbreak in the fishery and aquaculture sector, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the proposed action, 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 to achieve that objective.
- (13) Given the urgency of providing the support needed, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

- (14) In view of the COVID-19 outbreak and the urgency of addressing its social and economic impact in the fishery and aquaculture sector, 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.
- (15) Regulations (EU) No 508/2014 and (EU) No 1379/2013 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 508/2014

Regulation (EU) No 508/2014 is amended as follows:

- (1) Article 13 is replaced by the following:

'Article 13

Budgetary resources under shared management

1. The resources available for commitments from the EMFF for the period from 2014 to 2020 under shared management shall be EUR 5 749 331 600 in current prices, in accordance with the annual breakdown set out in Annex II.
 2. EUR 580 000 000 of the budgetary resources referred to in paragraph 1 shall be allocated to the control and enforcement measures referred to in Article 76.
 3. EUR 520 000 000 of the budgetary resources referred to in paragraph 1 shall be allocated to the measures on data collection referred to in Article 77.
 4. EUR 192 500 000 of the budgetary resources referred to in paragraph 1 shall be allocated to the compensation of outermost regions under Chapter V of Title V. That compensation shall not exceed, per year:
 - (a) EUR 6 450 000 for the Azores and Madeira;
 - (b) EUR 8 700 000 for the Canary Islands;
 - (c) EUR 12 350 000 for the French outermost regions referred to in Article 349 TFEU.
 5. Member States shall have the possibility of using interchangeably the resources available under paragraphs 2 and 3.
 6. 10 % of the budgetary resources referred to in paragraphs 2 and 3 may be allocated to measures related to the mitigation of the COVID-19 outbreak.;
- (2) in Article 16(1), the introductory part is replaced by the following:
- '1. The resources available for commitments by Member States referred to in Article 13(1) for the period from 2014 to 2020, as set out in the table in Annex II, shall be determined on the basis of the following objective criteria:';
- (3) Article 22 is amended as follows:
- (a) in paragraph 2, the following point is added:

'(e) amendments to operational programmes concerning the support referred to in point (d) of Article 33(1), Article 35, Article 44(4a), point (b) of Article 55(1), Articles 57, 66 and 67 and Article 69(3), including the reallocation of financial resources thereto to address the consequences of the COVID-19 outbreak.;
 - (b) paragraph 3 is replaced by the following:

'3. Paragraph 2 shall not apply to the support referred to in points (a), (b) and (c) of Article 33(1), Article 34 and Article 41(2).';

- (4) in Article 25(3), the introductory part is replaced by the following:

‘3. Without prejudice to paragraph 5 of this Article, the total financial contribution from the EMFF to the measures referred to in points (a), (b) and (c) of Article 33(1) and in Article 34 and to the replacement or modernisation of main or ancillary engines as referred to in Article 41 shall not exceed the higher of the following two thresholds:’;

- (5) Article 33 is amended as follows:

- (a) paragraphs 1 and 2 are replaced by the following:

‘1. The EMFF may support measures for the temporary cessation of fishing activities in the following cases:

- (a) the implementation of Commission measures or Member States emergency measures referred to in Articles 12 and 13, respectively, of Regulation (EU) No 1380/2013 or of conservation measures referred to in Article 7 of that Regulation, including biological recovery periods;
- (b) a non-renewal of Sustainable fisheries partnership agreements or protocols thereto;
- (c) where the temporary cessation of fishing activities is provided for in a management plan adopted in accordance with Council Regulation (EC) No 1967/2006 (*) or in a multiannual plan adopted under Articles 9 and 10 of Regulation (EU) No 1380/2013, where, based on scientific advice, a reduction of fishing effort is needed in order to achieve the objectives referred to in Article 2(2) and point (a) of Article 2(5) of Regulation (EU) No 1380/2013;
- (d) where the temporary cessation of fishing activities occurs between 1 February and 31 December 2020 as a consequence of the COVID-19 outbreak, including for vessels operating under a Sustainable fisheries partnership agreement.

In accordance with the second subparagraph of Article 65(9) of Regulation (EU) No 1303/2013 and by way of derogation from the first subparagraph thereof, expenditure for operations supported under point (d) of the first subparagraph of this paragraph shall be eligible as of 1 February 2020.

2. The support referred to in points (a), (b) and (c) of the first subparagraph of paragraph 1 may be granted for a maximum duration of six months per vessel during the period from 2014 to 2020. That maximum duration shall not apply to the support referred to in point (d) of that subparagraph.

(*) Council Regulation (EC) No 1967/2006 of 21 December 2006 concerning management measures for the sustainable exploitation of fishery resources in the Mediterranean Sea, amending Regulation (EEC) No 2847/93 and repealing Regulation (EC) No 1626/94 (OJ L 409, 30.12.2006, p. 11).’;

- (b) the following paragraph is inserted:

‘3a. For the purpose of point (d) of paragraph 1, the following derogations shall apply:

