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Contents

I *Legislative acts*

REGULATIONS

- ★ **Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices ⁽¹⁾ 1**

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

- ★ **Council Decision (EU) 2022/124 of 25 January 2022 on the conclusion, on behalf of the European Union, of the Protocol to amend the Air Transport Agreement between the United States of America and the European Community and its Member States 38**

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2022/125 of 19 November 2021 amending Annexes I to V to Regulation (EU) No 691/2011 of the European Parliament and of the Council on European environmental economic accounts ⁽¹⁾ 40**
- ★ **Commission Delegated Regulation (EU) 2022/126 of 7 December 2021 supplementing Regulation (EU) 2021/2115 of the European Parliament and of the Council with additional requirements for certain types of intervention specified by Member States in their CAP Strategic Plans for the period 2023 to 2027 under that Regulation as well as rules on the ratio for the good agricultural and environmental condition (GAEC) standard 1 52**

⁽¹⁾ Text with EEA relevance.

EN

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

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

★ Commission Delegated Regulation (EU) 2022/127 of 7 December 2021 supplementing Regulation (EU) 2021/2116 of the European Parliament and of the Council with rules on paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro	95
★ Commission Implementing Regulation (EU) 2022/128 of 21 December 2021 laying down rules for the application of Regulation (EU) 2021/2116 of the European Parliament and of the Council on paying agencies and other bodies, financial management, clearance of accounts, checks, securities and transparency	131
★ Commission Implementing Regulation (EU) 2022/129 of 21 December 2021 laying down rules for types of intervention concerning oilseeds, cotton and by-products of wine making under Regulation (EU) 2021/2115 of the European Parliament and of the Council and for the information, publicity and visibility requirements relating to Union support and the CAP Strategic Plans	197
★ Commission Implementing Regulation (EU) 2022/130 of 24 January 2022 entering a name in the register of protected designations of origin and protected geographical indications ‘Bračko maslinovo ulje’ (PDO)	206
★ Commission Implementing Regulation (EU) 2022/131 of 24 January 2022 entering a name in the register of protected designations of origin and protected geographical indications ‘Carne Ramo Grande’ (PDO)	207
★ Commission Regulation (EU) 2022/132 of 28 January 2022 amending Regulation (EC) No 1099/2008 of the European Parliament and of the Council on energy statistics, as regards the implementation of updates for the annual, monthly and short-term monthly energy statistics ⁽¹⁾	208

DECISIONS

★ Council Implementing Decision (EU) 2022/133 of 25 January 2022 authorising France to introduce a special measure derogating from Articles 218 and 232 of Directive 2006/112/EC on the common system of value added tax	272
★ Decision (EU) [2022/134] of the European Central Bank of 19 January 2022 laying down common rules on the transmission by the European Central Bank of supervisory information to authorities and bodies for the purpose of carrying out the tasks conferred on it by Council Regulation (EU) No 1024/2013 (ECB/2022/2)	275

Corrigenda

★ Corrigendum to Commission Delegated Regulation (EU) 2022/1 of 20 October 2021 amending Regulation (EU) 2021/821 of the European Parliament and of the Council as regards the list of dual-use items (OJ L 3, 6.1.2022)	282
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⁽¹⁾ Text with EEA relevance.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2022/123 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 25 January 2022****on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) Pursuant to Articles 9 and 168 of the Treaty on the Functioning of the European Union ('TFEU') and Article 35 of the Charter of Fundamental Rights of the European Union (the 'Charter'), the Union is to ensure a high level of human health protection in the definition and implementation of all Union policies and activities.
- (2) The COVID-19 pandemic has highlighted the interconnectedness of human, animal, and ecosystem health and the risks posed by the loss of biodiversity on Earth. As recognised by the World Health Organization, many of the same microbes infect animals and humans, so efforts that focus only on human health or only on animal health cannot prevent or eliminate the problem of disease transmission. Diseases may be transmitted from humans to animals or vice versa and therefore need to be tackled in both humans and animals, taking advantage of potential synergies in research and treatments. Approximately 70 % of emerging diseases, and almost all known pandemics, namely influenza, HIV/AIDS and COVID-19, are zoonoses. Those diseases have increased globally over the past 60 years. Changes in land use, deforestation, urbanisation, agricultural expansion and intensification, wildlife trafficking and consumption patterns are factors that have contributed to that increase. Zoonotic pathogens can be bacterial, viral or parasitic, and can include unconventional agents that are able to spread to humans through direct contact or

⁽¹⁾ OJ C 286, 16.7.2021, p. 109.

⁽²⁾ OJ C 300, 27.7.2021, p. 87.

⁽³⁾ Position of the European Parliament of 20 January 2022 (not yet published in the Official Journal) and decision of the Council of 25 January 2022.

through food, water or the environment. The COVID-19 pandemic is a clear example of the need to reinforce the application of the One Health approach in the Union to achieve better public health outcomes, since, as stated in Regulation (EU) 2021/522 of the European Parliament and of the Council ⁽⁴⁾, 'human health is connected to animal health and to the environment and ... actions to tackle threats to health must take into account those three dimensions'.

- (3) The unprecedented experience of the COVID-19 pandemic has also highlighted the difficulties of the Union and the Member States in addressing such a public health emergency. In that regard, it has demonstrated the need to strengthen the Union's role in order to be more effective in managing the availability of medicinal products and the availability of medical devices and *in vitro* diagnostic medical devices and their respective accessories (collectively 'medical devices') and in developing medical countermeasures to address the threats posed to public health at an early stage in a harmonised way that ensures cooperation and coordination between Union, national and regional competent authorities, medicinal products and medical devices industry and other actors in the supply chains for medicinal products and medical devices, including healthcare professionals. While the Union needs to give a higher priority to health, its ability to ensure the continued provision of high quality healthcare services and to be prepared to address pandemics and other health threats has been severely impeded by the absence of a clearly defined legal framework for managing its response to pandemics and by the limited mandates and resources of its health agencies, as well as by the limited degree of Union and Member States preparedness for public health emergencies that impact a majority of the Member States.
- (4) Shortages of medicinal products and medical devices have different and complex root causes which need to be further mapped, understood and analysed together with the different stakeholders in order to be comprehensively addressed. A better understanding of those shortages should include identification of vulnerabilities in the supply chain. In the specific case of the COVID-19 pandemic, the shortage of treatments for the disease had a variety of causes, ranging from production difficulties in third countries to logistical or production difficulties within the Union, where the shortage of vaccines was due to inadequate manufacturing capacity.
- (5) Disruptions to the often complex supply chains for medicinal products and medical devices, national export restrictions and bans, border closures impeding the free movement of such goods, uncertainty related to the supply for and demand of such goods in the context of the COVID-19 pandemic, and the lack of production in the Union of certain medicinal products or active substances, have led to significant impediments to the smooth functioning of the internal market and to addressing the serious threats to public health across the Union, with serious consequences for the Union's citizens.
- (6) Addressing the issue of shortages of medicinal products has been a long-standing priority for the Member States and European Parliament as illustrated by several reports from the European Parliament such as the European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem ⁽⁵⁾, as well as by discussions within the Council of the European Union. However, that issue has remained, to date, unaddressed.
- (7) Shortages of medicinal products represent a growing threat to public health, with a serious impact on healthcare systems and on the right of patients to access appropriate medical treatment. Increased global demand for medicinal products, which was exacerbated by the COVID-19 pandemic, has led to further shortages of medicinal products, weakening the healthcare systems in Member States and posing significant risks to patients' health and to the care of patients, particularly in terms of disease progression and worsening of symptoms, longer delays or interruptions in care or therapy, longer periods of hospitalisation, increased risk of exposure to falsified medicinal products, medication errors, adverse effects resulting from the substitution of unavailable medicinal products with alternative ones, significant psychological distress for patients and increased costs for healthcare systems.

⁽⁴⁾ 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).

⁽⁵⁾ OJ C 385, 22.9.2021, p. 83.

- (8) The COVID-19 pandemic has exacerbated the problem of shortages of certain medicinal products considered to be critical to addressing the pandemic, and has highlighted the Union's external dependence in terms of domestic production of medicinal products and medical devices, the lack of coordination and the structural limitations in the Union's and Member States' ability to rapidly and effectively react to such challenges during public health emergencies. It has also highlighted the need to support and strengthen the industrial capacities to produce those medicinal products and medical devices through appropriate policies, as well as the need for more active and extensive involvement of the Union institutions, bodies, offices and agencies in protecting the health of Union citizens.
- (9) The rapid evolution of COVID-19 and the spread of the virus led to a sharp increase in demand for medical devices such as ventilators, surgical masks, and COVID-19 test kits, while disruption of production or limited capacity to rapidly increase production and the complexity and global nature of the supply chain for medical devices led to severe supply difficulties and, at certain times, serious shortages of medical devices. It has also led Member States competing with each other when they respond to the legitimate needs of their citizens, thereby contributing to uncoordinated actions at national level, such as national hoarding and stockpiling. Those issues further resulted in new entities being involved in the expedited production of such medical devices, which subsequently resulted in delays in conformity assessments and the prevalence of medical devices that were over-priced, non-compliant, unsafe, and, in some cases, counterfeits. It is therefore appropriate and a matter of urgency that long-term structures be established within the European Medicines Agency (the 'Agency'), established by Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽⁶⁾, to ensure more solid and effective monitoring of shortages of medical devices that can occur during a public health emergency and coordination of the management of those shortages, as well as increased and early dialogue with the medical devices industry and healthcare professionals to prevent and mitigate those shortages.
- (10) The COVID-19 pandemic and the subsequent public health emergency revealed the need for a more coordinated Union approach in crisis management. Although the lack of an impact assessment accompanying the Commission proposal for this Regulation was due to the emergency-like nature of the situation, sufficient allocation of resources in terms of staff and funding should be secured, taking into account the specificities of the health sector in the different Member States.
- (11) Uncertainty of supply and demand and the risk of shortages of medicinal products and medical devices during a public health emergency like the COVID-19 pandemic can trigger export restrictions among Member States and other national protective measures, which can seriously impact the functioning of the internal market, thereby exacerbating the consequences for public health, as well as leading to the need for temporary export transparency and export authorisation mechanisms. Furthermore, shortages of medicinal products can result in serious risks to the health of patients in the Union due to their lack of availability, which can result in medication errors, increased duration of hospital stays, adverse reactions and increased risk of fatalities caused by the administration of unsuitable medicinal products used as a substitute for unavailable medicinal products. With respect to medical devices, shortages can lead to a lack of diagnostic resources with negative consequences for public health measures or to a disease deteriorating or not being treated, and may also prevent health professionals from adequately carrying out their tasks or being protected when doing so, as evidenced during the COVID-19 pandemic, with serious consequences for their health. Such shortages, for example, insufficient supply of COVID-19 test kits, can also have a significant impact on control of the spread of a given pathogen. It is therefore important to have an appropriate framework at Union level to coordinate the Union response to shortages of medicinal products and medical devices and to reinforce and formalise the monitoring of critical medicinal products and medical devices in the most efficient way and in a way that avoids creating unnecessary burdens for stakeholders which can place a strain on resources and cause additional delays.
- (12) Safe and efficacious medicinal products that treat, prevent or diagnose diseases which cause public health emergencies, should be identified, developed, notably through joint efforts by public authorities, the private sector and academia, and made available to Union citizens as soon as possible during such emergencies. The COVID-19 pandemic has also highlighted the need to coordinate assessments and conclusions on multinational clinical trials, in line with what was done on a voluntary basis by clinical trials experts of Member States prior to the date of

⁽⁶⁾ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

application of Regulation (EU) No 536/2014 of the European Parliament and of the Council ⁽⁷⁾, and the need for Union-level advice on the use of medicinal products in national compassionate use programmes or the use of medicinal products for indications that are not covered by the marketing authorisation in the Union, in order to avoid delays in the implementation of results of research and in the development and availability of new or repurposed medicinal products.

- (13) During the COVID-19 pandemic, ad hoc solutions, such as contingent arrangements between the Commission, the Agency, marketing authorisation holders, manufacturers or other actors in the supply chain for medicinal products, on the one side, and Member States, on the other, had to be found in order to make available safe and efficacious medicinal products to treat COVID-19 or prevent its spread, and in order to facilitate and speed up the development and marketing authorisation of treatments and vaccines.
- (14) In order to ensure the better functioning of the internal market for safe and efficacious medicinal products for the treatment of COVID-19 or prevention of its spread and to contribute to a high level of human health protection, it is therefore appropriate to approximate and strengthen the rules on monitoring of shortages of medicinal products and medical devices, and to facilitate the research and development of medicinal products which have the potential to treat, prevent or diagnose diseases that cause public health emergencies, with a view to strategically complementing the efforts of the Commission, including the Health Emergency Preparedness and Response Authority ('HERA'), established by Commission Decision of 16 September 2021 ⁽⁸⁾, and Union agencies, to that end.
- (15) In order to support the assessment of the crisis-preparedness and crisis-management framework provided for in this Regulation with regard to shortages of medicinal products and medical devices, the Commission should be able to use the outcomes of targeted stress tests performed by the Commission, the Agency, Member States or other relevant actors. Such stress tests entail a simulation of a public health emergency or major event in which some or all segments of the processes and procedures laid down in this Regulation are tested.
- (16) This Regulation aims to ensure a high level of protection for human health by ensuring the smooth functioning of the internal market as regards medicinal products and medical devices. Moreover, this Regulation aims to ensure the quality, safety and efficacy of medicinal products that have the potential to address public health emergencies. Both objectives are being pursued simultaneously and are inseparably linked, without one being secondary to the other. As regards Article 114 TFEU, this Regulation establishes a framework for the monitoring and reporting of shortages of medicinal products and medical devices during public health emergencies and major events. As regards Article 168(4), point (c), TFEU, this Regulation should provide for a strengthened Union framework for ensuring the quality and safety of medicinal products and medical devices.
- (17) This Regulation should establish a framework to address the issue of shortages of medicinal products and medical devices during public health emergencies and major events. However, those shortages are a persistent problem that has been increasingly affecting the health and lives of Union citizens for decades. Therefore, this Regulation should be a first step towards improving the Union response to that persistent problem. The Commission should subsequently assess the expansion of that framework to ensure that the issue of shortages of medicinal products and medical devices is addressed.
- (18) In order to improve crisis preparedness and management with respect to medicinal products and medical devices and to increase resilience and solidarity across the Union, the procedures and the respective roles and obligations of the different entities concerned should be clarified. The framework established by this Regulation should build on the ad hoc solutions identified to date in the response to the COVID-19 pandemic that have proven effective, and should build on experience, best practices and examples from third countries, while remaining flexible enough to tackle any future public health emergency and major event in the most efficient way to the benefit of public health and patients.

⁽⁷⁾ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

⁽⁸⁾ OJ C 393 I, 29.9.2021, p. 3.

- (19) A harmonised system of monitoring shortages of medicinal products and medical devices should be established. This would facilitate appropriate access to critical medicinal products and medical devices during public health emergencies and major events, which can have a serious impact on public health. That system should be complemented by improved structures for ensuring the appropriate management of public health emergencies and major events and for coordinating and providing advice on research and development relating to medicinal products which have the potential to mitigate public health emergencies or major events. In order to facilitate the monitoring and reporting of actual or potential shortages of medicinal products and medical devices, the Agency should be able to request and obtain information and data from the marketing authorisation holders concerned, manufacturers and Member States through designated single points of contact, while avoiding any duplication of the information requested and submitted. This should not interfere with the obligation on marketing authorisation holders under Article 23a of Directive 2001/83/EC of the European Parliament and of the Council⁽⁹⁾ to notify a Member State when a product ceases to be placed on the market of that Member State or the obligation under Article 81 of that Directive on marketing authorisation holders and wholesale distributors to ensure appropriate and continued supplies of that medicinal product to persons and legal entities that are authorised or entitled to supply medicinal products, so that the needs of patients in the Member State in question are met.
- (20) In order to facilitate the prevention, monitoring and reporting of shortages of medicinal products, the Agency should set up an information technology (IT) platform, to be known as the European shortages monitoring platform ('ESMP'), that is capable of processing information on the supply of and demand for critical medicinal products during public health emergencies or major events and, outside of those situations, to allow for reporting on shortages of medicinal products that are likely to lead to public health emergencies or major events. To facilitate the development of the ESMP, existing IT systems should be leveraged and used where possible. The ESMP should allow national competent authorities to submit and monitor information on unmet demand, including information received from marketing authorisation holders, wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products to the public, in order to anticipate shortages of medicinal products. The ESMP could also process additional information received from marketing authorisation holders, wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products to the public in order to avert a public health emergency or a major event. The ESMP, once it is fully implemented, should act as the sole portal for marketing authorisation holders to provide the information required during public health emergencies and major events, with a view to increasing efficiency and predictability during public health emergencies and major events, and to accelerating the decision-making process while avoiding duplication of efforts and unjustified burdens on stakeholders. In order to facilitate the coordination role of the Agency, the interoperability of data with existing Member States' IT platforms for monitoring shortages and other systems, as appropriate, is essential to allow the sharing of relevant information with the ESMP, which should be managed by the Agency.
- (21) In the event that the actual future demand is unknown due to a public health emergency or major event, it is important to make pragmatic predictions as to demand for certain medicinal products on the basis of the best available information. In that context, information and data on available stocks and planned minimum stocks should be collected by Member States and the Agency and taken into account in identifying the demand as far as possible. Those information and data are essential for making correct adjustments in the manufacturing of medicinal products to avoid or at least mitigate the impact of shortages of medicinal products. However, when data on stocks are not available or cannot be provided due to national security interests, Member States should provide the Agency with estimated data on volumes of demand.
- (22) With respect to medicinal products, an executive steering group should be established within the Agency to ensure a robust response to major events and to coordinate urgent actions within the Union in relation to the management of issues relating to the supply of medicinal products (the 'Medicine Shortages Steering Group – MSSG'). The MSSG should establish lists of critical medicinal products to ensure monitoring of those products and it should be able to provide advice and recommendations on the necessary action to take to safeguard the quality, safety and efficacy of medicinal products as well as to safeguard the supply of medicinal products and to ensure a high level of human health protection.

⁽⁹⁾ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- (23) To facilitate appropriate communication between patients and consumers, on the one hand, and the MSSG, on the other, Member States could collect data on the impact of shortages of medicinal products on patients and consumers, and share relevant information with the MSSG in order to inform approaches to management of shortages of medicinal products.
- (24) In order to ensure the inclusivity and transparency of the work of the MSSG, there should be appropriate engagement between the MSSG and relevant third parties, including representatives of medicinal product interest groups, marketing authorisation holders, wholesale distributors, any other appropriate actors in the supply chain for medicinal products, and representatives of healthcare professionals, of patients and consumers.
- (25) The MSSG should benefit from the Agency's extensive scientific expertise as regards the evaluation and supervision of medicinal products and should further develop the Agency's leading role in coordinating and supporting the response to shortages of medicinal products during the COVID-19 pandemic.
- (26) In order to ensure that high quality, safe and efficacious medicinal products, which have the potential to address public health emergencies, can be developed and made available within the Union as soon as possible during public health emergencies, an emergency task force should be established within the Agency to provide advice on such medicinal products (the 'Emergency Task Force – ETF'). The ETF should provide advice on scientific questions related to the development of treatments and vaccines and on clinical trial protocols free of charge to those entities involved in their development, such as marketing authorisation holders, clinical trial sponsors, public health bodies, and academia, irrespective of their role in the development of such medicinal products. Decisions on clinical trial applications should remain within the competence of the Member States, in accordance with Regulation (EU) No 536/2014.
- (27) The work of the ETF should be separate from the work of the scientific committees of the Agency and should be carried out without prejudice to the scientific assessments of those committees. The ETF should provide advice and recommendations with regard to the use of medicinal products in the fight to overcome public-health emergencies. The Committee for Medicinal Products for Human Use ('CHMP') established by Article 5 of Regulation (EC) No 726/2004 should be able to use those recommendations when preparing scientific opinions on compassionate or other early use of a medicinal product prior to marketing authorisation. The MSSG could also draw on the work of the ETF when developing the critical medicines lists.
- (28) The establishment of the ETF should build on the support provided by the Agency during the COVID-19 pandemic, in particular as regards scientific advice on clinical trials design and product development as well as the 'rolling' review of emerging evidence, i.e. on an on-going basis, to allow a more efficient assessment of medicinal products including vaccines during public health emergencies, while guaranteeing a high level of human health protection.
- (29) In order to ensure the better functioning of the internal market for medicinal products and to contribute to a high level of human-health protection, it is appropriate for the ETF to coordinate and provide advice to developers involved in the research and development of medicinal products that have the potential to treat, prevent or diagnose diseases causing the public health emergency.
- (30) The ETF should provide advice on clinical trial protocols and to developers of clinical trials that are conducted in the Union, providing guidance on clinically relevant endpoints and targets for vaccines and treatments in order to facilitate clinical trial design meeting the criteria for effective public health interventions.
- (31) Experience with clinical trials during the COVID-19 pandemic revealed a tremendous amount of duplication of investigations on the same interventions, a high number of small trials, under-representation of important population subgroups, based on gender, age, ethnicity or medical comorbidities, and a lack of collaboration, leading to a risk that research will be wasted. International regulators pointed out the need to improve the clinical research agenda in order to generate robust evidence on quality, safety and efficacy of medicinal products. The main way of

obtaining reliable evidence is through coordinated, well-designed, and adequately powered large randomised controlled trials. Clinical trial results and clinical data produced after the relevant marketing authorisation has been granted should be made publicly available in a timely manner. The publication of the trial protocol at the start of the clinical trial would allow public scrutiny.

- (32) Whenever necessary, considering that medicinal products for human use may impact the veterinary sector, a close liaison with the national competent authorities for veterinary medicinal products should be envisaged.
- (33) Although individual research entities may agree with each other or with another party to act as a sponsor in order to prepare a single harmonised Union-wide clinical trial protocol, experience during the COVID-19 pandemic has shown that initiatives to set up large multinational trials struggle to materialise due to the lack of a single entity that is able to take up all the responsibilities and activities of a sponsor within the Union as well as interact with multiple Member States. To address that problem, a new Union-wide and Union-funded vaccine trial network called VACCELERATE was launched following the Commission communication of 17 February 2021 entitled 'HERA Incubator: Anticipating together the threat of COVID-19 variants'. The Agency should identify and facilitate such initiatives by giving advice on the possibilities for acting as a sponsor or, where applicable, for allocating respective responsibilities as co-sponsors in accordance with Article 72 of Regulation (EU) No 536/2014 and coordinate the development of clinical trial protocols. Such an approach would strengthen the research environment in the Union, would promote harmonisation and would avoid subsequent delays in availability of results of research for marketing authorisation files. A Union sponsor could benefit from Union research funding available at the time of the public health emergency as well as from existing clinical trial networks to facilitate the development, application, submission, and running of trials. This may be particularly valuable for trials established by Union or international public health or research organisations.
- (34) The Agency publishes European Public Assessment Reports (EPARs) for medicinal products authorised in accordance with Regulation (EC) No 726/2004 which provide information on the assessment of those medicinal products by describing the data assessed and the reasons for recommending whether a medicinal product should be authorised. The EPAR includes detailed information with regard to all relevant pre-submission activities under that Regulation, including the names of the coordinators and experts involved, and, where a medicinal product developer requests scientific advice during the pre-submission phase, an overview of the scientific topics discussed in view to that advice.
- (35) With respect to medical devices, an executive steering group on shortages of medical devices should be established to coordinate urgent actions within the Union in relation to the management of supply and demand issues of medical devices, and to establish a list of critical medical devices in the case of a public health emergency (the 'Medical Device Shortages Steering Group – MDSSG'). To ensure such coordination, the MDSSG should also liaise with the Medical Devices Coordination Group ('MDCG') established by Article 103 of Regulation (EU) 2017/745 of the European Parliament and of the Council ⁽¹⁰⁾, where appropriate. In that respect, Member States should be able to appoint the same representatives to both the MDSSG and the MDCG.
- (36) The operational phase of the work of the MSSG, the MDSSG and the ETF should be triggered by the recognition of a public health emergency in accordance with Decision No 1082/2013/EU of the European Parliament and of the Council ⁽¹¹⁾ and, as regards the MSSG, also by the recognition of a major event. The continuous monitoring of risks to public health from major events, including manufacturing issues, natural disasters and bioterrorism that have the potential to affect the quality, safety, efficacy, or supply of medicinal products should also be ensured. In addition, such monitoring should follow the One Health approach.

⁽¹⁰⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽¹¹⁾ 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).

- (37) It is understood that all recommendations, advice, guidance and opinions provided for in this Regulation are inherently non-binding. Each of those instruments is intended to allow the Commission, the Agency, the MSSG, the MDSSG and the ETF to make their views known and to suggest a line of action without imposing any legal obligation on the addressees of those instruments.
- (38) It is imperative to have in place robust transparency measures and standards regarding the Agency's regulatory activities in relation to medicinal products and medical devices that fall under the scope of this Regulation. Those measures should include the timely publication of all relevant information on approved medicinal products and medical devices and of clinical data, including clinical trial protocols. The Agency should be highly transparent as regards the membership, recommendations, opinions and decisions of the MSSG, the MDSSG and the ETF. Members of the MSSG, the MDSSG and the ETF should not have financial or other interests in the medicinal products or medical device industries which could affect their impartiality.
- (39) In order to establish the list of categories of critical medical devices and to facilitate the process of monitoring shortages, the manufacturers of those medical devices, or their authorised representatives and, where necessary, relevant notified bodies should provide information requested by the Agency. In specific situations, namely where a Member State considers the need to provide for temporary exemptions pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 of the European Parliament and of the Council ⁽¹²⁾ with a view to mitigating actual or potential shortages of medical devices, the importer and distributor should also play a role in providing the requested information if the non-EU manufacturer has not designated an authorised representative.
- (40) This Regulation should provide the Agency with a role in supporting the expert panels on medical devices designated in accordance with Article 106(1) of Regulation (EU) 2017/745 (the 'expert panels') in providing independent scientific and technical assistance to the Member States, the Commission, the MDCG, notified bodies and manufacturers, while upholding maximum transparency as a condition for fostering trust and confidence in the Union regulatory system.
- (41) In addition to their role in clinical evaluation assessments and performance evaluations regarding certain high risk medical devices in accordance with Regulations (EU) 2017/745 and (EU) 2017/746, respectively, as well as in providing opinions in response to consultation by manufacturers and notified bodies, the expert panels are to provide scientific, technical, and clinical assistance to the Member States, the Commission and the MDCG. In particular, the expert panels are to contribute to the development of guidance on a number of points, including clinical and performance aspects of specific medical devices, categories, or groups of medical devices or specific hazards related to a category or group of medical devices, develop clinical evaluation and performance evaluation guidance in line with the state of the art, and contribute to the identification of concerns and emerging issues on safety and performance. In that context, the expert panels could play a relevant role in preparedness for and the management of public health emergencies relating to medical devices, particularly those of high risk including those medical devices which have the potential to address public health emergencies, without prejudice to tasks and obligations under Regulations (EU) 2017/745 and (EU) 2017/746.
- (42) Given the Agency's long-standing and proven record of expertise in the field of medicinal products and considering the Agency's experience from working with a multitude of groups of experts, it is appropriate to establish suitable structures within the Agency to monitor potential shortages of medical devices in the context of a public health emergency and provide that the Agency provide the secretariat for the expert panels. This would ensure that the expert panels operate sustainably in the long term and would provide clear synergies with related crisis-preparedness work in the area of medicinal products. Those structures would in no way change the regulatory system or decision-making procedures in the area of medical devices that are already in place in the Union, which should remain clearly distinct from those for medicinal products. To ensure a smooth transition to the Agency, the Commission should provide support for the expert panels until 1 March 2022.

⁽¹²⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

- (43) In order to facilitate the work and exchanges of information under this Regulation, provision should be made for the establishment and management of IT infrastructures and to create synergies with other existing IT systems and IT systems under development, including the European database on medical devices (Eudamed) provided for in Article 33 of Regulation (EU) 2017/745, alongside enhanced protection of data infrastructure and deterrence from possible cyber attacks. Within Eudamed, the European Medical Device Nomenclature provided for in Article 26 of Regulation (EU) 2017/745 and in Article 23 of Regulation (EU) 2017/746 should be used to help the gathering of relevant information on categorisation of medical devices. That work could also be facilitated by, where appropriate, emerging digital technologies such as computational models and simulations for clinical trials, as well as by data from the Union Space Programme established by Regulation (EU) 2021/696 of the European Parliament and of the Council ⁽¹³⁾, such as from the Galileo geolocation services, and Copernicus Earth observation data.
- (44) In order to ensure the completeness of information and data obtained by the Agency and considering the specific characteristics of the medical device sector, until Eudamed is fully functional, it should be possible to constitute the list of single points of contact for monitoring the shortages of medical devices included on the public health emergency critical devices list using as a source of information the relevant databases or medical device associations at Union or national level.
- (45) Rapid access to and exchanges of health data, including real world data, i.e. health data generated outside of clinical studies, are essential to ensuring the effective management of public health emergencies and major events. This Regulation should allow the Agency to use and facilitate such exchanges and to be part of the establishment and operation of the European Health Data Space interoperable infrastructure, taking advantage of all the potential of supercomputing, artificial intelligence and big data science to develop predicting models and take better and more timely and effective decisions, without compromising privacy rights.
- (46) In order to facilitate the reliable exchange of information on medicinal products in a robust and consistent manner, the identification of medicinal products should be based on the standards developed by the International Organization for Standardization for the identification of medicinal products for human use.
- (47) The handling of sensitive data, crucial for dealing with potential public health emergencies, requires a high level of protection against cyber attacks. Healthcare organisations have also been facing heightened cybersecurity threats in the midst of the COVID-19 pandemic. The Agency itself was the target of a cyber attack that resulted in some documents related to COVID-19 medicinal products and vaccines belonging to third parties being illegally accessed and some of those documents then being leaked on the internet. It is therefore necessary for the Agency to be equipped with a high level of security controls and processes against cyber attacks to ensure that the Agency operates normally at all times and especially during public health emergencies and major events. To that end, the Agency should establish a plan to prevent, detect, mitigate and respond to cyber attacks so that its operations are secure at all times, while preventing any illegal access to documentation held by the Agency.
- (48) Due to the sensitive nature of health data, the Agency should safeguard its processing operations and ensure that they respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where the processing of personal data is necessary for the purposes of this Regulation, such processing should be done in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation should take place in accordance with Regulations (EU) 2016/679 ⁽¹⁴⁾ and (EU) 2018/1725 ⁽¹⁵⁾ of the European Parliament and of the Council.

