

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The current initiative aims to support and facilitate measures taken at Union level in the public interest, in particular where the Union is acting in the execution of a mandate to acquire goods and services in order to distribute them free of charge to Member States according to their emergency needs. These measures are - inter alia - aimed at the prevention of, preparation for or response to emergencies in the context of current or future crises and disasters. The initiative supports these measures by eliminating value added tax (VAT) as a cost factor as well as related compliance burden. More specifically, this proposal provides for an exemption from VAT of goods or services supplied to and goods imported by the Commission or an EU agency or body where the Commission or any such agency or body acquires these goods or services in the fulfilment of a mandate conferred on them by Union law in the public interest.

The ongoing COVID-19 pandemic shows to a particular degree the importance of being well prepared and being able to respond quickly based on a structured, coherent and centralized approach at EU level. This conclusion also applies to other present and future situations that require coordinated action at Union level. Therefore, building on the experience with handling of the COVID-19 pandemic, this initiative aims to provide the European Union with a broad-based and future-proof solution. The objective is to align the EU VAT provisions, for example in respect of measures in the field of disaster and crisis management, and thus to facilitate the activities of the Commission, the EU agencies or other EU bodies when fulfilling any mandate conferred on them by Union law.

The experience gained in the Commission taking emergency measures during the course of the COVID 19 pandemic has shown that the VAT charged on some transactions ends up being a cost factor in procurement operations that strains limited budgets. Those amounts of VAT reduce the volume of goods and services, which the Commission can procure for stockpiling or immediate distribution to Member States, whilst adding complexity and delaying solidarity-based operations to address urgent needs. In addition, compliance costs become a burden for businesses who are providing goods and services to the Union, particularly as regards their registration with tax authorities in many or all Member States.

There is therefore an urgent need for immediate action as regards the fight against the current COVID-19 pandemic and in order to create readiness to act with a view to comparable future measures taken at Union level in the public interest. For this purpose, a broad-based VAT exemption for purchases made by the Commission or by an EU agency or body in order to donate, stockpile or otherwise provide goods or services to Member States or third parties should be introduced since that is the appropriate solution required to facilitate the coordination of measures at Union level.

Based on the lessons learned from the COVID-19 pandemic and in order to provide a solution that is future-proof, the scope of this proposal is broad-based, covering all types of goods and services. As regards goods, it would for instance apply to medical countermeasures (MCMs) of all kind such as biologic products[[1]](#footnote-1), drugs and medicines[[2]](#footnote-2) as well as medical devices[[3]](#footnote-3). The proposal would also cover non-medical items necessary for addressing humanitarian crises[[4]](#footnote-4). This proposal also covers a wide range of services with or without link to the health sector[[5]](#footnote-5).

The eligible purpose for which these goods and services are put to use by the Commission or an EU agency or body is any activity in the fulfilment of a mandate conferred on them under Union law and which is in the public interest. The goods or services acquired may, for example, be intended to be made available free of charge to Member States or to a third party[[6]](#footnote-6). They could also be part of a stockfiling strategy in view of future donations.

In the face of the COVID‑19 pandemic, the Commission has taken exceptional measures in the area of VAT to help victims of the outbreak. On 3 April 2020, the Commission adopted Decision (EU) 2020/491[[7]](#footnote-7) enabling Member States to temporarily exempt from VAT (and relieve from customs duties) vital goods needed to combat the effects of the COVID‑19 outbreak (covering among other personal protective equipment, in vitro diagnostic medical devices, medical devices such as ventilators and a limited number of medicines[[8]](#footnote-8)).

This decision covers only importation and not intra-Community or domestic supplies, because the autonomous powers of the Commission are limited to that particular field. The initial measure applied for a period of six months, and was further extended until 31 October 2020[[9]](#footnote-9) and 30 April 2021[[10]](#footnote-10). A further extension is currently under preparation.

