Council of the European Union

Brussels, 2 April 2020
(OR. en)

7141/20

Interinstitutional File: 2020/0056(NLE)

FIN 185
JAI 278
PROCIV 20
IPCR 11
SAN 119
PHARM 5

PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	2 April 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2020) 175 final
Subject:	Proposal for a Council Regulation activating the emergency support under Council Regulation (EU) 2016/369 of 15 March 2016 and amending its provisions in respect of the COVID-19 outbreak

Delegations will find attached document COM(2020) 175 final.

Encl.: COM(2020) 175 final

EUROPEAN
COMMISSION

Brussels, 2.4.2020
COM(2020) 175 final

2020/0056 (NLE)

Proposal for a

COUNCIL REGULATION

activating the emergency support under Council Regulation (EU) 2016/369 of 15 March 2016 and amending its provisions in respect of the COVID-19 outbreak

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The COVID-19 pandemic is leading to an unprecedented loss of life in the European Union and causing untold hardship for the people of Europe. Member States are adopting exceptional measures restraining personal freedoms to limit the loss of lives and contain the spread of the virus. As a consequence, economic activities are disrupted causing liquidity constraints and severe deterioration of the financial situation of economic actors.

The healthcare systems of Member States are under extreme pressure by the quick spread of the virus and the high number of patients that need hospitalisation. All Member States are forced to increase the spending on their healthcare systems in order to finance the increasing needs linked to the COVID-19 pandemic while continuing to provide essential medical services to all other patients. At the same time, EU countries have to allocate human resources to identify, procure and ensure the timely supply of the much needed medical equipment and accompanying provisions.

While presently the situation in the different Member States varies, it evolves quickly showing tangibly that the European Union as a whole is concerned and that a collective, coordinated and urgent response is needed to fight the spread of the virus effectively and mitigate its impact as fast as possible. Addressing this exceptional situation effectively requires a coordinated strategy of different measures aiming in particular at preserving people's lives, preventing and alleviating human suffering and protecting human dignity.

A coordinated action at EU level would make it possible to both address the current crisis and ensure a proper response in its aftermath inter alia through:

– wider and faster stock-piling and coordination of essential resource distribution across Europe;

– meeting the transport needs for protective gear to be imported from international partners as well as transport across the EU;

– transportation of patients in need to cross-border hospitals which can offer free capacity;

– cross-border cooperation to alleviate the pressure on health systems in the most affected EU regions;

– central procurement and distribution of essential medical supplies to hospitals and emergency supply of protective gear for hospital staff, such as respirators, ventilators, personal protective equipment, reusable masks, medicines, therapeutics and laboratory supplies and disinfectants;

– increasing and converting production capacities of EU enterprises to ensure rapid production and deployment of equipment and material needed to urgently address supplies shortages of essential products and medicines;

– increasing care facilities and resources, including temporary and semi-permanent field hospitals and support for reconverted facilities;

– increasing the production of testing kits and support for acquiring key basic substances;

– boosting the swift development of medication and testing methods;

– developing, purchasing and distributing testing supplies (testing kits, reagents, hardware).

The measures foreseen under the Union Civil Protection Mechanism/rescEU, the Coronavirus Response Investment Initiative to deploy European Structural and Investment Funds[1] and other Union instruments are contributing to partly address the current public health emergency. However, the scale and scope of the challenge requires a stronger response, directed in particular to the EU healthcare sector. That is why the Commission proposes to mobilise the Emergency Support Instrument to equip the EU with a broader toolbox commensurate to the large scale of the current COVID-19 pandemic.

In view of the above, support under the Emergency Support Regulation (No 2016/369) should be activated as soon as possible. This will allow the Union to deploy measures preventing and mitigating severe consequences in one or more Member States and addressing in a coordinated manner the needs related to the COVID-19 disaster, by complementing assistance provided through other EU instruments.

The Emergency Support Regulation offers a concrete means to express solidarity at EU level by involving citizens and civil society in the fight against the crisis. On the expenditure side the instrument allows involving of NGOs as well as international organisations, regional and national authorities (e.g. health sectors). On the revenue side it foresees not only additional contributions from the Member States but also donations by individuals, foundations and even crowd funding. The Commission is looking into putting in place all necessary modalities to allow speedy collection of contributions and donations.