⁽¹³⁾ Regulation (EU) 2021/696 of the European Parliament and of the Council of 28 April 2021 establishing the Union Space Programme and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013 and (EU) No 377/2014 and Decision No 541/2014/EU (OJ L 170, 12.5.2021, p. 69).

⁽¹⁴⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁽¹⁵⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

- (49) The credibility of the Agency and public trust in its decisions depend on a high degree of transparency. Therefore, the use of adequate communication tools to proactively engage with the general public should be provided for. In addition, the rapid strengthening of transparency standards and measures regarding the Agency's working bodies and clinical data that has been assessed for the evaluation and surveillance of medicinal products and medical devices are paramount to gain and uphold public trust. This Regulation should establish a framework for those strengthened transparency standards and measures, on the basis of the transparency standards and measures adopted by the Agency during the COVID-19 pandemic.
- (50) During public health emergencies or major events, the Agency should ensure cooperation with the European Centre for Disease Prevention and Control ('ECDC') established by Regulation (EC) No 851/2004 of the European Parliament and of the Council ⁽¹⁶⁾ and other Union agencies, as appropriate. Such cooperation should include the sharing of data, including data on epidemiological forecasting, regular communication at an executive level, and inviting representatives of the ECDC and other Union agencies to attend meetings of the ETF, the MSSG and the MDSSG, as appropriate. Such cooperation should also include strategic discussions with relevant entities of the Union that are in a position to assist research and development regarding appropriate solutions and technologies for mitigating the effects of the public health emergency or major event or preventing future similar public health emergencies or major events.
- (51) In cases of public health emergencies, or in relation to major events, it should be possible for the Agency to enable regular exchanges of information with Member States, marketing authorisation holders, relevant actors of the supply chain for medicinal products, and representatives of healthcare professionals, of patients and consumers, to ensure early discussions on potential shortages of medicinal products in the market and on supply constraints, so as to allow better coordination and synergies to mitigate and respond to the public health emergency or major event.
- (52) Given that the COVID-19 pandemic has not come to an end, and that the duration and evolution of public health emergencies, such as pandemics, are uncertain, provision should be made for a review of the effectiveness of the functioning of the structures and mechanisms established in accordance with this Regulation. In light of that review, those structures and mechanisms should be adjusted, if appropriate.
- (53) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States alone due to the cross-border dimension of public health emergencies and major events but can rather, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (54) In order to ensure that sufficient resources, including appropriate staffing and adequate expertise, are available for carrying out the tasks provided for under this Regulation, expenditure of the Agency should be covered by the contribution from the Union to the Agency's revenue. That expenditure should include remuneration for rapporteurs who are appointed to provide scientific services in relation to the ETF and, in line with usual practice, reimbursement of travel, accommodation and subsistence expenses related to meetings of the MSSG, the MDSSG, the ETF and their working parties.

⁽¹⁶⁾ 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).

- (55) The EU4Health Programme established by Regulation (EU) 2021/522 or the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European Parliament and of the Council ⁽¹⁷⁾ are some of the tools to provide additional support to national competent authorities in relation to shortages of medicinal products, including through the implementation of actions to mitigate shortages of medicinal products and improve the security of supply. Member States should be able to request financial support from the Union specifically for the implementation of their obligations set out in this Regulation.
- (56) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered formal comments on 4 March 2021.
- (57) In accordance with Article 168(7) TFEU, this Regulation fully respects the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care as well as the fundamental rights and principles recognised by the Charter including the protection of personal data.
- (58) One of the aims of this Regulation is to ensure a strengthened framework for monitoring of and reporting on shortages of medicinal products during public health emergencies and major events. As announced in the communication of the Commission of 25 November 2020 entitled 'Pharmaceutical Strategy for Europe', the Commission will propose to revise the pharmaceutical legislation to enhance the security of supply and address shortages of medicinal products through specific measures. That legislation could cover a further coordinating role for the Agency in monitoring and managing shortages of medicinal products. If, as a result of that revision, strengthened measures regarding monitoring of and reporting on supply of and demand for medicinal products at Union level are required, the ESMP should be considered as a suitable system to facilitate any new provisions relating to monitoring of and reporting on shortages of medicinal products. As part of the reporting on this Regulation, the Commission should consider the need to extend the scope of this Regulation to include veterinary medicinal products and personal protective equipment, to amend definitions and to introduce measures at Union or national level to strengthen compliance with the obligations set out in this Regulation. That review should include consideration of the remit and functioning of the ESMP. The extension of the functioning of the ESMP and the need for national shortages monitoring systems should be considered if necessary. In order to prepare for shortages of medicinal products during public health emergencies and major events and to support the monitoring of such shortages, capacity building that is supported by Union funding mechanisms should be considered in order to enhance cooperation among Member States. This could include the exploration of best practices and the coordination of the development of IT tools for monitoring and managing shortages of medicinal products in Member States and for connecting to the ESMP. To ensure that the ESMP is used to its full potential and to identify and forecast problems relating to supply of and demand for medicinal products, where appropriate, the ESMP should facilitate the use of big data techniques and artificial intelligence.
- (59) In order to allow for the prompt application of the measures provided for in this Regulation, it should enter into force on the day following that of its publication in the *Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject Matter

Within the European Medicines Agency (the 'Agency'), this Regulation provides for a framework for and the means of:

- (a) preparing for, preventing, coordinating and managing the impact of public health emergencies on medicinal products and on medical devices and the impact of major events on medicinal products and on medical devices at Union level;

⁽¹⁷⁾ Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p. 17).

- (b) monitoring, preventing, and reporting on shortages of medicinal products and on shortages of medical devices;
- (c) setting up an interoperable information technology (IT) platform at Union level to monitor and report on shortages of medicinal products;
- (d) providing advice on medicinal products that have the potential to address public health emergencies;
- (e) providing support for the expert panels provided for in Article 106(1) of Regulation (EU) 2017/745.

Article 2

Definitions

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

- (a) 'public health emergency' means a situation of public health emergency recognised by the Commission in accordance with Article 12(1) of Decision No 1082/2013/EU;
- (b) 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one Member State, which concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin, or a serious incident that can affect the supply of or demand for medicinal products, or quality, safety or efficacy of medicinal products, which may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection;
- (c) 'medicinal product' means a medicinal product as defined in Article 1, point (2), of Directive 2001/83/EC;
- (d) 'veterinary medicinal product' means a veterinary medicinal product as defined in Article 4, point (1), of Regulation (EU) 2019/6 of the European Parliament and the Council ⁽¹⁸⁾;
- (e) 'medical device' means a medical device as defined in Article 2, point (1), of Regulation (EU) 2017/745 or an *in vitro* diagnostic medical device as defined in Article 2, point (2), of Regulation (EU) 2017/746, and includes accessories for such devices within the meaning of Article 2, point (2), of Regulation (EU) 2017/745, and Article 2, point (4), of Regulation (EU) 2017/746, respectively;
- (f) 'supply' means the total volume of stock of a given medicinal product or medical device that is placed on the market by a marketing authorisation holder or a manufacturer;
- (g) 'demand' means the request for a medicinal product or a medical device by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product or the medical device is acquired in appropriate time and in sufficient quantity to allow continuity of the best care of patients;
- (h) 'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State or of a CE-marked medical device does not meet demand for that medicinal product or medical device at a national level, whatever the cause;
- (i) 'developer' means any legal or natural person seeking to generate scientific data with regard to the quality, safety and efficacy of a medicinal product as part of the development of that product.

⁽¹⁸⁾ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

CHAPTER II

MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICINAL PRODUCTS AND MANAGEMENT OF MAJOR EVENTS*Article 3***Executive Steering Group on Shortages and Safety of Medicinal Products**

1. The Executive Steering Group on Shortages and Safety of Medicinal Products (the 'Medicine Shortages Steering Group – MSSG') is hereby established within the Agency.

The MSSG shall be responsible for fulfilling the tasks referred to in Article 4(3) and (4) and Articles 5 to 8.

The MSSG shall meet regularly and also whenever the situation requires, either in person or remotely, in preparation for or during a public health emergency or when an issue of concern has been raised with the MSSG or when the Commission has recognised a major event in accordance with Article 4(3).

The Agency shall provide the secretariat of the MSSG.

2. The members of the MSSG shall consist of a representative of the Agency, a representative of the Commission and one representative appointed by each Member State.

Members of the MSSG may be accompanied to meetings of the MSSG by experts in specific scientific or technical fields.

The list of the members of the MSSG shall be published on the Agency's web portal.

A representative of the Agency's Patients' and Consumers' Working Party ('PCWP') and a representative of the Agency's Healthcare Professionals' Working Party ('HCPWP') may attend meetings of the MSSG as observers.

3. The MSSG shall be co-chaired by the representative of the Agency and by one of the representatives of the Member States, who shall be elected by and from among the representatives of the Member States in the MSSG.

The co-chairs of the MSSG, on their own initiative or at the request of one or more members of the MSSG, may invite, as observers and to provide expert advice, representatives of national competent authorities for veterinary medicinal products, representatives of other relevant competent authorities and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, wholesale distributors, any other appropriate actor in the supply chain for medicinal products, and representatives of healthcare professionals, of patients and consumers, to attend its meetings, as necessary.

4. The MSSG, in coordination with the national competent authorities for medicinal products, shall facilitate appropriate communication with marketing authorisation holders or their representatives, manufacturers, other relevant actors of the supply chain for medicinal products, and representatives of healthcare professionals, of patients and consumers, with a view to receiving relevant information on actual or potential shortages of medicinal products considered to be critical during a public health emergency or a major event as provided for in Article 6.

5. The MSSG shall establish its rules of procedure, including procedures relating to the working party referred to in paragraph 6 of this Article and procedures for adoption of the critical medicines lists, sets of information and recommendations referred to in Article 8(3) and (4).

The rules of procedure referred to in the first subparagraph shall enter into force once the MSSG has received a favourable opinion from the Commission and the Management Board of the Agency.

6. The MSSG shall be supported in its work by a working party established in accordance with Article 9(1), point (d).

The working party referred to in the first subparagraph shall consist of representatives of the national competent authorities for medicinal products, who shall be the single points of contact in relation to shortages of medicinal products.

7. The MSSG may consult with the Committee for Medicinal Products for Veterinary Use ("CVMP") established by Article 56(1), point (b), of Regulation (EC) No 726/2004 whenever the MSSG deems necessary to do so, in particular, in order to deal with public health emergencies or major events related to zoonoses or diseases that only affect animals and that have or may have a major impact on human health or where the use of active substances for veterinary medicinal products may be useful in addressing the public health emergency or major event.

Article 4

Monitoring of events and preparedness for public health emergencies and major events

1. The Agency, in collaboration with Member States, shall continuously monitor any event that is likely to lead to a public health emergency or major event. As necessary, the Agency shall cooperate with the European Centre for Disease Prevention and Control ("ECDC") and, where relevant, other Union agencies.

2. To facilitate the monitoring referred to in paragraph 1, the national competent authorities for medicinal products, acting through the single points of contact referred to in Article 3(6), or the platform referred to in Article 13 (the 'ESMP'), once it is fully functional, shall report in a timely manner to the Agency on any event that is likely to lead to a public health emergency or major event, including an actual or potential shortage of a medicinal product in a given Member State. Such reporting shall be based on the reporting methods and criteria pursuant to Article 9(1), point (b).

Where a national competent authority informs the Agency of a shortage of a medicinal product as referred to in the first subparagraph, it shall provide the Agency with any information that it has received from the marketing authorisation holder pursuant to Article 23a of Directive 2001/83/EC, if that information is not available in the ESMP.

Where the Agency receives a report of an event from a national competent authority for medicinal products, the Agency may request information from the national competent authorities, through the working party referred to in Article 3(6), in order to evaluate the impact of the event in other Member States.

3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall raise the issue of concern with the MSSG.

Following a positive opinion of the MSSG, the Commission may recognise the major event.

The Commission or at least one Member State may raise the issue of concern with the MSSG on its own initiative.

4. The MSSG shall inform the Commission and the Executive Director of the Agency once the MSSG considers that the major event has been sufficiently addressed and considers that its assistance is no longer needed.

On the basis of the information referred to in the first subparagraph or on its own initiative, the Commission or the Executive Director may confirm that the major event has been sufficiently addressed and therefore that the assistance of the MSSG is no longer needed.

5. Following the recognition of a public health emergency or the recognition of a major event in accordance with paragraph 3 of this Article, Articles 5 to 12 apply as follows:

- (a) where the public health emergency or the major event may affect the quality, safety or efficacy of medicinal products, Article 5 applies;
- (b) where the public health emergency or the major event may lead to shortages of medicinal products in more than one Member State, Articles 6 to 12 apply.

*Article 5***Evaluation of information and provision of recommendations on action in relation to the quality, safety and efficacy of medicinal products related to public health emergencies and major events**

1. Following the recognition of a public health emergency or the recognition of a major event in accordance with Article 4(3), the MSSG shall evaluate information related to the public health emergency or the major event and consider the need for urgent and coordinated action with regard to the quality, safety and efficacy of the medicinal products concerned.
2. The MSSG shall provide recommendations to the Commission and Member States on any appropriate action that it believes needs to be taken at Union level on the medicinal products concerned in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004.
3. The MSSG may consult with the CVMP whenever the MSSG deems necessary to do so, in particular, in order to deal with public health emergencies or major events related to zoonoses or diseases that only affect animals and that have or may have a major impact on human health, or where the use of active substances for veterinary medicinal products may be useful in addressing the public health emergency or the major event.

*Article 6***Lists of critical medicinal products and information to be provided**

1. Without prejudice to paragraph 2, the MSSG shall establish a list with the main therapeutic groups of medicinal products that are necessary for emergency care, surgery and intensive care, in order to inform the preparation of the critical medicines lists as referred to in paragraphs 2 and 3 to be used to respond to a public health emergency or major event. The list shall be established by 2 August 2022 and updated annually and whenever necessary.
2. Immediately following the recognition of a major event in accordance with Article 4(3) of this Regulation, the MSSG shall consult the working party referred to in Article 3(6) of this Regulation. Immediately following that consultation, the MSSG shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers to be critical during the major event (the 'major event critical medicines list').

The MSSG shall update the major event critical medicines list whenever necessary until the major event has been sufficiently addressed and it has been confirmed that the assistance of the MSSG is no longer needed pursuant to Article 4(4) of this Regulation.

3. Immediately following the recognition of a public health emergency, the MSSG shall consult the working party referred to in Article 3(6) of this Regulation. Immediately following that consultation, the MSSG shall adopt a list of medicinal products authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004 which it considers to be critical during the public health emergency (the 'public health emergency critical medicines list'). The MSSG shall update the public health emergency critical medicines list whenever necessary until the termination of the recognition of the public health emergency. The public health emergency critical medicines list may be updated to take into account the results of the review process under Article 18 of this Regulation, where appropriate. In such cases, the MSSG shall liaise with the Emergency Task Force referred to in Article 15 of this Regulation ('ETF').
4. For the purposes of Article 9(2), the MSSG shall adopt and make publicly available the set of information referred to in Article 9(2), points (c) and (d), that is necessary to monitor the supply of and demand for medicinal products included on the lists referred to in paragraphs 2 and 3 of this Article (the 'critical medicines lists') and shall inform the working party referred to in Article 3(6) of that set of information.
5. Following the adoption of critical medicines lists in accordance with paragraphs 2 and 3, the Agency shall immediately publish those lists and any updates to those lists on its web portal as referred to in Article 26 of Regulation (EC) No 726/2004.

6. The Agency shall establish within its web portal a publicly accessible webpage that provides information on actual shortages of medicinal products included in the critical medicines lists in cases in which the Agency has assessed the shortage and has provided recommendations to healthcare professionals and patients. The webpage shall provide at least the following information:

- (a) the name and common name of the medicinal product on the critical medicines lists;
- (b) the therapeutic indications for the medicinal product on the critical medicines lists;
- (c) the reason for the shortage of the medicinal product on the critical medicines lists;
- (d) the start and end dates of the shortage of the medicinal product on the critical medicines lists;
- (e) the Member States affected by the shortage of the medicinal product on the critical medicines lists;
- (f) other relevant information for healthcare professionals and patients, including information on whether alternative medicinal products are available.

The webpage referred to in the first subparagraph shall also provide references to national registries on shortages of medicinal products.

Article 7

Monitoring shortages of medicinal products on the critical medicines lists

Following the recognition of a public health emergency or the recognition of a major event in accordance with Article 4(3), the MSSG shall monitor the supply of and demand for medicinal products included on the critical medicines lists, with a view to identifying any actual or potential shortages of those medicinal products. The MSSG shall conduct such monitoring using the critical medicines lists and the information and data provided, in accordance with Articles 10 and 11, and available through the ESMP, once it is fully functional.

For the purposes of the monitoring referred to in the first paragraph of this Article, where relevant, the MSSG shall liaise with the Health Security Committee established by Article 17 of Decision No 1082/2013/EU ('HSC') and, in the case of a public health emergency, with any other relevant advisory committee on public health emergencies established pursuant to Union law and with the ECDC.

Article 8

Reporting and recommendations on shortages of medicinal products

1. For the duration of a public health emergency, or following the recognition of a major event as referred to in Article 4(3) until it has been confirmed that the major event has been sufficiently addressed pursuant to Article 4(4), the MSSG shall regularly report the results of the monitoring referred to in Article 7 to the Commission and the single points of contact referred to in Article 3(6), and, in particular, shall signal any actual or potential shortages of medicinal products included on the critical medicines lists or any event that is likely to lead to a major event.

The reports referred to in the first subparagraph may also be made available to other actors in the supply chain for medicinal products, where appropriate, in accordance with competition law.

2. Where requested by the Commission or one or more single point of contact as referred to in Article 3(6), the MSSG shall provide aggregated data and demand forecasts to support its findings and conclusions. In that regard, the MSSG shall:

- (a) use data from the ESMP, once it is fully functional;
- (b) liaise with the ECDC to obtain epidemiological data, models and development scenarios to help forecast medicinal product needs; and

- (c) liaise with the Executive Steering Group on Shortages of Medical Devices referred to in Article 21 ('MDSSG') where medicinal products included on the critical medicines lists are used jointly with a medical device.

The aggregated data and demand forecasts referred to in the first subparagraph may also be made available to other actors in the supply chain for medicinal products, where appropriate, in accordance with competition law, with a view to better preventing or mitigating actual or potential shortages of medicinal products.

3. As part of the reporting referred to in paragraphs 1 and 2, the MSSG may provide recommendations on measures that the Commission, Member States, marketing authorisation holders and other entities, including representatives of healthcare professionals and of patients, could take to prevent or mitigate actual or potential shortages of medicinal products.

Member States may request the MSSG to provide recommendations on measures referred to in the first subparagraph.

For the purposes of the second subparagraph, the MSSG shall liaise, as relevant, with the HSC and, in the case of a public health emergency, with any other relevant advisory committee on public health emergencies established pursuant to Union law.

4. The MSSG, on its own initiative or at the request of the Commission or a Member State, may provide recommendations on measures that the Commission, Member States, marketing authorisation holders, representatives of healthcare professionals and other entities could take to ensure preparedness for dealing with actual or potential shortages of medicinal products caused by public health emergencies or major events.

5. Where requested by the Commission, the MSSG may coordinate measures taken by the national competent authorities, the marketing authorisation holders and other entities, including representatives of healthcare professionals and of patients, as relevant, to prevent or mitigate actual or potential shortages of medicinal products in the context of a public health emergency or major event.

Article 9

Working methods and provision of information on medicinal products

1. In order to prepare for the fulfilment of the tasks referred to in Articles 4 to 8, the Agency, shall:
 - (a) specify the procedures and criteria for establishing and reviewing the critical medicines lists;
 - (b) specify the methods of and criteria for the monitoring, data collection and reporting provided for in Articles 4, 7 and 8, with a basic minimum data set;
 - (c) develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, that facilitate interoperability with other existing IT systems and IT systems under development until the ESMP is fully functional, on the basis of data fields that are harmonised across Member States;
 - (d) establish the working party referred to in Article 3(6) and ensure that each Member State is represented on that working party;
 - (e) establish and maintain a list of single points of contact for marketing authorisation holders for all medicinal products authorised in the Union, through the database provided for in Article 57(1), point (l), of Regulation (EC) No 726/2004;
 - (f) specify the methods for the provision of recommendations referred to in Article 5(2) and Article 8(3) and (4) and for the coordination of measures referred to in Article 8(5);
 - (g) publish information covered by points (a), (b) and (f) on a dedicated webpage on its web portal.

For the purposes of the first subparagraph, point (a), Member States, marketing authorisation holders, other relevant actors in the supply chain for medicinal products and representatives of healthcare professionals, of patients and consumers, may be consulted as necessary.

2. Following the recognition of a public health emergency or the recognition of a major event in accordance with Article 4(3), the Agency shall:

- (a) establish a list of single points of contact for the marketing authorisation holders for the medicinal products included on the critical medicines lists;
- (b) maintain the list of single points of contact referred to in point (a) for the duration of the public health emergency or major event;
- (c) request relevant information on medicinal products on the critical medicines lists from the single points of contact referred to in point (a) and set a deadline for the submission of that information, if that information is not available in the ESMP;
- (d) request information on medicinal products on the critical medicines lists from the single points of contact referred to in Article 3(6) on the basis of the set of information referred to in Article 6(4), and set a deadline for the submission of that information, if that information is not available in the ESMP.

3. The information referred to in paragraph 2, point (c), shall include at least:

- (a) the name of the marketing authorisation holder of the medicinal product;
- (b) the name of the medicinal product;
- (c) the identification of active manufacturing sites for finished products and active substances of the medicinal product;
- (d) the Member State in which the marketing authorisation is valid and the marketing status of the medicinal product in each Member State;
- (e) details of the actual or potential shortage of the medicinal product, such as actual or estimated start and end dates and suspected or known cause;
- (f) sales and market share data of the medicinal product;
- (g) available stocks of the medicinal product;
- (h) the forecast of supply for the medicinal product, including information on potential vulnerabilities in the supply chain, quantities already delivered and projected deliveries;
- (i) demand forecasts for the medicinal product;
- (j) details of available alternative medicinal products;
- (k) shortage prevention and mitigation plans that include, at a minimum, information on production and supply capacity and approved production sites of the finished medicinal product and of active substances, potential alternative production sites and minimum stock levels of the medicinal product.

4. In order to supplement the shortage prevention and mitigation plans for critical medicinal products referred to in paragraph 3, point (k), the Agency and national competent authorities for medicinal products may request information from wholesale distributors and other relevant actors regarding any logistical challenges incurred in the wholesale supply chain.

Article 10

Obligations on marketing authorisation holders

1. Marketing authorisation holders for medicinal products authorised in the Union shall provide the information for the purposes of Article 9(1), point (e), of this Regulation by 2 September 2022, in the form of an electronic submission to the database referred to in Article 57(1), point (l), of Regulation (EC) No 726/2004. Those marketing authorisation holders shall provide updates when necessary.

2. In order to facilitate the monitoring referred to in Article 7, the Agency may request marketing authorisation holders for medicinal products included on the critical medicines lists to submit the information referred to in Article 9(2) point (c).

The marketing authorisation holders referred to in the first subparagraph of this paragraph shall submit the requested information by the deadline set by the Agency, through the single points of contact referred to in Article 9(2), point (b), using the monitoring and reporting methods and systems established pursuant to Article 9(1), points (b) and (c), respectively. Those marketing authorisation holders shall provide updates where necessary.

3. The marketing authorisation holders referred to in paragraphs 1 and 2 shall justify any failure to provide any requested information and any delays in providing requested information by the deadline set by the Agency.

4. Where the marketing authorisation holders referred to in paragraph 2 indicate that the information that they submitted at the request of the Agency or the national competent authorities for medicinal products contains information of a commercially confidential nature, they shall identify the relevant parts of that information having such nature and explain why that information is of a commercially confidential nature.

The Agency shall assess the merits of each indication of information as being of a commercially confidential nature and protect such commercially confidential information against unjustified disclosure.

5. Where the marketing authorisation holders referred to in paragraph 2 or other relevant actors in the supply chain for medicinal products have any information in addition to that required under paragraph 2, second subparagraph, which provides evidence of an actual or potential shortage of medicinal products, they shall immediately provide such information to the Agency.

6. Following the reporting on the results of the monitoring referred to in Article 7 and any recommendations on preventive or mitigating measures provided in accordance with Article 8(3) and (4), the marketing authorisation holders referred to in paragraph 2 shall:

- (a) provide any comments they have to the Agency;
- (b) take into account any recommendations referred to in Article 8(3) and (4) and any guidelines referred to in Article 12, point (c);
- (c) comply with any measures taken at Union or Member State level pursuant to Articles 11 and 12;
- (d) inform the MSSG of any measures taken and report on the monitoring and results of those measures, including providing information on the resolution of the actual or potential shortage of medicinal products.

Article 11

Role of Member States in the monitoring and mitigation of shortages of medicinal products

1. In order to facilitate the monitoring referred to in Article 7, unless the information concerned is available on the ESMP, the Agency may request a Member State to:

- (a) submit the set of information referred to in Article 6(4) including available and estimated data on volume of demand and demand forecasts, through the single point of contact referred to in Article 3(6) and using the reporting methods and systems established pursuant to Article 9(1), points (b) and (c), respectively;
- (b) indicate the existence of any commercially confidential information and explain why that information is of a commercially confidential nature, in accordance with Article 10(4);
- (c) indicate any failure to provide requested information, and whether there are any delays in providing that information by the deadline set by the Agency in accordance with Article 10(3).

Member States shall comply with the Agency's request by the deadline set by the Agency.

2. For the purposes of paragraph 1, wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products included on the critical medicines lists to the public shall provide that Member State with relevant information and data, including information and data on the levels of stock of those medicinal products at the request of that Member State.

3. Where Member States have any information in addition to the information to be provided in accordance with paragraphs 1 and 2 of this Article on volumes of sales of and volumes of prescriptions for medicinal products which provides evidence of an actual or potential shortage of a medicinal product included on the critical medicines lists, including data referred to in Article 23a, third paragraph, of Directive 2001/83/EC, they shall immediately provide such information to the MSSG through their respective single points of contact referred to in Article 3(6) of this Regulation.

4. Following the reporting on the results of the monitoring referred to in Article 7 and any recommendations on preventive or mitigating measures provided in accordance with Article 8(3) and (4), Member States shall:

- (a) take into account any recommendations and guidelines referred to in Article 12, point (c), and coordinate their actions in relation to any actions taken at Union level pursuant to Article 12, point (a);
- (b) inform the MSSG of any measures taken and report on the results of the actions referred to in point (a), including providing information on the resolution of the actual or potential shortage of medicinal products.

For the purposes of the first subparagraph, points (a) and (b), Member States that take an alternative course of action at national level shall share the reasons for doing so with the MSSG in a timely manner.

The recommendations, guidelines and actions referred to in the first subparagraph, point (a), and a summary report of the lessons learned, shall be made publicly available via the web portal referred to in Article 14.

Article 12

Role of the Commission regarding the monitoring and mitigation of shortages of medicinal products

The Commission shall take into account the information from and recommendations of the MSSG referred to in Article 8(1) and (2) and in Article 8(3) and (4), respectively, and shall:

- (a) take all necessary action within the limits of the powers conferred on the Commission, with a view to mitigating actual or potential shortages of medicinal products included on the critical medicines lists;
- (b) facilitate the coordination between marketing authorisation holders and other relevant entities to address demand surges, where necessary;
- (c) consider the need for guidelines and recommendations to be addressed to Member States, marketing authorisation holders, and other entities, including relevant entities from the supply chain for medicinal products, where relevant;
- (d) inform the MSSG of any measures taken by the Commission and report on the results of those measures;
- (e) request the MSSG to provide recommendations or coordinate measures as provided for in Article 8(3), (4) and (5);
- (f) consider the need for medical countermeasures in accordance with Decision No 1082/2013/EU and other applicable Union law;
- (g) liaise with third countries and relevant international organisations, as appropriate, to mitigate actual or potential shortages of medicinal products included on the critical medicines lists or their active substances, where those medicinal products or active substances are imported into the Union and where such actual or potential shortages have international implications, and report on any related actions as well as the results of those actions to the MSSG, where relevant.

*Article 13***European shortages monitoring platform**

1. The Agency shall set up, maintain, and manage an IT platform to be known as the European shortages monitoring platform ('ESMP'), which shall be linked to the database referred to in Article 57(1), point (l), of Regulation (EC) No 726/2004.

The ESMP shall be used to facilitate the collection of information on shortages of, supply of, and demand for medicinal products, including information on whether the medicinal product is placed or ceases to be placed on the market in a Member State.

2. The information collected through the ESMP shall be used to monitor, prevent, and manage:

- (a) actual or potential shortages of medicinal products on the critical medicines lists during public health emergencies and major events; and
- (b) actual or potential shortages of medicinal products that are likely to lead to a public health emergency or a major event in accordance with Article 4(2).

3. For the purposes of paragraph 2, during public health emergencies and major events:

- (a) marketing authorisation holders shall use the ESMP to report information relating to medicinal products on the critical medicines lists to the Agency, through the single points of contact referred to in Article 9(2), point (a), in accordance with Articles 9 and 10;
- (b) Member States shall use the ESMP to report information relating to medicinal products on the critical medicines lists to the Agency, through the single points of contact referred to in Article 9(1), point (d), in accordance with Articles 9 and 11.

The reporting referred to in the first subparagraph, point (b), shall include information in addition to that referred to in that point received from marketing authorisation holders and wholesale distributors, or other persons or legal entities that are authorised or entitled to supply to the public medicinal products included on the critical medicines lists, where relevant.

4. For the purposes of paragraph 2, and as regards ensuring preparedness for public health emergencies and major events:

- (a) marketing authorisation holders shall use the ESMP to report to the Agency:
 - (i) the information referred to in Article 13(4) of Regulation (EC) No 726/2004 for authorisations granted in accordance with that Regulation;
 - (ii) information based on the categories set out in Article 9(3) that relate to actual or potential shortages of medicinal products that are likely to lead to a public health emergency or major event, where appropriate;
- (b) Member States shall use the ESMP to report to the Agency on shortages of medicinal products that are likely to lead to a public health emergency or major event in accordance with Article 4(2), through the single points of contact referred to in Article 9(1), point (e).

5. The reporting referred to in paragraph 4, point (b):

- (a) shall include the information referred to in Article 23a of the Directive 2001/83/EC that was reported to national competent authorities for medicinal products for authorisations granted in accordance with that Directive;
- (b) may include additional information received from marketing authorisation holders, wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products to the public.