On 7 December 2020[[11]](#footnote-11), the Council adopted a proposal from the Commission[[12]](#footnote-12) introducing an amendment to Council Directive 2006/112/EC[[13]](#footnote-13) (the VAT Directive) and allowing Member States to apply a reduced rate of VAT to the supply of COVID-19 *in vitro* diagnostic medical devices and services closely linked thereto. In addition, Member States are allowed to grant an exemption with deductibility of VAT paid at the preceding stage in respect of the supply of these devices and closely linked services as well as the supply of COVID-19 vaccines and services closely linked to those vaccines.

These measures provided fast, efficient and targeted solutions for urgent needs occurring in the course of the COVID-19 pandemic. They are however very limited in scope of application and temporary in nature and not all Member States have chosen to apply the option of zero rates where that has been made available.

The VAT Directive provides, subject to certain conditions and limits, for an exemption[[14]](#footnote-14) with deductibility of VAT at the preceding stage concerning the importation of goods by and the supply of goods and services to European bodies (including the Commission) to which the Protocol on the privileges and immunities of the European Union (PPI[[15]](#footnote-15)) applies. Based on the respective interpretation of the PPI, that exemption is strictly limited to purchases made for the official use of that EU body. It would not apply to the purchase of goods and services which are, for instance, intended for being made available for free to Member States or a third party such as a national health authority or hospital as this is not regarded as official use. Precisely such cases can however become particularly important in response to crises and hence the currently applicable VAT exemptions are insufficient in this respect.

The 2018 Commission proposal[[16]](#footnote-16) to amend the VAT Directive as regards VAT rates, which is pending before the Council, could neither provide a satisfactory solution in lifting VAT from all transactions at which this initiative aims. If adopted unanimously by Council, it would allow Member States to apply a reduced rate or even a zero rate[[17]](#footnote-17) to certain supplies, if such supplies benefit only the final consumer and pursue an objective of general interest. It would in any event remain the discretionary decision of Member States to apply any such favourable VAT treatment.

In order to help Member States to cope better with the challenges of the digital age and to reduce administrative burden associated with the use of the paper version of the exemption certificate provided for in Annex II of Council Implementing Regulation (EU) No 282/2011[[18]](#footnote-18) particularly in situations of crises such as pandemics, an electronic form should be introduced. The purpose of that form is to confirm that the transaction qualifies for the exemption under the first subparagraph of Article 151(1) of the VAT Directive. As already done under Article 199b(4) of the VAT Directive, the Commission should be empowered to adopt by means of implementing acts the technical details of that form, including a common electronic message by which the information is to be transmitted, in consultation of the Standing Committee on Administrative Cooperation established by Article 58 of Council Regulation (EU) No 904/2010[[19]](#footnote-19), applying the examination procedure referred to in Article 5 of Regulation (EU) No 182/2011[[20]](#footnote-20).

• Consistency with existing policy provisions in the policy area

The proposal complements Commission Decision (EU) 2020/491 of 3 April 2020 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID‑19 outbreak during 2020, which has been extended until the end of April 2021. It also complements Council Directive (EU) No 2020/2020 of 7 December 2020 amending Directive 2006/112/EC as regards temporary measures in relation to value added tax applicable to COVID-19 vaccines and *in vitro* diagnostic medical devices in response to the COVID-19 pandemic. It is also in line with the 2018 Commission proposal to amend the VAT Directive as regards VAT rates, which is pending before the Council.

• Consistency with other Union policies

The proposal is consistent with the initiatives taken under EU policies such as the European Health Union and the Pharmaceutical Strategy for Europe. It is particularly consistent with the initiatives described below.

On 14 April 2020, the Council activated the Emergency Support Instrument (ESI[[21]](#footnote-21)), which helps Member States respond to the COVID-19 pandemic by addressing urgent needs in a strategic and coordinated manner at EU level.