- **Consistency with existing policy provisions in the policy area**

Taking into account the above considerations, the Commission proposes to activate the emergency assistance support in accordance with Article 2 of Regulation 2016/369 and to amend some of its provisions to address the special needs of the COVID-19 outbreak. In particular, the Commission proposes:

– activation of EU support from the 1 February 2020 and for a period of two years;

– extending the scope of the eligible actions and eligible implementing partners in view of the large scope of the measures required to address the COVID–19 crisis and further defining the scope of eligible costs;

– retroactive application of the Regulation as from 1 February 2020 with eligibility of relevant actions as of that date in view of ensuring equality of treatment between the Member States;

– extended period for concluding legal commitments to ensure flexibility in the implementation of emergency support;

– possibility for the Commission to procure emergency support for the Member States to address their needs related to COVID-19 pandemic, including through joint procurement, and centralised procurement on behalf of the Member States.

The coordinated action and measures allowed under the proposed Regulation will be complementary to support provided under other EU instruments.

- **Consistency with other Union policies:**

The proposal to activate the Emergency Support Instrument is part of the package of EU measures to respond to the current COVID-19 pandemic. Such measures are based on a coordinated and

[1] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 1303/2013, Regulation (EU) No 1301/2013 and Regulation (EU) No 508/2014 as regards specific measures to mobilise investments in the health care systems of the Member States and in other sectors of their economies in response to the COVID-19 outbreak [Coronavirus Response Investment Initiative], of 13 March 2020 COM(2020) 113 final.

ambitious approach to make the most effective use of available resources from the EU budget[2], including the Coronavirus Response Investment Initiative, the proposed extension of the scope of the EU Solidarity Fund to public health crises[3], exploiting all possibilities under financial instruments and the EFSI budgetary guarantee to strengthen investment support (e.g. the Competitiveness of Small and Medium-Sized Enterprise - COSME - programme and the InnovFin SME Guarantees under the Horizon 2020 programme).

This proposal complements all the measures mentioned above.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

As specified above, the COVID-19 pandemic is a sudden and exceptional event entailing a massive and disruptive impact on the Member States' financial, economic and health care systems. This EU action is needed to respond to the current COVID-19 crisis in a spirit of solidarity. It is therefore under Article 122(1) TFEU for the Union to adopt the envisaged measures and coordinated action aiming at tackling the encountered serious difficulties.

• Subsidiarity (for non-exclusive competence)

The activation of the Emergency Support Instrument to combat the COVID-19 within the EU is underpinned by the subsidiarity principle. Due to the global dimension of the COVID-19 pandemic, the large scale of its economic and social effects and the high strain of the health care systems in all Member States, the Union is better placed than Member States alone to address the crisis in a holistic and coordinated manner across the board.

Only a coordinated action motivated by a spirit of solidarity between Member States can ensure that the spread of COVID-19 is stopped efficiently and rapidly, the impact of the disaster is mitigated as much as possible and its aftermath is addressed to prevent its resurgence. Due to the pressing demands to mobilise resources in sufficient scale and deploy them across the EU Member States on the basis of their needs, it is necessary that the EU acts in cooperation with all Member States hit by the COVID-19 pandemic.

• Proportionality

The mobilisation and use by the EU of all resources necessary to contain the spread of the COVID-19 would significantly help to increase the actions for preserving human life, human health and dignity and to revive the Member States' economies. Given the unprecedented consequences of the COVID-19 for all EU citizens and all sectors of the economy and considering the need for rapid and efficient action, the proposal does not go beyond what is necessary to achieve the objectives laid down in the current instrument.

• Choice of the instrument

Taking into account the dimension of the COVID-19 pandemic and of the scope of its social, economic and financial impact, the Commission deems suitable to act by way of a regulation which is of general scope and directly and immediately applicable. This would result in a swift, uniform and Union-wide financial assistance mechanism.

---

2 Communication from the Commission to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup, Coordinated economic response to the COVID-19 Outbreak, 13 March 2020, COM(2020) 112 final

3 Proposal for a Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 2012/2002 in order to provide financial assistance to Member States and countries negotiating their accession to the Union seriously affected by a major public health emergency, 13 March 2020, COM(2020) 114 final.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

Due to the urgency to prepare the proposal so that it can be adopted on time by the Council, a stakeholder consultation could not be carried out.

- **Collection and use of expertise**

Not relevant.

- **Impact assessment**

Due to the urgent nature of the proposal, no impact assessment was carried out.

- **Regulatory fitness and simplification**

Not relevant.

- **Fundamental rights**

Not relevant.

4. BUDGETARY IMPLICATIONS

An allocation of EUR 2,7 billion is proposed for 2020 to support the financing of actions envisaged under the re-activated Emergency Support Instrument. Sources of financing are further described in the Legislative Financial Statement submitted with this proposal and reflected in the draft amending budget No. 2/2020.

Additional financing may be provided depending on the evolution of the crisis and the related needs that cannot be covered by other instruments.