6. To ensure the optimal use of the ESMP, the Agency shall:

- (a) develop the technical and functional specifications of the ESMP, including the data exchange mechanism for exchanging with the existing national systems and the format for electronic submissions, in collaboration with the MSSG;
- (b) require that data submitted to the ESMP comply with the standards developed by the International Organization for Standardization for the identification of medicinal products and be based on the domains of master data in pharmaceutical regulatory processes, namely substance, product, organisation, and referential data, where relevant;

- (c) develop standardised reporting terminology to be used by marketing authorisation holders and Member States when reporting to the ESMP, in collaboration with the MSSG;
- (d) establish relevant guidance for reporting through the ESMP, in collaboration with the MSSG;
- (e) ensure that data is interoperable between the ESMP, Member States' IT systems and other relevant IT systems and databases, without any duplication of reporting;
- (f) ensure that the Commission, the Agency, national competent authorities and the MSSG have appropriate levels of access to the information contained in the ESMP;
- (g) ensure that commercially confidential information submitted to the system is protected against unjustified disclosure;
- (h) ensure the ESMP is fully operational by 2 February 2025 and draw up a plan for the implementation of the ESMP.

Article 14

Communication regarding the MSSG

1. The Agency shall provide information to the public and interest groups with regard to the work of the MSSG in a timely manner and shall respond to disinformation targeting the work of the MSSG as appropriate, via a dedicated webpage on its web portal and other appropriate means, in cooperation with national competent authorities.
2. Proceedings of the MSSG shall be transparent.

The summaries of the agenda and of the minutes of the meetings of the MSSG, as well as its rules of procedure referred to in Article 3(5) and recommendations referred to in Article 8(3) and (4), shall be documented and made publicly available on a dedicated webpage on the Agency web portal.

Where the rules of procedure referred to in Article 3(5) allow members of the MSSG to have divergent opinions recorded, the MSSG shall make such divergent opinions, and the grounds on which they are based, available to national competent authorities for medicinal products at their request.

CHAPTER III

MEDICINAL PRODUCTS WITH THE POTENTIAL TO ADDRESS PUBLIC HEALTH EMERGENCIES

Article 15

Emergency Task Force

1. The Emergency Task Force ('ETF') is hereby established within the Agency.

The ETF shall be convened in preparation for and during public health emergencies, either in person or remotely.

The Agency shall provide the secretariat of the ETF.

2. During public health emergencies, the ETF shall undertake the following tasks:
 - (a) in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency, providing scientific advice and reviewing the available scientific data on medicinal products that have the potential to address the public health emergency, including requesting data from developers and engaging with them in preliminary discussions;

- (b) providing advice on the main aspects of clinical trial protocols, and providing advice to developers on clinical trials for medicinal products intended to treat, prevent or diagnose the disease causing the public health emergency, in accordance with Article 16 of this Regulation without prejudice to the tasks of the Member States as regards the assessment of submitted clinical trial applications to be conducted within their territories in accordance with Regulation (EU) No 536/2014;
- (c) providing scientific support to facilitate clinical trials for medicinal products intended to treat, prevent or diagnose the disease causing the public health emergency;
- (d) contributing to the work of the scientific committees, working parties and scientific advisory groups of the Agency;
- (e) in liaison with the scientific committees, working parties, and scientific advisory groups of the Agency, providing scientific recommendations with regard to the use of any medicinal product which have the potential to address public health emergencies, in accordance with Article 18;
- (f) cooperating with national competent authorities, Union bodies and agencies, the World Health Organization, third countries, and international scientific organisations, on scientific and technical issues that relate to the public health emergency and to medicinal products which have the potential to address public health emergencies, as necessary.

The support referred to in the first subparagraph, point (c), shall include advice to sponsors of similar or linked planned clinical trials on the establishment of joint clinical trials and may include advice on establishing agreements to act as a sponsor or as co-sponsor in accordance with Article 2(2), point (14), and Article 72 of Regulation (EU) No 536/2014.

3. The members of the ETF shall consist of:

- (a) chairs or vice chairs, or both, of the scientific committees of the Agency, and other representatives of those committees;
- (b) representatives of the working parties of the Agency, including representatives of the PCWP and representatives of the HCPWP;
- (c) staff members of the Agency;
- (d) representatives of the coordination group established in accordance with Article 27 of Directive 2001/83/EC;
- (e) representatives of the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) No 536/2014; and
- (f) other clinical trial experts who represent national competent authorities for medicinal products.

The members of the ETF shall be nominated by the entities they represent.

External experts may be appointed to the ETF on an ad hoc basis, as necessary, especially in the cases referred to in Article 5(3).

Representatives of other Union bodies and agencies shall be invited on an ad hoc basis, as necessary, to participate in the work of the ETF, especially in the cases referred to in Article 5(3).

The ETF shall be chaired by the representative of the Agency and co-chaired by the chair or vice-chair of the CHMP.

4. The composition of the ETF shall be approved by the Management Board of the Agency, taking into account specific expertise relevant to the therapeutic response to the public health emergency.

The Executive Director of the Agency or the representative of the Executive Director, as well as representatives of the Commission and of the Management Board of the Agency, shall be entitled to attend all meetings of the ETF.

The composition of the ETF shall be made publicly available.

5. The co-chairs of the ETF may invite other representatives of Member States, members of scientific committees and working parties of the Agency, and third parties, including representatives of medicinal product interest groups, marketing authorisation holders, developers, clinical trial sponsors, representatives of clinical trial networks, independent clinical trial experts and researchers, and representatives of healthcare professionals and of patients to attend its meetings.

6. The ETF shall establish its rules of procedure, including rules on the adoption of recommendations.

The rules of procedure referred to in the first subparagraph shall enter into force once the ETF has received a favourable opinion from the Commission and the Management Board of the Agency.

7. The ETF shall perform its tasks as an advisory and support body separate from, and without prejudice to, the tasks of the scientific committees of the Agency as regards the authorisation, supervision and pharmacovigilance of the medicinal products concerned and related regulatory actions to ensure the quality, safety and efficacy of those medicinal products.

The CHMP and other relevant scientific committees of the Agency shall take the ETF recommendations into consideration when adopting their opinions.

The ETF shall take account of any scientific opinion issued by the committees referred to in the second subparagraph of this paragraph in accordance with Regulation (EC) No 726/2004 and Directive 2001/83/EC.

8. Article 63 of Regulation (EC) No 726/2004 applies to the ETF as regards transparency and the independence of its members.

9. The Agency shall publish information regarding the medicinal products that the ETF considers to have the potential to address public health emergencies and any updates on its web portal. The Agency shall inform Member States and the HSC, as appropriate, of any such publication without undue delay and, in any case, prior to such publication.

Article 16

Advice on clinical trials

1. During a public health emergency, the ETF shall provide advice on the main aspects of clinical trials and clinical trial protocols submitted or intended to be submitted in a clinical trial application by developers as part of an accelerated scientific advice process, without prejudice of the responsibility of the Member State or States concerned under Regulation (EU) No 536/2014.

2. Where a developer engages in an accelerated scientific advice process, the ETF shall provide the advice referred to in paragraph 1 free of charge at the latest 20 days after the developer submits a complete set of the requested information and data to the Agency. The advice shall be endorsed by the CHMP.

3. The ETF shall establish procedures and guidance for requesting and submitting of the set of information and data required, including information on the Member State or States where an application for authorisation of a clinical trial is submitted or is intended to be submitted.

4. The ETF shall involve representatives of the Member States with clinical trial expertise in the preparation of the scientific advice, in particular in cases where an application for authorisation of a clinical trial is submitted or is intended to be submitted.

5. When authorising a clinical trial application for which the ETF has provided scientific advice, Member States shall take that advice into consideration. The scientific advice provided by the ETF shall be without prejudice to the ethical review provided for in Regulation (EU) No 536/2014.

6. Where a developer is the recipient of the scientific advice referred to in paragraph 5 of this Article, that developer shall subsequently submit the data resulting from clinical trials to the Agency if the Agency makes a request for those data pursuant to Article 18.

7. Without prejudice to paragraphs 1 to 6 of this Article, the scientific advice referred to in paragraph 5 of this Article shall otherwise be provided in accordance with the procedures established pursuant to Article 57 of Regulation (EC) No 726/2004.

Article 17

Public information regarding clinical trials and marketing authorisation decisions

1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the Union shall, in particular, make the following information publicly available through the EU portal and EU database established respectively by Articles 80 and 81 of Regulation (EU) No 536/2014:

- (a) the clinical trial protocol, at the start of each trial for all trials authorised under Regulation (EU) No 536/2014 that examine medicinal products which have the potential to address the public health emergency;
- (b) the summary of the results, within a timeline set by the Agency that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.

2. Where a medicinal product of relevance to the public health emergency receives a marketing authorisation, the Agency shall publish, in particular:

- (a) the product information with details of the conditions of use at the time of the marketing authorisation;
- (b) the European Public Assessment Reports as soon as possible and, where possible, within seven days of the marketing authorisation;
- (c) the clinical data submitted to the Agency in support of the application, where possible within two months of the marketing authorisation by the Commission;
- (d) the entire risk management plan referred to in Article 1, point 28c, of Directive 2001/83/EC, and any updated versions thereof.

For the purposes of the first subparagraph, point (c), the Agency shall anonymise all personal data and redact commercially confidential information.

Article 18

Review of medicinal products and recommendations on their use

1. Following the recognition of a public health emergency, the ETF shall undertake a review of the available scientific data on medicinal products which have the potential to be used to address the public health emergency. That review shall be updated whenever needed during the public health emergency, including where the ETF and the CHMP agree on the preparation of the assessment of a marketing authorisation application.

2. In the preparation of the review referred to in paragraph 1, the ETF may request information and data from marketing authorisation holders and from developers and may engage with them in preliminary discussions. The ETF may also make use of health data generated outside of clinical studies, where available, taking into account the reliability of those data.

The ETF may liaise with the third country agencies for medicinal products with respect to additional information and data exchanges.

3. Following a request from one or more Member States, or the Commission, the ETF shall provide recommendations to the CHMP for an opinion in accordance with paragraph 4 on:

- (a) the compassionate use of medicinal products falling under the scope of Directive 2001/83/EC or Regulation (EC) No 726/2004; or
- (b) the use and distribution of an unauthorised medicinal product in accordance with Article 5(2) of Directive 2001/83/EC.

4. Following receipt of a recommendation provided pursuant to paragraph 3, the CHMP shall adopt its opinion on the conditions to be imposed on the use and distribution of the medicinal product concerned and on the patients targeted. That opinion shall be updated where necessary.

5. Member States shall take account of the opinions referred to in paragraph 4 of this Article. Article 5(3) and (4) of Directive 2001/83/EC applies to the use of such an opinion.

6. In the preparation of its recommendations provided pursuant to paragraphs 3, the ETF may consult the Member State concerned and request it to provide any available information or data that the Member State used for its decision to make the medicinal product available for compassionate use. Following such a request, the Member State shall provide all of the requested information and data.

Article 19

Communication regarding the ETF

The Agency shall provide information to the public and relevant interest groups with regard to the work of the ETF in a timely manner and shall respond to disinformation targeting the work of the ETF, as appropriate, via a dedicated webpage on its web portal and other appropriate means, in cooperation with national competent authorities.

The Agency shall regularly publish on its web portal the list of the members of the ETF, the rules of procedure referred to in Article 15(6) and the list of medicinal products under review, as well as the opinions adopted pursuant to Article 18(4).

Article 20

IT tools and data

In preparation for and to support the work of the ETF during public health emergencies, the Agency shall:

- (a) develop and maintain IT tools, including an interoperable IT platform, for the submission of information and data, including electronic health data generated outside of clinical studies, that facilitate interoperability with other existing IT tools and with IT tools under development, and provide adequate support to national competent authorities;
- (b) coordinate independent monitoring studies on the use, effectiveness and safety of medicinal products intended to treat, prevent or diagnose diseases related to the public health emergency, using relevant data, including, where relevant, data held by public authorities;
- (c) as part of its regulatory tasks, make use of digital infrastructures or IT tools in order to facilitate rapid access to or analysis of available electronic health data generated outside of clinical studies and to facilitate the exchange of such data between Member States, the Agency and other Union bodies;
- (d) provide the ETF with access to external sources of electronic health data to which the Agency has access, including health data generated outside of clinical studies.

For the purposes of the first paragraph, point (b), coordination as regards vaccines shall be conducted in conjunction with the ECDC, in particular, through a new vaccine monitoring IT platform.

CHAPTER IV

MONITORING AND MITIGATING SHORTAGES OF CRITICAL MEDICAL DEVICES AND SUPPORT FOR EXPERT PANELS*Article 21***Executive Steering Group on Shortages of Medical Devices**

1. The Executive Steering Group on Shortages of Medical Devices (the 'Medical Device Shortages Steering Group – MDSSG') is hereby established within the Agency.

The MDSSG shall be responsible for fulfilling the tasks referred to in Articles 22, 23 and 24.

The MDSSG shall meet regularly and also whenever the situation requires, either in person or remotely, in preparation for or during a public health emergency.

The Agency shall provide the secretariat of the MDSSG.

2. The members of the MDSSG shall consist of a representative of the Agency, a representative of the Commission and one representative appointed by each Member State.

The representatives of the Member States shall have expertise in the field of medical devices, as relevant. Those representatives may be the same as the representatives appointed to the Medical Devices Coordination Group established by Article 103 of Regulation (EU) 2017/745 ('MDCG'), where appropriate.

Members of the MDSSG may be accompanied to meetings of the MDSSG by experts in specific scientific or technical fields.

The list of the members of the MDSSG shall be published on the Agency's web portal.

A representative of the PCWP and a representative of the HCPWP may attend meetings of the MDSSG as observers.

3. The MDSSG shall be co-chaired by the representative of the Agency and by one of the representatives of the Member States, who shall be elected by and from among the representatives of the Member States in the MDSSG.

The co-chairs of the MDSSG, on their own initiative or at the request of one or more members of the MDSSG, may invite, as observers and to provide expert advice, third parties, including representatives of medical device interest groups, such as representatives of manufacturers and notified bodies, or any other relevant actor in the supply chain for medical devices, and representatives of healthcare professionals, of patients and consumers, to attend its meetings, as necessary.

4. The MDSSG shall establish its rules of procedure, including procedures relating to the working party referred to in paragraph 5 of this Article, and procedures for adoption of the lists referred to in Article 22, sets of information and recommendations referred to in Article 24(3) and (4).

The rules of procedure referred to in the first subparagraph shall enter into force once the MDSSG has received a favourable opinion from the Commission and the Management Board of the Agency.

5. The MDSSG shall be supported in its work by a working party established in accordance with Article 25(1).

The working party referred to in the first subparagraph shall consist of representatives of the national competent authorities responsible for shortage monitoring and management of medical devices, who shall be the single points of contact in relation to shortages of medical devices.

*Article 22***List of critical medical devices and information to be provided**

1. Immediately following the recognition of a public health emergency, the MDSSG shall consult the working party referred to in Article 21(5). Immediately following that consultation, the MDSSG shall adopt a list of categories of critical medical devices which it considers to be critical during the public health emergency ('public health emergency critical devices list').

To the extent possible, relevant information on critical medical devices and related manufacturers shall be gathered from Eudamed, once it is fully functional. The information shall also be gathered from importers and distributors, as appropriate. Until Eudamed is fully functional, available information may also be gathered from national databases or other available sources.

The MDSSG shall update the public health emergency critical devices list whenever necessary until the termination of the recognition of the public health emergency.

2. For the purposes of Article 25(2), the MDSSG shall adopt and make publicly available the set of information referred to in Article 25(2), points (b) and (c), that is necessary to monitor the supply of and demand for medical devices included on the public health emergency critical devices list, and inform the working party referred to in Article 21(5) of that set of information.

3. The Agency shall publish on a dedicated webpage on its web portal:

- (a) the public health emergency critical devices list, as well as any updates to that list; and
- (b) information on actual shortages of critical medical devices included on the public health emergency critical devices list.

*Article 23***Monitoring shortages of medical devices on the public health emergency critical devices list**

1. During a public health emergency the MDSSG shall monitor the supply of and demand for medical devices included on the public health emergency critical devices list, with a view to identifying any actual or potential shortages of those medical devices. The MDSSG shall conduct such monitoring using the public health emergency critical devices list and the information and data provided in accordance with Articles 26 and 27.

For the purposes of the monitoring referred to in the first subparagraph of this paragraph, where relevant, the MDSSG shall liaise with the MDCG, the HSC and any other relevant advisory committee on public health emergencies established pursuant to Union law.

2. For the purposes of the monitoring referred to in paragraph 1 of this Article, the MDSSG may make use of data from device registries and databases where such data is available to the Agency. In so doing, the MDSSG may take into account the data generated pursuant to Article 108 of Regulation (EU) 2017/745 and Article 101 of Regulation (EU) 2017/746.

*Article 24***Reporting and recommendations on shortages of medical devices**

1. For the duration of the public health emergency, the MDSSG shall regularly report the results of the monitoring referred to in Article 23 to the Commission and the single points of contact referred to in Article 25(2), point (a), and, in particular, shall signal any actual or potential shortages of medical devices included on the public health emergency critical devices list.

2. Where requested by the Commission, Member States or one or more single point of contact referred to in Article 25(2), point (a), the MDSSG shall provide aggregated data and demand forecasts to support its findings and conclusions.

For the purposes of the first subparagraph, the MDSSG shall liaise with the ECDC to obtain epidemiological data to help forecast medical device needs, and with the MSSG where medical devices included on the public health emergency critical devices list are used jointly with a medicinal product.

The findings and conclusions of the MDSSG referred to in the first subparagraph may be made available to other actors in the medical device sector, where appropriate, in accordance with competition law, with a view to better preventing or mitigating or actual or potential shortages.

3. As part of the reporting referred to in paragraphs 1 and 2, the MDSSG may provide recommendations on measures that the Commission, Member States, medical device manufacturers, notified bodies and other entities could take to prevent or mitigate actual or potential shortages of medical devices.

For the purposes of the first subparagraph, the MDSSG shall liaise, where relevant, with the MDCG, with the HSC and with any other relevant advisory committee on public health emergencies established pursuant to Union law.

4. The MDSSG, on its own initiative or at the request of the Commission, may provide recommendations on measures that the Commission, Member States, manufacturers of medical devices, notified bodies and other entities could take to ensure preparedness for dealing with actual or potential shortages of medical devices caused by public health emergencies.

5. Where requested by the Commission, the MDSSG may coordinate measures taken by the national competent authorities for medical devices, manufacturers of medical devices, notified bodies, and other entities, as relevant, to prevent or mitigate actual or potential shortages of medical devices in the context of a public health emergency or major event.

Article 25

Working methods and provision of information on medical devices

1. In order to prepare for the fulfilment of the tasks referred to in Articles 22, 23 and 24, the Agency shall:

- (a) specify the procedures and criteria for establishing and reviewing the public health emergency critical devices list;
- (b) develop streamlined IT monitoring and reporting systems, in coordination with the relevant national competent authorities, that facilitate interoperability with existing IT tools and Eudamed, once it is fully functional, and provide the adequate support to national competent authorities for monitoring and reporting;
- (c) establish the working party referred to in Article 21(5) and ensure that each Member State is represented on that working party;
- (d) specify the methods for the provision of recommendations referred to in Article 24(3) and (4) and for the coordination of measures referred to in Article 24.

For the purposes of the first subparagraph, point (a), the MDCG, representatives of manufacturers, other relevant actors in the supply chain for the medical device sector and representatives of healthcare professionals, of patients and consumers may be consulted as necessary.

2. Following the recognition of a public health emergency, the Agency shall:

- (a) establish a list of single points of contact for the manufacturers of medical devices, or their authorised representatives, importers and notified bodies, for the medical devices included on the public health emergency critical devices list;
- (b) maintain the list of single points of contact referred to in point (a) for the duration of the public health emergency;

- (c) request relevant information on medical devices included on the public health emergency critical devices list from the single points of contact referred to in point (a) on the basis of the set of information adopted by the MDSSG and set a deadline for the submission of that information;
- (d) request relevant information on medical devices included on the public health emergency critical devices list from the single points of contact referred to in Article 21(5), second subparagraph, on the basis of the set of information adopted by the MDSSG in accordance with Article 22(2) and set a deadline for the submission of that information.

The Agency may use sources other than those referred to in the first subparagraph, including existing databases and databases in development, to gather information required under paragraph 3.

For the purposes of the first subparagraph, point (a), where it is considered relevant, national or Union databases, including Eudamed, once it is fully functional, or medical device associations may be used as sources of information.

3. The information referred to in paragraph 2, point (c), shall include at least:

- (a) the name of the manufacturer of the medical device and, if applicable, the name of its authorised representative;
- (b) the information identifying the medical device and the intended purpose and where necessary, specific characteristics of the medical device;
- (c) if applicable, the name and number of the notified body and information regarding the relevant certificate or certificates;
- (d) details of the actual or potential shortage of the medical device, such as actual or estimated start and end dates and the suspected or known cause;
- (e) sales and market share data of the medical device;
- (f) available stocks of the medical device;
- (g) the forecast of supply of the medical device, including information on the potential vulnerabilities in the supply chain;
- (h) quantities already delivered and projected deliveries of the medical device;
- (i) the demand forecasts for the medical device;
- (j) shortage prevention and mitigation plans that include, at a minimum, information on production and supply capacity;
- (k) information from relevant notified bodies regarding their capacity to process applications and carry out and complete conformity assessments in relation to medical devices included in the public health emergency critical devices list, within an appropriate period of time considering the emergency;
- (l) information on the number of applications received by relevant notified bodies in relation to medical devices included in the public health emergency critical devices list and on the relevant conformity assessment procedures;
- (m) where conformity assessments are ongoing, the status of the conformity assessment by the relevant notified bodies in relation to medical devices included in the public health emergency critical devices list and possible critical issues on the final outcome of the assessment and which need to be considered in order to complete the conformity assessment process.

For the purposes of the first subparagraph, point (k), the relevant notified bodies shall communicate the date by which the assessment is expected to be completed. In that regard, notified bodies shall prioritise conformity assessments of medical devices included in the public health emergency critical devices list.

*Article 26***Obligations on manufacturers of medical devices, authorised representatives, importers, distributors and notified bodies**

1. In order to facilitate the monitoring referred to in Article 23, the Agency may request manufacturers of medical devices, or their authorised representatives, as applicable, and, if appropriate, importers and distributors, included on the public health emergency critical devices list and, where necessary, relevant notified bodies, to submit the information requested by a deadline set by the Agency.

The manufacturers of medical devices, or their authorised representatives, as applicable, and, if appropriate, importers and distributors, referred to in the first subparagraph, shall submit the requested information through the single points of contact referred to in Article 25(2), point (a), using the monitoring and reporting systems established pursuant to Article 25(1), point (b). They shall provide updates where necessary.

2. Manufacturers of medical devices, or their authorised representatives, as applicable, notified bodies and, if appropriate, importers or distributors shall justify any failure to provide requested information and any delays in providing requested information by the deadline set by the Agency.

3. Where manufacturers of medical devices, or their authorised representatives, notified bodies, or, if appropriate, importers or distributors indicate that the information that they submitted contains information of a commercially confidential nature, they shall identify the relevant parts of that information having such nature and explain why that information is of a commercially confidential nature.

The Agency shall assess the merits of each indication of information as being of a commercially confidential nature and protect such commercially confidential information against unjustified disclosure.

4. Where manufacturers of medical devices, or their authorised representatives, notified bodies, or, if appropriate, importers or distributors have any information in addition to that required under paragraph 1, which provides evidence of an actual or potential shortage of medical devices, they shall immediately provide such information to the Agency.

5. Following the reporting on the results of the monitoring referred to in Article 23 and any recommendations on preventive or mitigating measures provided in accordance with Article 24, manufacturers of medical devices, or their authorised representatives, and, if appropriate, importers and distributors referred to in paragraph 1, shall:

- (a) provide any comments they have to the Agency;
- (b) take into account any recommendations referred to in Article 24(3) and (4) and any guidelines referred to in Article 28, point (b);
- (c) comply with any measures taken at Union or Member State level pursuant to Article 27 or 28;
- (d) inform the MDSSG of any measures taken and report on the results of those measures, including providing information on the resolution of the actual or potential shortage of medical devices.

6. Where manufacturers of medical devices referred to in paragraph 1 are established outside the Union, the information requested in accordance with this Article shall be provided by the authorised representatives, or, if appropriate, by importers or distributors.

*Article 27***Role of Member States in the monitoring and mitigation of shortages of medical devices**

1. In order to facilitate the monitoring referred to in Article 23, the Agency may request a Member State to:

- (a) submit the set of information referred to in Article 22(2), including available information about needs related to the medical devices included in the public health emergency critical devices list, and available and estimated data on volume of demand and demand forecasts for those medical devices, through the respective single point of contact referred to in Article 25(2), point (a), and using the monitoring and reporting methods and systems established pursuant to Article 25(1), point (b);

- (b) indicate the existence of any commercially confidential information and explain why that information is of a commercially confidential nature, in accordance with Article 26(3);
- (c) indicate any failure to provide requested information and whether there are any delays in providing that information by the deadline set by the Agency in accordance with Article 26(2).

Member States shall comply with the Agency's request by the deadline set by the Agency.

2. For the purposes of paragraph 1, Member States shall gather information from manufacturers of medical devices and their authorised representatives, healthcare providers, importers and distributors, as applicable, and notified bodies on medical devices included on the public health emergency critical devices list.

3. Where Member States have any information in addition to the information to be provided in accordance with paragraphs 1 and 2 of this Article, which provides evidence of an actual or potential shortage of medical devices, they shall immediately provide such information to the MDSSG through their respective single point of contact referred to in Article 25(2), point (a).

4. Following the reporting on the results of the monitoring referred to in Article 23 and any recommendations on preventive or mitigating measures provided in accordance with Article 24, Member States shall:

- (a) consider the need to provide for temporary exemptions at Member State level pursuant to Article 59(1) of Regulation (EU) 2017/745 or Article 54(1) of Regulation (EU) 2017/746 with a view to mitigating actual or potential shortages of medical devices included on the public health emergency critical devices list while ensuring a high level of patient and product safety;
- (b) take into account any recommendations referred to in Article 24(3) and any guidelines referred to in Article 28, point (b), and coordinate their actions in relation to any actions taken at Union level pursuant to Article 12, point (a);
- (c) inform the MDSSG of any measures taken and report on the results of the actions referred to in point (b), including providing information on the resolution of the actual or potential shortage of medical devices concerned.

For the purposes of the first subparagraph, points (b) and (c), Member States that take an alternative course of action at national level shall share the reasons for doing so with the MDSSG.

The recommendations, guidelines and actions referred to in the first subparagraph, point (b), of this paragraph, and a summary report of the lessons learned shall be made publicly available via the web portal referred to in Article 29.

Article 28

Role of the Commission regarding the monitoring and mitigation of shortages of medical devices

The Commission shall take into account the information from and recommendations of the MDSSG and shall:

- (a) take all necessary action within the limits of the powers conferred on the Commission, with a view to mitigating actual or potential shortages of medical devices included on the public health emergency critical devices list, including, where necessary, granting temporary exemptions at Union level pursuant to Article 59(3) of Regulation (EU) 2017/745 or Article 54(3) of Regulation (EU) 2017/746, while respecting the conditions set out in those Articles and seeking to ensure both patient and product safety;
- (b) consider the need for guidelines and recommendations to be addressed to Member States, manufacturers of medical devices, notified bodies, and other entities, where relevant;

- (c) request the MDSSG to provide recommendations or coordinate measures provided for in Article 24(3), (4) and (5);
- (d) consider the need for medical countermeasures in accordance with Decision No 1082/2013/EU and other applicable Union law;
- (e) liaise with third countries and relevant international organisations, as appropriate, to mitigate actual or potential shortages of medical devices included on the public health emergency critical devices list or their component parts, where those devices or parts of such devices are imported into the Union, and where such actual or potential shortages have international implications, and report on any related actions as well as the results of those actions to the MDSSG, where relevant.

Article 29

Communication regarding the MDSSG

1. The Agency shall provide information to the public and relevant interest groups with regard to the work of the MDSSG in a timely manner and shall respond to disinformation targeting the work of the MDSSG, as appropriate, via a dedicated webpage on its web portal and other appropriate means, in cooperation with national competent authorities.
2. Proceedings of the MDSSG shall be transparent.

The summaries of the agenda and of the minutes of the meetings of the MDSSG, as well as its rules of procedure referred to in Article 21(4) and recommendations referred to in Article 24(3) and (4), shall be documented and made publicly available on the dedicated webpage on the Agency web portal.

Where the rules of procedure referred to in Article 21(4) allow members of the MDSSG to have divergent opinions recorded, the MDSSG shall make such divergent opinions, and the grounds on which they are based, available to national competent authorities at their request.

Article 30

Support for the expert panels on medical devices

From 1 March 2022, on behalf of the Commission, the Agency shall provide the secretariat for the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 (the 'expert panels') and shall provide the support necessary to ensure that those expert panels can efficiently perform the tasks set out in Article 106(9) and (10) of that Regulation.

The Agency shall:

- (a) provide administrative and technical support to the expert panels for the provision of scientific opinions, views and advice;
- (b) facilitate and manage remote and physical meetings of the expert panels;
- (c) ensure that the work of the expert panels is carried out in an independent manner in accordance with Article 106(3), second subparagraph, and Article 107 of Regulation (EU) 2017/745 and with the systems and procedures established by the Commission pursuant to that Regulation to actively manage and prevent potential conflicts of interest in accordance with Article 106(3), third subparagraph, of that Regulation;
- (d) maintain and regularly update a webpage for the expert panels and make all necessary information not already publicly available in Eudamed publicly available on that webpage in order to ensure the transparency of the activities of the expert panels, including providing the justifications of notified bodies where those bodies did not follow the advice of the expert panels provided pursuant to Article 106(9) of Regulation (EU) 2017/745;
- (e) publish the scientific opinions, views and advice of the expert panels while ensuring confidentiality in accordance with Article 106(12), second subparagraph, and Article 109 of Regulation (EU) 2017/745;

- (f) ensure that remuneration and expenses are provided to the experts in accordance with implementing acts adopted by the Commission pursuant to Article 106(1) of Regulation (EU) 2017/745;
- (g) monitor compliance with the expert panels' common rules of procedure and available guidelines and methodologies relevant to the functioning of the expert panels;
- (h) provide annual reports to the Commission and the MDCG on the work of the expert panels, including information on the number of opinions delivered and the views and advice provided by the expert panels.