On 2 June 2020, the Commission proposed[[22]](#footnote-22) targeted changes to the EU Civil Protection Mechanism[[23]](#footnote-23), allowing the Union and the Member States to be better prepared for and react quickly and effectively to future crises, in particular those with a high-impact given the potential disruption to our economies and societies, as seen so clearly in the COVID-19 emergency. The overall objective of the EU Civil Protection Mechanism is to strengthen cooperation between the EU Member States and six participating States[[24]](#footnote-24) in the field of civil protection, with a view to improve prevention, preparedness and response to disasters. When the scale of an emergency overwhelms the response capabilities of a country, it can request assistance via the Mechanism. Through the Mechanism, the Commission plays a key role in coordinating the response to disasters in Europe and beyond and contributes to at least 75% of the transport and/or operational costs of deployments. The Emergency Response Coordination Centre (ERCC)[[25]](#footnote-25) of the Commission is the heart of the EU Civil Protection Mechanism and coordinates the delivery of assistance to disaster stricken countries, such as relief items, expertise, civil protection teams and specialised equipment.

In the 2020 State of the Union address of 16 September 2020, the President of the Commission stressed the need to draw lessons from the current crisis and build a European Health Union. In parallel, she outlined the corresponding key initiatives for 2021 in a Letter of Intent[[26]](#footnote-26) to the President of the European Parliament and the Council Presidency. Those initiatives also contain legislative proposals aimed at establishing a new European Biomedical Research and Development Agency, extending the mandates of the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) as well as establishing a European health data space.

In its 2021 Work Programme[[27]](#footnote-27), the Commission underlined the need to strengthen our crisis preparedness and management of cross-border health threats and confirmed that it is time to build a stronger European Health Union. The Work Programme contains legislative proposals to reinforce the EU’s framework for detecting and responding to serious cross-border health threats, and to strengthen the roles of existing agencies. Further initiatives will cover a proposal to establish an agency for biomedical advanced research and development, a new pharmaceutical strategy ensuring citizens can rely on safe, affordable and high quality medicines and a European health data space to harness data for better healthcare, better research, and better policy making to the benefit of patients.

In March 2021, the new Programme for the Union’s action in the field of health (‘EU4Health Programme’)[[28]](#footnote-28) was adopted, which aims to make health systems more resilient to deal with cross-border health threats like COVID-19 and improve crisis management capacity. Moreover, it will make the European Health Union a reality by investing in cancer care, better pandemic preparedness, availability of medicines and innovation and boost digital health and disease prevention.

With its Communication of 11 November 2020[[29]](#footnote-29), the Commission set out the first building blocks for a European Health Union. The Communication was accompanied by three legislative proposals: a Regulation on serious cross-border threats to health replacing Decision 1082/2013/EU[[30]](#footnote-30), a strengthening of the mandates of the ECDC[[31]](#footnote-31) and of the EMA[[32]](#footnote-32).

The new European Health Union initiative advocates the strengthening of existing structures and mechanisms for better EU level protection, prevention, preparedness and response against human health hazards. It recommends a reinforced framework for cross-border cooperation against all health threats in order to protect lives better and to safeguard the internal market as well as to maintain the highest standards in the protection of human rights and civil liberties. It also strengthens the EU role in international coordination and cooperation to prevent and control cross-border health threats and improve global health security.

In the context of the new European Health Union, the Commission also announced a legislative proposal to be presented before the end of 2021 setting up the Health Emergency Response Authority (HERA).

With its Communication of 25 November 2020[[33]](#footnote-33), the Commission put forward a new Pharmaceutical Strategy for Europe, presenting concrete actions to ensure accessibility, availability and affordability of medicines. These will support diversified and secure supply chains, ensuring the EU's open strategic autonomy in the world, and will promote environmentally sustainable pharmaceuticals. The strategy also aims at enhancing crisis preparedness and response mechanisms.

It is important to note that existing and future EU agencies as well as other EU bodies play an increasingly important role in pursuing the objectives of the aforementioned or other future initiatives. Hence, the present legislative proposal should also cover supplies made to or imports made by these agencies or bodies.