- (a) by way of derogation from point (a) of paragraph 3, where a fishing vessel has been registered in the Union fishing fleet register for less than two years at the date of submission of the application for support, Member States may calculate the minimum days of fishing activities required for that vessel as the proportion of 120 days in the last two calendar years;
- (b) by way of derogation from point (b) of paragraph 3, where a fisherman has started working on board a Union fishing vessel less than two years prior to the date of submission of the application for support, Member States may calculate the minimum days of work required for that fisherman as the proportion of 120 days in the last two calendar years;
- (c) by way of derogation from paragraph 3, support shall also be granted to fishermen on foot who have worked at least 120 days during the last two calendar years preceding the date of submission of the application for support. Where a fisherman on foot has started working less than two years prior to the date of submission of the application for support, Member States may calculate the minimum days of work required for that fisherman on foot as the proportion of 120 days in the last two calendar years.’;

- (6) Article 44 is amended as follows:

- (a) the following paragraph is inserted:

‘4a. The EMFF may support measures for temporary cessation of fishing activities caused by the COVID-19 outbreak, as provided for in point (d) of Article 33(1), under the conditions laid down in Article 33.’;

(b) paragraph 5 is replaced by the following:

‘5. For the purposes of paragraphs 1 and 4a:

- (a) references made in Articles 30, 32, 33, 38, 39, 41 and 42 to fishing vessels shall be understood as references to vessels operating exclusively in inland waters;
- (b) references made in Article 38 to the marine environment shall be understood as references to the environment in which the inland fishing vessel operates.’;

(7) Article 55 is replaced by the following:

‘Article 55

Public health measures

1. The EMFF may support the following compensation schemes:

- (a) compensation to mollusc farmers for the temporary suspension of the harvesting of farmed molluscs, where such suspension occurs exclusively for reasons of public health;
- (b) granting working capital and compensation to aquaculture farmers.

Compensation referred to in point (b) of the first subparagraph may be granted for the temporary suspension or reduction of production and sales or for the additional storage costs occurring between 1 February and 31 December 2020 as a consequence of the COVID-19 outbreak.

2. Support under point (a) of paragraph 1 may only be granted where the suspension of harvesting due to the contamination of molluscs is the result of the proliferation of toxin-producing plankton or the presence of plankton containing biotoxins, and provided that:

- (a) the contamination lasts for more than four consecutive months; or
- (b) the loss, resulting from the suspension of harvesting, amounts to more than 25 % of the annual turnover of the business concerned, calculated on the basis of the average turnover of that business over the three calendar years preceding the year in which the harvest was suspended.

For the purposes of point (b) of the first subparagraph, Member States may establish special calculation rules in respect of companies with less than three years of activity.

3. The duration for which compensation under point (a) of paragraph 1 may be granted shall be a maximum of 12 months over the entire programming period. In duly justified cases, it may be extended once for a maximum of an additional 12 months up to a combined maximum of 24 months.

In accordance with the second subparagraph of Article 65(9) of Regulation (EU) No 1303/2013 and by way of derogation from the first subparagraph thereof, expenditure for operations supported under point (b) of paragraph 1 of this Article shall be eligible as of 1 February 2020.’;

(8) in Article 66, paragraphs 3 and 4 are replaced by the following:

‘3. Support granted per producer organisation per year under this Article shall not exceed 12 % of the average annual value of the production placed on the market by that producer organisation during the preceding three calendar years. For a newly recognised producer organisation, that support shall not exceed 12 % of the average annual value of the production placed on the market by the members of that organisation during the preceding three calendar years.

4. The Member State concerned may grant an advance of between 50 % and 100 % of the financial support after approval of the production and marketing plan in accordance with Article 28(3) of Regulation (EU) No 1379/2013.’;

(9) in Article 67, paragraphs 1 and 2 are replaced by the following:

‘1. Where needed to respond to the COVID-19 outbreak, the EMFF may support compensation to recognised producer organisations and associations of producer organisations which store fishery or aquaculture products listed in Annex II to Regulation (EU) No 1379/2013 or products falling within CN code 0302 as listed in point (a) of Annex I to that Regulation, provided that those products are stored in accordance with Articles 30 and 31 of that Regulation, and subject to the following conditions:

- (a) the amount of the storage aid does not exceed the amount of the technical and financial costs of the actions required for the stabilisation and storage of the products in question;

- (b) the quantities eligible for storage aid do not exceed 25 % of the annual quantities of the products concerned put up for sale by the producer organisation;
- (c) the financial support per year does not exceed 20 % of the average annual value of the production placed on the market by the members of the producer organisation in the period 2017–2019.

For the purposes of point (c) of the first subparagraph, where a member of the producer organisation did not place any production on the market in the period 2017 to 2019, the average annual value of production placed on the market in the first three years of production of that member shall be taken into account.

2. The support referred to in paragraph 1 shall end on 31 December 2020.

In accordance with the second subparagraph of Article 65(9) of Regulation (EU) No 1303/2013 and by way of derogation from the first subparagraph thereof, expenditure for operations supported under this Article shall be eligible as of 1 February 2020.;

- (10) in Article 69, the following paragraph is added:

‘3. The EMFF may support granting working capital and compensation to processing enterprises within the scope set out in the second subparagraph of Article 55(1) for aquaculture farmers.’;

- (11) in Article 70, paragraph 1 is replaced by the following:

‘1. The EMFF may support the compensation of additional costs incurred by operators in the fishing, farming, processing and marketing of certain fishery and aquaculture products from the outermost regions referred to in Article 349 TFEU.