CHAPTER V

FINAL PROVISIONS

Article 31

Cooperation between the MSSG, the MDSSG, the ETF and the expert panels

1. The Agency shall ensure that the MSSG and the MDSSG cooperate in relation to measures to address public health emergencies and major events.
2. Members of the MSSG and MDSSG, and members of the working parties referred to in Article 3(6) and in Article 25(2), point (a), respectively, may attend one another's meetings and working parties and, where appropriate, cooperate on monitoring exercises, reporting and the preparation of opinions.
3. With the agreement of the respective chairs or co-chairs, joint meetings of the MSSG and the MDSSG may be held.
4. Where relevant, the Agency shall ensure that the ETF and the expert panels cooperate in relation to preparedness and management of public health emergencies.

Article 32

Transparency and conflicts of interest

1. The MSSG and the MDSSG shall carry out their activities in an independent, impartial and transparent manner.
2. The members of the MSSG and of the MDSSG and, where relevant, observers, shall not have any financial or other interests in the medicinal products industry or medical devices industry which could affect their independence or impartiality.
3. The members of the MSSG and the MDSSG and, where relevant, observers, shall make a declaration of their financial and other interests and shall update those declarations of interest annually and whenever necessary.

The declarations referred to in the first subparagraph shall be made publicly available on the Agency's web portal.

4. The members of the MSSG and the MDSSG and, where relevant, observers, shall disclose any other facts of which they become aware that might reasonably be expected in good faith to involve or give rise to a conflict of interest.
5. Before each meeting, the members of the MSSG and the MDSSG and, where relevant, observers who participate in meetings of the MSSG and the MDSSG shall declare any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda.
6. Where the Agency decides that an interest declared in accordance with paragraph 5 constitutes a conflict of interest, the member or observer concerned shall not take part in any discussions or decision making, or obtain any information, concerning the item of concern on the agenda.

7. The declarations and the decisions of the Agency referred to in paragraphs 5 and 6, respectively, shall be recorded in the summary minutes of the meeting.
8. The members of the MSSG and the MDSSG and, where relevant, observers, shall be subject to a requirement of professional secrecy, even after their duties have ceased.
9. Members of the ETF shall update the annual declaration of their financial or other interests provided for in Article 63 of Regulation (EC) No 726/2004 whenever a relevant change to their declaration occurs.

Article 33

Protection against cyber attacks

The Agency shall equip itself with a high level of security controls and processes against cyber attacks, cyber espionage and other data breaches to ensure the protection of health data and the normal functioning of the Agency at all times, especially during public health emergencies or major events at Union level.

For the purposes of the first paragraph, the Agency shall actively identify and implement cybersecurity best practices adopted within Union institutions, bodies, offices and agencies for preventing, detecting, mitigating, and responding to cyber attacks.

Article 34

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 of the European Parliament and of the Council⁽¹⁹⁾ and Directive (EU) 2019/1937 of the European Parliament and of the Council⁽²⁰⁾, and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the commercially confidential information and trade secrets of natural or legal persons in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council⁽²¹⁾, including intellectual property rights.
2. Without prejudice to paragraph 1, all parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition within the meaning of Article 101 TFEU.
3. Without prejudice to paragraph 1, information exchanged on a confidential basis between national competent authorities and between national competent authorities and the Commission and the Agency shall not be disclosed without the prior agreement of the authority from which that information originates.
4. Paragraphs 1, 2, and 3 do not affect the rights and obligations of the Commission, the Agency, Member States or other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor do they affect the obligations of the persons concerned to provide information under criminal law.
5. The Commission, the Agency, and Member States may exchange commercially confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

⁽¹⁹⁾ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

⁽²⁰⁾ Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).

⁽²¹⁾ Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

*Article 35***Personal data protection**

1. Transfers of personal data under this Regulation shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.
2. As regards transfers of personal data to a third country, in the absence of an adequacy decision or appropriate safeguards as referred to in Article 46 of Regulation (EU) 2016/679 and Article 48 of Regulation (EU) 2018/1725 respectively, the Commission, the Agency, and Member States may carry out certain transfers of personal data to regulatory authorities of third countries with which they have put in place confidentiality arrangements where those transfers are necessary for important reasons of public interest, such as the protection of public health. Such transfers shall be made in conformity with the conditions laid down in Article 49 of Regulation (EU) 2016/679 and Article 50 of Regulation (EU) 2018/1725.

*Article 36***Reporting and review**

1. By 31 December 2026, and every fourth year thereafter, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation. In particular, that report shall review:
 - (a) the crisis preparedness and management framework for medicinal products and medical devices, including the outcomes of periodic stress tests;
 - (b) instances of non-compliance with the obligations set out in Articles 10 and 26 by marketing authorisation holders, manufacturers of medical devices, authorised representatives, importers, distributors and notified bodies;
 - (c) the remit and functioning of the ESMP.
2. Notwithstanding paragraph 1, following a public health emergency or a major event, the Commission shall present, in a timely manner, a report to the European Parliament and the Council on the instances referred to in paragraph 1, point (b).
3. Based on the report referred to in paragraph 1, the Commission shall, where appropriate, present a legislative proposal in order to amend this Regulation. In particular, the Commission shall consider the need for:
 - (a) extending the scope of this Regulation to veterinary medicinal products and to personal protective equipment for medical use;
 - (b) amending Article 2;
 - (c) introducing measures to strengthen at Union or national level compliance with the obligations established in Articles 10 and 26; and
 - (d) expanding the remit of the ESMP, the need for further facilitating the ESMP interoperability with national and Union IT systems, the need for national shortage monitoring platforms, and the need for meeting any additional requirements to address structural shortages of medicinal products that may be introduced in the context of a revision of Directive 2001/83/EC and Regulation (EC) No 726/2004.

*Article 37***Union financing**

1. The Union shall provide the financing of the Agency's activities in support of the work of the MSSG and the MDSSG, the ETF, the working parties referred to in Article 3(6) and in Article 25(1), point (c), and the expert panels, that involve its cooperation with the Commission and the ECDC.

The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽²³⁾.

2. The Agency shall remunerate the assessment activities of the rapporteurs in relation to the ETF under this Regulation, in addition to reimbursing the expenses incurred by Member States' representatives and experts in relation to the meetings of the MSSG, the MDSSG, the ETF and the working parties referred to in Article 3(6) and in Article 21(5), in accordance with financial arrangements established by the Management Board of the Agency. Such remuneration shall be paid to the relevant national competent authorities.

3. The Union contribution provided for in Article 67 of Regulation (EC) No 726/2004 shall cover the tasks of the Agency provided for under this Regulation, and shall cover the full amount of remuneration paid to national competent authorities for medicinal products where fee exemptions apply in accordance with Council Regulation (EC) No 297/95 ⁽²³⁾.

Article 38

Entry into Force and date of application

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

It shall apply from 1 March 2022.

However, with the exception of Article 30, Chapter IV shall apply from 2 February 2023.

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

Done at Brussels, 25 January 2022

For the European Parliament
The President
R. METSOLA

For the Council
The President
C. BEAUNE

⁽²³⁾ 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).

⁽²³⁾ Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2022/124

of 25 January 2022

on the conclusion, on behalf of the European Union, of the Protocol to amend the Air Transport Agreement between the United States of America and the European Community and its Member States

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 100(2), in conjunction with Article 218(6)(a) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament ⁽¹⁾,

Whereas:

- (1) In accordance with Decision 2010/465/EU of the Council and the Representatives of the Governments of the Member States of the European Union, meeting within the Council ⁽²⁾, the Protocol to amend the Air Transport Agreement between the United States of America and the European Community and its Member States, signed on 25 and 30 April 2007 (the 'Protocol'), was signed on 24 June 2010, subject to its conclusion at a later date.
- (2) The Protocol has been ratified by all Member States, except for the Republic of Croatia. The Republic of Croatia is to accede to the Protocol in accordance with Article 6(2) of the 2012 Act of Accession.
- (3) The Protocol should be approved.
- (4) As Article 5 of Decision 2010/465/EU, on the provision of information by the Member States, is no longer necessary, that Article should cease to apply from the date of entry into force of this Decision,

HAS ADOPTED THIS DECISION:

Article 1

The Protocol to amend the Air Transport Agreement between the United States of America and the European Community and its Member States, signed on 25 and 30 April 2007 (the 'Protocol'), is hereby approved on behalf of the European Union ⁽³⁾.

⁽¹⁾ Consent of 14 December 2021 (not yet published in the Official Journal).

⁽²⁾ Decision 2010/465/EU of the Council and the Representatives of the Governments of the Member States of the European Union, meeting within the Council of 24 June 2010 on the signing and provisional application of the Protocol to Amend the Air Transport Agreement between the United States of America, of the one part, and the European Community and its Member States, of the other part (OJ L 223, 25.8.2010, p. 1).

⁽³⁾ The text of the Protocol has been published in OJ L 223, 25.8.2010, p. 3, together with the decision on signature.

Article 2

The President of the Council shall proceed, on behalf of the Union, to the exchange of diplomatic notes provided for in Article 10 of the Protocol.

Article 3

Article 5 of Decision 2010/465/EU shall cease to apply from the date of entry into force of this Decision.

Article 4

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

Done at Brussels, 25 January 2022.

For the Council
The President
C. BEAUNE

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2022/125

of 19 November 2021

amending Annexes I to V to Regulation (EU) No 691/2011 of the European Parliament and of the Council on European environmental economic accounts

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 691/2011 of the European Parliament and of the Council of 6 July 2011 on European environmental economic accounts ⁽¹⁾, and in particular Article 3(3) thereof,

Whereas:

- (1) To carry out its tasks under the Treaties, especially those related to the environment, sustainability and climate change, the Commission requires access to full, up-to-date and reliable information. Regulation (EU) No 691/2011 establishes a common framework for European environmental economic accounts, including lists of characteristics for which data are to be compiled and transmitted, and rules on the frequency and transmission deadlines for the compilation of the accounts.
- (2) The lists of characteristics of environmental accounts are essential to ensure comparability of statistical data across Member States. They now need to be updated to align to updates in the data sources for the accounts and to keep relevance for users.
- (3) To better monitor progress towards a green, competitive and resilient circular economy ⁽²⁾ and progress towards the sustainable development goals relevant to the EU, additional up-to-date data concerning the links of the environment and the economy is required.
- (4) The lists of characteristics of environmental accounts are essential to ensure comparability of statistical data across Member States.
- (5) The list of air pollutants in Annex I to Regulation (EU) No 691/2011 should be updated to align to the list of greenhouse gases that are reported under the United Nations Framework Convention on Climate Change (UNFCCC), which was revised after the second commitment period of the Kyoto Protocol, as well as to the guidelines for emission inventories under the Convention on long-range transboundary air pollution (CLRTAP) and definitions of Directive (EU) 2016/2284 of the European Parliament and of the Council on the reduction of national emissions of certain atmospheric pollutants (National Emissions Ceilings Directive) ⁽³⁾.
- (6) To better serve climate policies, Member States should be required to provide a breakdown of taxes recorded for government revenue arising from the EU Emissions Trading System (EU ETS) and other CO₂ taxes. Those taxes should therefore be included in the list of characteristics in Annex II to Regulation (EU) No 691/2011.

⁽¹⁾ OJ L 192, 22.7.2011, p. 1.

⁽²⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A new Circular Economy Action Plan For a cleaner and more competitive Europe, COM(2020)98 final.

⁽³⁾ Directive (EU) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants, amending Directive 2003/35/EC and repealing Directive 2001/81/EC (OJ L 344, 17.12.2016, p. 1).

- (7) The information in Tables C and E of Annex III to Regulation (EU) No 691/2011 is no longer necessary to produce Union aggregates, as Eurostat has developed a new method based on other readily available data. Those tables should therefore be deleted.
- (8) To better serve thematic environmental policies for the European Green Deal, the environmental accounts protection expenditure accounts must distinguish for all sectors the environmental purposes of Protection of ambient air and climate (Classification of environmental protection activities (CEPA) 1), Wastewater management (CEPA 2), Waste management (CEPA 3), Protection and remediation of soil, groundwater and surface water (CEPA 4), Noise and vibration abatement (CEPA 5), Protection of biodiversity and landscapes (CEPA 6), Protection against radiation, R & D and other environmental protection activities (CEPA 7–9). Annex IV to Regulation (EU) No 691/2011 should therefore be updated to reflect those changes.
- (9) Information on the marketed share of the environmental goods and services sector is not sufficient to serve environmental policies. Annex V to Regulation (EU) No 691/2011 should therefore be updated to require Member States to provide information on the total size of the sector.
- (10) To make it easier for users to interpret data and to allow Member States to assure quality during data compilation, Member States should provide information on all components of national expenditure on environmental protection. This includes estimates and information on the intermediate consumption of environmental protection services. Eurostat's experience with validating Member States' data demonstrates that, based on the accounting relations between other mandatory reporting categories, Eurostat cannot derive the data on the intermediate consumption of environmental protection services, such as costs of waste disposal or wastewater treatment services incurred by corporations, with sufficient quality for all Member States. Annex IV to Regulation (EU) No 691/2011 should therefore be updated so that Member States compile and report data for this item, undertaking all relevant quality assurance measures.
- (11) To accurately measure the total national expenditure on environmental protection, there is a need to identify all expenditure for environmental protection services that have been incurred for the purpose of producing other environmental protection services, and thus have already been covered in the value of relevant final products. Therefore, it is essential that Member States report all intermediate consumption of environmental protection services for the production of environmental protection services, whether by specialist producers or not.
- (12) Reporting deadlines for European environmental economic accounts should be reduced, to improve the usefulness of the accounts for policy making purposes.
- (13) To reduce the reporting burden for the Member States, the required level of detail of the classification NACE should be reduced for the environmental goods and services sector accounts and for the environmental protection expenditure accounts for NACE category 'Manufacturing'. That is a cost-effective measure which also enhances data availability to users, by reducing the number of confidentiality flags and data disclosure restrictions. Annexes IV and V to Regulation (EU) No 691/2011 should therefore be updated.
- (14) To offset the additional burden imposed by shorter reporting deadlines and updated lists of characteristics, a burden reduction should be introduced in the form of a threshold of 1 % for breakdowns by economic activity in the environmental protection expenditure account.
- (15) The first reference year for the updated data must be established.
- (16) Regulation (EU) No 691/2011 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I to V to Regulation (EU) No 691/2011 are amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 19 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes I to V to Regulation (EU) No 691/2011 are amended as follows:

(1) Annex I is amended as follows:

(a) Section 3 is replaced by the following:

‘Section 3

LIST OF CHARACTERISTICS

Member States shall produce statistics on the emissions of the following air pollutants:

Name	Symbol	Reporting unit
Carbon dioxide without emissions from biomass	CO ₂	1 000 tonnes (Gg)
Carbon dioxide from biomass	Biomass CO ₂	1 000 tonnes (Gg)
Nitrous oxide	N ₂ O	tonnes (Mg)
Methane	CH ₄	tonnes (Mg)
Perfluorocarbons	PFCs	tonnes (Mg) CO ₂ -equivalents
Hydrofluorocarbons	HFCs	tonnes (Mg) CO ₂ -equivalents
Sulphur hexafluoride and nitrogen trifluoride	SF ₆ NF ₃	tonnes (Mg) CO ₂ -equivalents
Nitrogen oxides	NO _x	tonnes (Mg) NO ₂ -equivalents
Non-methane volatile organic compounds	NMVOCs	tonnes (Mg)
Carbon monoxide	CO	tonnes (Mg)
Particulate matter < 10 µm	PM ₁₀	tonnes (Mg)
Particulate matter < 2,5 µm	PM _{2,5}	tonnes (Mg)
Sulphur oxides	SO _x	tonnes (Mg) SO ₂ -equivalents
Ammonia	NH ₃	tonnes (Mg)

All data shall be reported to one decimal place.’;

(b) Section 5 is replaced by the following:

‘Section 5

REPORTING TABLES

1. For each of the characteristics referred to in Section 3, data shall be produced by a hierarchical classification of economic activities, NACE Rev. 2 (A*64 aggregation level), fully compatible with ESA 95. In addition, data shall be produced for:

- Household air emissions,
- Bridging items, by which is meant reporting items which clearly reconcile the differences between the air emissions accounts reported under this Regulation and those data reported in official national air emission inventories.

2. The hierarchical classification referred to in paragraph 1 is as follows:

Air emissions by industry – NACE Rev. 2 (A*64)

Household air emissions

- Transport
- Heating/cooling
- Other

Bridging items

Total air emission accounts (production activities + households) for each of the characteristics referred to in Section 3

Less national residents abroad

- National fishing vessels operating abroad
- Land transport
- Water transport
- Air transport

Plus non-residents on the territory

- + Land transport
- + Water transport
- + Air transport

(+ or –) Other adjustments and statistical discrepancies

= Total emissions of pollutant X as reported to UNFCCC ⁽¹⁾/CLRTAP ⁽²⁾;

(2) in Annex II, Sections 3 and 4 are replaced by the following:

‘Section 3

LIST OF CHARACTERISTICS

Member States shall produce statistics on environmentally related taxes according to the following characteristics:

- energy taxes,
- transport taxes,
- pollution taxes,
- resource taxes,

Member States shall also report, as a distinct characteristic, government tax revenue recorded in the European System of Accounts in relation to their participation in the EU Emissions Trading System.

Member States shall also report, as a distinct characteristic, other environmentally related taxes which have been included in total energy, transport, pollution or resource taxes and are levied on carbon content of fuels (other CO₂ taxes).

All data shall be reported in million national currency.

Section 4

FIRST REFERENCE YEAR, FREQUENCY AND TRANSMISSION DEADLINES

1. Statistics shall be compiled and transmitted on a yearly basis.
2. Statistics shall be transmitted within 16 months of the end of the reference year. This applies from the reference year 2020.
3. In order to meet user needs for complete and timely datasets, the Commission (Eurostat) shall produce, as soon as sufficient country data becomes available, estimates for the EU-27 totals for the main aggregates of this module. The Commission (Eurostat) shall, wherever possible, produce and publish estimates for data that have not been transmitted by Member States within the deadline specified in point 2.

⁽¹⁾ United Nations Framework Convention on Climate Change.

⁽²⁾ Convention on Long-Range Transboundary Air Pollution.

4. The first reference year is the year 2020.
 5. In each data transmission to the Commission, Member States shall provide annual data for the years n-4, n-3, n-2, n-1 and n, where n is the reference year. Member States may provide any available data for the years preceding 2016.;
- (3) in Annex III, Sections 4 and 5 are replaced by the following:

‘Section 4

FIRST REFERENCE YEAR, FREQUENCY AND TRANSMISSION DEADLINES

1. Statistics shall be compiled and transmitted on a yearly basis.
2. Statistics shall be transmitted within 16 months of the end of the reference year. This applies from the reference year 2021.
3. In order to meet user needs for complete and timely datasets, the Commission (Eurostat) shall produce, as soon as sufficient country data becomes available, estimates for the EU-27 totals for the main aggregates of this module. The Commission (Eurostat) shall, wherever possible, produce and publish estimates for data that have not been transmitted by Member States within the deadline specified in point 2.
4. The first reference year is 2021.
5. In each data transmission to the Commission, Member States shall provide annual data for the years n-4, n-3, n-2, n-1 and n, where n is the reference year. Member States may provide any available data for the years preceding 2017.

Section 5

REPORTING TABLES

Data, expressed in mass units, shall be produced for the characteristics listed in the following tables.

Table A – Domestic extraction

MF.1	Biomass
MF.1.1	Crops (excluding fodder crops)
MF.1.1.1	Cereals
MF.1.1.2	Roots, tubers
MF.1.1.3	Sugar crops
MF.1.1.4	Pulses
MF.1.1.5	Nuts
MF.1.1.6	Oil-bearing crops
MF.1.1.7	Vegetables
MF.1.1.8	Fruits
MF.1.1.9	Fibres
MF.1.1.A	Other crops (excluding fodder crops) n.e.c.
MF.1.2	Crop residues (used), fodder crops and grazed biomass
MF.1.2.1	Crop residues (used)
MF.1.2.1.1	Straw
MF.1.2.1.2	Other crop residues (sugar and fodder beet leaves, etc.)
MF.1.2.2	Fodder crops and grazed biomass
MF.1.2.2.1	Fodder crops (including biomass harvest from grassland)

MF.1.2.2.2	Grazed biomass
MF.1.3	Wood
MF.1.3.1	Timber (industrial roundwood)
MF.1.3.2	Wood fuel and other extraction
MF.1.4	Wild fish catch, aquatic plants and animals, hunting and gathering
MF.1.4.1	Wild fish catch
MF.1.4.2	All other aquatic animals and plants
MF.1.4.3	Hunting and gathering
MF.2	Metal ores (gross ores)
MF.2.1	Iron
MF.2.2	Non-ferrous metal
MF.2.2.1	Copper
MF.2.2.2	Nickel
MF.2.2.3	Lead
MF.2.2.4	Zinc
MF.2.2.5	Tin
MF.2.2.6	Gold, silver, platinum and other precious metals
MF.2.2.7	Bauxite and other aluminium
MF.2.2.8	Uranium and thorium
MF.2.2.9	Other non-ferrous metals
MF.3	Non-metallic minerals
MF.3.1	Marble, granite, sandstone, porphyry, basalt, other ornamental or building stone (excluding slate)
MF.3.2	Chalk and dolomite
MF.3.3	Slate
MF.3.4	Chemical and fertiliser minerals
MF.3.5	Salt
MF.3.6	Limestone and gypsum
MF.3.7	Clays and kaolin
MF.3.8	Sand and gravel
MF.3.9	Other non-metallic minerals n.e.c.
MF.3.A	Excavated earthen materials (including soil), only if used (optional reporting)
MF.4	Fossil energy materials/carriers
MF.4.1	Coal and other solid energy materials/carriers
MF.4.1.1	Lignite (brown coal)
MF.4.1.2	Hard coal
MF.4.1.3	Oil shale and tar sands
MF.4.1.4	Peat
MF.4.2	Liquid and gaseous energy materials/carriers
MF.4.2.1	Crude oil, condensate and natural gas liquids (NGL)
MF.4.2.2	Natural gas

Tables B (Imports – Total trade) and D (Exports – Total trade)

MF.1	Biomass
MF.1.1	Crops (excluding fodder crops)
MF.1.1.1	Cereals
MF.1.1.2	Roots, tubers
MF.1.1.3	Sugar crops
MF.1.1.4	Pulses
MF.1.1.5	Nuts
MF.1.1.6	Oil-bearing crops
MF.1.1.7	Vegetables
MF.1.1.8	Fruits
MF.1.1.9	Fibres
MF.1.1.A	Other crops (excluding fodder crops) n.e.c.
MF.1.2	Crop residues (used), fodder crops and grazed biomass
MF.1.2.1	Crop residues (used)
MF.1.2.1.1	Straw
MF.1.2.1.2	Other crop residues (sugar and fodder beet leaves, etc.)
MF.1.2.2	Fodder crops and grazed biomass
MF.1.2.2.1	Fodder crops (including biomass harvest from grassland)
MF.1.3	Wood
MF.1.3.1	Timber (industrial roundwood)
MF.1.3.2	Wood fuel and other extraction
MF.1.4	Wild fish catch, aquatic plants and animals, hunting and gathering
MF.1.4.1	Wild fish catch
MF.1.4.2	All other aquatic animals and plants
MF.1.5	Live animals and animal products (excluding wild fish, aquatic plants and animals, hunted and gathered animals)
MF.1.5.1	Live animals (excluding wild fish, aquatic plants and animals, hunted and gathered animals)
MF.1.5.2	Meat and meat preparations
MF.1.5.3	Dairy products, birds, eggs and honey
MF.1.5.4	Other products from animals (animal fibres, skins, furs, leather, etc.)
MF.1.6	Products mainly from biomass
MF.2	Metal ores (gross ores)
MF.2.1	Iron
MF.2.2	Non-ferrous metal
MF.2.2.1	Copper
MF.2.2.2	Nickel
MF.2.2.3	Lead
MF.2.2.4	Zinc
MF.2.2.5	Tin
MF.2.2.6	Gold, silver, platinum and other precious metals
MF.2.2.7	Bauxite and other aluminium
MF.2.2.8	Uranium and thorium

- MF.2.2.9 Other non-ferrous metals
- MF.2.3 Products mainly from metals
- MF.3 Non-metallic minerals
- MF.3.1 Marble, granite, sandstone, porphyry, basalt, other ornamental or building stone (excluding slate)
- MF.3.2 Chalk and dolomite
- MF.3.3 Slate
- MF.3.4 Chemical and fertiliser minerals
- MF.3.5 Salt
- MF.3.6 Limestone and gypsum
- MF.3.7 Clays and kaolin
- MF.3.8 Sand and gravel
- MF.3.9 Other non-metallic minerals n.e.c.
- MF.3.B Products mainly from non-metallic minerals
- MF.4 Fossil energy materials/carriers
- MF.4.1 Coal and other solid energy materials/carriers
- MF.4.1.1 Lignite (brown coal)
- MF.4.1.2 Hard coal
- MF.4.1.3 Oil shale and tar sands
- MF.4.1.4 Peat
- MF.4.2 Liquid and gaseous energy materials/carriers
- MF.4.2.1 Crude oil, condensate and natural gas liquids (NGL)
- MF.4.2.2 Natural gas
- MF.4.2.3 Fuels bunkered (Imports: by resident units abroad; Exports: by non-resident units domestically)
- MF.4.2.3.1 Fuel for land transport
- MF.4.2.3.2 Fuel for water transport
- MF.4.2.3.3 Fuel for air transport
- MF.4.3 Products mainly from fossil energy products
- MF.5 Other products
- MF.6 Waste for final treatment and disposal;

(4) in Annex IV, Sections 3, 4 and 5 are replaced by the following:

‘Section 3

LIST OF CHARACTERISTICS

Member States shall produce environmental protection expenditure accounts according to the following characteristics which are defined in accordance with ESA:

- output of environmental protection services. Market output, non-market output and output of ancillary activities are distinguished,
- intermediate consumption of environmental protection services
- intermediate consumption of environmental protection services for production of environmental protection services,
- imports and exports of environmental protection services,
- valued added tax (VAT) and other taxes less subsidies on products on environmental protection services,

- gross fixed capital formation and acquisitions less disposals of non-financial non-produced assets for the production of environmental protection services,
- final consumption of environmental protection services,
- environmental protection transfers (received/paid).

All data shall be reported in million national currency.

Section 4

FIRST REFERENCE YEAR, FREQUENCY AND TRANSMISSION DEADLINES

1. Statistics shall be compiled and transmitted on a yearly basis.
2. Statistics shall be transmitted within 24 months of the end of the reference year. This applies from the reference year 2020.
3. In order to meet user needs for complete and timely datasets, the Commission (Eurostat) shall produce, as soon as sufficient country data becomes available, estimates for the EU-28 totals for the main aggregates of this module. The Commission (Eurostat) shall, wherever possible, produce and publish estimates for data that have not been transmitted by Member States within the deadline specified in point 2.
4. The first reference year is 2020.
5. In each data transmission to the Commission, Member States shall provide annual data for the years $n - 2$, $n - 1$ and n , where n is the reference year. Member States may provide any available data for the years preceding 2018.

Section 5

REPORTING TABLES

1. For the characteristics referred to in Section 3, data shall be reported in a breakdown by:
 - type of producers/consumers of environmental protection services as defined in Section 2,
 - classes of the classification of environmental protection activities (CEPA) grouped as follows:
 - CEPA 1
 - CEPA 2
 - CEPA 3
 - CEPA 4
 - CEPA 5
 - CEPA 6
 - Sum of CEPA 7, CEPA 8 and CEPA 9
 - The following NACE breakdowns for the ancillary production of environmental protection services: NACE Rev. 2 B, C, D, Division 36. Data for section C shall be presented as follows:
 - NACE C10-C12 – Manufacture of food products; beverages and tobacco products
 - NACE C17 – Manufacture of paper and paper products
 - NACE C19-20 – Manufacture of coke, chemicals and refined petroleum and chemical products
 - NACE C 21-23 – Manufacture of pharmaceuticals, rubber, plastic and other non-metallic products
 - NACE C 24 – Manufacture of basic metals
 - NACE C 25-30 – Manufacture of fabricated metal products, including machinery and equipment
 - NACE C13-16, 18, 31-33 – other manufacturing activities

Member States where the total amount of the turnover or the number of persons employed in one or more of these NACE breakdowns represents less than 1 % of the Union total do not need to provide data for those NACE breakdowns.

2. The CEPA classes referred to in point 1 are as follows:

CEPA 1 – Protection of ambient air and climate

CEPA 2 – Wastewater management

CEPA 3 – Waste management

CEPA 4 – Protection and remediation of soil, groundwater and surface water

CEPA 5 – Noise and vibration abatement

CEPA 6 – Protection of biodiversity and landscapes

CEPA 7 – Protection against radiation

CEPA 8 – Environmental research and development

CEPA 9 – Other environmental protection activities.’;

(5) in Annex V, Sections 3, 4 and 5 are replaced by the following:

‘Section 3

LIST OF CHARACTERISTICS

Member States shall produce statistics on the environmental goods and services sector according to the following characteristics:

- output of the total environmental goods and services sector and of market activities,
- exports of the total environmental goods and services sector,
- value added of the total environmental goods and services sector and of market activities,
- employment in the total environmental goods and services sector and of market activities.

All data shall be reported in million national currency, except for the characteristic “employment” for which the reporting unit shall be “full time equivalent”.

Section 4

FIRST REFERENCE YEAR, FREQUENCY AND TRANSMISSION DEADLINES

1. Statistics shall be compiled and transmitted on a yearly basis.
2. Statistics shall be transmitted within 22 months of the end of the reference year. This applies from the reference year 2020.
3. In order to meet user needs for complete and timely datasets, the Commission (Eurostat) shall produce, as soon as sufficient country data becomes available, estimates for the EU-28 totals for the main aggregates of this module. The Commission (Eurostat) shall, wherever possible, produce and publish estimates for data that have not been transmitted by Member States within the deadline specified in point 2.
4. The first reference year is 2020.
5. In each data transmission to the Commission, Member States shall provide annual data for the years $n - 2$, $n - 1$ and n , where n is the reference year. Member States may provide any available data for the years preceding 2018.