The EMA was founded in 1995[[34]](#footnote-34) and its mission is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health. Its mandate will be reinforced in the context of the new European Health Union as to include monitoring and mitigating potential shortages of critical medicines and medical devices, providing scientific advice on medicines with potential to treat, prevent or diagnose diseases causing crises, coordinating studies to monitor the effectiveness and safety of vaccines as well as coordinating clinical trials.

Established in 2005[[35]](#footnote-35), the ECDC’s mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases. Its future mandate will cover epidemiological (real-time) surveillance, preparedness and response planning, reporting and auditing, provision of non-binding recommendations and options for risk management, capacity to mobilise and deploy EU Health Task Force to assist local response in Member States and building a network of EU reference laboratories and a network for substances of human origin.

The future HERA’s mission will be to enable the EU and its Member States to deploy rapidly the most advanced medical and other measures in the event of a health emergency, by covering the whole value chain from conception to distribution and use[[36]](#footnote-36).

Several joint procurements[[37]](#footnote-37) have been carried out or are planned during 2020/2021 covering goods necessary to cope with the COVID-19 pandemic such as personal protective equipment (PPE), ventilators, laboratory equipment, vaccination material, rapid-antigen tests and therapeutics (e.g. Remdesivir). Under the Emergency Support Instrument, the Commission has directly procured masks, therapeutics and tests for donation to Member States.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The legal basis of the proposal is Article 113 of the Treaty on the Functioning of the EU. This Article provides for the Council, acting unanimously in accordance with a special legislative procedure and after consulting the European Parliament and the Economic and Social Committee, to adopt provisions for the harmonisation of Member States’ rules in the area of indirect taxation.

• Subsidiarity (for non-exclusive competence)

According to the principle of subsidiarity, as set out in Article 5(3) of the Treaty on European Union, action at Union level may only be taken if the envisaged aims cannot be achieved sufficiently by the Member States alone and can therefore, by reason of the scale or effects of the proposed actions, be better achieved by the EU. The current VAT Directive prevents Member States from applying a general exemption from VAT to the importation of goods by and the supply of goods and services to the Commission or an EU agency or body intended to support and facilitate measures taken at EU level in the public interest. A legislative initiative at EU level to amend the Directive is the most efficient way to ensure the functioning of such measures by fully eliminating VAT as a cost factor as well as removing additional burden through related compliance costs.

• Proportionality

The proposal is consistent with the principle of proportionality because it does not go beyond what is necessary and is proportionate for achieving the intended objective. The initiative exempts from VAT the importation of goods and the supply of goods and services which the Commission or an EU agency or body acquires in the fulfilment of a mandate conferred on them by Union law, particularly order to prepare measures against crises and disasters. Given the impact that crises or disasters such as the COVID-19 pandemic can have on Member States' economies, the proposed measures are proportionate in view of their budgetary impact on certain Member States as a result of the VAT exemption.

• Choice of the instrument

A Directive is required to amend the current VAT Directive.

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

• Stakeholder consultations

No stakeholder consultation has been conducted, due to the urgent character of this initiative, presented in the context of the COVID-19 pandemic.

• Collection and use of expertise

The Commission has relied on the information publicly available on the epidemiological situation as well as relevant available scientific evidence with regard to the ongoing COVID‑19 pandemic and its implications for comparable future challenges.

• Impact assessment

No separate impact assessment has been conducted, due to the urgent character of this initiative, presented in the context of the COVID-19 pandemic.

• Fundamental rights

This proposal will to a large extent facilitate Union measures, notably with regard to health protection. Health is a fundamental human right. The proposal is consistent with Article 168 of the Treaty on the Functioning of the European Union stipulating that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Moreover, it is consistent with Article 35 of the EU Charter of Fundamental Rights, which stipulates that everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices.

4. BUDGETARY IMPLICATIONS

The proposal will remove VAT as a cost factor for EU programmes. With the same budget, this will allow the EU to purchase more goods and services that are, for instance, intended for free distribution to a Member State, a national health authority or a hospital.