5. OTHER ELEMENTS

Not relevant.

2020/0056 (NLE)

Proposal for a

COUNCIL REGULATION

activating the emergency support under Council Regulation (EU) 2016/369 of 15 March 2016 and amending its provisions in respect of the COVID-19 outbreak

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 122(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The COVID-19 crisis, declared a pandemic by the World Health Organisation (WHO) on 11 March 2020, has affected the European Union society and economy in a dramatic way, requiring the Member States to adopt a set of exceptional measures.

(2) In addition to the economic and social impact of the pandemic, the health care systems of Member States are severely strained by the crisis. All Member States are faced with increased demands in particular for medical equipment and provisions, essential public services and production capacities for such materials.

(3) Rapid and diversified measures are needed to allow the Union as a whole to address the crisis in a spirit of solidarity under the constraints caused by the quick spread of the virus. In particular, such measures should aim to preserve life, prevent and alleviate human suffering and maintain human dignity wherever the need arises as a result of the current COVID-19 crisis.

(4) The nature and consequences of the COVID-19 outbreak are large-scale and transnational and therefore require a comprehensive response. The measures provided for under the Union Civil Protection Mechanism ("rescEU") established by Decision No 1313/2013/EU of the European Parliament and of the Council[4] and other existing Union instruments are limited in scale and therefore do not allow a sufficient response or make it possible to address effectively the large-scale consequences of the COVID-19 crisis within the Union.

(5) Therefore, it is necessary to activate the emergency support under Council Regulation (EU) 2016/369.

(6) To allow for the level of flexibility needed to ensure a prolonged coordinated response under unforeseen circumstances as it is the case for the COVID-19 crisis, e.g. provision of medical supplies and medication, recovery measures, relevant medical research, it is necessary to ensure that budgetary commitments made during the activation period can be used for concluding legal commitments during the entire duration of the activation period, without prejudice to the general financial rules applicable to the general budget of the Union laid down in Article 114(2) of

[4] Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[5]. Costs incurred under such legal commitments should be eligible for the whole period of their implementation.

(7) In order to ensure equal treatment and a level playing field for all Member State it is also necessary to allow for retroactive eligibility of costs as of the date of activation of the support including for actions already completed provided they have started after that date.

(8) In order to preserve the subsidiary nature of emergency support under Regulation (EU) 2016/369, such a support should be strictly complementary to any assistance made available under other Union instruments.

(9) In the context of the COVID-19 crisis it has become apparent that it is necessary to extend the scope of Regulation (EU) 2016/369 in order to provide financing to cover urgent needs for medical equipment and materials, such as respiratory ventilators and protective gear, chemical supplies for tests, the costs for the development, production and distribution of medication, other supplies and materials. It should also be made possible to finance actions to support the necessary steps to obtain approval for the use of medical products.

(10) To alleviate the acute strain on the medical workforce and on state resources due to insufficient capacities of essential public services, and to maintain the viability of the healthcare system, a temporary reinforcement and exchange of medical professionals as well as the treatment of patients from other Member States should be supported financially or by organisational means.

(11) Professionals in healthcare and logistics should receive training also in view of the fight against counterfeiting of healthcare supplies.

(12) In view of the large-scale consequences of COVID-19, a rapid and comprehensive engagement of all relevant partners is required, including public authorities, public and private primary and hospital care suppliers and nursing homes, etc. Activities to relieve pressure on the health infrastructure and to support groups of vulnerable persons at risk are needed.

(13) In order to address supply shortages, production capacities for essential medical products such as medication, diagnostic tests, laboratory supplies, protective gear, etc. should be supported and funding should be provided to maintain a stock of these products.

(14) Additional or alternative testing methods to increase capacity and relevant medical research should be assisted by financial and/or organisational means.

(15) Contracting authorities from Member States are facing considerable legal and practical difficulties in purchasing supplies or services in emergency situations. In order to allow contracting authorities to derive maximum benefit from the potential of the internal market in terms of economies of scale and risk-benefit sharing, it is of utmost importance to extend the possibilities for the Commission to purchase supplies or services on behalf of the Member States. The Commission should be enabled to

[5] 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).

conduct the relevant procurement procedures. Where a contracting authority of a Member State conducts certain parts of the procedure, for instance the reopening of competition under a framework agreement or the award of individual contracts based on a dynamic purchasing system, that contracting authority would be responsible for the stages it conducts.

(16) For emergency situations, where it is necessary to carry out a joint procurement between the Commission and one or more contracting authorities from the Member States, it should be made possible that Member States acquire, rent or lease fully the capacities jointly procured.