The EMFF may also support measures to compensate the economic losses resulting from the COVID-19 outbreak, in particular those resulting from the deterioration in the price of fish or from increased storage cost.’;

- (12) in Article 72, paragraph 2 is replaced by the following:

‘2. Member States may amend the content of the compensation plan referred to in paragraph 1. Member States shall submit such amendments to the Commission. The Commission shall adopt implementing acts setting out its decision whether to approve those amendments. Where the amendments concern measures to compensate the economic losses resulting from the COVID-19 outbreak under the second subparagraph of Article 70(1), the Commission shall adopt such implementing acts within 15 days of the submission of the amendment. Notwithstanding paragraph 4 of this Article, the implementing acts concerning measures to compensate the economic losses resulting from the COVID-19 outbreak shall also set out the methods of calculation of the additional costs and the methods of implementation by the Member States.’;

- (13) in Article 79, paragraph 2 is deleted;

- (14) in Article 94(3), point (c) is replaced by the following:

‘(c) 50 % of the eligible public expenditure for the support referred to in points (a), (b) and (c) of Article 33(1), Article 34 and Article 41(2).’;

- (15) in Article 95(2), point (e) is replaced by the following:

‘(e) the operation is related to support under Article 33 or 34 or to compensation under Article 54, Article 55 or Article 56 or Article 69(3).’;

Article 2

Amendments to Regulation (EU) No 1379/2013

Regulation (EU) No 1379/2013 is amended as follows:

- (1) in Article 8(3), the following point is added:

‘(f) managing temporary storage for aquaculture products in accordance with Articles 30 and 31 of this Regulation.’;

(2) Article 30 is replaced by the following:

‘Article 30

Storage mechanism

Fishery and aquaculture producer organisations may receive financial support for the storage of products listed in Annex II or products falling within CN code 0302 as listed in point (a) of Annex I to this Regulation, provided that:

- (a) the conditions for storage aid, laid down in Regulation (EU) No 508/2014 of the European Parliament and of the Council (*), are complied with;
- (b) the products have been placed on the market by producer organisations and no buyer for them has been found at the trigger price referred to in Article 31;
- (c) where applicable, the products meet the common marketing standards established in accordance with Article 33 and are of adequate quality for human consumption;
- (d) the products are stabilised or processed and stored in tanks or cages, by way of freezing, either on board vessels or in land facilities, of salting, of drying, of marinating or, where relevant, of boiling and pasteurisation, whether or not the products are filleted, cut-up or, where appropriate, headed;
- (e) aquaculture products are not stored alive;
- (f) the products are reintroduced from storage into the market for human consumption at a later stage, and
- (g) the products remain in storage for at least five days.

(*) Regulation (EU) No 508/2014 of the European Parliament and of the Council of 15 May 2014 on the European Maritime and Fisheries Fund and repealing Council Regulations (EC) No 2328/2003, (EC) No 861/2006, (EC) No 1198/2006 and (EC) No 791/2007 and Regulation (EU) No 1255/2011 of the European Parliament and of the Council (OJ L 149, 20.5.2014, p. 1).;

(3) Article 31 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Before the beginning of each year, each producer organisation may individually make a proposal for a price triggering the storage mechanism referred to in Article 30 for products listed in Annex II or products falling within CN code 0302 as listed in point (a) of Annex I to this Regulation.’;

(b) the following paragraph is added:

‘5. Where a Member State has not determined the trigger prices pursuant to paragraph 4 prior to the COVID-19 outbreak, that Member State shall, without delay, determine the trigger prices concerned on the basis of the criteria referred to in paragraphs 2 and 3. The prices shall be made publicly available.’.

Article 3

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, 23 April 2020.

For the European Parliament
The President
D.M. SASSOLI

For the Council
The President
G. GRLIĆ RADMAN

REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 23 April 2020****amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions****(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 point (c) of Article 168(4) 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) Regulation (EU) 2017/745 of the European Parliament and of the Council ⁽²⁾ establishes a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices covered by that Regulation, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, Regulation (EU) 2017/745 sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such devices. Furthermore, Regulation (EU) 2017/745 significantly reinforces key elements of the existing regulatory approach in Council Directives 90/385/EEC ⁽³⁾ and 93/42/EEC ⁽⁴⁾, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding medical devices, to improve health and safety.
- (2) The COVID-19 outbreak and the associated public health crisis presents an unprecedented challenge to Member States and constitutes an immense burden for national authorities, health institutions, Union citizens, and economic operators. The public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as an increased availability of vitally important medical devices, that could not reasonably have been anticipated at the time of adoption of Regulation (EU) 2017/745. Those extraordinary circumstances have a significant impact on various areas covered by Regulation (EU) 2017/745, such as the designation and work of notified bodies and the placing on the market and making available on the market of medical devices in the Union.
- (3) Medical devices, such as medical gloves, surgical masks, equipment for intensive care and other medical equipment, play a crucial role in the context of the COVID-19 outbreak and the associated public health crisis to ensure the health and safety of Union citizens and to enable Member States to give necessary medical treatment to patients who are urgently in need of such treatment.
- (4) Given the unprecedented magnitude of the current challenges, and taking into account the complexity of Regulation (EU) 2017/745, it is very likely that Member States, health institutions, economic operators and other relevant parties will not be in a position to ensure the proper implementation and application of that Regulation from 26 May 2020 as laid down therein.