By introducing a new VAT exemption, the proposal could reduce VAT revenue collected by Member States and therefore the VAT own resource. While there will be no negative implications for the EU budget, as the own resource based on gross national income (GNI) compensates for any expenditure not covered by traditional own resources and the VAT own resource, the non-collected VAT own resources from certain Member States would have to be compensated by all Member States through the GNI own resource. However, given that the current volume of goods and services purchased by EU institutions and subject to VAT is small (in comparison to the overall economy), this effect is likely to be extremely limited.

5. OTHER ELEMENTS

• Explanatory documents (for directives)

The proposal does not require Explanatory Documents on the transposition.

• Detailed explanation of the specific provisions of the proposal

Points 1 and 2(a) of Article 1 aim at amending the VAT Directive by introducing an exemption from VAT for the importation of goods (new point (fb) in Article 143(1)) by and for the supply of goods or services (new point (ab) in Article 151(1)) to the European Commission or an agency or a body established under Union law where the Commission or the agency or body acquires these goods or services in the fulfilment of a mandate conferred on them by Union law in the public interest.

Point 2(b) of Article 1 aims to empower the Commission to render exemption certificate, which serves to confirm that the transaction qualifies for the exemption under the first subparagraph of Article 151(1) of the VAT Directive, electronic. That electronic form should be put in place in order to enable Member States to cope better with the challenges of the digital age and to reduce administrative burden associated with the use of the paper version of the form particularly in situations of crises such as pandemics. The electronic form should be adopted in consultation of the Standing Committee on Administrative Cooperation established by Article 58 of Council Regulation (EU) No 904/2010[[38]](#footnote-38), applying the examination procedure referred to in Article 5 of Regulation (EU) No 182/2011[[39]](#footnote-39).

The proposal will thus support and facilitate measures taken at Union level in the public interest by eliminating VAT amounts that become a cost factor as well as related compliance burden. The transactions covered by this proposal are not in any respect limited to the “activities in the public interest” referred to under Title IX, Chapter 2, of the VAT Directive.

Although the present initiative aims at facilitating measures taken in various policy fields, it is particularly urgent in view of the ongoing COVID-19 pandemic. Certain measures, which fall under the scope envisaged by this initiative, are already in progress. In order to safeguard their maximum benefit, Member States should apply the VAT exemption introduced by the proposal to transactions carried out as from 1 January 2021 retroactively.

2021/0097 (CNS)

Proposal for a

COUNCIL DIRECTIVE

amending Directive 2006/112/EC as regards exemptions on importations and on certain supplies, in respect of Union measures in the public interest

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 113 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Parliament[[40]](#footnote-40),

Having regard to the opinion of the European Economic and Social Committee[[41]](#footnote-41),

Acting in accordance with a special legislative procedure,

Whereas:

(1) In accordance with Council Directive 2006/112/EC[[42]](#footnote-42), Member States are to exempt from value added tax (VAT) the importation of goods by and the supply of goods and services to the European Union, the European Atomic Energy Community, the European Central Bank or the European Investment Bank, or by the bodies set up by the European Union to which the Protocol (No 7) on the privileges and immunities of the European Union, annexed to the Treaty on the Functioning of the European Union (“the Protocol”), applies, within the limits and under the conditions of the Protocol and the agreements for its implementation or the headquarters agreements, in so far as it does not lead to distortion of competition. That exemption is, however, strictly limited to purchases made for official use and it does not extend to situations where goods and services are purchased by Union bodies in the public interest, particularly when they are to be made available for free to Member States or third parties such as national authories or institutions.

(2) Experience gained during the course of the COVID-19 pandemic shows an urgent need for the adoption of measures in order to create readiness to act when dealing with comparable situations in the future. To enable such action, it is necessary to introduce a broad-based VAT exemption for the acquisition of goods and services by the Commission or by an agency or body established under Union law in the fulfilment of a mandate conferred on it by Union law in the public interest. Such exemption is in particular a prerequisite for the ability to deliver solutions required to facilitate coordinated measures of crisis management at Union level. It would ensure that measures to be taken under the various Union initiatives are not hampered by amounts of VAT to be collected or related compliance burden imposed on suppliers of the goods or services needed. The transactions covered by the exemption introduced by this proposal shall not in any respect be limited to the “activities in the public interest” referred to under Title IX, Chapter 2, of of Directive 2006/112/EC.