Section 5

REPORTING TABLES

1. For the characteristics referred to in Section 3, data shall be reported cross-classified by:
 - classification of economic activities, NACE Rev. 2 grouped as follows:
 - NACE A

- NACE B
- NACE C
- NACE D
- NACE E
- NACE F
- NACE J
- NACE M
- NACE O
- NACE P
- Sum of NACE G+NACE H+NACE I+NACE K+NACE L+ NACE N+NACE Q+NACE R+ NACE S + NACE T + NACE U
- classes of the classification of environmental protection activities (CEPA) and the classification of resource management activities (CReMA) grouped as follows:
 - CEPA 1
 - CEPA 2
 - CEPA 3
 - CEPA 4
 - CEPA 5
 - CEPA 6
 - Sum of CEPA 7, CEPA 8 and CEPA 9
 - CReMA 10
 - CReMA 11
 - CReMA 13
 - CReMA 13A
 - CReMA 13B
 - CReMA 13C
 - CReMA 14
 - Sum of CReMA 12, CReMA 15 and CReMA 16

2. The CEPA classes referred to in point 1 are as set out in Annex IV. The CReMA classes referred to in point 1 are as follows:

CReMA 10 – Management of water

CReMA 11 – Management of forest resources

CReMA 12 – Management of wild flora and fauna

CReMA 13 – Management of energy resources:

CReMA 13A – Production of energy from renewable resources

CReMA 13B – Heat/energy saving and management

CReMA 13C – Minimisation of the use of fossil energy as raw materials

CReMA 14 – Management of minerals

CReMA 15 – Research and development activities for resource management

CReMA 16 – Other resource management activities.’.

COMMISSION DELEGATED REGULATION (EU) 2022/126**of 7 December 2021****supplementing Regulation (EU) 2021/2115 of the European Parliament and of the Council with additional requirements for certain types of intervention specified by Member States in their CAP Strategic Plans for the period 2023 to 2027 under that Regulation as well as rules on the ratio for the good agricultural and environmental condition (GAEC) standard 1**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulation (EU) No 1305/2013 of the European Parliament and of the Council and Regulation (EU) No 1307/2013 of the European Parliament and of the Council ⁽¹⁾, and in particular Articles 4(8), 13(3), 37(5), 38(5) and 39(3) and Articles 45, points (a) to (i), 56, points (a), (b) and (c), and 84, points (a) and (b), thereof,

Whereas:

- (1) Regulation (EU) 2021/2115 lays down a new legal framework for the common agricultural policy (CAP) to improve its delivery on the Union's objectives set out in the Treaty on the Functioning of the European Union. That Regulation further specifies these Union objectives to be achieved by the CAP and defines the types of intervention as well as the common Union requirements applicable to Member States, while leaving flexibility for Member States in the design of the interventions to be provided in their CAP Strategic Plans.
- (2) In order to ensure the common nature of the CAP and the internal market, Regulation (EU) 2021/2115 empowers the Commission to adopt additional requirements for the design of the interventions to be specified in the CAP Strategic Plans, in the area of direct payments, of certain agricultural sectors referred to in Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽²⁾ and in the area of rural development as well as common rules for these areas as regards the ratio for the good agricultural and environmental condition (GAEC) standard 1. All those additional requirements have to be considered by Member States when designing their CAP Strategic Plans which cover all areas concerned and should therefore be all laid down in this Regulation.
- (3) As regards the interventions to be specified by Member States in their CAP Strategic Plans, in the area of direct payments, additional requirements for the interventions on hemp and cotton should be laid down. The granting of payments should be made conditional upon the use of certified seeds of certain hemp varieties.
- (4) In addition, the procedure for the determination of hemp varieties and the verification of their tetrahydrocannabinol content (THC content) referred to in Article 4(4) second subparagraph, of Regulation (EU) 2021/2115 should be laid down. The verification of the THC content is necessary to protect the financial interests of the Union, but is also strategic to preserve public health, and to ensure coherence with other legislative frameworks, namely criminal law in the field of illicit drug trafficking and the commitments under international obligations such as the Single Convention on Narcotic Drugs ⁽³⁾. It is therefore appropriate to lay down rules harmonising the methods and the procedures used by the Member States for the verification of hemp varieties and for the quantitative determination of the THC content in hemp, in order to ensure comparable results.

⁽¹⁾ OJ L 435, 6.12.2021, p. 1.

⁽²⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

⁽³⁾ <https://www.unodc.org/unodc/en/treaties/single-convention.html>

- (5) It is necessary to provide for a time period during which hemp grown for fibre may not be harvested after flowering, in order to enable the effective and reliable determination of the THC content in hemp.
- (6) In the interest of clarity and legal certainty, when a variety exceeds the THC content referred to in Article 4(4), second subparagraph, of Regulation (EU) 2021/2115 for 2 consecutive years, the Member States should take the necessary measures to inform timely the operators that the cultivation of that variety would not give the right to direct payments.
- (7) The rules for the verification of hemp varieties and the quantitative determination of the THC content should take into account that hemp may be cultivated either as main crop or as catch crop. In that context, it is appropriate to provide a definition of hemp cultivated as catch crop.
- (8) Title III, Chapter II, Section 3, Subsection 2, of Regulation (EU) 2021/2115 provides for a crop-specific payment for cotton. It is appropriate to lay down the rules and conditions for the authorisation of agricultural land and varieties for the purposes of that payment. Furthermore, additional conditions should be laid down to ensure a minimum activity in line with the support's objective.
- (9) The Member States referred to in Article 36 of Regulation (EU) 2021/2115 should approve interbranch cotton producing organisations on the basis of objective criteria relating to their scale and internal organisation. The scale of an interbranch organisation should be fixed, taking into account the requirement for the ginner belonging to the organisation to be able to take delivery of sufficient quantities of unginned cotton.
- (10) Specific obligations with regard to the farmers, as members of interbranch organisations, should be laid down. These aim at facilitating the administration and control of farmers' membership, as well as enhancing the organisations' potential efficiency gain arising from the number and dedication of their members.
- (11) Additional requirements as regards investments, agri-environment-climate interventions, coaching, promotion, communication and marketing, mutual funds, replanting of orchards, olive groves or vineyards following mandatory grubbing-up, green harvesting and non-harvesting, harvest and production insurance, market withdrawals for destinations other than free distribution and collective storage should be set out for the interventions to be specified by Member States, in their CAP Strategic Plans, in the fruit and vegetables sector, in the apiculture sector, in the wine sector, in the hops sector, in the olive oil and table olives sectors as well as other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115. In addition, provisions regarding forms of support and types of expenditure, including the use of flat-rates and scales of unit costs or lump sums, as well as administrative and personnel costs should be laid down. For reasons of sound financial management and legal certainty, a list of expenditure that may not be covered by the CAP Strategic Plans and a non-exhaustive list of expenditure that may be covered in the fruit and vegetables, the apiculture, the wine, the hops, the olive oil and table olives sectors as well as other sectors should be drawn up.
- (12) Furthermore, specific rules regarding certain sectoral types of intervention, namely, in the fruit and vegetables, the apiculture, the wine, the hops and the livestock sectors should be laid down in order to take into account certain specificities of those sectors.
- (13) Regarding sectoral types of intervention managed by producer organisations, associations of producer organisations, transnational producer organisations, transnational associations of producer organisations, or producer groups through operational programmes, in the fruit and vegetables, olive oil and table olives and other sectors, specific rules should be laid down as regards products coverage and market withdrawals for free distribution, namely transport and conditioning costs, taking into account the potential importance of that intervention. In particular, maximum levels of support for market withdrawals should be fixed in order to ensure that withdrawals do not become a permanent alternative outlet for products compared to placing them on the market. In all cases, for similar reasons, it is appropriate to set a quantitative limit of withdrawals per product per producer organisation. In addition, specific rules should be laid down regarding the destinations for withdrawn products, the conditions for the recipients of withdrawn products and relevant standards to be complied with by withdrawn products.

- (14) To facilitate the use of sectoral interventions through operational programmes, the method of calculation of the value of marketed production of producer organisations should be established, including the use of a flat rate for the purpose of calculating the value of fruit and vegetables intended for processing. The method of calculation of the value of marketed production should attenuate yearly fluctuations or insufficient data for newly recognised organisations or groups. To prevent misuse of the scheme, producer organisations should not be permitted in general to change the methodology for fixing the reference period within the duration of a programme.
- (15) To ensure a good functioning of the types of intervention in the fruit and vegetables sector, it would be appropriate to lay down specific objectives regarding agri-environment-climate interventions.
- (16) Rules should be laid down concerning the national financial assistance that Member States may grant in regions where the degree of organisation of producers of fruit and vegetables is particularly low, including rules on how the degree of organisation is calculated and a low degree of organisation is confirmed.
- (17) To ensure a good functioning of the types of intervention in apiculture sector, rules regarding beehives should be laid down.
- (18) To ensure a good functioning of the types of intervention in the wine sector, it is appropriate to draw up a non-exhaustive list of operators which may be the beneficiaries of the support for the different types of intervention. It is also necessary to provide for some specific eligibility requirements as regards beneficiaries of the types of intervention 'restructuring and conversion of vineyards', 'green harvesting' and 'harvest insurance', bodies governed by public law and private companies. It is further appropriate to exclude from Union support producers farming unlawful plantings or unauthorised planted areas.
- (19) To ensure that Union funds are spent properly, it is necessary to lay down rules on expenditure for the 'replanting of vineyards for health or phytosanitary reasons' in the wine sector. In particular, it is appropriate to provide for such expenditure not to exceed a certain amount of the total annual expenditure on restructuring and conversion of vineyards paid by the Member State concerned in any given financial year. It should be also clarified that the costs for grubbing-up and for compensating the income foregone should not constitute eligible expenditure under this intervention, which only aims at supporting the costs for replanting after mandatory phytosanitary measures.
- (20) For the purposes of the 'restructuring and conversion of vineyards' and 'green harvesting' interventions, it is appropriate to lay down rules on the measurement of areas, in particular to define what corresponds to the area planted with vines, which is of particular importance where support is paid on the basis of area-based standard scales of unit costs.
- (21) To ensure a good functioning of the types of intervention in the hops sector, it is appropriate to lay down rules on the Union financial assistance calculation.
- (22) To ensure a good functioning of the types of intervention in the livestock sector, it is appropriate to lay down rules on the restocking with livestock following compulsory slaughter or because of losses resulting from natural disasters.
- (23) The conditions applicable to commitments to preserve on farm endangered breeds and plant varieties under threat of genetic erosion, and to activities for the conservation, the sustainable use, and the development of genetic resources in agriculture and in forestry, should contribute to the specific environmental and climate-related objectives of the CAP set out in Article 6(1), points (d), (e) and (f), of Regulation (EU) 2021/2115. In particular, they should address the need to ensure the protection, the conservation, and the promotion of genetic diversity.
- (24) Levels of animal welfare should be improved by providing support to farmers who undertake to adopt higher standards of animal husbandry, which go beyond the relevant mandatory requirements. Where animal welfare commitments are made to provide for upgraded standards of production methods, the areas should be defined. In doing so, it should be avoided that those animal welfare commitments overlap with standard farming practices, in particular vaccination to prevent pathologies.

- (25) National recognised quality schemes can provide consumers with assurances on the quality and characteristics of the product or the production process. Criteria about the specificity of the final product, the access to the scheme, the verification of binding product specifications, the transparency of the scheme and the traceability of the products should be laid down with a view to optimising their support under rural development interventions. Given the special characteristics of cotton as a farm product, national quality schemes for cotton should also be covered.
- (26) With a view to supporting voluntary agricultural product certification schemes recognised by the Member States under rural development interventions and being aligned to sectoral interventions, certain objective criteria should be laid down.
- (27) With a view to ensure a level playing field as regards the ratio for the good agricultural and environmental condition (GAEC) standard 1 as referred to in Annex III to Regulation (EU) 2021/2115, rules should be provided for the method to determine both the reference ratio and the annual ratio of permanent grassland, as well as the level at which these can be established.
- (28) With a view to ensuring the protection of the share of permanent grassland, it is also appropriate to lay down that Member States should take steps to ensure reconversion of areas in the case where the share of permanent grassland has decreased below the 5 % limit. However, derogations should be provided for the cases where the absolute area of permanent grassland remain relatively stable or where the decrease of the share below the threshold is the result of conversions of area for environmentally- and climate-friendly objectives, in particular afforestation and rewetting of areas.
- (29) Since Member States need to take the rules laid down in this Regulation into account when developing their CAP Strategic Plans, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

TITLE I

SUBJECT MATTER

Article 1

Subject matter

This Regulation supplements Regulation (EU) 2021/2115 with:

- (a) additional requirements for certain types of intervention, specified by Member States in their CAP Strategic Plans covering the period from 1 January 2023 to 31 December 2027:
- (i) in the form of direct payments for the cultivation of hemp and cotton;
 - (ii) in the agricultural sectors referred to in Article 42 of Regulation (EU) 2021/2115;
 - (iii) for genetic resources and animal welfare in the framework of environmental, climate and other management commitments and for quality schemes in the area of rural development;
- (b) rules on the ratio for the good agricultural and environmental condition (GAEC) standard 1.

TITLE II

ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF INTERVENTION IN THE FORM OF DIRECT PAYMENTS

CHAPTER I

Hemp

Article 2

Additional eligibility requirements

When providing, in their CAP Strategic Plans, the definitions foreseen in Article 4(1) of Regulation (EU) 2021/2115, Member States shall make the granting of payments for the production of hemp conditional upon the use of seeds of hemp varieties which fulfil the following requirements:

- (a) they are listed in the Common Catalogue of Varieties of Agricultural Plant Species on 15 March of the year in respect of which the payment is granted and published in accordance with Article 17 of Council Directive 2002/53/EC ⁽⁴⁾;
- (b) their Δ^9 -tetrahydrocannabinol content (hereinafter referred to as 'THC content') did not exceed for 2 consecutive years the limit as laid down in Article 4(4), second subparagraph, of Regulation (EU) 2021/2115;
- (c) they are certified in accordance with Council Directive 2002/57/EC ⁽⁵⁾ or in accordance with Article 10 of Commission Directive 2008/62/EC ⁽⁶⁾ in the case of conservation varieties.

Article 3

Verification of hemp varieties and quantitative determination of THC content

1. Member States shall establish a verification system for determining the THC content in hemp varieties which allows them to apply the method for the verification of hemp varieties and quantitative determination of the THC content in hemp varieties set out in Annex I.
2. The competent authority of the Member State shall keep the records related to findings on the THC content. Such records shall comprise, for each variety, at least the results in terms of THC content from each sample expressed in percentage to two decimal places, the procedure used, the number of tests carried out, an indication of the point at which the sample was taken and measures taken at national level.
3. If an average of all the samples of a given variety exceeds the THC content laid down in Article 4(4), second subparagraph, of Regulation (EU) 2021/2115, Member States shall use procedure B described in Annex I to this Regulation for the variety concerned in the course of the following claim year. That procedure shall be used in the course of the next claim years unless all the analytical results for the given variety are below the THC content laid down in Article 4(4), second subparagraph, of Regulation (EU) 2021/2115.

⁽⁴⁾ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

⁽⁵⁾ Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

⁽⁶⁾ Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties (OJ L 162, 21.6.2008, p. 13).

4. If for the second year the average of all the samples of a given variety exceeds the THC content laid down in Article 4(4), second subparagraph, of Regulation (EU) 2021/2115, the Member State shall notify the Commission of the name of the variety concerned by 15 January of the following claim year at the latest. Starting from that claim year, the cultivation of the given variety shall not give a right to direct payments in the Member State concerned.

5. Member States shall ensure that the hemp producers are timely informed about the names of hemp varieties which are ineligible for direct payment in accordance with Article 4(4), second subparagraph, of Regulation (EU) 2021/2115 following a notification pursuant to paragraph 4 of this Article by making the information notified public not later than the date for submitting the single application.

Article 4

Catch crop

For the purposes of this Chapter, 'hemp cultivated as catch crop' means crop of hemp sown after 30 June of a given year.

Article 5

Cultivation requirements

Crops of hemp shall continue to be cultivated under normal growing conditions in accordance with local practice for at least 10 days from the date of the end of flowering so that the checks necessary for the application of this Article can be made.

Hemp cultivated as catch crop shall continue to be cultivated under normal growing conditions in accordance with local practice at least until the end of the vegetation period.

Member States may authorise hemp to be harvested before the end of the 10-day period after the end of flowering, provided that the harvest takes place after flowering has begun and that the inspectors indicate which representative parts of each plot concerned shall continue to be cultivated for at least 10 days following the end of flowering for inspection purposes, in accordance with the method set out in Annex I.

CHAPTER II

Cotton

Article 6

Authorisation of agricultural land for cotton production

The Member States referred to in Article 36 of Regulation (EU) 2021/2115 shall establish, in their CAP Strategic Plans, objective criteria for the authorisation of agricultural land pursuant to Article 37(3) of that Regulation.

Those criteria shall be based on one or more of the following:

- (a) the agricultural economy of those regions where cotton is a major crop;
- (b) the soil and climate in the areas in question;
- (c) the management of irrigation water;
- (d) rotation systems and cultivation methods likely to respect the environment.

*Article 7***Authorisation of varieties for sowing**

The Member States referred to in Article 36 of Regulation (EU) 2021/2115 shall set out, in their CAP Strategy Plans, which varieties, registered in the Common Catalogue of Varieties of Agricultural Plant Species provided for in Directive 2002/53/EC and adapted to their market needs, are authorised for sowing.

*Article 8***Additional conditions for receiving the crop-specific payment for cotton**

For the crop-specific payments for cotton referred to in Article 37(1) of Regulation (EU) 2021/2115, the Member States referred to in Article 36 of that Regulation shall set out, in their CAP Strategy Plans, a minimum plant density on the sown area fixed on the basis of the soil and weather conditions and, where appropriate, specific regional characteristics.

*Article 9***Approval of interbranch organisations**

1. The approval of an interbranch organisation in the sense of Article 39(1) of Regulation (EU) 2021/2115 shall be granted by the Member State where the ginneries are established and for a period of one year starting in due time before the sowing season of that year, provided that the organisation fulfils the following criteria:

- (a) it covers a total area of at least 4 000 ha that meet authorisation criteria as referred to in Article 6 of this Regulation;
- (b) it has adopted internal operating rules, in particular on membership conditions and fees, in accordance with Union and national rules.

2. Where it is found that an approved interbranch organisation no longer fulfils the criteria for approval provided for in paragraph 1, the Member State that granted the approval shall withdraw the approval, unless the non-compliance is remedied within a deadline to be fixed by the Member State in the withdrawal decision. The competent authority of the responsible Member State shall notify the interbranch organisation of its intention to withdraw an approval, together with the reasons for the withdrawal, in advance. It shall grant the interbranch organisation the opportunity to submit its observations within a period specified in the notification of the planned withdrawal.

Farmers who are members of an approved interbranch organisation whose approval is withdrawn in accordance with the first subparagraph of this paragraph shall not be eligible to receive the increase of the crop-specific payment for cotton pursuant to Article 40(2) of Regulation (EU) 2021/2115.

*Article 10***Obligations for farmers producing cotton**

1. A farmer shall not be a member of more than one approved interbranch organisation referred to in Article 39(1) of Regulation (EU) 2021/2115.
2. A farmer who is a member of an approved interbranch organisation shall deliver cotton only to a ginner belonging to that same organisation.
3. The participation of farmers in an approved interbranch organisation shall be the result of voluntary membership.

TITLE III

ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF INTERVENTION IN THE SECTORS REFERRED TO IN ARTICLE 42 OF REGULATION (EU) 2021/2115

CHAPTER I

Common rules applicable to interventions in the fruit and vegetables sector, in the apiculture sector, in the wine sector, in the hops sector, in the olive oil and table olives sector and in the other sectors referred to in Title III, Chapter III, of Regulation (EU) 2021/2115

Section 1

Common rules on investments, agri-environment-climate related types of intervention, coaching, promotion and communication, mutual funds, replanting, green harvesting and non-harvesting, harvest insurance, market withdrawals and collective storage

Article 11

Investments in tangible and intangible assets

1. When Member States include, in their CAP Strategic Plans, investments in tangible and intangible assets as foreseen in the fruit and vegetables sector, in the apiculture sector, in the wine sector, in the hops sector, in the olive oil and table olives sector in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, they shall provide for the following:

- (a) the tangible and the intangible assets acquired are used according to the nature, objectives and intended use by the beneficiary, as described in the related interventions of the CAP Strategic Plan and, where relevant, in the approved operational programme;
- (b) without prejudice to paragraph 10, the tangible and the intangible assets acquired remain both in the property and possession of the beneficiary until the end of the fiscal depreciation period or during a period of at least 5 years to be set by Member States taking into account the nature of the assets. Each of these periods shall be calculated as of the date of the asset acquisition or as of the date on which the asset is put at the disposal of the beneficiary.

However, Member States may provide for a shorter period during which the asset shall remain in the property and possession of the beneficiary, but this period shall not be less than 3 years for the purpose of maintenance of investments or jobs created by micro, small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC ⁽⁷⁾.

The investments in tangible assets referred to in the first subparagraph shall be made at the premises of the beneficiary or, where relevant, at the premises of its producer members or of its subsidiaries complying with the 90 % requirement referred to in Article 31(7) of this Regulation. However, in the apiculture sector, Member States may also provide in their CAP Strategic Plans, for investments in tangible assets made outside the premises of the beneficiary.

Where the investment is made on ground rented under particular national property rules, the requirement of being in the property of the beneficiary may not apply provided the asset have been in the possession of the beneficiary at least for the period required in paragraph (b) of first subparagraph.

2. Member States may provide in their CAP Strategic Plans that support for investments in tangible and intangible assets, including those under leasing contracts, may be financed in one amount or in instalments that were approved, where relevant, in the operational programme or as so specified by Member States in the relevant interventions.

⁽⁷⁾ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

If the period referred to in paragraph 1, first subparagraph, point (b), for a given investment exceeds the length of the operational programme, Member States shall ensure that it may be carried over to a subsequent operational programme.

When Member States provide, in their CAP Strategic Plans, support for investments in tangible and intangible assets, pursuing the agro-environmental-climate related objectives referred to in Articles 46, points (e) and (f), and 57, point (b), of Regulation (EU) 2021/2115, such investments shall pursue one or more of the objectives listed in Article 12(1) of this Regulation.

3. Member States may provide, in their CAP Strategic Plans, support for investments in tangible assets consisting of systems which generate energy provided that the amount of energy generated does not exceed the amount of energy that can be used on a yearly basis for the normal activities of the beneficiary.

4. Member States may provide, in their CAP Strategic Plans, support for investments in irrigation provided that:

- (a) percentages for minimum water savings targets are set up, both in terms of potential and effective reduction in water use, to be reached by the beneficiary of support, and subject to the CAP Strategic Plan demonstrating that such water savings targets have been determined taking into account the needs set out in the river basin management plans referred to in Directive 2000/60/EC of the European Parliament and of the Council ⁽⁸⁾;
- (b) a water meter system enabling measurement of water use at the level of the holding or the relevant production unit is in place or is put in place as part of the investment;
- (c) in case of specific investments in irrigation referred to in paragraphs 5 to 8 the conditions laid down in those paragraphs are complied with.

5. Support for investments in the improvement of an existing irrigation installation or element of irrigation infrastructure may be provided under the following conditions:

- (a) the investments are assessed by the beneficiary *ex ante* as showing potential water savings reflecting the technical parameters of the existing installations or infrastructures;
- (b) the investments affect bodies of groundwater or surface water whose status have been identified as less than good in the relevant river basin management plan as provided for in Directive 2000/60/EC for reasons related to water quantity, and an effective reduction in water use will be achieved contributing to the achievement of good status of these water bodies, as laid down in Article 4(1) of that Directive.

The conditions set out in the first subparagraph, points (a) and (b), shall not apply to investments, made in support of improvements of an existing irrigation installation or element of irrigation infrastructure, relating to the creation of a reservoir or to the use of reclaimed water which does not affect a body of groundwater or surface water.

6. Support for investments in irrigation resulting in a net increase of the irrigated area affecting a given body of groundwater or surface water may be provided under the following conditions that:

- (a) the status of the water body has not been identified as less than good in the relevant river basin management plan for reasons related to water quantity;
- (b) an environmental impact analysis shows that there will be no significant negative environmental impact from the investment; that environmental impact analysis shall be either carried out by or approved by the competent authority.

7. Support for investments in the use of reclaimed water as an alternative water supply may be provided under the condition that the use of such water is compliant with Regulation (EU) 2020/741 of the European Parliament and of the Council ⁽⁹⁾.

⁽⁸⁾ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

⁽⁹⁾ Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse (OJ L 177, 5.6.2020, p. 32).

8. Support for investments in the creation or expansion of a reservoir for the purpose of irrigation may be provided under the condition that it does not lead to significant negative environmental impact.

9. Member States shall ensure the recovery of the Union financial assistance from the beneficiary, if one of the following situations occurs within the period referred to in paragraph 1, first subparagraph, point (b):

- (a) a cessation of activity of the beneficiary or a transfer to another entity;
- (b) a relocation of a productive activity outside the geographical cultivated area by the beneficiary or, where relevant, its members;
- (c) a change in ownership, in particular where it gives to a firm or a public body an undue advantage; or
- (d) any other significant change affecting the nature, objectives or implementation conditions of the intervention concerned which would result in undermining its original objectives.

In case of non-compliance by the beneficiary with the conditions provided by Member States in their CAP Strategic Plans on the basis of paragraphs 1 to 8 and the first subparagraph of this paragraph, Member States shall ensure the recovery of the Union financial assistance in proportion to the duration of non-compliance.

Member States may choose not to recover the Union financial assistance when the beneficiary ceases a productive activity due to a non-fraudulent bankruptcy.

If a producer member leaves its organisation or producer group, Member States shall ensure that the investment or its residual value is recovered by the beneficiary and that its residual value is added to the operational fund.

In duly justified circumstances, Member States may provide that the beneficiary is not required to recover the investment or its residual value.

10. Where the assets, for which investments were supported, are replaced, the residual value of the investments replaced shall be:

- (a) added to the operational fund of the producer organisation; or
- (b) subtracted from the cost of the replacement.

Notwithstanding the first subparagraph, Member States cannot provide in their CAP Strategic Plans the mere replacement of investments by identical assets.

11. Member States shall not provide support for investments specified as interventions in their CAP Strategic Plans, if those interventions receive support pursuant to Article 58(1), first subparagraph, points (h) to (k), of that Regulation.

Article 12

Interventions related to agri-environment-climate objectives

1. When Member States include, in their CAP Strategic Plans, interventions pursuing agri-environment-climate objectives in the fruit and vegetables sector, in the apiculture sector, in the wine sector, in the hops sector, in the olive oil and table olives sector or in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, they shall provide in their CAP Strategic Plans that the interventions covered pursue one of the following aims:

- (a) achieving a reduction in the current use of production inputs, emission of pollutants or waste from the production process;
- (b) achieving the replacement of the use of energy from fossil fuel sources with renewable energy sources;

- (c) achieving a reduction in the environmental risks linked to the use of certain production inputs or to the production of certain residues, including plant protection products, fertilisers, manure or other animal dejections;
- (d) achieving a reduction in water use;
- (e) being linked to non-productive investments needed to achieve the agri-environment-climate related objectives, in particular where those objectives relate to the protection of habitats and biodiversity;
- (f) achieving an effective and measurable reduction of greenhouse gas emissions or a durable carbon sequestration;
- (g) increasing the resilience of the production to risks linked to climate change, such as soil erosion;
- (h) achieving conservation, sustainable use and development of genetic resources; or
- (i) leading to the protection or an improvement of the environment.

Member States shall ensure that beneficiaries provide evidence of the expected positive contribution to one or more environmental objectives at the moment of the submission for approval of the proposed operational programme, of the intervention or of the amendment of such programme or intervention.

2. The interventions referred to in paragraph 1, shall be made at the premises of the beneficiary or, where relevant, at the premises of its producer members or at the premises of its subsidiaries complying with the 90 % requirement referred to in Article 31(7) of this Regulation. However, in the apiculture sector, Member States may also provide in their CAP Strategic Plans, for such interventions made outside the premises of the beneficiary. The expected benefit and additional impact of the intervention related to agri-environment-climate objectives has to be demonstrated *ex ante* through project specifications or other technical documents to be presented by the beneficiary at the moment of the submission for approval of the operation, operational programme or amendment of such a programme or operation, showing the results that could be obtained through the implementation of the intervention.

3. When determining the expenditure to be covered, Member States shall take into account the additional costs incurred and income foregone resulting from the implemented interventions related to agri-environment-climate objectives, and the targets set.

4. Member States shall ensure that beneficiaries implementing interventions related to agri-environment-climate objectives have access to the relevant knowledge and information required to implement such interventions, and that appropriate training is made available for those who require it, as well as access to expertise in order to assist farmers who commit to change their production systems.

5. Member States shall ensure that a revision clause is provided in the operational programmes for operations implemented under interventions related to agri-environment-climate objectives in the fruit and vegetables sector, in the hops sector, in the olive oil and table olives sector, and in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, in order to ensure their adjustment in the case of amendments to any relevant mandatory standards, requirements or obligations.

Article 13

Coaching

1. When Member States include, in their CAP Strategic Plans, coaching interventions in the fruit and vegetables sector, in the hops sector, in the olive oil and table olives sector, or in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, they shall provide in their CAP Strategic Plans that the interventions covered pursue one of the following objectives:

- (a) exchanging best practices related to crisis prevention and management interventions helping the beneficiary to benefit from experience with implementation of crisis prevention and risk management interventions;

- (b) promoting the setting-up of new producer organisations, merging existing ones or enabling individual producers to join an existing producer organisation as well as advising producers groups on their way to reach the recognition as producer organisation pursuant to Regulation (EU) No 1308/2013;
 - (c) creating networking opportunities for coaching providers and recipients, in particular marketing channels as a means of crisis prevention and management.
2. The coaching provider shall be a producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group. The coaching provider shall benefit from the support for the coaching intervention.
3. The coaching recipient shall be a producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group, the individual producers members or non-members of a producer organisation, their associations or a producer group.
4. All eligible costs related to the coaching activity shall be paid to the coaching provider which includes this intervention in its operational programme.
5. Coaching interventions shall not be outsourced.

Article 14

Promotion, communication and marketing

When Member States include, in their CAP Strategic Plans, promotion, communication and marketing interventions in the fruit and vegetables sector, in the wine sector, in the hops sector, in the olive oil and table olives sector or in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, they shall provide in their CAP Strategic Plans that the interventions covered pursue one of the following objectives:

- (a) increasing awareness of the merits of Union agricultural products and of the high standards applicable to their production methods in the Union;
- (b) increasing the competitiveness and consumption of Union agricultural products and certain processed products produced in the Union and raising their profile both inside and outside the Union for sectors other than wine;
- (c) increasing awareness about Union quality schemes both inside and outside the Union;
- (d) increasing the market share of Union agricultural products and certain processed products produced in the Union, specifically focusing on the markets in third countries that have the highest growth potential;
- (e) contributing, where relevant, to restore the normal market conditions in the Union market in the event of serious market disturbance, loss of consumer confidence or other specific problems;
- (f) increasing awareness of sustainable production;
- (g) increasing consumer awareness of brands or trademarks of producer organisations, associations of producer organisations, transnational producer organisations, transnational associations of producer organisation in the fruit and vegetables sector;
- (h) diversifying, opening and consolidating the markets for Union wines in third countries and increasing awareness of the intrinsic qualities of Union wines on those markets. A reference to wine origin and brands may only be used when it complements the promotion, communication and marketing of Union wines in third countries;

- (i) informing consumers about the responsible consumption of wine. Member States shall ensure that promotional material for generic promotion and promotion of quality labels bears the Union emblem and include the following statement: 'Funded by the European Union'. The emblem and the funding statement shall be displayed in accordance with the technical characteristics laid down in Commission Implementing Regulation (EU) No 821/2014 ⁽¹⁰⁾.