⁽¹⁾ Position of the European Parliament of 17 April 2020 (not yet published in the Official Journal) and decision of the Council of 22 April 2020.

⁽²⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽³⁾ Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

⁽⁴⁾ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

- (5) In order to ensure the smooth functioning of the internal market, a high level of protection of public health and patient safety, to provide legal certainty and to avoid potential market disruption, it is necessary to defer the application of certain provisions of Regulation (EU) 2017/745. Taking into account the COVID-19 outbreak and the associated public health crisis, its epidemiological development, as well as the additional resources required by Member States, health institutions, economic operators and other relevant parties, it is appropriate to defer the application of those provisions of Regulation (EU) 2017/745 by one year.
- (6) The application should be deferred for provisions of Regulation (EU) 2017/745 that would otherwise start to apply from 26 May 2020. To ensure the continuous availability of medical devices on the Union market, including medical devices that are vitally important in the context of the COVID-19 outbreak and the associated public health crisis, it is also necessary to adapt certain transitional provisions of Regulation (EU) 2017/745 that would otherwise no longer apply.
- (7) Both Directives 90/385/EEC and 93/42/EEC, as well as Regulation (EU) 2017/745, empower national competent authorities, on a duly justified request, to authorise the placing on the market of medical devices for which the relevant conformity assessment procedures have not been carried out, but the use of which is in the interest of protection of health, or in the interest of public health or patient safety or health respectively ('national derogation'). Regulation (EU) 2017/745 also allows the Commission to extend, in exceptional cases, the validity of a national derogation for a limited period of time to the territory of the Union ('Union-wide derogation'). Taking into account the COVID-19 outbreak and the associated public health crisis, the Commission should be able to adopt Union-wide derogations in response to national derogations in order to address potential Union-wide shortages of vitally important medical devices in an effective manner. It is for that reason appropriate that the relevant provision of Regulation (EU) 2017/745 applies at the earliest date possible and that the corresponding provisions of Directives 90/385/EEC and 93/42/EEC are repealed from that date. Taking into account that the possibility to adopt Union-wide derogations, for a transitional period, is to be given to the Commission in relation to national derogations from Directives 90/385/EEC and 93/42/EEC, certain amendments to the relevant provisions of Regulation (EU) 2017/745 are necessary.
- (8) In order to cover any national derogations granted by Member States in accordance with Directive 90/385/EEC or 93/42/EEC in the context of the COVID-19 outbreak before the entry into force of this Regulation, it is necessary to provide for the possibility for Member States to notify those national derogations and for the Commission to extend their validity to the territory of the Union.
- (9) To ensure the continuous presence of a functioning and effective regulatory framework for medical devices, it is necessary to defer the application of the provision repealing Directives 90/385/EEC and 93/42/EEC.
- (10) Since the objectives of this Regulation, namely to defer the application of certain provisions of Regulation (EU) 2017/745 and to allow for the extension of the validity of national derogations, authorised under Directive 90/385/EEC or 93/42/EEC, to the territory of the Union, 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 those objectives.
- (11) The adoption of this Regulation takes place under exceptional circumstances arising from the COVID-19 outbreak and the associated public health crisis. To attain the intended effect of amending Regulation (EU) 2017/745 as regards the dates of application of certain provisions, it is necessary for this Regulation to enter into force before 26 May 2020. It was therefore 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.
- (12) In light of the overriding need to immediately address the public health crisis associated with the COVID-19 outbreak, 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*.

- (13) Regulation (EU) 2017/745 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2017/745 is amended as follows:

- (1) in Article 1(2), the second subparagraph is amended as follows:

- (a) in the first sentence, the date '26 May 2020' is replaced by '26 May 2021';
- (b) in the second sentence, the date '26 May 2020' is replaced by '26 May 2021';

- (2) Article 17 is amended as follows:

- (a) paragraph 5 is amended as follows:

- (i) in the first sentence, the date '26 May 2020' is replaced by '26 May 2021';
- (ii) in the third sentence, the date '26 May 2020' is replaced by '26 May 2021';

- (b) in paragraph 6, the date '26 May 2020' is replaced by '26 May 2021';

- (3) in Article 34(1), the date '25 March 2020' is replaced by '25 March 2021';

- (4) Article 59 is amended as follows:

- (a) paragraph 1 is replaced by the following:

'1. By way of derogation from Article 52 of this Regulation or, for the period from 24 April 2020 to 25 May 2021, by way of derogation from Article 9(1) and (2) of Directive 90/385/EEC or from Article 11(1) to (6) of Directive 93/42/EEC, any competent authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific device for which the applicable procedures referred to in those Articles have not been carried out but use of which is in the interest of public health or patient safety or health.';

- (b) in paragraph 2, the following subparagraph is added:

'The Member State may inform the Commission and the other Member States of any authorisation granted in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC before 24 April 2020.';

- (c) in paragraph 3, the first subparagraph is replaced by the following:

'Following a notification pursuant to paragraph 2 of this Article, the Commission, in exceptional cases relating to public health or patient safety or health, may, by means of implementing acts, extend for a limited period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 of this Article or, when granted before 24 April 2020, in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).';

- (5) in Article 113, the date '25 February 2020' is replaced by '25 February 2021';