(3) There is already an exemption certificate in place, set out in Annex II to Council Implementing Regulation (EU) No 282/2011[[43]](#footnote-43), which serves to confirm that a supply of goods or services made to an eligible body or individual qualifies for the exemption under Article 151 of Directive 2006/112/EC. The Commission, agency or body established under Union law acquiring the goods and services to which the new exemption from VAT applies should be required to produce a certificate for their suppliers confirming that the relevant transaction qualifies for exemption. To facilitate issuance and transmission, that certificate should be electronic. In order to ensure uniform conditions for the implementation of Article 151(1) of Directive 2006/112/EC, implementing powers should be conferred on the Commission in respect of the technical details for the content and the issuance of the exemption certificate as well as the specifications as regards the electronic message by which the information contained in the certificate is to be transmitted. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[[44]](#footnote-44).

(4) Directive 2006/112/EC should therefore be amended accordingly.

(5) In view of the current COVID-19 pandemic, some measures that could fall under these exemptions are already underway. In order to make the best use of the Union budget in the public interest, the exemptions introduced by this Directive should apply from 1 January 2021,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2006/112/EC is amended as follows:

(1) in Article 143(1), the following point (fb) is inserted:

‘(fb) the importation of goods by the Commission or by an agency or a body established under Union law where the Commission or any such agency or body acquires these goods or services in the fulfilment of a mandate conferred on it by Union law in the public interest;’;

(2) Article 151(1) is amended as follows:

(a) in the first subparagraph, the following point (ab) is inserted:

‘(ab) the supply of goods or services to the Commission or to an agency or a body established under Union law where the Commission or any such agency or body acquires these goods or services in the fulfilment of a mandate conferred on it by Union law in the public interest;’;

(b) the following subparagraph is added:

‘An exemption certificate shall be established, which serves to confirm that the transaction qualifies for the exemption under the first subparagraph of this paragraph. The Commission shall specify, by means of implementing acts, the technical details regarding the content and the issuance of the exemption certificate as well as the specifications as regards the electronic message by which the information contained in the certificate is to be transmitted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 5 of Regulation (EU) No 182/2011 and for this purpose the committee shall be the committee established by Article 58 of Council Regulation (EU) No 904/2010.’.

Article 2

Transposition

1. Member States shall adopt and publish, by 30 April 2021 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those measures from 1 January 2021.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

It shall apply from 1 January 2021.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

The President

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

Proposal for a COUNCIL DIRECTIVE amending Council Directive 2006/112/EC to lift the cost of VAT on Union measures in the public interest.

2. BUDGET LINES

2021

Chapter 13, Article 130

Amount budgeted for the year 2021: 17 967 491 250 €

3. FINANCIAL IMPACT

The Proposal has a financial impact on both expenditure and revenue – the effect is as follows:

|  |  |
| --- | --- |
|  |  |
| Budget line | Revenue  *Impact on own resources* | Period: 01/01/2021 to 31/12/2021  (€ million to one decimal place) |
| *Savings in the Commission's expenditure on VAT amounts (potentially on very different budget lines)* |  | - 110.00 |
| Article 130 Chapter 13 |  | 1.65 |
| **Total** |  | **- 108.35** |

The new exemption from VAT introduced by this proposal is limited to imports of goods made by and supplies of goods and services made to the Commission or an agency or other body established under Union law and is not open to imports or purchases made by commercial operators.