(17) The Commission should be allowed to buy, stock, resell and donate supplies and services, including rentals, to Member States or partner organisations selected by the Commission.

(18) Regulation (EU) 2016/369 should therefore be amended accordingly.

(19) Given the situation related to the COVID-19 crisis, it is necessary for this Regulation to enter into force as a matter of urgency.

(20) In order to ensure equal treatment and a level playing field for all Member States and provide coverage regardless of when the outbreak occurred in each Member State it is necessary to apply this Regulation from 1 February 2020,

HAS ADOPTED THIS REGULATION:

Article 1

Emergency support under Regulation (EU) 2016/369 is hereby activated to finance expenditure necessary to address the COVID-19 pandemic for the period 1 February 2020 to 31 January 2022.

Article 2

By way of derogation from and without prejudice to Article 114(2) of Regulation (EU, Euratom) 2018/1046 the global budgetary commitments giving rise to expenditure for support under this Regulation shall cover the total costs of the corresponding legal commitments entered into until the end of the activation period referred to in Article 1.

Expenditure shall be eligible as from the date of activation of the support referred to in Article 1.

By way of derogation from Article 193(3) of Regulation (EU, Euratom) 2018/1046, grants may be awarded for actions already completed before the date of entry into force of this Regulation provided that the actions started after the date of the activation referred to in Article 1.

Article 3

Regulation (EU) 2016/369 is amended as follows:

(1) Articles 3 and 4 are replaced by the following:

"Article 3

Eligible actions

1. Emergency support under this Regulation shall provide a needs-based emergency response, complementing the response of the affected Member States aimed at preserving life, preventing and alleviating human suffering, and maintaining human dignity wherever the need arises as a result of a disaster referred to in Article 1(1). Without prejudice to the activation period as referred to in Article 2(1) support may also be granted in view of addressing needs in the aftermath of a disaster or preventing its resurgence.

2. Emergency support, as referred to in paragraph 1, may include any of the humanitarian aid actions which would be eligible for Union financing pursuant to Articles 2, 3 and 4 of Regulation (EC) No 1257/96, and may consequently encompass assistance, relief and, where necessary, protection operations to save and preserve life in disasters or in their immediate aftermath. It may also be used to finance any other expenditure directly related to the implementation of emergency support under this Regulation. In particular, support may be used to finance the actions laid down in Annex 1.

3. Without prejudice to paragraph 4, emergency support under this Regulation shall be granted and implemented in compliance with the fundamental humanitarian principles of humanity, neutrality, impartiality and independence.

4. The actions referred to in paragraph 2 shall be carried out by the Commission or by partner organisations selected by the Commission. The Commission may notably select, as partner organisations, non-governmental organisations, specialised services of the Member States, national authorities and other public bodies, international organisations and their agencies and, where appropriate and necessary for the implementation of an action, other organisations and entities having the requisite expertise or active in the sectors relevant for disaster relief, such as private service providers, equipment manufacturers as well as scientists and research institutions. In doing so, the Commission shall maintain a close cooperation with the affected Member State.

Article 4

Types of financial intervention and implementing procedures

1. The Commission shall implement the Union's financial support in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[6]. In particular, Union financing for support actions under this Regulation shall be implemented by means of direct or indirect management in accordance with points (a) and (c), respectively, of Article 62(1) of that Regulation.

[6] 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. Emergency support under this Regulation shall be financed by the general budget of the Union and by contributions which may be made by Member States and by other public or private donors as external assigned revenue in accordance with Article 21(5) of Regulation (EU, Euratom) No 2018/1046.

3. Union financing for support actions under this Regulation to be implemented by means of direct management may be awarded directly by the Commission without a call for proposals, in accordance with Article 195 of Regulation (EU, Euratom) No 2018/1046. To that effect, the Commission may enter into framework partnership agreements or rely on existing framework partnership agreements concluded pursuant to Regulation (EC) No 1257/96.

4. Where the Commission implements emergency support operations through non-governmental organisations, the criteria concerning financial and operational capacity shall be deemed to be satisfied where there is a framework partnership agreement in force between that organisation and the Commission pursuant to Regulation (EC) No 1257/96.

5. Emergency support under this Regulation may be granted in any of the following forms:

(a) joint procurement with the Member States as referred to in Article 165 (2) of Regulation (EU, Euratom) 2018/1046 whereby Member States may acquire, rent or lease fully the capacities jointly procured;

(b) procurement by the Commission on behalf of the Member States based on an agreement between the Commission and the Member States.

(c) procurement by the Commission as wholesaler by buying, stocking and reselling or donating supplies and services, including rentals, to Member States or partner organisations selected by the Commissions.