- (6) Article 120 is amended as follows:

- (a) in paragraph 1, the date '26 May 2020' is replaced by '26 May 2021';

- (b) in paragraph 3, the first subparagraph is replaced by the following:

'3. By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.';

(c) paragraph 4 is replaced by the following:

‘4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.’;

(d) in paragraph 5, the date ‘26 May 2020’ is replaced by ‘26 May 2021’;

(e) paragraph 6 is replaced by the following:

‘6. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2021. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2021.’;

(f) paragraph 10 is replaced by the following:

‘10. Devices falling within the scope of this Regulation in accordance with point (g) of Article 1(6) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2021 may continue to be placed on the market and put into service in the Member States concerned.’;

(g) paragraph 11 is amended as follows:

(i) in the first sentence, the date ‘26 May 2020’ is replaced by ‘26 May 2021’;

(ii) in the second sentence, the date ‘26 May 2020’ is replaced by ‘26 May 2021’;

(7) in Article 122, the first paragraph is amended as follows:

(a) in the introductory part, the date ‘26 May 2020’ is replaced by ‘26 May 2021’;

(b) the following indent is added:

‘— Article 9(9) of Directive 90/385/EEC and Article 11(13) of Directive 93/42/EEC, which are repealed with effect from 24 April 2020.’;

(8) Article 123 is amended as follows:

(a) in paragraph 2, the date ‘26 May 2020’ is replaced by ‘26 May 2021’;

(b) paragraph 3 is amended as follows:

(i) in point (a), the date ‘26 May 2020’ is replaced by ‘26 May 2021’;

(ii) in the first sentence of point (d), the date ‘26 May 2020’ is replaced by ‘26 May 2021’;

(iii) point (g) is replaced by the following:

‘(g) with regard to reusable devices that are required to bear the UDI carrier on the device itself, Article 27(4) shall apply to:

(i) implantable devices and class III devices from 26 May 2023;

(ii) class IIa and class IIb devices from 26 May 2025;

(iii) class I devices from 26 May 2027.’;

(iv) the following point is added:

‘(j) Article 59 shall apply from 24 April 2020.’;

(9) in point (h) of Section 5.1 of Annex IX, the date ‘26 May 2020’ is replaced by ‘26 May 2021’.

Article 2

This Regulation shall enter into force on the day 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, 23 April 2020.

For the European Parliament
The President
D.M. SASSOLI

For the Council
The President
G. GRLIĆ RADMAN

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2020/562

of 23 April 2020

implementing Regulation (EU) No 401/2013 concerning restrictive measures in respect of Myanmar/Burma

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) No 401/2013 of 2 May 2013 concerning restrictive measures in respect of Myanmar/Burma and repealing Regulation (EC) No 194/2008 ⁽¹⁾, and in particular Article 4i thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 2 May 2013, the Council adopted Regulation (EU) No 401/2013.
- (2) In accordance with Article 4i of Regulation (EU) No 401/2013, the Council has reviewed the list of designated persons and entities set out in Annex IV to that Regulation.
- (3) For one listing, updated information has been received.
- (4) Annex IV to Regulation (EU) No 401/2013 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EU) No 401/2013 is amended as 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, 23 April 2020.

For the Council
The President
G. GRLIĆ RADMAN

⁽¹⁾ OJ L 121, 3.5.2013, p. 1

ANNEX

Entry 3 in the list of persons and entities set out in Annex IV to Regulation (EU) No 401/2013 is replaced by the following entry:

	Name	Identifying information	Reasons	Date of listing
'3.	Than Oo	Date of birth: 12 October 1973 Gender: male Military identification number: BC 25723	Brigadier General Than Oo was the Commander of the 99th Light Infantry Division of the Myanmar Armed Forces (Tatmadaw) until May 2018. In that context, he is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State in the second half of 2017 by the 99th Light Infantry Division. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018'

DECISIONS

COUNCIL DECISION (CFSP) 2020/563

of 23 April 2020

amending Decision 2013/184/CFSP concerning restrictive measures against Myanmar/Burma

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union and in particular Article 29 thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 22 April 2013, the Council adopted Decision 2013/184/CFSP ⁽¹⁾, concerning restrictive measures against Myanmar/Burma.
- (2) On the basis of a review of Decision 2013/184/CFSP, the restrictive measures should be renewed until 30 April 2021.
- (3) For one listing, updated information has been received.
- (4) Decision 2013/184/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2013/184/CFSP is amended as follows:

- (1) Article 12 is replaced by the following:

'Article 12

This Decision shall apply until 30 April 2021. It shall be kept under constant review. It shall be renewed, or amended as appropriate, if the Council deems that its objectives have not been met.;

- (2) the Annex is amended as set out in the Annex to this Decision.

Article 2

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

Done at Brussels, 23 April 2020.

For the Council
The President
G. GRLIĆ RADMAN

⁽¹⁾ Council Decision 2013/184/CFSP of 22 April 2013 concerning restrictive measures against Myanmar/Burma and repealing Decision 2010/232/CFSP (OJ L 111, 23.4.2013, p. 75).