The purpose of the proposal is to remove the amounts of VAT from the budgetary expenditures of the Commission or an agency or other body established under Union law. This will mainly concern procurements of goods or services intended to be given free of charge (donated) to Member States or third parties. For reasons of simplification and due to the lack of availability of data on actual VAT amounts paid from EU budgets, the budgetary savings for 2021 have been estimated in retrospect of the 2020 budget for the Emergency Support Instrument (ESI) amounting to EUR 3 450 million. From this, the budget for the vaccine instrument of EUR 2 900 million was deducted because these transactions have been made to Member States directly (not to the Commission).

On this basis, the total estimated value of imports and supplies of goods and services concerning “buy and donate” activities covered by the proposal for the period is **EUR 550 million**. The amount of VAT saved on budgetary expenditures is estimated using a deemed tax rate of 20% and hence amounts to EUR 110 million.

The effect on the EU budget of the decrease in the VAT own resource, taking into account the uniform rate of call (0.30%), is estimated at EUR 1.65 million.

Although most of these expenditures under the ESI have actually be VAT exempt to Decision (EU) 2020/491 (imports of health material) and Council Directive (EU) No 2020/2020 (zero-rating of tests), “buy and donate” activities can virtually be on any good or service in the future and the above mentioned legal acts are of a temporary nature. It is therefore reasonable to take the total amount of the ESI (minus the part on vaccines) as an assumption.

4. ANTI-FRAUD MEASURES

The Decision contains provisions by which Member State authorities are bound to communicate to the Commission the text of the main provisions of national law, which they adopt in the field covered by the proposal.