6. In the event of a procurement procedure as referred to in paragraph 5(b), the ensuing contracts shall be concluded by either of the following:

(a) by the Commission whereby the services or goods shall be rendered or delivered to Member States or to partner organisations selected by the Commission;

(b) by the participant Member States whereby they shall directly acquire, rent or lease the capacities procured for them by the Commission.

7. In the event of procurement procedures as referred to in paragraph 5(b) and (c), the Commission shall follow the rules of Regulation (EU, Euratom) 2018/1046 for its own procurement."

(2) In Article 5, paragraphs 1 and 2 are replaced by the following:

"1. Union financing may cover any direct costs necessary for the implementation of the eligible actions set out in Article 3, including the purchase, preparation, collection, transport, storage and distribution of goods and services under those actions as well as investment costs of actions or projects directly related to the achievement of the objectives of the emergency support activated in accordance with this Regulation. "

2. The indirect costs of the partner organisations may also be covered in accordance with Regulation (EU, Euratom) 2018/1046. ”

(3) The following Annex 1 is added:

“**ANNEX 1**

Eligible actions

The following actions may be financed in case of pandemics with large scale effect:

(a) temporary reinforcement of the medical workforce, exchange of medical professionals, hosting foreign patients or other type of mutual support;

(b) deployment of temporary health care facilities and temporary extension of existing health care facilities to relieve pressure on existing structures and increase overall health care capacity;

(c) activities to support the administration of large-scale application of medical tests and prepare the necessary scientific testing strategies and protocols;

(d) setting up temporary quarantine facilities and other appropriate measures at the Union borders;

(e) development, production or purchase and distribution of medical products;

(f) increases and conversions of production capacities for medical products as referred to in point (e) to address supply shortages;

(g) maintenance of the stock of medical products as referred to in point (e) and their disposal;

(h) actions to support the necessary steps to obtain approval for the use of the medical products as referred to in point (e) if required;

(j) actions to develop appropriate methods to track the development of the epidemic and the results of measures implemented to address it;

(k) organisation of ad-hoc clinical trials of potential therapies or diagnostics according to trial standards agreed at Union level;

(l) scientific validation of medical products, including potential new testing methods.

The above list is not exhaustive.”

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,

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

1.4. Objective(s)

1.5. Grounds for the proposal/initiative

1.6. Duration and financial impact

1.7. Management mode(s) planned

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

2.2. Management and control system

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

3.2.2. Estimated impact on operational appropriations

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.4. Compatibility with the current multiannual financial framework

3.2.5. Third-party contributions

3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Council Regulation activating the emergency support under Council Regulation (EU) 2016/369 of 15 March 2016 and amending its provisions in respect of COVID-19 outbreak.

1.2. Policy area(s) concerned in the ABM/ABB structure[7]

Migration and home affairs (Title 18 of the general budget of the European Union, Section 3 Commission)

1.3. Nature of the proposal/initiative

X The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action[8]**

☐ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objective(s)

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

Emergency support may be awarded under Regulation (EU) 2016/369 in the event of an ongoing or potential natural or man-made disaster, where the exceptional scale and impact of the disaster is such that it gives rises to severe wide-ranging humanitarian consequences in one or more Member States and only in exceptional circumstances where no other instrument available to Member States and to the Union is sufficient.

Activating emergency support under Council Regulation (EU) 2016/369 should directly contribute to protect the fundamental rights of those people who would benefit from the actions receiving financial assistance as part of the activation, including the protection of human dignity, and the rights to life and integrity of the person (Articles 1, 2 and 3 of the EU Charter of Fundamental Rights).

The objective of this Council Regulation is to lay down measures to respond to the urgent and exceptional humanitarian needs experienced in Member States as a result of the spreading of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the related disease (COVID-19), which has been characterised by the World Health Organization (WHO) as a public health emergency of international concern and a global pandemic. All EU Member States (as well as the EEA countries and the UK) are affected.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective

[7] ABM: activity-based management; ABB: activity-based budgeting.

[8] As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

To provide emergency support within the Union to address urgent humanitarian needs in the form of support to Member States, assistance, relief and, where need be, operations to preserve life.

This initiative shall be a concrete sign of solidarity within the Union.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal will enable the European Union to address, within its territory, the urgent humanitarian needs of EU citizens and residents as a consequence of the COVID-19 outbreak.

In particular, undertaking actions aimed at transportation of equipment, provision of temporary hospitals and medical teams, specialised hospitals for COVID patients, medical supplies (including ventilators, personal protective equipment, diagnostics and therapeutics), flying medical teams, transport of COVID and non-COVID patients.