ANNEX

Entry 3 in the list of persons and entities set out in the Annex to Decision 2013/184/CFSP is replaced by the following entry:

	Name	Identifying information	Reasons	Date of listing
'3.	Than Oo	Date of birth: 12 October 1973 Gender: male Military identification number: BC 25723	Brigadier General Than Oo was the Commander of the 99th Light Infantry Division of the Myanmar Armed Forces (Tatmadaw) until May 2018. In that context, he is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State in the second half of 2017 by the 99th Light Infantry Division. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018'

COUNCIL DECISION (CFSP) 2020/564**of 23 April 2020****amending Decision (CFSP) 2018/298 on Union support for the activities of the Preparatory Commission for the Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO) in order to strengthen its monitoring and verification capabilities and in the framework of the implementation of the EU Strategy against Proliferation of Weapons of Mass Destruction**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty of the European Union, and in particular Articles 28(1) and 31(1) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 26 February 2018, the Council adopted Decision (CFSP) 2018/298 ⁽¹⁾.
- (2) The second paragraph of Article 5 of Decision (CFSP) 2018/298 provides for a 24-month implementation period from the date of conclusion of the financing agreement referred to in Article 3(3) of that Decision, for the activities referred to in Article 1 thereof.
- (3) The financing agreement with the Preparatory Commission for the Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO) was signed on 28 April 2018 and is therefore due to expire on 27 April 2020.
- (4) On 19 March 2020, Dr Lassina ZERBO, the Executive Secretary of the Preparatory Commission for the CTBTO requested an extension, until 30 November 2020, of the implementation period provided for in Decision (CFSP) 2018/298, due to the emerging worldwide COVID-19 crisis and the related temporary suspension of non-critical CTBTO activities.
- (5) Decision (CFSP) 2018/298 should therefore be amended.
- (6) The extension of the activities referred to in Article 1 of Decision (CFSP) 2018/298 until 30 November 2020 does not affect resources,

HAS ADOPTED THIS DECISION:

Article 1

The second paragraph of Article 5 of Decision (CFSP) 2018/298 is replaced by the following:

‘This Decision shall expire on 30 November 2020.’.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 23 April 2020.

For the Council
The President
G. GRLIĆ RADMAN

⁽¹⁾ Council Decision (CFSP) 2018/298 of 26 February 2018 on Union support for the activities of the Preparatory Commission for the Comprehensive Nuclear-Test-Ban Treaty Organization (CTBTO) in order to strengthen its monitoring and verification capabilities and in the framework of the implementation of the EU Strategy against Proliferation of Weapons of Mass Destruction (OJ L 56, 28.2.2018, p. 34).

RULES OF PROCEDURE

DECISION OF THE MANAGEMENT BOARD OF THE AGENCY FOR SUPPORT FOR BEREK (BEREC OFFICE)

of 10 September 2019

laying down internal rules concerning restrictions of certain rights of data subjects in relation to the processing of personal data in the framework of activities carried out by the BEREC Office

THE MANAGEMENT BOARD,

Having regard to Regulation (EU) 2018/1971 of the European Parliament and of the Council of 11 December 2018 establishing the Body of European Regulators for Electronic Communications (BEREC) and the Agency for Support for BEREC (BEREC Office), amending Regulation (EU) 2015/2120 and repealing Regulation (EC) No 1211/2009 ⁽¹⁾, and in particular Article 36(4) thereof,

Having regard to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC ⁽²⁾ ('the Regulation'), and in particular Article 25 thereof,

Whereas:

- (1) The BEREC Office may, in the context of its functioning, conduct administrative inquiries, pre-disciplinary, disciplinary and suspension proceedings, on the basis of Annex IX to the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union ⁽³⁾ and in compliance with Decision MC/2012/3 by the Management Committee of the Office of the Body of European Regulators for Electronic Communications (BEREC Office) laying down general implementing provisions on the conduct of administrative inquiries and disciplinary procedures, which implies processing of information including personal data.
- (2) The BEREC Office staff members have the obligation to report possible illegal activities, including fraud or corruption, detrimental to the interests of the Union, or of conduct relating to the discharge of professional duties, which may constitute a serious failure to comply with the obligations of staff members of the Union. This is regulated by Decision No MC/2018/11 of the Management Committee of the Office of the Body of European Regulators for Electronic Communications (BEREC Office) laying down guidelines on whistleblowing of the BEREC Office.
- (3) The BEREC Office has set out a policy to prevent and deal effectively and efficiently with actual or potential cases of psychological or sexual harassment at the workplace, as provided for by Decision No MC/2016/15 of the Management Committee of the Office of the Body of European Regulators for Electronic Communications (BEREC Office) on the policy on protecting the dignity of the person and preventing psychological harassment and sexual harassment.
- (4) In the context of the above-mentioned activities, the BEREC Office collects and processes relevant information and several categories of personal data, including identification data of a natural person, contact information, professional roles and tasks, information on private and professional conduct and performance, and financial data. The BEREC Office acts as data controller.
- (5) Adequate safeguards are in place to protect personal data and prevent them from accidental or unlawful access or transfer, both if they are stored in a physical or in an electronic environment. After processing, the data are retained in accordance with the applicable BEREC Office's retention rules, as defined in data protection records based on Article 31 of the Regulation. At the end of the retention period, the case related information, including personal data, is deleted, anonymised or transferred to the historical archives.
- (6) Within this context, the BEREC Office is bound to fulfil its obligation to provide information to the data subjects in relation to the above processing activities and respect the rights of the data subjects, as laid down in the Regulation.