1. Such as vaccines, blood products or antibodies. [↑](#footnote-ref-1)
2. Such as antimicrobials and antibiotics, chemical threat antidotes, treatments for radiation injury, antitoxins, iodine tablets for nuclear accidents. [↑](#footnote-ref-2)
3. Such as diagnostic tests and testing materials, laboratory equipment, personal protective equipment (PPE) such as gloves, respirators/masks, gowns, disinfection products and equipment. [↑](#footnote-ref-3)
4. Such as tents, camp beds, clothing and food; search and rescue equipment for earthquake regions; sandbags, life jackets and inflatable boats for flood regions; radiation measuring devices for nuclear accidents. [↑](#footnote-ref-4)
5. Such as development, production and procurement of necessary products; research and innovation activities; joint procurement activities; strategic stockpiling of products; pharmaceutical licences; application of therapeutics; hosting of patients; exchange of medical professionals or other experts; provision of quarantine facilities; clinical trials; scientific validation of medical products; disinfection of premises. [↑](#footnote-ref-5)
6. Such as a hospital, a national health or disaster response authority or a private company in charge of disaster response. [↑](#footnote-ref-6)
7. Commission Decision (EU) 2020/491 of 3 April 2020 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID‑19 outbreak during 2020 (OJ L 103 I, 3.4.2020, p. 1). [↑](#footnote-ref-7)
8. See indicative list of goods covered on <https://ec.europa.eu/taxation_customs/sites/taxation/files/03-04-2020-import-duties-vat-exemptions-on-importation-covid-19-list-of-goods.pdf> [↑](#footnote-ref-8)
9. Commission Decision (EU) 2020/1101 of 23 July 2020 amending Decision (EU) 2020/491 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID‑19 outbreak during 2020 (OJ L 241, 27.7.2020, p. 36). [↑](#footnote-ref-9)
10. Commission Decision (EU) 2020/1573 of 28 October 2020 amending Decision (EU) 2020/491 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID‑19 outbreak during 2020 (OJ L 359, 29.10.2020, p. 8). [↑](#footnote-ref-10)
11. Council Directive (EU) No 2020/2020 of 7 December 2020 amending Directive 2006/112/EC as regards temporary measures in relation to value added tax applicable to COVID-19 vaccines and *in vitro* diagnostic medical devices in response to the COVID-19 pandemic (OJ L 419, 11.12.2020, p. 1). [↑](#footnote-ref-11)
12. Proposal for a Council Directive amending Council Directive 2006/112/EC as regards temporary measures in relation to value added tax for COVID-19 vaccines and *in vitro* diagnostic medical devices in response to the COVID-19 pandemic (COM(2020) 688  final). [↑](#footnote-ref-12)
13. Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ L 347, 11.12.2006, p. 1), as amended. [↑](#footnote-ref-13)
14. Articles 143(1)(fa) and 151(1)(aa). [↑](#footnote-ref-14)
15. Protocol (No 7) on the Privileges and Immunities of the European Union (OJ C 326, 26.10.2012, p. 1). [↑](#footnote-ref-15)
16. Proposal for a Council Directive amending Directive 2006/112/EC as regards rates of value added tax (COM(2018) 20 final of 18 January 2018). [↑](#footnote-ref-16)
17. Exemption from VAT with deductibility of the VAT paid at the preceding stage of the supply chain. [↑](#footnote-ref-17)
18. Council Implementing Regulation (EU) No 282/2011 of 15 March 2011 laying down implementing measures for Directive 2006/112/EC on the common system of value added tax (recast) (OJ L 77, 23.3.2011, p. 1). [↑](#footnote-ref-18)
19. Council Regulation (EU) No 904/2010 of 7 October 2010 on administrative cooperation and combating fraud in the field of value added tax (OJ L 268, 12.10.2010, p. 1). [↑](#footnote-ref-19)
20. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers, (OJ L 55, 28.2.2011, p. 13). [↑](#footnote-ref-20)
21. Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID‑19 outbreak (OJ L 117, 15.4.2020, p. 3). [↑](#footnote-ref-21)
22. Proposal for a Decision of the European Parliament and of the Council amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (COM(2020) 220 final). [↑](#footnote-ref-22)
23. Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924). [↑](#footnote-ref-23)
24. Iceland, Norway, Serbia, North Macedonia, Montenegro, and Turkey. [↑](#footnote-ref-24)
25. <https://ec.europa.eu/echo/what/civil-protection/emergency-response-coordination-centre-ercc_en> [↑](#footnote-ref-25)
26. <https://ec.europa.eu/info/sites/info/files/state_of_the_union_2020_letter_of_intent_en.pdf> [↑](#footnote-ref-26)
27. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 19 October 2020 – A union of vitality in a world of fragility (COM(2020) 690 final) [↑](#footnote-ref-27)
28. Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1). [↑](#footnote-ref-28)
29. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats (COM(2020) 724 final). [↑](#footnote-ref-29)
30. Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1). [↑](#footnote-ref-30)
31. Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control (COM(2020) 726 final). [↑](#footnote-ref-31)
32. Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (COM(2020) 725 final). [↑](#footnote-ref-32)
33. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Pharmaceutical Strategy for Europe (COM(2020) 761 final). [↑](#footnote-ref-33)
34. Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ L 214, 24.8.1993, p. 1). [↑](#footnote-ref-34)
35. Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1) [↑](#footnote-ref-35)
36. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Building a European Health Union: Reinforcing the EU’s resilience for cross-border health threats (COM(2020) 724 final). [↑](#footnote-ref-36)
37. Article 5 of Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1). [↑](#footnote-ref-37)
38. Council Regulation (EU) No 904/2010 of 7 October 2010 on administrative cooperation and combating fraud in the field of value added tax (OJ L 268, 12.10.2010, p. 1). [↑](#footnote-ref-38)
39. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers, (OJ L 55, 28.2.2011, p. 13). [↑](#footnote-ref-39)
40. OJ C , , p. . [↑](#footnote-ref-40)
41. OJ C , , p. . [↑](#footnote-ref-41)
42. Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ L 347, 11.12.2006, p. 1). [↑](#footnote-ref-42)
43. Council Implementing Regulation (EU) No 282/2011 of 15 March 2011 laying down implementing measures for Directive 2006/112/EC on the common system of value added tax (recast) (OJ L 77, 23.3.2011, p. 1). [↑](#footnote-ref-43)
44. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers (OJ L 55, 28.2.2011, p. 13). [↑](#footnote-ref-44)