Article 15

Mutual funds

1. When Member States include, in their CAP Strategic Plans, mutual funds interventions in the fruit and vegetables sector, in the hops sector, in the olive oil and table olives sector or in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, they shall provide the implementing conditions for the administrative cost of setting up, for filling and, where appropriate, the refilling of mutual funds.
2. The eligible expenditure on administrative cost of setting up mutual funds in the fruit and vegetables sector, in the hops sector, in the olive oil and table olives sector and in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115 shall comprise both the Union financial assistance and the contribution from the beneficiary. The amount of the eligible expenditure shall not exceed 20 %, 16 % or 8 % of the contribution of the beneficiary to the capital of the mutual fund in the first, second and third year of its operation, respectively.
3. A beneficiary may receive support for the administrative cost of setting up mutual funds in the fruit and vegetables sector, in the hops sector, in the olive oil and table olives sector and in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, only once and only within the 3 first years of the operation of the mutual fund.

Where a beneficiary only applies for that support in the second or the third year of operation of the mutual funds, the support shall be 16 % or 8 % of the contribution of the beneficiary to the capital of the mutual fund in the second and third year of its operation, respectively.

4. When Member States include, in their CAP Strategic Plans, mutual funds interventions in the wine sector as referred to in Article 58(1), first subparagraph, point (l), of Regulation (EU) 2021/2115, they shall limit the Union support to administrative cost of setting up mutual funds in the wine sector to:

- (a) 20 % of the producers' contribution to the mutual fund in the first year;
- (b) 16 % of the producers' contribution to the mutual fund in the second year;
- (c) 8 % of the producers' contribution to the mutual fund in the third year.

The support period shall not exceed 3 years.

Article 16

Replanting of orchards, olive groves or vineyards following mandatory grubbing-up

1. When Member States include, in their CAP Strategic Plans, interventions in the fruit and vegetables sector, in the olive oil and table olives sector, in the wine sector or in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, in the form of replanting of orchards, olive groves or vineyards following mandatory grubbing-up for health or phytosanitary reasons or, in the case of orchard and olive groves, to adapt to climate change, they shall ensure that the beneficiaries comply with Regulation (EU) 2016/2031 of the European Parliament and of the Council ⁽¹¹⁾ when implementing these interventions.

⁽¹⁰⁾ Commission Implementing Regulation (EU) No 821/2014 of 28 July 2014 laying down rules for the application of Regulation (EU) No 1303/2013 of the European Parliament and of the Council as regards detailed arrangements for the transfer and management of programme contributions, the reporting on financial instruments, technical characteristics of information and communication measures for operations and the system to record and store data (OJ L 223, 29.7.2014, p. 7).

⁽¹¹⁾ Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

2. The expenditure for replanting of orchards or olives groves shall not exceed 20 % of the total expenditure under each operational programme or relevant intervention.

Article 17

Green harvesting and non-harvesting

1. When Member States include, in their CAP Strategic Plans, interventions in the fruit and vegetables sector, in the wine sector, in the hops sector, in the olive oil and table olives sector or in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, in the form of 'green harvesting' for these sectors and 'non-harvesting' for these sectors except for wine, Member States shall ensure that these interventions are additional to and different from normal cultivation practices, and that they concern 100 % of the expected production of the product concerned in a given parcel.

'Green harvesting' shall consist of the total harvesting on a given area of unripe non-marketable products which have not been damaged prior to the green harvesting. 'Non-harvesting' shall consist of the termination of the current production cycle on the area concerned where the product is well developed and is of sound, fair and of marketable quality.

2. Member States shall ensure that green harvesting interventions are implemented during the growing seasons in advance of the product reaching a marketable stage and shall not be undertaken in respect of the products for which the normal harvest has already begun.

3. Member States shall set, in their CAP Strategic Plans, maximum time limits during the production season for the application of the green harvesting interventions for each product subject to such interventions as well as other eligibility conditions for green harvesting and non-harvesting, including varieties and categories of products where relevant.

4. Member States shall exclude financial compensation for non-harvesting interventions undertaken where commercial production has been taken from the area concerned during the normal production cycle.

5. Support for green harvesting shall only cover the products which are physically on the fields and which are actually green harvested. For sectors other than the wine sector, compensation amounts, comprising both the Union financial assistance and contribution from the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group for green harvesting and non-harvesting shall be set by the Member State, per hectare payments, at a level corresponding to not more than 90 % of the maximum support level for market withdrawals, other than free distribution, applicable to the same product.

6. Member States shall provide that the beneficiary has to notify the competent authorities of the Member State in writing or by electronic means in advance of an intention of green harvesting or non-harvesting.

7. Member States shall set in their CAP Strategic Plans:

- (a) detailed provisions on the implementation of those interventions including their content and deadlines, on the amount of compensation to be paid and on the application of the interventions, as well as the list of products eligible under the interventions;
- (b) provisions to ensure that no negative impact on the environment nor any negative phytosanitary consequences results from the implementation of the interventions;
- (c) a prohibition to grant support in the fruit and vegetables sector in the case of green harvesting, if a significant part of the normal harvest has been carried out and, in the case of non-harvesting, if a significant part of the commercial production has already been taken.

8. Member States shall ensure that:

- (a) the area concerned has been well maintained, that no harvest has already taken place, that the product is well developed, not damaged and would in general be sound, fair and of marketable quality;
- (b) the harvested products are not denatured;
- (c) there is no negative impact on the environment or any negative phytosanitary consequences resulting from the intervention for which the producer organisation is responsible;
- (d) the area of any vine parcel which has undergone green harvesting is not taken into consideration when calculating the yield limits set in the technical specifications of wines with a protected designation of origin or a protected geographical indication;
- (e) by way of derogation from paragraphs 2 and 4, in the fruit and vegetables sector, where fruit and vegetable plants have a harvesting period exceeding one month, green harvesting might take place after the normal harvest has already begun and non-harvesting might take place even if commercial production has been taken from the area concerned during the normal production cycle. In such cases, the financial compensation shall only compensate for the production that would be harvested in the six weeks following the green harvesting and non-harvesting operation and is not marketed as a result of such operations. Those fruit and vegetable plants shall not be used for further production purposes in the same growing season;
- (f) in the fruit and vegetables sector, except for the case referred to in point (e), green harvesting and non-harvesting interventions cannot apply simultaneously for the same product and the same area in any given year.

Article 18

Harvest and production insurance

When Member States include in their CAP Strategic Plans, harvest and production insurance as an intervention in the fruit and vegetables sector, in the hops sector, in the olive oil and table olives sector, or in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, they may grant additional national financing to support harvest and production insurance actions which are benefiting from the operational fund. The total public support shall not exceed 80 % of the cost of the insurance premiums paid for by producers for insurance against losses.

Harvest and production insurance interventions shall not cover insurance payments which compensate producers for more than 100 % of the income loss suffered, taking into account any compensation the producers obtain from other support or insurance schemes related to the insured risk.

Article 19

Market withdrawals for destinations other than free distribution

When Member States include in their CAP Strategic Plans, interventions in the form of 'market withdrawals for destinations other than free distribution', they shall ensure the definitive withdrawal from the market of a certain product in a manner that it cannot be reverted to the market for food purposes.

Member States may only provide in their CAP Strategic Plans, interventions in the form of 'market withdrawal for destinations other than free distribution' in the fruit and vegetables sector as well as in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, respectively, and only in respect of perishable products that cannot be durably stored at their normal commercial stage without refrigeration.

Member States shall not provide in their CAP Strategic Plans, interventions in the form of 'market withdrawals for destinations other than free distribution' in respect of animal products and products of the sugar sector as referred to in Article 1(2) of Regulation (EU) No 1308/2013.

*Article 20***Collective storage**

1. When Member States include, in their CAP Strategic Plans, collective storage interventions as referred to in Article 47(2), point (c), of Regulation (EU) 2021/2115, they shall provide for a temporary withdrawal of a product from the market in period of certain market pressure, and adopt rules to ensure that the product is stored under the responsibility of the beneficiary in such conditions that preserves its normal commercial value and in respect of the applicable sanitary rules. For products with a short shelf-life in their fresh stage, Member States shall provide for the product to be stored frozen or in a processed form. Products for which a certain maturation period is required in their normal production process, or where such maturation process increases the value of the product, are only eligible for collective storage once that maturation period is fully completed.

2. Member States shall fix, for each product for which this intervention is provided in their CAP Strategic Plans, the minimum storage duration and the maximum amount of compensation per unit of product and per day of storage, as well as the relevant storage conditions. The maximum amount that can be financed with the operational fund shall not be higher than the sum of the cost of the physical storage, in the frozen or processed form where relevant, and the financial cost due to immobilising the value of the product at current market prices. This maximum amount shall not include the possible freezing or processing costs or the possible devaluation of the product. Member States shall fix also the control procedures, including on-the-spot checks, to assure the non-substitution of the products as well as the respect of the storage conditions and of the storage period.

*Section 2***Forms of support and types of expenditure***Article 21***Forms of support**

1. In the sectors referred to in Article 42 of Regulation (EU) 2021/2115, Member States shall provide for payments of support on the basis of the actual costs incurred by the beneficiary, supported by documents, such as invoices, submitted by the beneficiaries for the implementation of an intervention specified in their CAP Strategic Plan.

However, Member States may choose to provide for payment of support on the basis of standard flat rates, scales of unit costs or lump sums. When establishing those flat rates, scales and lump sums, Member States shall take into account regional or local specificities and base their calculation on documentary evidence demonstrating that the calculation reflects the market price of the operations or actions covered by the intervention concerned.

2. In the fruit and vegetables sector, Member States shall respect the maximum amounts of expenditure and the conditioning costs which may be paid in relation to the relevant interventions specified in their CAP Strategic Plans set out in Annexes V and VII.

3. Where Member States provide, in their CAP Strategic Plans, for payment of support in the form of standard flat rates, scales of unit costs or lump sums, those shall be reviewed periodically in order to take account an indexation or an economic change.

4. When Member States use the fair, equitable and verifiable calculation method established pursuant to Article 44(2), point (a), of Regulation (EU) 2021/2115, they shall keep all the documentary evidence concerning the establishment of standard flat rates, scales of unit costs or lump sums and their review as referred to in paragraph 3 of this Article.

5. Where Member States include, in their CAP Strategic Plans, interventions in the wine sector related to the restructuring and conversion of vineyards and investments in tangible and intangible assets, the following rules shall apply:

- (a) if Member States decide to calculate the amount of the support on the basis of standard scales of unit costs based on a surface measurement unit, the amount shall correspond to the actual surface measured in accordance with Article 42 of this Regulation;
 - (b) if Member States decide to calculate the amount of the support on the basis of standard scales of unit costs based on other measurement units or on the basis of the actual costs resulting from supporting documents to be submitted by the beneficiaries, they shall lay down rules on appropriate control methods to establish the actual extent of implementation of the operation.
6. This Article shall not apply to Union financial assistance for the distillation of by-products of wine making carried out in accordance with the restrictions laid down in Part II, Section D, of Annex VIII to Regulation (EU) No 1308/2013.

Article 22

Types of expenditure

1. Types of expenditure covered by the types of intervention referred to in Title III, Chapter III, of Regulation (EU) 2021/2115 shall not compensate the value added tax of the eligible expenditure incurred by the beneficiary, except where it is non-recoverable under national VAT legislation.
2. Types of expenditure referred to in paragraph 1 shall not include the types of expenditure listed in Annex II.
3. The types of expenditure listed in Annex III shall be considered eligible by Member States when defining the relevant interventions and may be covered by the operational programmes or as so specified by Member States in the relevant interventions. Member States may consider eligible other types of expenditure in their CAP Strategic Plans provided they are not listed in Annex II.
4. Member States shall establish, in their CAP Strategic Plans, the conditions under which expenditures linked to interventions referred to in Articles 11 and 12 may be counted as contributing to the objectives of 15 % and 2 % of expenditure under operational programmes as referred to in Article 50(7), points (a) and (c), of Regulation (EU) 2021/2115, respectively, and of 5 % of expenditure under interventions as referred to in Article 60(4) of that Regulation. Such conditions shall ensure that these interventions pursue effectively the related objectives set out in Articles 46 and 57 of that Regulation, respectively, for the fruit and vegetables and the wine sectors.

Article 23

Administrative and personnel costs

1. Personnel costs incurred by the beneficiary, subsidiaries within the meaning of Article 31(7) or, subject to Member State's approval, by a cooperative which is member of a producer organisation shall be considered eligible for support if they are incurred in relation to the preparation, implementation or follow-up of a particular supported intervention.

Such personnel costs shall include, inter alia, costs of personnel contracted by the beneficiary and the costs corresponding to the share of the working hours invested in the implementation of an intervention by its permanent staff.

Member States shall ensure that the beneficiary submits supporting documents setting out the details of the work actually carried out in relation to the particular intervention and that the value of the related personnel cost can be independently assessed and verified. The value of personnel cost related to a particular intervention shall not exceed the costs generally accepted on the market in question for the same kind of service.

For the purpose of determining personnel costs linked to the implementation of an intervention by the permanent personnel of the beneficiary, the hourly rate applicable may be calculated by dividing the last documented annual gross employment costs of the specific employees that have worked in the implementation of the operation by 1 720 hours, or on pro rata basis in case of part-time employees.

For the interventions 'promotion, communication and marketing' and 'communication actions' referred to in Article 47(1), point (f), and (2), point (l), of Regulation (EU) 2021/2115 and for the actions by interbranch organisations and promotion and communication carried out in third countries as referred to in Article 58(1), first subparagraph, points (i), (j) and (k), of that Regulation, the expenditure paid for administrative and personnel costs directly incurred by the beneficiaries shall not exceed 50 % of the overall cost of the intervention.

2. Administrative costs incurred by the beneficiary, subsidiaries within the meaning of Article 31(7) or, subject to Member State's approval, by a cooperative which is member of a producer organisation shall be considered eligible for support if they are incurred in relation to the preparation, implementation or follow-up of a particular supported intervention.

The administrative costs shall be considered eligible if they do not exceed 4 % of the total eligible costs of the implemented intervention.

The costs of external audits shall be considered eligible for support where such audits are performed by an independent and qualified external body.

3. Member States may provide in their CAP Strategic Plans, for the fruit and vegetables sector, for the hops sector, for the olive oil and table olives sector or for other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, a standard flat rate for the personnel and administrative costs linked to the management of the operational fund or the preparation, implementation and follow-up of the operational programme up to a maximum of 2 % of the operational fund approved, comprising both the Union financial assistance and the contribution of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group.

CHAPTER II

Specific rules applicable to the fruit and vegetables sector, to the olive oil and table olives sector, and to the other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115

Section 1

Products covered and transport costs

Article 24

Products covered

Only products for which the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group is recognised shall be covered by the type of intervention provided that the value of the products covered by the operational programme account for more than 50 % of the value of all products marketed by that organisation in the sector covered by that operational programme. In addition, the products concerned shall come from the producer organisation's members or producer members of another producer organisation or association of producer organisations.

Article 25

Transport costs and conditioning requirement for free distribution

1. When Member States include in their CAP Strategic Plans, interventions in the form of 'market withdrawal for free-distribution or other destinations' referred to in Article 47(2), point (f), of Regulation (EU) 2021/2115, they shall fix the costs of transport for the free distribution of all products withdrawn from the market under operational programmes on the basis of scale of unit costs set according to the distance between the place of withdrawal and the place of delivery for free distribution. Only transport costs up to a distance of 750 km can be reimbursed.

2. The transport costs shall be paid to the party that actually bears the financial cost of the transport operation in question. Payment shall be subject to the presentation of supporting documents certifying, in particular:

- (a) the names of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group;
- (b) the quantity of the products concerned;
- (c) acceptance by the recipients as referred to in Article 52(6), point (a), of Regulation (EU) 2021/2115 and the means of transport used;
- (d) the distance between the place of withdrawal and the place of delivery.

3. Conditioning of products withdrawn from the market for free distribution under operational programmes shall be subject to the following:

- (a) packages of products for free distribution display the Union emblem referred to in Article 15(2), together with one or more of the statements set out in Annex IV; payment is subject to the presentation of supporting documents certifying in particular:
 - (i) the names of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations;
 - (ii) the quantity of the products concerned;
- (b) acceptance by the recipient as referred to in Article 52(6), point (a), of Regulation (EU) 2021/2115, specifying the presentation.

Section 2

Maximum level of Union financial assistance for market withdrawals

Article 26

Support

1. For the type of intervention 'market withdrawal for free distribution or other destinations' referred to in Article 47(2), point (f), of Regulation (EU) 2021/2115, in relation to products listed in Annex V, the sum of costs of transport, conditioning costs of products withdrawn for free distribution referred to in Article 33 of this Regulation, added to the amount of support for market withdrawals, shall not exceed the average 'ex-producer organisation' market price of the product concerned in the previous last 3 years, including after processing where relevant.

2. For the type of intervention 'market withdrawal for free distribution or other destinations' referred to in Article 47(2), point (f), of Regulation (EU) 2021/2115 applicable to products other than those listed in Annex V to this Regulation, Member States shall set maximum amounts of support, comprising the Union financial assistance, the national contribution where relevant and contribution from the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group, at a level not exceeding 40 % of the average 'ex-producer organisation' market prices for the previous 5 years in case of free distribution and at a level not exceeding 30 % of the average 'ex-producer organisation' market prices for the previous 5 years for destinations other than free distribution.

3. Where the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group has received compensation from third parties for withdrawn products, the support referred to in the first subparagraph shall be reduced by an amount equivalent to the compensation received. In order to be eligible for support, the products concerned shall not enter again the commercial market.

4. The share of market withdrawals, other than for free distribution, of any given product of any given producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group undertaken in a given year shall be as follows:

- (a) it shall not exceed 10 % of the average volume of marketed production by that producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group during the 3 previous years;
- (b) and, for fruit and vegetables, in total, the sum of the percentages over 3 consecutive years shall not exceed 15 when adding the share calculated in accordance with point (a) for the current year and the shares of the market withdrawals of the 2 previous years calculated on the basis of the respective volume of marketed production by that producer organisation during those 2 previous years.

If the information on the volume of marketed production of any or all of the previous years is not available, the volume of marketed production for which the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group was recognised shall be used.

However, amounts of withdrawals for free distribution which are disposed of in one of the ways referred to in Article 52(6) of Regulation (EU) 2021/2115 or any other equivalent destination approved by Member States as referred to in Article 27(2) of this Regulation shall not be taken into account in the share of market withdrawals.

5. In relation to products listed in Annex V, the support for market withdrawals comprising both the Union financial assistance and the producer organisation contribution, shall be no more than the amounts set out in that Annex.

The Union financial assistance in case of market withdrawals of fruit and vegetables which are disposed of by way of free distribution to charitable organisations, foundations and institutions as referred to in Article 52(6) of Regulation (EU) 2021/2115 shall only cover payment for the disposed products in accordance with paragraphs 1 or 2 of this Article where the conditioning costs shall be those referred to in Article 33 of this Regulation.

Article 27

Destinations for withdrawn products

1. When Member States include in their CAP Strategic Plans interventions in the form of 'market withdrawal for free distribution or other destinations' in the fruit and vegetables sector, in the olive oil and table olives sector and in other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115, they shall determine the permissible destinations for products withdrawn from the market and ensure that no negative impact on the environment nor any negative phytosanitary consequences result from the withdrawal or its destination.

2. Upon request of charitable organisations, foundations or institutions as referred to in Article 52(6), point (a), of Regulation (EU) 2021/2115, Member States may authorise the charitable organisations, foundations or institutions to ask for a contribution from the final recipients of products withdrawn from the market.

When the charitable organisations, foundations or institutions referred to in Article 52(6), point (a), of Regulation (EU) 2021/2115 concerned have obtained such authorisation, they shall keep financial accounts for the operation in question.

Member States may authorise payment in kind by the beneficiaries of free distribution to processors of products where such payment only compensates for processing costs and where the Member State in which the payment takes place has adopted rules ensuring that processed products are intended for consumption by the final recipients referred to in the second subparagraph.

Member States shall take all the necessary steps to facilitate contacts and cooperation between producer organisations and charitable organisations foundations or institutions as referred to in Article 52(6), point (a), of Regulation (EU) 2021/2115.

3. Disposal of products withdrawn to the industry for processing into non-food products shall be possible. Member States shall adopt detailed provisions to ensure that no distortion of competition occurs for the industries concerned within the Union or for imported products and that products withdrawn do not enter the commercial food market again. The alcohol resulting from distillation shall be used exclusively for industrial or energy purposes.

Article 28

Conditions for the recipients of withdrawn products

1. The recipients of withdrawn products for free distribution in the sectors referred to in Articles 42, points (a), (e) and (f), of Regulation (EU) 2021/2115 shall undertake to:

- (a) comply with the rules concerning marketing standards laid down in Regulation (EU) No 1308/2013;
- (b) keep separate stock records for the withdrawal operations in question;
- (c) accept the checks provided for by Union and national law;
- (d) provide the supporting documents on the final destination of each of the products concerned, in the form of a take-over certificate or equivalent document certifying that the withdrawn products have been taken over by a third party with a view to their free distribution.

Member States may decide that recipients do not have to keep records as referred to in the first subparagraph, point (b), if they receive quantities below a maximum to be determined by them based on a documented risk analysis.

2. The recipients of withdrawn products for destinations other than free distribution shall undertake to:

- (a) comply with the rules concerning marketing standards laid down in Regulation (EU) No 1308/2013;
- (b) keep separate stock records and financial accounts for the operations in question if the Member State considers it as necessary despite the fact that the product has been denatured before delivery;
- (c) accept the checks provided for by Union and national law;
- (d) not request additional aid for the alcohol produced from the products concerned in the case of withdrawn products intended for distillation.

Article 29

Marketing standards of withdrawn products

1. A product withdrawn from the market for destinations other than free distribution, in the sectors referred to in Articles 42, points (a), (e) and (f), of Regulation (EU) 2021/2115, shall comply with the relevant standard and rules for the marketing of that product as referred to in Regulation (EU) No 1308/2013, except the rules on the presentation and marking of products.

Where fruits and vegetables are withdrawn in bulk, the minimum requirements for class II as defined in Commission Implementing Regulation (EU) No 543/2011 ⁽¹²⁾ shall be complied with.

However, miniature produce from the fruit and vegetables sector, as defined in the relevant standard, shall comply with the applicable marketing standard, including the provisions on the presentation and marking of products.

⁽¹²⁾ Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors (OJ L 157, 15.6.2011, p. 1).

2. If a specific marketing standard is not laid down for a given fruit or vegetable, the minimum requirements set out in Annex VI shall be met. Member States may lay down additional rules supplementing those minimum requirements.

Section 3

Basis for the calculation of Union financial assistance

Article 30

Value of marketed production for newly recognised organisations or groups

Where, during the 3 years following its recognition, historical data on marketed production for a producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations, or producer group in the sectors referred to in Articles 42, points (a), (e) and (f), of Regulation (EU) 2021/2115 is not available for the 3 previous years, Member States shall accept the value of marketed or marketable production during a period of 12 consecutive months communicated by the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations, or producer group for which the organisation concerned or the producer group can prove at the satisfaction of the Member State that it has the actual capacity to market it on behalf of its producer members.

However, if the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group has communicated the value of the marketed production for the purpose of its recognition, only this value shall be accepted by the Member State.

Article 31

Basis for calculation of the value of marketed production

1. The value of marketed production for a producer organisation, transnational producer organisation, or producer group in the sectors referred to in Article 42, points (a), (e) and (f), of Regulation (EU) 2021/2115 shall be calculated on the basis of the production of the producer organisation, transnational producer organisation, or producer group itself and its producer members that has been put on the market by this organisation or group, and shall only include the production of those products for which the producer organisation, transnational producer organisation, or producer group is recognised. The value of marketed production may include products that are not required to conform to the marketing standards, where those standards do not apply.

The value of marketed production for an association of producer organisation or a transnational association of producer organisations shall be calculated on the basis of the production marketed by the association of producer organisations or transnational association of producer organisations itself and by its member producer organisations, and shall only include the production of those products for which the association of producer organisations or transnational association of producer organisations is recognised. However, where operational programmes are approved for an association of producer organisation or a transnational association of producer organisations and separately for its member producer organisations, the value of marketed production counted for the operational programmes of the members shall not be taken into account for the calculation of the value of the marketed production of the association.

In addition, for sectors listed in Article 42, points (e) and (f), of Regulation (EU) 2021/2115, the value of marketed production may also include the value of the production covered by contracts negotiated by the producer organisation, transnational producer organisation, association of producer organisations, transnational association of producer organisations or producer group on behalf of its members.

2. The value of marketed production shall be calculated at fresh stage or the first processing stage on which the product is normally marketed, in bulk where products are allowed to be marketed in bulk, and shall not include the cost of further processing or further conditioning or the value of final processed products. Member States shall indicate in their CAP Strategic Plans how the value of marketed production is calculated for each sector.

The value of the marketed production of fruit and vegetables intended for processing, which have been transformed into one of the processed fruit and vegetable products listed in Annex I, Part X, to Regulation (EU) No 1308/2013 or any other processed product referred to in this paragraph, by either a producer organisation, an association of producer organisations or their producer members or subsidiaries complying with paragraph 7 of this Article, either by themselves or through outsourcing, shall be calculated as a flat rate in percentage applied to the invoiced value of those processed products. That flat rate shall be:

- (a) 53 % for fruit juices;
- (b) 73 % for concentrated juices;
- (c) 77 % for tomato concentrate;
- (d) 62 % for frozen fruit and vegetables;
- (e) 48 % for canned fruit and vegetables;
- (f) 70 % for canned mushrooms of *Agaricus bisporus* and other cultivated mushrooms preserved in brine;
- (g) 81 % for fruits provisionally preserved in brine;
- (h) 81 % for dried fruits;
- (i) 27 % for processed fruit and vegetables other than those referred to in points (a) to (h);
- (j) 12 % for processed aromatic herbs;
- (k) 41 % for paprika powder.

3. Member States may allow the beneficiary to include the value of the by-products in the value of marketed production.

4. The value of marketed production shall include the value of market withdrawals for free distribution. The value of withdrawals for free distribution shall be calculated on the basis of the average price of those products marketed by the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group in the period concerned.

5. Only the production of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations, producer group, or its producer members which is marketed by that producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group shall be counted in the value of marketed production.

The production of the producer members of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group marketed by another producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group designated by their own organisation shall be counted in the value of marketed production of the organisation, association or group that marketed the production. Double counting shall be prohibited.

6. Except where paragraph 7 applies, the marketed production of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group shall be invoiced at the 'ex-producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group' stage ready for marketing, excluding:

- (a) VAT;
- (b) costs of transport internal to the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group.

7. However, the value of marketed production may also be calculated at the 'ex-subsidary' stage, on the basis set out in paragraph 6, provided that at least 90 % of the shares or capital of the subsidiary is owned:

- (a) by one producer organisation or association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group; or
- (b) subject to Member State approval, by producer members of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group, if doing so contributes to the objectives listed in Article 152(1), point (c), of Regulation (EU) No 1308/2013.

8. In case of outsourcing, the value of marketed production shall be calculated at the 'ex-producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group' stage and shall include the added economic value of the activity that has been outsourced by the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group to its members, third parties or to another subsidiary than the one referred to in paragraph 7.

9. Where a reduction in production occurs due to a natural disaster, climatic event, plant or animal diseases or pest infestations, any insurance indemnification received in respect of harvest or production insurance actions referred to in Article 18, or equivalent actions managed by the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group, or its producer members, due to those causes may be included in the value of marketed production of the 12-month reference period in which it is actually paid.

Article 32

Reference period and ceiling on Union financial assistance

1. Member States shall determine for each producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group a 12-month reference period, starting no earlier than 1 January of the year that is 3 years prior to the year for which the aid is requested and ending no later than 31 December of the year preceding the year for which the aid is requested.

The 12-month reference period shall be the accounting period of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group concerned.

The methodology for fixing the reference period shall not vary during a programme except in duly justified situations.

2. Member States shall decide whether the ceiling on Union financial assistance to the operational fund is calculated each year, either:

- (a) on the basis of the value of the marketed production during the reference period of the producers who are members of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group on 1 January of the year for which the aid is requested; or
- (b) on the basis of the actual value of the marketed production in the reference period concerned of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group concerned. In that case, the rule shall apply to all non-transnational beneficiaries in that Member State.

3. Where for a product a reduction of at least 35 % in the value of marketed production for a given year in relation to the average of three previous 12-month reference periods has occurred, the following shall apply:

- (a) if the reduction occurred due to reasons falling outside the responsibility and control of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group, the value of marketed production of that product shall be deemed to represent 65 % of the average value in the three previous 12-month reference periods;
- (b) if the reduction occurred due to natural disasters, climatic events, plant diseases or pest infestations falling outside the responsibility and control of the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group, the value of marketed production of that product shall be deemed to represent 85 % of the average value in the three previous 12-month reference periods.

In both cases, the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group shall prove to the competent authority of the Member State concerned that those reasons were falling outside its responsibility and control.

Where the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations or producer group proves to the Member State concerned that those reasons were falling outside its responsibility and control and that they have taken the necessary preventive measures, the value of marketed production of that product shall be deemed to represent 100 % of its average value in the three previous 12-month reference periods.

CHAPTER III

Fruit and vegetables sector

Article 33

Conditioning costs for free distribution

The payments of expenditure to the producer organisation, association of producer organisations, transnational producer organisation, transnational association of producer organisations related to the costs of conditioning of fruit and vegetables withdrawn from the market for free distribution under operational programmes are set out in Annex VII.

Article 34

Calculation of the degree of organisation of producers for the purpose of the national financial assistance

1. When determining the level of national financial assistance in the fruit and vegetables sector in accordance with Article 53 of Regulation (EU) 2021/2115, the degree of organisation in a region of a Member State shall be calculated on the basis of the value of fruit and vegetables produced in the region concerned and marketed by the organisations and shall only include those products for which those organisations are recognised. Article 31 of this Regulation shall apply *mutatis mutandis*.