⁽¹⁾ OJ L 321, 17.12.2018, p. 1.

⁽²⁾ OJ L 295, 21.11.2018, p. 39.

⁽³⁾ Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations and the Conditions of Employment of Other Servants of the European Communities and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1).

- (7) It may be necessary to reconcile the rights of data subjects pursuant to the Regulation with the needs of the above-mentioned activities, while fully respecting fundamental rights and freedoms of other data subjects. To that effect, Article 25 of the Regulation provides, under strict conditions, the possibility to restrict the application of Articles 14 to 20, 35 and 36, as well as Article 4 insofar as its provisions correspond to the rights and obligations provided for in Articles 14 to 20. In this case, it is necessary to adopt internal rules under which the BEREC Office may restrict those rights in line with the same Article of the Regulation.
- (8) This might in particular be the case when providing information about the processing of personal data to the data subject at the preliminary assessment phase of an administrative enquiry or during the enquiry itself, prior to a possible dismissal of the case or a pre-disciplinary stage. In certain circumstances, providing such information might seriously affect the BEREC Office's capacity to conduct the enquiry in an effective way, whenever, for example, there is a risk that the person concerned destroys evidence or interferes with potential witnesses before they are interviewed. Furthermore, the BEREC Office might need to protect their rights and freedoms as well as the rights and freedoms of other persons involved.
- (9) It might be necessary to protect the confidentiality of a witness or a whistle-blower who has asked not to be identified. In such a case, the BEREC Office may decide to restrict access to the identity, statements and other personal data of the whistle-blower and other persons involved, in order to protect their rights and freedoms.
- (10) It might be necessary to protect the confidentiality of a staff member who has contacted BEREC Office's confidential counsellors in the context of a harassment procedure. In such a case, the BEREC Office may decide to restrict access to the identity, statements and other personal data of the alleged victim, the alleged harasser and other persons involved, in order to protect their rights and freedoms.
- (11) The BEREC Office should apply restrictions only when they respect the essence of the fundamental rights and freedoms, and are strictly necessary and a proportionate measure in a democratic society. The BEREC Office should give justifications explaining the grounds for those restrictions.
- (12) Based on the principle of accountability, the BEREC Office should keep a record of the application of the restrictions.
- (13) Article 25(6) of the Regulation obliges the controller to inform data subjects of the principal reasons on which the application of the restriction is based and of their right to lodge a complaint with the EDPS.
- (14) Pursuant to Article 25(8) of the Regulation, the BEREC Office may defer, omit or deny the provision of information on the reasons for the application of a restriction to the data subject if this would in any way cancel the effect of the restriction. The BEREC Office should assess on a case-by-case basis whether the communication of the restriction would cancel its effect.
- (15) The BEREC Office should lift the restriction as soon as the conditions that justify the restriction no longer apply, and assess those conditions on a regular basis.
- (16) To guarantee the utmost protection of the rights and freedoms of data subjects and in accordance with Article 44(1) of the Regulation, the DPO should be informed in due time of any restrictions being applied and verify compliance with this Decision.
- (17) The application of the above-mentioned restrictions is without prejudice to the possible application of the provisions of Article 16(5) and 17(4) of the Regulation, relating, respectively, to the right of information when data have not been obtained from the data subject, and to the right of access by the data subject.
- (18) The European Data Protection Supervisor ('EDPS') has been consulted on 27 May 2019,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

This Decision lays down rules relating to the conditions under which the BEREC Office may restrict the application of Articles 14 to 20, 35 and 36, as well as Article 4 thereof based on Article 25 of the Regulation.

Article 2

Restrictions

1. In accordance with Article 25(1) of the Regulation, the BEREC Office may restrict the application of Articles 14 to 20, 35 and 36, as well as Article 4 thereof, in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 20, when:
 - (a) conducting administrative inquiries, pre-disciplinary, disciplinary and suspension proceedings, on the basis of Annex IX to the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union and in compliance with Decision MC/2012/3 by the Management Committee of the Office of the Body of European Regulators for Electronic Communications (BEREC Office) laying down general implementing provisions on the conduct of administrative inquiries and disciplinary procedures, which implies processing of information including personal data. Relevant restrictions may be based on Article 25(1)(c), (g), (h) of the Regulation;
 - (b) ensuring that BEREC Office's staff members may confidentially report facts where they believe there are serious irregularities in compliance with Decision No MC/2018/11 of the Management Committee of the Office of the Body of European Regulators for Electronic Communications (BEREC Office) laying down guidelines on whistleblowing of the BEREC Office. Relevant restrictions may be based on Article 25(1)(h) of the Regulation;
 - (c) ensuring that BEREC Office's staff members may confidentially report to confidential counsellors in the context of a harassment procedure in compliance with Decision No MC/2016/15 of the Management Committee of the Office of the Body of European Regulators for Electronic Communications (BEREC Office) on the policy on protecting the dignity of the person and preventing psychological harassment and sexual harassment. Relevant restrictions may be based on Article 25(1)(h) of the Regulation.
2. The categories of data include identification data of a natural person, contact information, professional roles and tasks, information on private and professional conduct and performance, and financial data.
3. Any restriction shall respect the essence of the fundamental rights and freedoms and be necessary and proportionate in a democratic society.
4. A necessity and proportionality test shall be carried out on a case-by-case basis before restrictions are applied. Restrictions shall be limited to what is strictly necessary to achieve the set objectives taking into account the risks to the rights and freedoms of the data subjects.
5. The BEREC Office shall file, for accountability purposes, a record describing the reasons for the restrictions applied, which grounds among those listed in paragraph 1 apply and the outcome of the necessity and proportionality test. Those records shall be part of an ad hoc register, which shall be made available on request to the EDPS. A report on the application of Article 25 of the Regulation shall be made available periodically.