Emergency support ill be provided in compliance with the fundamental humanitarian principles of humanity, neutrality, impartiality and independence.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

Number of people benefitting from emergency support within the European Union in absolute number and, if available, as percentage of the total of those needing assistance.

Number of temporary hospitals and medical teams, flying medical teams.

Magnitude of the medical supplies provided (in absolute number and, if available, as percentage of total needs).

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The current proposal for a Council Regulation aims at complementing the existing Union instruments and legal bases, and namely to provide in a more targeted way, emergency support to people within the Union to address urgent humanitarian needs as a consequence of the COVID-19 outbreak in Member States. The provision of emergency support within the European Union is necessary where the exceptional scale and impact is such that it gives rise to severe, wide-ranging humanitarian consequences.

1.5.2. Added value of EU involvement

Actions taken by the affected Member States, including with Union financial support to be made available under other Union instruments would not appear to be able to address effectively the public health related humanitarian consequences of the outbreak within the Union, in light notably of the timeframe within which such Union financial support may be made available.

As the conditions set out in Article 1 of Council regulation (EU) 2016/369 are satisfied, it is appropriate for the Council to activate emergency support under the Regulation in respect of the COVID-2019 outbreak.

Lessons learned from similar experiences in the past

The Council Regulation on the provision of emergency support within the Union. was adopted by the Council on 15 March 2016. The Emergency Support Instrument was activated in 2016 in order to cope with the large influx of refugees and migrants in Greece that created a humanitarian emergency.

In line with Article 8(2) of Council Regulation (EU) 2016/369, the Commission submitted an evaluation of the operation of the Regulation to the Council in March 2019. The evaluation was positive and led to the Regulation being kept in force even though inactivated and without there being proposed any amendment thereto.

1.5.3. Lessons learned from similar experiences in the past

The financing of this initiative requires an amendment of the MFF Regulation.

Through its Civil Protection Mechanism ("the Union Mechanism"), the Union seeks to strengthen the cooperation between the Union and the Member States and to facilitate coordination in the field of civil protection in order to improve the effectiveness of systems for preventing, preparing for and responding to natural and man-made disasters. The Union Mechanism can be activated by Member States in case of natural and man-made disasters, including acute health emergencies occurring inside the Union.

Building up rescEU capacities is still work in progress in relation to assets directly relevant for the crises for which the activation is proposed.

Therefore, while it is beyond doubt that any support to be awarded under the proposed activation would need to be complementary to any assistance offered through the Mechanism, any assistance to be made available thereunder is most unlikely to be of such a scale that it could be considered as being sufficient to address effectively the public health related humanitarian consequences of the outbreak within the Union. Measures under the Civil Protection Mechanism and the Emergency Support Instrument are therefore complementary.

To the extent that it serves to provide emergency assistance to meet the needs of people affected by disasters, emergency support under Council Regulation (EU) 2016/369 could be considered to be close to the type of assistance to be awarded under Council regulation (EC) No 1257/96 of 20 June 1996 concerning humanitarian aid. Council Regulation (EC) No 1247/96 can however only be used to finance humanitarian aid operations outside of the Union, and is therefore no substitute to Council Regulation (EU) 2016/369 in case of disasters within the Union.

1.5.4. Compatibility and possible synergy with other appropriate instruments

All possible redeployments have been exhausted in the current context of the COVID-19 outbreak. The magnitude of the COVID-19 outbreak in Member States and the potential, related needs justify the use of special instruments as provided in the MFF Regulation.

1.6. Duration and financial impact

X Proposal of **limited duration**

– in effect from the date of adoption for a period of 24 months (‘activation period’); actions receiving financial support under Regulation (EU) 2016/369 as part of this activation may have an implementation period ending after the end of the

activation period provided any such implementation period does not end more than 24 months after the end of the activation period

– Financial impact: 2020 for commitment appropriations and from 2020 to 2023 for payment appropriations.

1.7. Management mode(s) planned[9]

X **Direct management** by the Commission

– X by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

X **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated;

– X international organisations and their agencies (to be specified);

– ☐the EIB and the European Investment Fund;

– ☐ bodies referred to in Articles 208 and 209 of the Financial Regulation;

– X public law bodies;

– X bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

– ☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

– *If more than one management mode is indicated, please provide details in the 'Comments' section.*

Comments

None.

[9] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

Actions receiving financial assistance under this proposal shall be monitored regularly.

The Commission shall prepare and submit to the Council an ex post evaluation report 3 years after the entry into force of the regulation.