2. Only fruit and vegetables produced in the region referred to in paragraph 3 shall be considered for the purposes of this Article.

3. Member States shall define the regions as a distinct part of their national territory in accordance with objective and non-discriminatory criteria, such as their agronomic and economic characteristics and their regional agricultural or fruit and vegetable potential, or their institutional or administrative structure and for which data are available in order to calculate the degree of organisation referred to in paragraph 1.

The list of regions established by a Member State shall not be amended at least for 5 years unless such amendment is objectively justified, in particular for reasons that are not related to the calculation of the degree of organisation of producers in the region or regions concerned.

4. Member States shall notify the Commission by 31 January each year of the list of the regions that meet the criteria referred to in Article 53(1) and (2) of Regulation (EU) 2021/2115, and of the amount of national financial assistance granted to the producer organisations in those regions.

Member States shall notify the Commission of any amendment of the list of the regions.

5. A producer organisation wishing to apply for national financial assistance shall, if necessary, amend its operational programme.

Article 35

3-year average for market withdrawals for free distribution

1. The limit of 5 % of the volume of marketed production referred to in Article 52(6), point (a), of Regulation (EU) 2021/2115 shall be calculated on the basis of the average of the overall volumes of products for which the producer organisation is recognised and which are marketed through the producer organisation during the 3 previous years.

2. For newly recognised producer organisations, the data for marketing years prior to recognition shall be:

- (a) where the organisation was a producer group, the equivalent data for that producer group; or
- (b) the volume applicable to the application for recognition.

CHAPTER IV

Apiculture sector

Article 36

Definition of beehive

For the purposes of this Chapter, the term 'beehive' means the unit containing a honeybee colony used for the production of honey, other apiculture products or honeybee breeding material, and all the elements necessary for its survival.

Article 37

Method to calculate the number of beehives

The number of beehives ready for wintering in the territory of the Member States between 1 September and 31 December shall be calculated each year according to an established reliable method laid down in the CAP Strategic Plans.

Article 38

Notification of the number of beehives

The annual notification of the number of beehives referred to in Article 55(7) of Regulation (EU) 2021/2115 as calculated in accordance with Article 37 of this Regulation, shall be made by 15 June of each year, starting in 2023.

*Article 39***Minimum Union contribution**

The minimum Union contribution to the expenditure related to the implementation of the types of intervention in the apiculture sector referred to in Article 55 of Regulation (EU) 2021/2115 and specified by Member States in their CAP Strategic Plans shall be 30 %.

*CHAPTER V***Wine sector***Article 40***Beneficiaries**

1. Member States shall establish which operators, may benefit from interventions in the wine sector specified in their CAP Strategic Plans. Those operators shall include beneficiaries as referred to in paragraphs 2, 3 and 4 as well as professional organisations, wine producer organisations, associations of wine producer organisations, temporary or permanent associations of two or more wine producers and interbranch organisations.
2. Member States shall provide for wine growers to be the sole beneficiaries of the types of intervention 'restructuring and conversion of vineyards', 'green harvesting' and 'harvest insurance' referred to in Article 58(1), first subparagraph, points (a), (c) and (d), of Regulation (EU) 2021/2115, respectively.
3. A body governed by public law may not benefit from support under the types of intervention in the wine sector. However, Member States may allow a body governed by public law to benefit from the support:
 - (a) for actions implemented by interbranch organisations as referred to in Article 58(1), first subparagraph, points (i) and (j), of Regulation (EU) 2021/2115;
 - (b) for information actions and promotion and communication carried out in third countries as referred to in Article 58(1), first subparagraph, points (h) and (k), of Regulation (EU) 2021/2115, provided that, it is not the sole beneficiary of the support granted in respect of those interventions.
4. Private companies may be beneficiaries for the promotion and communications carried out in third countries as referred to in Article 58(1), first subparagraph, point (k), of Regulation (EU) 2021/2115.
5. No support shall be granted to producers farming unlawful plantings and areas planted with vines without authorisation pursuant to Article 71 of Regulation (EU) No 1308/2013.

*Article 41***Replanting of vineyards for health or phytosanitary reasons**

The annual expenditure paid by Member States for support to interventions specified in their CAP Strategic Plans in relation to the replanting of vineyards following mandatory grubbing-up shall not exceed 15 % of the total annual expenditure on restructuring and conversion of vineyards under Article 58(1), first subparagraph, point (a), of Regulation (EU) 2021/2115 paid by the Member State concerned during any given financial year.

The grubbing-up costs and the compensation of the income foregone shall not constitute eligible expenditure under this type of intervention.

*Article 42***Area planted**

1. For the purposes of Article 58(1), first subparagraph, points (a) and (c), of Regulation (EU) 2021/2115, an area planted with vines is defined by the external perimeter of the vine stocks with the addition of a buffer whose width corresponds to half of the distance between the rows.
2. Where a Member State decides to verify the eligible costs of operations for the restructuring and conversion of vineyards and green harvesting exclusively on the basis of standard scales of unit costs based on measurement units different from the surface or of supporting documents to be submitted by the beneficiaries, the competent authorities may decide not to measure the area planted as set out in paragraph 1.

*CHAPTER VI***Hops sector***Article 43***Union financial assistance**

The maximum Union financial assistance to be allocated to each producer organisation or association, as referred to in Article 62(1) of Regulation (EU) 2021/2115, shall be calculated pro rata based on the eligible hop areas of its producer members. To be eligible, the hop areas shall be planted at a uniform density of at least 1 500 plants per hectare in the case of double stringing/wiring, or at least 2 000 plants per hectare in the case of single stringing/wiring.

The areas shall only include areas bounded by a line joining the outer stays of the poles. Where there are hop plants on that line, an additional strip of a width corresponding to the average width of an alleyway within that parcel may be added to each side of that area. The additional strip shall not form part of a public right of way. The two headlands at the ends of the hop rows that are needed for manoeuvring agricultural machinery may be included in the area, provided that the length of neither headland exceeds 8 metres and they are counted only once, and they do not form part of a public right of way.

The areas shall not include areas planted with young hop plants grown chiefly as nursery products.

*CHAPTER VII***Livestock sector***Article 44***Restocking with livestock following compulsory slaughter for health reasons or because of losses resulting from natural disasters**

1. Member States shall ensure that the type of intervention 'restocking with livestock after compulsory slaughter for health reasons or because of losses resulting from natural disasters' as referred to in Article 47(2), point (e), of Regulation (EU) 2021/2115, is only implemented when disease control measures have been taken in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council ⁽¹³⁾.
2. Expenditure for restocking with livestock shall not exceed 20 % of the total expenditure under operational programmes.

⁽¹³⁾ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

TITLE IV

ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF INTERVENTION IN RURAL DEVELOPMENT

Article 45

Conservation, sustainable use and development of genetic resources in agriculture and in forestry

1. Member States which include, in their CAP Strategic Plans, interventions related to the conservation, sustainable use and development of genetic resources in agriculture and in forestry as referred to in Article 70 of Regulation (EU) 2021/2115 may provide support only as:

- (a) agri-environment-climate commitments for preserving on farm endangered breeds and plant varieties under threat of genetic erosion; or
- (b) support for activities regarding the conservation, the sustainable use and development of genetic resources in agriculture and in forestry.

Activities covered by the type of agri-environment-climate commitments referred to in the first subparagraph, point (a), shall not be eligible for support pursuant to that subparagraph, point (b).

2. Member States shall ensure that agri-environment-climate commitments for preserving on farm endangered breeds and plant varieties under threat of genetic erosion, referred to in paragraph 1, first subparagraph, point (a), shall require:

- (a) to rear farm animals of local breeds, recognised by a Member State to be endangered, genetically adapted to one or more traditional production systems or environments in that Member State, where the endangered status is scientifically established by a body possessing the necessary skills and knowledge in the area of endangered breeds, as defined in Article 2, point (24), of Regulation (EU) 2016/1012 of the European Parliament and of the Council ⁽¹⁴⁾; or
- (b) to preserve plant genetic resources naturally adapted to the local and regional conditions and under threat of genetic erosion.

3. The following species of farm animals of local breeds referred to in paragraph 2, point (a), may be eligible for support:

- (a) cattle;
- (b) sheep;
- (c) goats;
- (d) equidae (*Equus caballus* and *Equus asinus*);
- (e) pigs;
- (f) birds;
- (g) rabbits;
- (h) bees.

4. Member States shall only consider as eligible for support local breeds referred to in paragraph 2, point (a), if the following requirements are complied with:

- (a) the number, at national level, of breeding females concerned is stated;

⁽¹⁴⁾ Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation') (OJ L 171, 29.6.2016, p. 66).

(b) a duly recognised relevant breed society registers and keeps up-to-date the herd or flockbreeding book for the breed.

5. Member States shall consider plant genetic resources referred to in paragraph 2, point (b), as being under threat of genetic erosion on condition that sufficient evidence of genetic erosion, based upon scientific results or indicators for the reduction of landraces or primitive local varieties, their population diversity and, where relevant, for modifications in the prevailing agricultural practices at local level, is provided.

6. Member States shall ensure that operations for the conservation, the sustainable use and development of genetic resources in agriculture and in forestry, referred to in paragraph 1, first subparagraph, point (b), include the following:

- (a) targeted actions promoting *in situ* and *ex situ* conservation, characterisation, collection and utilisation of genetic resources in agriculture and forestry, including web-based inventories of genetic resources currently conserved *in situ*, including on-farm or on-forest holding conservation, and *ex situ* collections and databases;
- (b) concerted actions promoting the exchange of information for the conservation, characterisation, collection and utilisation of genetic resources in Union agriculture or forestry among competent Member State organisations;
- (c) accompanying action: information, dissemination, advice, training, and technical report preparation, involving non-governmental organisations and other stakeholders.

7. For the purposes of paragraph 1, first subparagraph, point (b), the following definitions shall apply:

- (a) '*in situ* conservation' in agriculture means the conservation of genetic material in ecosystems and natural habitats and the maintenance and recovery of viable population of species or feral breeds in their natural surroundings and, in the case of domesticated animal breeds or cultivated plant species, in the farmed environment where they have developed their distinctive properties;
- (b) '*in situ* conservation' in forestry means the conservation of genetic material in ecosystems and natural habitats and the maintenance and recovery of viable population of species in their natural surroundings;
- (c) 'on-farm or on-forest holding conservation' means *in situ* conservation and development at farm or forest holding level;
- (d) '*ex situ* conservation' means the conservation of genetic material for agriculture or forestry outside their natural habitat;
- (e) '*ex situ* collection' means a collection of genetic material for agriculture or forestry maintained outside their natural habitat.

Article 46

Animal welfare

Member States which include in their CAP Strategic Plans interventions related to animal welfare commitments referred to in Article 70 of Regulation (EU) 2021/2115 shall ensure that animal welfare commitments provide upgraded standards of production methods in at least one of the following areas:

- (a) water, feed, and animal care in accordance with the natural needs of animals;
- (b) housing conditions that improve the comfort of animals and their freedom of movement, such as increased space allowances, flooring surfaces, natural light, microclimate control, as well as housing conditions such as free farrowing or group housing, depending on the natural needs of animals;
- (c) conditions allowing for expression of natural behaviour, such as enrichment of living environment or late weaning;
- (d) outdoor access and grazing;
- (e) practices that increase animal robustness and longevity, including slower growing breeds;

- (f) practices to avoid mutilation or castration of animals. In specific cases when mutilation or castration of animals is deemed necessary, anaesthetics, analgesia and anti-inflammatory medication or immunocastration shall be used;
- (g) sanitary measures, preventing non-transmissible diseases, that do not require the use of medical substances such as vaccines, insecticides or anti-parasitic drugs.

Article 47

Quality schemes

Member States which include in their CAP Strategic Plans interventions related to quality schemes, referred to in Article 77(1), point (c), of Regulation (EU) 2021/2115, shall ensure that national recognised quality schemes cover:

- (a) quality schemes, including farm certification schemes, for agricultural products, cotton or foodstuffs, recognised by the Member States as complying with the following criteria:
 - (i) the specificity of the final product under such schemes is derived from clear obligations to guarantee any of the following:
 - specific product characteristics,
 - specific farming or production methods, or
 - a quality of the final product that goes significantly beyond the commercial commodity standards as regards public, animal or plant health, animal welfare or environmental protection;
 - (ii) the scheme is open to all producers;
 - (iii) the scheme involves binding product specifications and compliance with those specifications is verified by public authorities or by an independent inspection body;
 - (iv) the scheme is transparent and assures complete traceability of products;
- (b) voluntary agricultural product certification schemes recognised by the Member States as meeting the Union best practice guidelines for the operation of voluntary certification schemes referred to in Commission Communication of 16 December 2010 entitled 'EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs' ⁽¹⁵⁾ relating to agricultural products and foodstuffs.

TITLE V

RULES ON THE RATIO FOR GAEC STANDARD 1

Article 48

Rules on the ratio for GAEC standard 1

1. For the maintenance of permanent grassland in relation with GAEC standard 1 as listed in Annex III to Regulation (EU) 2021/2115, Member States shall ensure that the ratio of permanent grassland in relation to agricultural area does not decrease by more than 5 % compared to a reference ratio to be established by each Member State in its CAP Strategic Plan by dividing areas of permanent grassland by the total agricultural area.

For the purpose of establishing the reference ratio referred to in the first subparagraph:

⁽¹⁵⁾ OJ C 341, 16.12.2010, p. 5.

- (a) 'areas of permanent grassland' means permanent grassland declared in 2018 in accordance with Article 72(1), first subparagraph, point (a), of Regulation (EU) No 1306/2013 of the European Parliament and of the Council ⁽¹⁶⁾ by farmers receiving direct payments, and determined as referred to in Article 2(1), second subparagraph, point (23), of Commission Delegated Regulation (EU) No 640/2014 ⁽¹⁷⁾, where necessary adjusted by Member States to take into account the impact of a possible change, in particular in the definition of permanent grassland to be established by Member States in accordance with Article 4(3), point (c), of Regulation (EU) 2021/2115;
- (b) 'total agricultural area' means the agricultural area declared in 2018 in accordance with Article 72(1), first subparagraph, point (a), of Regulation (EU) No 1306/2013 by farmers receiving direct payments and determined as referred to in Article 2(1), second subparagraph, point (23), of Delegated Regulation (EU) No 640/2014, where necessary adjusted by Member States, in particular to take into account the impact of a possible change in the definition of agricultural areas to be established by Member States in accordance with Article 4(3) of Regulation (EU) 2021/2115.
2. The ratio of permanent grassland shall be established each year on the basis of the areas declared for that year by the beneficiaries receiving direct payments pursuant to Title III, Chapter II, of Regulation (EU) 2021/2115 or the annual payments pursuant to Articles 70, 71 and 72 of that Regulation in accordance with Article 67(1) of Regulation (EU) 2021/2116 of the European Parliament and of the Council ⁽¹⁸⁾.

Member States may establish the ratio of permanent grassland and the reference ratio at national, regional, sub-regional, group of holdings or holding level.

3. Where it is established that the ratio referred to in paragraph 2 has decreased by more than 5 % at the level at which the GAEC standard 1 is implemented, the Member State concerned shall impose obligations at holding level to reconvert land into permanent grassland or to establish an area of permanent grassland for some or all of the farmers who have land at their disposal which was converted from permanent grassland into land for other uses during a period in the past.

However, where the area of permanent grassland in a given year is maintained, in absolute, terms within 0,5 % of the areas of permanent grassland established in accordance with paragraph 1, second subparagraph, point (a), the obligation set out in paragraph 1, first subparagraph, shall be considered to have been complied with.

4. Paragraph 3, first subparagraph, shall not apply where the decrease below the threshold of 5 % is the result of commitments undertaken or obligations, as referred to in Article 4(4), points (b) and (c), of Regulation (EU) 2021/2115 due to which an agricultural activity is no longer performed on the areas in question, and which do not include plantations of Christmas trees or cultivation of crops or trees for energy production.

5. For the purpose of calculating the ratio referred to in paragraph 2, areas reconverted into permanent grassland or established as permanent grassland in accordance with paragraph 3, or established as permanent grassland as part of the Member States implementation of GAEC standard 1, shall be considered as permanent grassland as of the first day of the reversion or establishment. Those areas shall be used to grow grasses or other herbaceous forage in compliance with the definition provided for in Article 4(3), point (c), of Regulation (EU) 2021/2115, at least for 5 consecutive years following the reversion or establishment, or for areas already used to grow grasses or other herbaceous forage, for the remaining number of years to reach 5 consecutive years.

⁽¹⁶⁾ Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

⁽¹⁷⁾ Commission Delegated Regulation (EU) No 640/2014 of 11 March 2014 supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to the integrated administration and control system and conditions for refusal or withdrawal of payments and administrative penalties applicable to direct payments, rural development support and cross compliance (OJ L 181, 20.6.2014, p. 48).

⁽¹⁸⁾ Regulation (EU) 2021/2116 of the European Parliament and of the Council of 2 December 2021 on the financing, management and monitoring of the common agricultural policy and repealing Regulation (EU) No 1306/2013 (OJ L 435, 6.12.2021, p. 187).

TITLE VI

FINAL PROVISIONS*Article 49***Entry into force**

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

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

Done at Brussels, 7 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Union method for the verification of hemp varieties and the determination of the Δ^9 -tetrahydrocannabinol content in hemp varieties referred to in Article 3**1. Scope**

The method set out in this Annex seeks to determine the Δ^9 -tetrahydrocannabinol (hereinafter referred to as 'THC content' of varieties of hemp (*Cannabis sativa* L.). As appropriate, the method involves applying procedure A or B as described in this Annex.

The method is based on the quantitative determination of THC by gas chromatography (GC) after extraction with a suitable solvent.

1.1. Procedure A

Procedure A shall be used for checks on the production of hemp, where the control sample for on-the-spot checks carried out each year cover at least 30 % of the areas declared for the production of hemp in accordance with Article 4(4), second subparagraph, of Regulation (EU) 2021/2115.

1.2. Procedure B

Procedure B shall be used where a Member State introduces a system of prior approval for the cultivation of hemp, and the minimum level for the on-the-spot checks covers at least 20 % of the areas declared for the production of hemp in accordance with Article 4(4), second subparagraph, of Regulation (EU) 2021/2115.

2. Sampling**2.1. Conditions for taking the samples**

The samples shall be taken during the day following a systematic pattern to ensure that the sample is representative of the field, but excluding the edges of the crop.

2.1.1. Procedure A

In a standing crop of a given variety of hemp, a 30 cm part containing at least one female inflorescence of each plant selected shall be taken. Sampling shall be carried out during the period running from 20 days after the start of flowering to 10 days after the end of flowering.

Member States may authorise sampling to be carried out during the period from the start of flowering to 20 days after the start of flowering provided that, for each variety grown, other representative samples are taken in accordance with the first paragraph during the period from 20 days after the start of flowering to 10 days after the end of flowering.

For hemp cultivated as catch crop, in the absence of female inflorescences, the top 30 cm of the plant stem shall be taken. In that case sampling shall be carried out just before the end of the vegetation period, once the leaves begin presenting the first signs of yellowing, however no later than the onset of a forecast period of frost.

2.1.2. Procedure B

In a standing crop of a given variety of hemp, the upper third of each plant selected shall be taken. Sampling shall be carried out during the 10 days following the end of flowering or, for hemp cultivated as catch crop, in the absence of female inflorescences, just before the end of the vegetation period, once the leaves begin presenting the first sign of yellowing, but no later than the onset of a forecast period of frost. In the case of dioecious varieties, only female plants shall be taken.

2.2. Sample size

Procedure A: the sample shall comprise parts of 50 plants per field.

Procedure B: the sample shall comprise parts of 200 plants per field.

Each sample shall be placed in a fabric or paper bag, without crushing it, and be sent to the laboratory for analysis.

Member States may provide for a second sample to be collected for counter-analysis, if required, to be kept either by the producer or by the body responsible for the analysis.

2.3. *Drying and storage of the sample*

Drying of the samples shall begin as soon as possible and, in any case, within 48 hours using any method below 70 °C.

Samples shall be dried to a constant weight and to a moisture content of between 8 % and 13 %.

After drying, the samples shall be stored without crushing them at below 25 °C in a dark place.

3. **Determination of THC content**

3.1. *Preparation of the test sample*

Stems and seeds over 2 mm in size shall be removed from the dried samples.

The dried samples shall be grinded to obtain a semi-fine powder (passing through a 1 mm mesh sieve).

The powder may be stored for 10 weeks at below 25 °C in a dark, dry place.

3.2. *Reagents and extraction solution*

Reagents

- Δ^9 -tetrahydrocannabinol, pure for chromatographic purposes,
- squalane, pure for chromatographic purposes, as an internal standard.

Extraction solution

- 35 mg of squalane per 100 ml hexane.

3.3. *Extraction of THC*

100 mg of the powdered test sample shall be weighed, be placed in a centrifuge tube and 5 ml of extraction solution shall be added containing the internal standard.

The sample shall be placed in an ultrasound bath and be left for 20 minutes. It shall be centrifuged for 5 minutes at 3 000 r.p.m. and then the supernatant THC solution shall be removed. The solution shall be injected into the chromatograph and a quantitative analysis shall be carried out.

3.4. *Gas chromatography*

(a) Apparatus

- gas chromatograph with a flame ionisation detector and a split/splitless injector,
- column allowing good separation of cannabinoids, for example a glass capillary column 25 m long and 0,22 mm in diameter impregnated with a 5 % non-polar phenyl-methyl-siloxane phase.

(b) Calibration ranges

At least three points for procedure A and five points for procedure B, including points 0,04 and 0,50 mg/ml THC in extraction solution.

(c) Experimental conditions

The following conditions are given as an example for the column referred to in point (a):

- oven temperature 260 °C,
- injector temperature 300 °C,
- detector temperature 300 °C.

(d) Volume injected: 1 µl.

4. Results

The findings shall be expressed to two decimal places in grams of THC per 100 grams of analytical sample dried to constant weight. A tolerance of 0,03 g per 100 g shall apply.

— Procedure A: one determination per test sample.

However, where the result obtained is above the limit laid down in Article 4(4), second subparagraph, of Regulation (EU) 2021/2115, a second determination shall be carried out per analysis sample and the mean value of the two determinations shall be taken as the result.

— Procedure B: the result shall correspond to the mean value of two determinations per test sample.

ANNEX II

List of non-eligible types of expenditure referred to in Article 22(2)

PART I

In the fruit and vegetables sector, the apiculture sector, the hops sector, the olive oil and table olives sector and the other sectors referred to in Article 42, point (f), of Regulation (EU) 2021/2115

1. General production costs and, in particular, costs for (even certified) mycelium, seeds and non-perennial plants; plant protection products (including integrated control materials); fertilisers and other inputs; costs of collection or transport (internal or external); storage costs; packaging costs (including use and management of packaging), even as part of new processes; operating costs (in particular electricity, fuel and maintenance).
2. Reimbursement of loans taken out for an intervention.
3. Purchase of land not built on costing more than 10 % of all the eligible expenditure on the operation concerned.
4. Investments in means of transport to be used by the beneficiary in the apiculture sector or for marketing or distribution by the producer organisation.
5. Operating costs of goods hired.
6. Expenditure linked to leasing contracts (taxes, interest, insurance costs, etc.) and operating costs.
7. Subcontracting or outsourcing contracts relating to the operations or expenditure mentioned as not eligible in this list.
8. Any national or regional taxes or fiscal levies.
9. Interest on debt except where the contribution is made in a form other than a non-repayable direct assistance.
10. Investments in shares or capital of companies if the investment represents a financial investment.
11. Costs incurred by parties other than the beneficiary, producer organisation or its members, associations of producer organisations, or their producer members, or a subsidiary, or an entity within a chain of subsidiaries within the meaning of Article 31(7), or subject to Member State's approval, by a cooperative which is member of a producer organisation.
12. Interventions not taking place on the holdings and/or premises of the producer organisation, association of producer organisations, or their producer members, or a subsidiary, or an entity within a chain of subsidiaries within the meaning of Article 31(7), or subject to Member State's approval, by a cooperative which is member of a producer organisation.
13. Interventions outsourced or implemented by the beneficiary, the producer organisation outside the Union, except promotion, communication and marketing type of intervention as referred to in Article 47(1), point (f), of Regulation (EU) 2021/2115.

PART II

In the wine sector

1. Day-to-day management of a vineyard
2. Protection against damage by game, birds or hail.

3. Construction of windbreaks and wind protection walls.
 4. Driveways and elevators.
 5. Purchase of tractors or any kind of transport vehicles.
 6. Grubbing-up of infected vineyards and loss of revenue following mandatory grubbing up for health or phytosanitary reasons.
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ANNEX III

List of eligible types of expenditure referred to in Article 22(3)

1. Specific costs for:
 - quality improvement measures,
 - biological plant protection materials (such as pheromones and predators) whether used in organic, integrated or conventional production,
 - agri-environment-climate interventions referred to in Article 12,
 - organic, integrated or experimental production, including specific costs for organic seeds and seedlings,
 - monitoring of compliance with the standards referred to in Title II of Implementing Regulation (EU) No 543/2011, with plant-health rules and with maximum level of residues.

Specific costs shall mean the additional costs, calculated as the difference between the conventional production costs and the costs actually incurred, and income foregone resulting from an action excluding additional income and costs savings.
 2. Veterinary medicinal products for the treatment of beehive invaders and diseases affecting bees.
 3. Costs associated with the restocking of beehives and bee breeding.
 4. Purchase of machinery and equipment for the improvement of honey production and collection.
 5. Administrative and personnel costs relating to the implementation of operational programmes or to the relevant interventions, including reports, studies, costs of keeping accounts and the management of accounts, compulsory charges linked to wages and salaries if borne directly by the beneficiary, subsidiaries or an entity within a chain of subsidiaries within the meaning of Article 31(7), or, subject to Member State's approval, by a cooperative which is member of a producer organisation.
 6. Purchase of land not built on where purchase is necessary to carry out an investment included in the operational programme provided it costs less than 10 % of all the eligible expenditure on the operation concerned. In exceptional and duly justified cases, a higher percentage may be fixed for operations concerning environmental conservation.
 7. Purchase or leasing of tangible assets, including second hand tangible assets provided they have not been purchased with Union or national support in a period of 5 years preceding the purchase or leasing within the limit of the net market value of the tangible asset.
 8. Hire of physical assets where economically justified as an alternative to purchase, at the approval of the Member State.
 9. For the sectors referred to in Article 42, points (a), (d), (e) and (f), of Regulation (EU) 2021/2115, investments in transport vehicles where the producer organisation duly justifies to the Member State concerned that the transport vehicle is used for transport internal to the premises of the producer organisation; and investments in additional on-the-truck facilities for cold-storage or controlled atmosphere transport.
 10. Investments in shares or capital of companies contributing directly to the achievement of the goals of the operational programme.
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ANNEX IV

Statement for packaging of products referred to in Article 25(3), point (a)

- Продукт, предназначен за безвъзмездно разпределяне (Делегиран регламент (ЕС) 2022/126)
 - Producto destinado a su distribución gratuita [Reglamento Delegado (UE) 2022/126]
 - Produkt určený k bezplatné distribuci (nařízení v přenesené pravomoci (EU) 2022/126)
 - Produkt til gratis uddeling (delegeret forordning (EU) 2022/126)
 - Zur kostenlosen Verteilung bestimmtes Erzeugnis (delegierte Verordnung (EU) 2022/126)
 - Tasuta jagamiseks mõeldud tooted [delegeeritud määrus (EL) 2022/126]
 - Προϊόν προοριζόμενο για δωρεάν διανομή [κατ'εξουσιοδότηση κανονισμός (ΕΕ) 2022/126]
 - Product for free distribution (Delegated Regulation (EU) 2022/126)
 - Produit destiné à la distribution gratuite [règlement délégué (UE) 2022/126]
 - Proizvod za besplatnu distribuciju (Delegirana uredba (EU) 2022/126)
 - Prodotto destinato alla distribuzione gratuita [regolamento delegato (UE) 2022/126]
 - Produkts paredzēts bezmaksas izplatīšanai [Deleģētā regula (ES) 2022/126]
 - Nemokamai platinamas produktas (Deleguotasis reglamentas (ES) 2022/126)
 - Ingyenes szétosztásra szánt termék ((EU) 2022/126 felhatalmazáson alapuló rendelet)
 - Prodott għad-distribuzzjoni bla ħlas (Ir-Regolament Delegat (UE) 2022/126)
 - Voor gratis uitreiking bestemd product (Gedelegeerde Verordening (EU) 2022/126)
 - Produkt przeznaczony do bezpłatnej dystrybucji [Rozporządzenie delegowane (UE) 2022/126]
 - Produto destinado a distribuição gratuita [Reglamento Delegado (UE) 2022/126]
 - Produs destinat distribuirii gratuite [Regulamentul delegat (UE) 2022/126]
 - Výrobok určený na bezplatnú distribúciu [delegované nariadenie (EÚ) 2022/126]
 - Proizvod, namenjen za prosto razdelitev (Delegirana uredba (EU) 2022/126)
 - Ilmaisjakeluun tarkoitettu tuote (delegoitu asetus (EU) 2022/126)
 - Produkt för gratisutdelning (delegerad förordning (EU) 2022/126)
 - Táirge lena dháileadh saor in aisce (Rialachán Tarmligthe (AE) 2022/126)
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ANNEX V

Maximum amounts of support for market withdrawals referred to in Article 26(1) and (4), first subparagraph

Products	Maximum support (EUR/100 kg)	
	Free distribution	Other destinations
Cauliflowers	21,05	15,79
Tomatoes (withdrawn from 1 June to 31 October)	7,25	7,25
Tomatoes (withdrawn from 1 November to 31 May)	33,96	25,48
Apples	24,16	18,11
Grapes	53,52	40,14
Apricots	64,18	48,14
Nectarines	37,82	28,37
Peaches	37,32	27,99
Pears	33,96	25,47
Aubergines	31,2	23,41
Melons	48,1	36,07
Watermelons	9,76	7,31
Oranges	21,00	21,00
Mandarins	25,82	19,50
Clementines	32,38	24,28
Satsumas	25,56	19,50
Lemons	29,98	22,48

ANNEX VI

Minimum requirements for withdrawal of products referred to in Article 29(2)

1. The products shall be:
 - whole, when it applies to fresh raw products,
 - sound; products affected by rotting or deterioration such as to make them unfit for consumption shall be excluded,
 - clean, practically free from any visible foreign matter,
 - practically free from pests and damage caused by pests where applicable,
 - free of abnormal moisture,
 - free of any foreign taste or smell.
 2. Products must be suitable for marketing and consumption, sufficiently developed and ripe where applicable, taking account of their normal characteristics.
 3. Products must be characteristic of the variety or commercial type or quality where applicable.
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ANNEX VII

Conditioning costs referred to in Article 33

Product	Sorting and packing costs (EUR/t)
Apples	187,70
Pears	159,60
Oranges	240,80
Clementines	296,60
Peaches	175,10
Nectarines	205,80
Watermelons	167,00
Cauliflowers	169,10
Other products	201,10

COMMISSION DELEGATED REGULATION (EU) 2022/127**of 7 December 2021****supplementing Regulation (EU) 2021/2116 of the European Parliament and of the Council with rules on paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/2116 of the European Parliament and of the Council of 2 December 2021 on the financing, management and monitoring of the common agricultural policy and repealing Regulation (EU) No 1306/2013 ⁽¹⁾, and in particular Articles 11(1), 23(2), 38(2), 40(3), 41(3), 47(1), 52(1), 54(4), 55(6), 64(3), 76(2), 94(5) and (6) thereof,

Whereas:

- (1) Regulation (EU) 2021/2116 lays down the basic provisions concerning, inter alia, the accreditation of paying agencies and coordination bodies, the obligations of the paying agencies as regards public intervention, the financial management and the clearance procedures, securities and use of euro. In order to ensure the smooth functioning of the new legal framework, certain rules have to be adopted to supplement the provisions laid down by that Regulation in the areas concerned. The new rules should replace the relevant provisions of Commission Delegated Regulation (EU) No 907/2014 ⁽²⁾.
- (2) In accordance with Article 9(2) of Regulation (EU) 2021/2116, paying agencies may only be accredited by Member States if they comply with certain minimum criteria established at Union level. Those criteria are to cover four basic areas: internal environment, control activities, information and communication, and monitoring. Member States should be free to lay down additional accreditation criteria to take account of any specific features of a paying agency.
- (3) In accordance with Article 8(1), point (b), of Regulation (EU) 2021/2116, a competent authority at ministerial level is to be responsible for the issuing, reviewing and withdrawing of the accreditation of the coordinating body referred to in Article 10 of that Regulation. Coordinating bodies should only be accredited by Member States if they comply with certain minimum criteria established at Union level and by the competent authority. Those criteria should cover the specific tasks of the coordinating body as regards the processing of the information of a financial character as referred to in Article 10(1), point (a), and (2) of Regulation (EU) 2021/2116.
- (4) Public intervention measures may be financed only if the expenditure concerned is incurred by the paying agencies designated by the Member States as being responsible for certain obligations with respect to public intervention. However, the performance of tasks relating, in particular, to the administration and checking of intervention measures, with the exception of payment of aid, may be delegated in accordance with Article 9(1), second subparagraph, of Regulation (EU) 2021/2116. It should also be possible for several paying agencies to perform these tasks. It should also be laid down that the management of certain public storage measures may be entrusted to third parties, whether public or private bodies, under the responsibility of the paying agency. It is therefore appropriate to specify the scope of the responsibility of the paying agencies in this context, specify their obligations

⁽¹⁾ OJ L 435, 6.12.2021, p. 187.