Article 3

Risks to the rights and freedoms of data subjects

The assessment of the risks to the rights and freedoms of data subjects whose personal data may be subject to restrictions, as well as their retention period, are referenced in the record of the relevant processing activities in accordance with Article 31 of the Regulation and, if applicable, in relevant data protection impact assessments based on Article 39 of the Regulation.

*Article 4***Storage periods and safeguards**

The BEREC Office shall implement safeguards to prevent abuse or unlawful access or transfer of personal data that may be subject to restrictions. These safeguards shall include technical and organisational measures and be detailed, as necessary, in BEREC Office's internal decisions, procedures and implementing rules. The safeguards shall include:

- (a) an adequate definition of roles, responsibilities and procedural steps;
- (b) if applicable, a secure electronic environment which prevents unlawful or accidental access or transfer of electronic data to unauthorised persons;
- (c) if applicable, secure storage and processing of paper-based documents.
- (d) due monitoring of restrictions and a periodical revision, which shall be done at least every six months. A revision must also be carried out when essential elements of the case at hand change. The restrictions shall be lifted as soon as the circumstances that justify them no longer apply.

*Article 5***Information to and review by the Data Protection Officer**

1. The DPO of the BEREC Office shall be informed without undue delay whenever the data subject rights are restricted in accordance with this Decision and shall be provided access to the record and any documents underlying factual and legal elements.
2. The DPO of the BEREC Office may request to review the application of the restriction. The BEREC Office shall inform its DPO in writing about the outcome of the requested review.
3. The involvement of the DPO of the BEREC Office in the restrictions procedure, including information exchanges, shall be documented in the appropriate form.

*Article 6***Information to data subjects on restrictions to their rights**

1. The BEREC Office shall include in the data protection notices published on its website general information to the data subjects related to the potential restrictions of all data subjects' rights described in Article 2(1) of this Decision. The information shall cover which rights may be restricted, the reasons and the potential duration of the restriction.
2. Additionally, the BEREC Office shall inform data subjects individually on present or future restrictions of their rights without undue delay and in a written form, as further specified in Articles 7, 8 and 9 of this Decision.

*Article 7***Right to information to be provided to data subjects and communication on data breaches**

1. Where in the context of the activities mentioned in this Decision, the BEREC Office restricts, wholly or partly, their rights mentioned in Articles 14 to 16 and 35 of the Regulation, data subjects shall be informed of the principal reasons on which the application of the restriction is based, and of their right to lodge a complaint with the EDPS as well as seeking a judicial remedy before the Court of Justice of the European Union.
2. The BEREC Office may defer, omit or deny the provision of information concerning the reasons for the restriction referred to in paragraph 1 for as long as it would cancel the effect of the restriction. This assessment shall take place on a case-by-case basis.

*Article 8***Data subjects' right of access, rectification, erasure and restriction of processing**

1. Where in the context of the activities mentioned in this Decision, the BEREC Office restricts, wholly or partly, the right of access to personal data, the right to rectification, erasure, and restriction of processing, as referred to in Articles 17 to 20 respectively of the Regulation, it shall inform the data subject concerned, in its reply to their request, of the principal reasons on which the application of the restriction is based, and of the possibility of lodging a complaint with the EDPS or of seeking a judicial remedy before the Court of Justice of the European Union.
2. The BEREC Office may defer, omit or deny the provision of information concerning the reasons for the restriction referred to in paragraph 1 if it would cancel the effect of the restriction. This assessment shall take place on a case-by-case basis.

*Article 9***Confidentiality of electronic communication**

1. The BEREC Office, under exceptional circumstances, and in line with the provisions and the rationale of Directive 2002/58/EC of the European Parliament and of the Council ⁽⁴⁾, may restrict the right to confidentiality of electronic communications, as referred to in Article 36 of the Regulation. In this case, the BEREC Office shall detail circumstances, grounds, relevant risks and related safeguards in specific internal rules.
2. Where the BEREC Office restricts the right to confidentiality of electronic communications, it shall inform the data subject concerned, in its reply to their request, of the principal reasons on which the application of the restriction is based, and of the possibility of lodging a complaint with the EDPS or of seeking a judicial remedy before the Court of Justice of the European Union.
3. The BEREC Office may defer, omit or deny the provision of information concerning the reasons for the restriction referred to in paragraph 1 and 2 for as long as it would cancel the effect of the restriction. This assessment shall take place on a case-by-case basis.

*Article 10***Entry into force**

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

Done at Riga, 10 September 2019.

For the Agency for Support for BEREC
Jeremy GODFREY
Chairperson of the Management Board

⁽⁴⁾ Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).

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