2.2. Management and control system

2.2.1. Risk(s) identified

Implementation will be made through actions carried out by selected partner organisations, including NGOs and United Nations and its Agencies, International Organisations and Member States Specialised Agencies through direct and indirect management. Certain activities may be implemented through specific actions by other organisations through direct management when necessary. This set-up is considered the most appropriate to achieve the objectives of the instrument by fully taking into consideration the principles of economy, efficiency and best value for money.

For activities close in nature to humanitarian aid activities the payment modalities applicable to the Humanitarian Aid instrument and the Union's Civil Protection Mechanism in both direct and indirect management modes will be applied as they proved to be adequate.

2.2.2. Information concerning the internal control system set up

The European Commission's existing internal control system applies to ensure that funds available under the Union Mechanism are used properly and in line with appropriate legislation.

The current system is setup as follows:

1. The internal control team within the lead service (Directorate-General for European Civil Protection and Humanitarian Aid Operations /DG ECHO) focuses on compliance with administrative procedures and legislation in force. The Internal Control Framework of the Commission is used for this purpose. Other Commission services involved in the implementation of the Instrument will follow the same Control Framework.

2. Regular audit of grants and contracts by external auditors, which will be awarded under this instrument will be fully incorporated in annual audit plans.

3. Evaluation of overall activities by external evaluators.

Actions performed may be audited by the European Anti-Fraud office (OLAF) and the Court of Auditors.

On supervision and monitoring of activities close to humanitarian aid activities, the extensive experience acquired by implementing the Humanitarian Aid instrument and the Union's Civil Protection Mechanism in both direct and indirect management modes will be applied.

2.2.3. Estimate of the costs and benefits of the controls and assessment of the expected level of risk of error

As a reference, the estimated cost of DG ECHO's control strategy represents 0.3% of indirect management of the 2018 budget and 0.5 % of direct management of the 2018 budget. The main components of this indicator are:

– the total staff costs of DG ECHO experts in the field, plus those of the financial and operational units multiplied by the estimated portion of time dedicated to quality assurance, control and monitoring activities;

– the total resources in DG ECHO's external audit sector devoted to audits and verifications.

Taking into account the low cost of such controls together with the quantifiable (corrections and recoveries) and unquantifiable (deterrent effect and quality insurance effect of controls) benefits linked to these, the Commission is able to conclude that the quantifiable and unquantifiable benefits from controls largely outweigh the limited cost of these.

With regard to the entrusted entities implementing EU funding under indirect management mode, the Commission contributes up to 7% of their indirect eligible costs to ensure supervision and management of the EU funding.

This is confirmed by the 0.5% multi-annual residual error rate reported by the Commission in 2018 for its humanitarian aid and civil protection department.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

As a reference, DG ECHO's anti-fraud strategy, in line with the Commission's anti-fraud strategy, is used in order to ensure that:

– DG ECHO's internal anti-fraud related controls are fully aligned with the Commission's anti-fraud strategy;AFS;

– DG ECHO's fraud risk management approach is geared to identify fraud risk areas and adequate responses.

The systems used for spending EU funds in third countries enable relevant data to be retrieved so that this data can be fed into fraud risk management (e.g. to detect double funding).

Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the sector may be set up.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[10]	from EFTA countries [11]	from candidate countries[12]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
3	18 01 04 05 Support expenditure for emergency support within the Union	Non-diff.	NO	NO	NO	NO
3	18 07 01 Instrument for emergency support within the Union	Diff	NO	NO	NO	NO

- No new budget lines requested

[10] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
[11] EFTA: European Free Trade Association.
[12] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework	3	Security and Citizenship

DG: ECHO			Year **2020**	Year **2021**	Year **2022**	Year **2023**	**TOTAL**
• Operational appropriations							
18 07 01	Commitments	(1)	2 646,000	-	-	-	**2 646,000**
	Payments	(2)	1 326,000	790,000	265,000	265,000	**2 646,000**
Appropriations of an administrative nature financed from the envelope of specific programmes[13]							
18 01 04 05		(3)	54,000	-	-	-	**54,000**
TOTAL appropriations for DG ECHO	Commitments	=1+1a +3	2 700,000	-	-	-	**2 700,000**
	Payments	=2+2a +3	1 380,000	790,000	265,000	265,000	**2 700,000**

• TOTAL operational appropriations	Commitments	(4)	2 646,000	-	-	-	**2 646,000**
	Payments	(5)	1 326,000	790,000	265,000	265,000	**2 646,000**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	54,000	-	-	-	**54,000**

[13] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

TOTAL appropriations under HEADING 3 of the multiannual financial framework	Commitments	=4+ 6	**2 700,000**	**-**	**-**	**-**	**2 700,000**
	Payments	=5+ 6	**1 380,000**	**790,000**	**265,000**	**265,000**	**2 700,000**

Heading of multiannual financial framework	**5**	'Administrative expenditure'

EUR million (to three decimal places)

		Year **2020**	Year **2021**	Year **2022**	Year **2023**	**TOTAL**
Commission						
• Human resources		2,700	2,700	1,550	1,150	**8,100**
• Other administrative expenditure		**-**	**-**	**-**	**-**	**-**
TOTAL Commission	Appropriations	2,700	2,700	1,550	1,150	**8,100**

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	**2,700**	**2,700**	**1,550**	**1,150**	**8,100**

EUR million (to three decimal places)

		Year **2020**	Year **2021**	Year **2022**	Year **2023**	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	**2 702,700**	**2,700**	**1,550**	**1,150**	**2 708,100**
	Payments	**1 382,700**	**792,700**	**266,550**	**266,150**	**2 708,100**

3.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– X The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs⇩		Year **2020**		Year **2021**		**TOTAL**	
		OUTPUTS					
	Average cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE[14]:							
Transportation of equipment	1	80	80	20	20	100	100
Temporary hospitals and medical teams	10	9,6	96	2,4	24	12	120
Specialised hospitals for COVID	100	8	800	2	200	10	1 000
Medical supplies (ventilators)	0,018	14 000	252	3 500	63	17 500	315
Medical supplies (other)	0,002	428 000	856	107 000	214	535 000	1 070
Flying medical teams	0,04	800	32	200	8	1 000	40
Subtotal for specific objective No 1		442 898	2 116	110 724	529	553 622	2 645
TOTALS		442 898	2 116	110 724	529	**553 622**	**2 645**

[14] As described in point 1.4.2. 'Specific objective(s)…'

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– X The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year **2020**	Year **2021**	Year **2022**	Year **2023**	**TOTAL**
HEADING 5 of the multiannual financial framework					
Human resources	2,700	2,700	1,550	1,150	**8,100**
Other administrative expenditure					
Subtotal HEADING 5 of the multiannual financial framework	2,700	2,700	1,550	1,150	**8,100**

Outside HEADING 5[15] of the multiannual financial framework					
Human resources					
Other expenditure of an administrative nature	54,000	-	-	-	**54,000**
Subtotal outside HEADING 5 of the multiannual financial framework					

TOTAL	**56,700**	**2,700**	**1,550**	**1,150**	**62,100**

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

15 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources.

– X The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

		Year **2020**	Year **2021**	Year **2022**	Year **2013**
• Establishment plan posts (officials and temporary staff)					
XX 01 01 01 (Headquarters and Commission's Representation Offices)		10	10	5	5
XX 01 01 02 (Delegations)					
XX 01 05 01/11/21 (Indirect research)					
10 01 05 01/11 (Direct research)					
External staff (in Full Time Equivalent unit: FTE)[16]					
XX 01 02 01 (AC, END, INT from the 'global envelope')		15	15	10	5
XX 01 02 02 (AC, AL, END, INT and JPD in the delegations)					
XX 01 04 **yy** [17]	- at Headquarters				
	- in Delegations				
XX 01 05 02/12/22 (AC, END, INT - Indirect research)					
10 01 05 02/12 (AC, END, INT - Direct research)					
Other budget lines (specify)					
TOTAL		**25**	**25**	**15**	**10**

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DGs who are already assigned to management of the action and/or have been redeployed within the DGs, together if necessary with any additional allocation which may be granted to the managing DGs under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	
External staff	

16 AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JPD= Junior Professionals in Delegations.

17 Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

3.2.4. Compatibility with the current multiannual financial framework

– ☐ The proposal/initiative is compatible the current multiannual financial framework.

– ☐ The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

– X The proposal/initiative requires the use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments or revision of the multiannual financial framework.

Given the absence of margins and room for redeployment under heading 3 of the MFF, the Commission proposes in parallel to this initiative: • to amend the MFF Regulation so as to remove the limitations in the scope of the Global Margin for Commitment and to use the remaining amount under this instrument for this initiative (in draft amending budget No°2/2020); • to mobilise the remaining amount of the Flexibility Instrument; • to mobilise the Contingency Margin for the balance.

3.2.5. Third-party contributions

– X The proposal/initiative does not provide for co-financing by third parties.[18]

– ☐ The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to three decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

[18] Article 4(2) of Council Regulation 2016/369 provides for the possibility of public or private donors to contribute to the Emergency Support Instrument. If such contributions become available they will constitute external assigned revenue in accordance with that provision and with Article 21(5) of the Financial Regulation.

3.3. Estimated impact on revenue

– X The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on miscellaneous revenue