⁽²⁾ Commission Delegated Regulation (EU) No 907/2014 of 11 March 2014 supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro (OJ L 255, 28.8.2014, p. 18).

and determine under what conditions and according to which rules the management of certain public storage measures may be entrusted to third parties, whether public or private bodies. In this case, it should be provided that the bodies concerned have to act under contract on the basis of general obligations and principles which should be laid down.

- (5) Union agricultural legislation includes, for the European Agricultural Guarantee Fund (EAGF) and interventions financed by the European Agricultural Fund for Rural Development (EAFRD) and governed under the integrated administration and control system (IACS), periods for payment of aids to beneficiaries, which have to be complied with by Member States. Payments effected outside those periods are to be regarded as ineligible for Union financing. However, analysis has shown that in a number of cases late payments of aid are made by Member States due to additional checks by Member States related to contentious claims, appeals and other national legal disputes. Therefore and in accordance with the principle of proportionality, a fixed margin related to expenditure should be laid down within which no reductions of payments are to be made for these cases. In addition, once this margin is exceeded, in order to modulate the financial impact in proportion to the delay incurred in payment, provision should be made for the Commission to proportionally reduce the Union payments according to the length of delay in payment recorded.
- (6) Payments of aid before the earliest possible date of payment as laid down by Union law cannot be justified by the same reasons as payments after the latest possible date of payment. Therefore, no proportional reduction should be provided for those early payments. However, an exception should be provided for cases where Union agricultural legislation provides the payment of an advance up to a certain maximum amount.
- (7) The Commission is to make payments to the Member States on the basis of declarations of expenditure sent by the Member States, in accordance with Articles 21 and 32 of Regulation (EU) 2021/2116. The Commission should, however, take into account the revenue received by the paying agencies on behalf of the Union budget. The conditions under which certain types of expenditure and revenue effected under the EAGF and the EAFRD are to be offset should therefore be laid down.
- (8) Pursuant to Article 16(2), third subparagraph, of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽⁷⁾, if the Union budget has not been adopted by the beginning of the financial year, payments may be made monthly per chapter to a maximum of one twelfth of the allocated appropriations in the relevant chapter of the budget for the preceding financial year. To allocate the available appropriations fairly among the Member States, provision should be made for the monthly payments under the EAGF and the interim payments under the EAFRD to be made in this case as a percentage of the declarations of expenditure submitted by each Member State and for the balance not used in a given month to be reallocated in the subsequent monthly or interim payments.
- (9) It should be provided that the Commission, after having informed the Member States concerned, may defer the compensation of the expenditure and the assigned revenue for the next monthly payments in case there is late submission of the required information or there are discrepancies that needs to be further clarified with the Member State.
- (10) To avoid the application, by the Member States which have not adopted the euro, of different exchange rates in accounts of revenue received or aid paid to beneficiaries and registered in the account of the paying agencies, in a currency other than the euro, on the one hand, and in the declaration of expenditure drawn up by the paying agency, or the accredited coordinating body, on the other, additional requirements need to be laid down.

⁽⁷⁾ 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).

- (11) For cases where the exchange rate for the operative event have not been established by the Union law it needs be established requirements for the exchange rate that Member States which have not adopted the euro, have to use in their declaration of expenditure and for the purpose of the financial and performance clearance for the assigned revenue resulting from financial consequences of non-recovery.
- (12) In the context of the performance clearance, it is appropriate to lay down rules on the criteria for justifications to be provided by the Member State concerned and the methodology and criteria for applying reductions.
- (13) In order to enable the Commission to verify that Member States respect their obligation to protect the financial interests of the Union and to ensure an efficient application of the conformity clearance procedure provided for in Article 55 of Regulation (EU) 2021/2116, provisions should be laid down concerning the criteria and methodology to apply corrections. The different types of corrections referred to in that Article 55 should be defined and principles should be laid down on how the circumstances of each case will be taken into account to determine the amounts of correction. Moreover, rules should be established on how recoveries made by the Member States from the beneficiaries will be credited to the EAGF and the EAFRD.
- (14) In respect of the specific eligibility rules for the crop-specific payment for cotton set out in Title III, Chapter II, Section 3, Subsection 2, of Regulation (EU) 2021/2115 of the European Parliament and of the Council ⁽⁴⁾ and support for early retirement as referred to in Article 155(2) of that Regulation, cases of non-compliance need to be assessed under a conformity procedure, which would assess the compliance with legality and regularity at beneficiary level.
- (15) Under the new delivery model, the compliance of the Member States' systems with the Union rules will be assessed and in cases of serious deficiencies with the governance systems, the Commission will propose to exclude certain expenditure from Union financing in a conformity procedure. The assessment should not extend to cases of non-compliance with the eligibility conditions for individual beneficiaries laid down in the national CAP Strategic Plans and national rules. As the assessment is at systems level, the proposal for exclusion from Union financing should be based on flat-rate corrections. However, where the specific circumstances allow, Member States could provide a detailed calculation or an extrapolated calculation of the risk for the EAGF or the EAFRD, to be assessed by the Commission in the conformity procedure.
- (16) Numerous provisions in agricultural regulations of the Union require that a security be given to ensure payment of a sum due if an obligation is not met. Therefore, in order to avoid unequal competitive conditions, the conditions applying to that requirement should be laid down.
- (17) In the interest of clarity and legal certainty, Delegated Regulation (EU) No 907/2014 should be repealed. However, Article 5a, Article 7(3) and (4), Article 11(1), second subparagraph, and (2) and Article 13 of that Regulation should continue to apply to the implementation of rural development programmes pursuant to Regulation (EU) No 1305/2013 of the European Parliament and of the Council ⁽⁵⁾ and to the operational programmes approved under Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽⁶⁾, while Article 13 of that Regulation should continue to apply for ongoing recoveries launched under Article 54 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council ⁽⁷⁾.

⁽⁴⁾ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).

⁽⁵⁾ Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

⁽⁶⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

⁽⁷⁾ Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

- (18) In the interest of the correct implementation of Regulation (EU) 2021/2116, it is appropriate to specify that where a paying agency, accredited in accordance with Regulation (EU) No 1306/2013, assumes responsibility for expenditure for which it was not previously responsible, it should be accredited with the new responsibilities before 1 January 2023.
- (19) Finally, in view of Point 31 of the Inter-institutional Agreement of 13 April 2016 on Better Law-Making, the Commission considers that there is a substantive link between the empowerments in Regulation (EU) 2021/2116 regarding the rules on paying agencies' accreditation, financial management, clearance and securities, and there is an interconnection between them in the day-to-day management of the CAP expenditure. It is, therefore, appropriate to lay down those rules in the same delegated act,

HAS ADOPTED THIS REGULATION:

CHAPTER I

Paying agencies and other bodies

Article 1

Conditions for the accreditation of paying agencies

1. Member States shall accredit as paying agencies departments or bodies, which fulfil the conditions laid down in this paragraph and meet the criteria referred to in paragraphs 2 and 3. Paying agencies carrying out the management and control of expenditure as provided for in Article 9(1) of Regulation (EU) 2021/2116 shall provide, in respect of payments made by them and as regards communicating and keeping information, sufficient guarantees that:
- (a) as regards types of intervention referred to in Regulation (EU) 2021/2115, the expenditure matches the corresponding reported output and that it has been effected in accordance with the applicable governance systems;
 - (b) payments are legal and regular as regards the measures laid down in Regulations (EU) No 228/2013 ⁽⁸⁾, (EU) No 229/2013 ⁽⁹⁾, (EU) No 1308/2013 and (EU) No 1144/2014 of the European Parliament and of the Council ⁽¹⁰⁾;
 - (c) accurate and exhaustive accounts are kept of the payments made;
 - (d) the checks laid down by Union legislation are made;
 - (e) the requisite documents are presented within the time limits and in the form set out by Union rules;
 - (f) the documents are accessible and kept in a manner which ensures their completeness, validity and legibility over time, including with regard to electronic documents within the meaning of Union rules.
2. In order to be accredited, a paying agency shall have an administrative organisation and a system of internal control which comply with the criteria set out in Annex I regarding:
- (a) internal environment;
 - (b) control activities;
 - (c) information and communication;
 - (d) monitoring.
3. Member States may lay down further accreditation criteria to take account of the size, responsibilities and other specific features of the paying agency.

⁽⁸⁾ Regulation (EU) No 228/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 (OJ L 78, 20.3.2013, p. 23).

⁽⁹⁾ Regulation (EU) No 229/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in favour of the smaller Aegean islands and repealing Council Regulation (EC) No 1405/2006 (OJ L 78, 20.3.2013, p. 41).

⁽¹⁰⁾ Regulation (EU) No 1144/2014 of the European Parliament and of the Council of 22 October 2014 on information provision and promotion measures concerning agricultural products implemented in the internal market and in third countries and repealing Council Regulation (EC) No 3/2008 (OJ L 317, 4.11.2014, p. 56).

*Article 2***Conditions for the accreditation of coordinating bodies**

1. Where more than one paying agency is accredited, in accordance with Article 10(1) of Regulation (EU) 2021/2116, the Member State concerned shall accredit as coordinating bodies departments or bodies, which fulfil the conditions laid down in paragraph 2 and meet the criteria referred to in paragraphs 3 and 4. That Member State shall, by a formal act at ministerial level, decide on the accreditation of the coordinating body after it has satisfied itself that the administrative arrangements of that body guarantee that it is capable of fulfilling the tasks referred to in that Article.
2. In order to be accredited, the coordinating body shall ensure that:
 - (a) declarations to the Commission are based on information from properly authorised sources;
 - (b) the annual performance report referred to in Article 54(1) of Regulation (EU) 2021/2116 and Article 134 of Regulation (EU) 2021/2115 is covered by the scope of the opinion referred to in Article 12(2) of Regulation (EU) 2021/2116 and its transmission is accompanied by a management declaration covering the compilation of the entire report;
 - (c) declarations to the Commission are properly authorised before transmission;
 - (d) a proper audit trail exists to support the information transmitted to the Commission;
 - (e) a record of information received and transmitted is securely stored in computerised format.
3. In order to be accredited, a coordinating body shall have an administrative organisation and a system of internal control as regards the compilation of the annual performance report, which complies with requirements set by the competent authority as regards the procedures involved, and especially the criteria on information and communication as set out in Annex II.
4. Member States may lay down further accreditation criteria to take account of the size, responsibilities and other specific features of the coordinating body.

*Article 3***Obligations of the paying agency as regards public intervention**

1. The paying agencies referred to in Article 9(1) of Regulation (EU) 2021/2116 shall manage and ensure control of the operations linked to intervention measures relating to public storage for which they are responsible, under the terms laid down in Annex III to this Regulation and, where appropriate, in the sectoral agricultural legislation, in particular on the basis of the minimum checking rates fixed in that Annex.

The paying agencies may delegate their powers in relation to public intervention measures to intervention agencies which meet the conditions of approval laid down in point 1.D of Annex I to this Regulation or act through other paying agencies.

2. The paying agencies or intervention agencies may, without prejudice to their overall responsibility relating to public storage:
 - (a) entrust the management of certain public storage measures to natural or legal persons storing bought-in agricultural products ('storers');
 - (b) mandate natural or legal persons to carry out certain specific tasks laid down by the sectoral agricultural legislation.

If the paying agencies entrust the management to storers as referred to in the first subparagraph, point (a), such management shall be carried out under storage contracts on the basis of the obligations and general principles set out in Annex IV.

3. The obligations of paying agencies with regard to public storage shall be, in particular, as follows:

- (a) to keep stock accounts and financial accounts for each product covered by an intervention measure involving public storage, based on the operations they carry out from 1 October of one year to 30 September of the following year, this period being referred to as an 'accounting year';
- (b) to keep an up-to-date list of the storers with whom they have concluded public storage contracts. This list shall contain references allowing the exact identification of all storage points, their capacity, the number of warehouses, cold stores and silos, and drawings and diagrams thereof;
- (c) to make available to the Commission the standard contracts used for public storage, the rules laid down for the taking-over of products, their storage and removal from the storehouses of the storers, and the rules applicable to the liability of storers;
- (d) to keep centralised, computerised stock accounts of all stocks, covering all storage places, all products and all the quantities and qualities of the different products, specifying in each case the weight (net and gross, where applicable) or the volume;
- (e) to perform all operations relating to the storage, conservation, transport or transfer of intervention products in accordance with Union and national legislation, without prejudice to the responsibility of the purchasers, of the other paying agencies involved in an operation and of any other persons acting on instruction in this regard;
- (f) to conduct checks on places where intervention stocks are held, throughout the year, at irregular intervals and without prior warning. However, provided that the purpose of the control is not jeopardised, advance notice may be given, but shall be strictly limited to the minimum time-period necessary. Such notice shall not exceed 24 hours, except in duly justified cases;
- (g) to conduct an annual stocktaking in accordance with Article 4.

Where, in a Member State, management of the public storage accounts for one or more products is carried out by more than one paying agency, the stock accounts and financial accounts referred to in the first subparagraph, points (a) and (d), shall be consolidated at Member State level before the corresponding information is notified to the Commission.

4. The paying agencies shall ensure:

- (a) that products covered by Union intervention measures are properly conserved by checking the quality of stored products at least once a year;
- (b) the integrity of intervention stocks.

5. The paying agencies shall inform the Commission immediately:

- (a) of cases where extending the storage period of a product is likely to result in its deterioration;
- (b) of quantitative losses or deterioration of the product due to natural disasters.

Where situations referred to in the first subparagraph are applicable, the Commission shall adopt the appropriate decision:

- (a) as regards the situations referred to in the first subparagraph, point (a), in accordance with the examination procedure referred to in Article 229(2) of Regulation (EU) No 1308/2013;
- (b) as regards the situations referred to in the first subparagraph, point (b), in accordance with the examination procedure referred to in Article 102(3) of Regulation (EU) 2021/2116.

6. The paying agencies shall bear any financial consequences of poor conservation of products covered by Union intervention measures, in particular those resulting from unsuitable storage methods. Without prejudice to any recourse against storers, the paying agencies shall bear financial responsibility for failure to comply with their undertakings or obligations.

7. The paying agencies shall make the public storage accounts and all documents, contracts and files drawn up or received in the context of intervention operations permanently available to Commission agents or persons mandated by the Commission, either electronically or at the premises of the paying agencies.

Article 4

Inventory

1. During each accounting year, the paying agencies shall draw up an inventory for each product, which has been the subject of Union intervention.

They shall compare the results of the inventory with the accounting data. Any differences in quantities found, and the amounts resulting from differences in quality found during checks, shall be accounted for in accordance with the rules adopted pursuant to Article 47(3), point (a) of Regulation (EU) 2021/2116.

2. For the purposes of paragraph 1, missing quantities resulting from normal storage operations shall be equal to the difference between the theoretical stock shown by the accounts inventory, on the one hand, and the actual physical stock as established on the basis of the inventory provided for in paragraph 1 or the stock shown as remaining on the books after the physical stock of a store has been exhausted, on the other hand and shall be subject to the tolerance limits set out in Annex V.

CHAPTER II

Financial management

Article 5

Non-compliance with the latest payment deadline

1. Payments to a beneficiary made after the latest possible payment date may be considered eligible under the circumstances and conditions laid down in paragraphs 2 to 6.

2. Where European Agricultural Guarantee Fund (EAGF) expenditure under Article 5(2) or European Agricultural Fund for Rural Development (EAFRD) expenditure under Article 6 for interventions referred to in Article 65(2) of Regulation (EU) 2021/2116 effected after the deadline laid down by Union law is equal to the threshold of 5 % or less of the expenditure effected before the deadlines for the EAGF and the EAFRD respectively, no reduction of the monthly or interim payments shall be made.

Where EAGF or EAFRD expenditure effected after the deadlines laid down by Union law is above the threshold of 5 % for the EAGF and the EAFRD respectively, all further expenditure effected late shall be reduced in accordance with the following rules:

(a) for EAGF expenditure:

- (i) expenditure effected in the first month following the month in which the payment deadline expired shall be reduced by 10 %;
- (ii) expenditure effected in the second month following the month in which the payment deadline expired shall be reduced by 25 %;
- (iii) expenditure effected in the third month following the month in which the payment deadline expired shall be reduced by 45 %;
- (iv) expenditure effected in the fourth month following the month in which the payment deadline expired shall be reduced by 70 %;
- (v) expenditure effected later than the fourth month following the month in which the payment deadline expired shall be reduced by 100 %;

(b) for EAFRD expenditure:

- (i) expenditure effected between 1 July and 15 October of the year in which the payment deadline expired shall be reduced by 25 %;
- (ii) expenditure effected between 16 October and 31 December of the year in which the payment deadline expired shall be reduced by 60 %;
- (iii) expenditure effected later than 31 December of the year in which the payment deadline expired shall be reduced by 100 %.

3. By way of derogation from paragraph 2, the following conditions shall apply:

- (a) where for expenditure for interventions in the form of direct payments or EAFRD expenditure the threshold referred to in paragraph 2, first subparagraph, has not been used in full for payments made in respect of calendar year N no later than 15 October of year N + 1 for the EAGF and no later than 31 December of year N + 1 for the EAFRD and the remainder of the threshold exceeds 2 %, that remainder shall be reduced to 2 %;
- (b) during a financial year N + 1, payments for interventions in the form of direct payments, other than payments provided for in Regulations (EU) No 228/2013 and (EU) No 229/2013, in respect of calendar years N-1 or earlier made after the payment deadline shall only be eligible for financing by the EAGF if the total amount of interventions in the form of direct payments made within financial year N+1, where applicable corrected to amounts before the adjustment provided for in Article 17 of Regulation (EU) 2021/2116, does not exceed the ceiling laid down in Annex V to Regulation (EU) 2021/2115 in respect of calendar year N, in accordance with Article 87(1) of that Regulation;
- (c) expenditure exceeding the limits referred to in point (a) or (b) shall be reduced by 100 %.

The amounts of the reimbursements referred to in Article 17(3), second subparagraph, of Regulation (EU) 2021/2116 shall not be taken into account to check whether the condition laid down in the first subparagraph, point (b), of this paragraph is fulfilled.

4. Where exceptional management conditions are encountered for certain interventions and measures or where justified reasons are advanced by the Member States, the Commission shall apply either different time scales from those laid down in paragraphs 2 and 3, and/or lower reductions or apply no reduction at all.

However, the first subparagraph shall not apply for expenditure exceeding the ceiling referred to in paragraph 3, first subparagraph, point (b).

5. Checks on compliance with the payment deadline shall be made once each financial year on expenditure made by 15 October.

Any overrun of payment deadline shall be taken into account in the accounts clearance decision referred to in Article 53 of Regulation (EU) 2021/2116, at the latest.

6. The reductions referred to in this Article shall be applied without prejudice to the subsequent decision on annual performance clearance, referred to in Article 54 of Regulation (EU) 2021/2116 and the conformity procedure, referred to in Article 55 of that Regulation.

Article 6

Non-compliance with the earliest date of payment

As regards EAGF expenditure, if Member States are allowed to pay advances up to a certain maximum amount before the earliest payment date laid down by Union law, this expenditure shall be considered as expenditure eligible for Union financing. Any expenditure paid above this maximum amount shall be ineligible for Union financing except in duly justified cases where exceptional management conditions are encountered for certain interventions or measures or where justified reasons are provided by the Member States. In such cases, the expenditure paid above the maximum amount shall be eligible for Union financing subject to a reduction of 10 %.

The corresponding reduction shall be taken into account in the accounts clearance decision referred to in Article 53 of Regulation (EU) 2021/2116, at the latest.

*Article 7***Compensation by paying agencies**

1. In its decision on the monthly payments to be adopted pursuant to Article 21(3) of Regulation (EU) 2021/2116, the Commission shall establish the balance of the expenditure declared by each Member State in its monthly declarations, less the assigned revenue which that Member State has included in its declarations of expenditure. This set-off shall be regarded as equivalent to collection of the corresponding revenue.

Commitment appropriations and payment appropriations generated by assigned revenue shall be open once this revenue has been assigned to budget lines.

2. If the amounts referred to in Article 45(1), point (b), of Regulation (EU) 2021/2116 were withheld before the payment of the aid concerned by the irregularity or negligence, they shall be deducted from the corresponding expenditure.

3. The amounts of the EAFRD contributions recovered from beneficiaries under the Member State's CAP Strategic Plan concerned during each reference period shall be deducted from the amount to be paid by the EAFRD in the declaration of expenditure for that period.

4. The greater or lesser amounts resulting, where applicable, from the annual financial clearance may be re-used under the EAFRD and shall be added to or deducted from the amount of the EAFRD contribution when the first declaration after the clearance of accounts decision is drawn up.

5. Financing from the EAGF shall be equal to the expenditure, calculated on the basis of the information notified by the paying agency, after deduction of any revenue accruing from the intervention measures, validated by the computerised system set up by the Commission and included by the paying agency in its declaration of expenditure.

*Article 8***Late adoption of Union budget**

1. If the Union budget has not been adopted by the beginning of the budgetary year, the monthly payments referred to in Article 21 of Regulation (EU) 2021/2116 and the interim payments referred to in Article 32 of that Regulation shall be made proportionally to the authorised appropriations per chapter as a percentage of the declarations of expenditure received from each Member State, for the EAGF and the EAFRD respectively, and within the limits laid down in Article 16 of Regulation (EU, Euratom) 2018/1046.

The Commission shall take into account the balance of amounts not reimbursed to the Member States in subsequent payments.

2. As regards the EAFRD, if the Union budget has not been adopted by the beginning of the budgetary year as regards the budgetary commitments referred to in Article 29 of Regulation (EU) 2021/2116, the first annual instalments following the adoption of the Member States' CAP Strategic Plans shall respect the order of adoption of those plans. The budget commitments for the subsequent annual instalments shall be made in the order of the Member States' CAP Strategic Plans having exhausted the respective commitments. The Commission may make partial annual commitments to the Member States' CAP Strategic Plans if the available commitment appropriations are limited. The remaining balance for those plans shall be committed only once additional commitment appropriations become available.

*Article 9***Deferral of monthly payments**

The monthly payments referred to in Article 21 of Regulation (EU) 2021/2116 to the Member States may be deferred where the communications as referred to in Article 90(1), point (c)(i) and (ii), of that Regulation arrive late or contain discrepancies, which necessitate further checks. The Commission shall inform the Member States concerned in due time of its intention to defer payments.

*Article 10***Suspension of payments in relation to the annual clearance**

1. Where the Commission suspends the monthly payments referred to in Article 21(3) of Regulation (EU) 2021/2116 pursuant to Article 40(1), first subparagraph, of that Regulation, the following rates of suspension of payments shall apply:
 - (a) if the Member State does not submit the documents referred to in Articles 9(3) and 12(2) of Regulation (EU) 2021/2116 by 1 March, 1 % of the total amount of the monthly payments referred to in Article 21(3) of that Regulation;
 - (b) if the Member State does not submit the documents referred to in Articles 9(3) and 12(2) of Regulation (EU) 2021/2116 by 1 April, 1,5 % of the total amount of the monthly payments referred to in Article 21(3) of that Regulation.
2. The suspension shall be lifted after the submission of all the relevant documents referred to in Articles 9(3) and 12(2) of Regulation (EU) 2021/2116.

*Article 11***Suspension of payments in relation to the performance clearance**

1. Where the Commission suspends the monthly payments referred to in Article 21(3) of Regulation (EU) 2021/2116 or the interim payments referred to in Article 32 of that Regulation pursuant to Article 40(2) of that Regulation following the performance clearance as referred to in Article 54 of Regulation (EU) 2021/2116, the rate of suspension shall correspond to the difference between the reduction rate applied pursuant to Article 54(1) of Regulation (EU) 2021/2116 and 50 percentage points, multiplied by 2. The rate of suspension to be applied shall not be less than 10 %.
2. The suspensions referred to in paragraph 1 shall be without prejudice to Articles 53 and 55 of Regulation (EU) 2021/2116.

*Article 12***Applicable exchange rate for drawing up declarations of expenditure**

1. In accordance with Article 94(4) of Regulation (EU) 2021/2116, as regards the EAGF, for drawing up their declarations of expenditure, Member States which have not adopted the euro shall apply the same exchange rate as that which they used to make payments to beneficiaries or receive revenue, in accordance with Chapter V of this Regulation and the sectoral agricultural legislation.
2. As regards the EAFRD, for drawing up their declarations of expenditure, Member States which have not adopted the euro shall apply, for each payment or recovery operation, the last-but-one exchange rate established by the European Central Bank prior to the month in which the operations are registered in the accounts of the paying agency.
3. As regards the clearance decisions referred to in Articles 53 and 54 of Regulation (EU) 2021/2116 and the conformity procedure referred to in Article 55 of that Regulation, the first exchange rate established by the European Central Bank after the date of adoption of the clearance implementing acts shall be used.
4. In cases other than those referred to in paragraphs 1, 2 and 3, as well as for operations for which an operative event has not been laid down by Union law, the applicable exchange rate for Member States which have not adopted the euro shall be the last-but-one exchange rate established by the European Central Bank before the month in respect of which the expenditure or assigned revenue is declared.

CHAPTER III

Clearance of accounts and other checks

Article 13

Criteria and methodology for applying reductions in the framework of the performance clearance

1. For the purpose of adopting the decision pursuant to Article 54(1) of Regulation (EU) 2021/2116 on the amounts to be reduced from Union financing, the Commission shall assess the annual expenditure declared by the Member State for the intervention against its corresponding output as reported in the annual performance report referred to in Article 54(1) of Regulation (EU) 2021/2116, submitted pursuant to Article 9(3), first subparagraph, point (b), and Article 10(1), point (b), of that Regulation, and Article 134 of Regulation (EU) 2021/2115.
2. Where the declared expenditure does not have a corresponding output for the relevant financial year and where such deviations as regards the outputs and the realised unit amounts have not been previously explained by the Member State in accordance with Article 134(5) to (9) of Regulation (EU) 2021/2115 in the annual performance report or where the justifications for the deviations are insufficient, the Member State shall provide further justifications within the time-periods set by the Commission. The justifications shall cover the expenditure declared that does not have a corresponding output in the relevant budgetary year.
3. The justifications to be provided by the Member State shall contain relevant information explaining the deviation at unit amount level and the period concerned. It shall contain quantitative information, as well as, qualitative explanations, where necessary.

The Member State shall also provide explanations regarding the extent and effect of the corrective actions already taken to remedy the deviation and to prevent it from reoccurring.

Where the Member State cannot provide justifications for the deviations in accordance with paragraph 2, it may provide justifications for a part of the deviations.

4. Where the Member State fails to provide duly justified reasons for the deviations or where those are considered insufficient by the Commission in accordance with paragraphs 2 and 3, or cover only part of the deviations, the Commission shall reduce the relevant amounts from Union financing. The Commission shall notify the Member State of its opinion in a separate communication.
5. The reductions referred to in this Article shall be applied without prejudice to the subsequent decision on conformity clearance referred to in Article 55 of Regulation (EU) 2021/2116.

Article 14

Criteria and methodology for applying corrections in the framework of the conformity procedure for the expenditure outside the scope of Regulation (EU) 2021/2115 or for the crop-specific payment for cotton and support for early retirement

1. For the purpose of adopting the decision on the amounts to be excluded from Union financing pursuant to Article 55(1) of Regulation (EU) 2021/2116, the Commission shall distinguish between those amounts or parts of the amounts identified as amounts unduly spent and those determined by applying extrapolated or flat rate corrections.

In order to determine the amounts that may be excluded from Union financing, when finding that expenditure outside the scope of Regulation (EU) 2021/2115, for the crop-specific payment for cotton or support for early retirement under Title III, Chapter II, Section 3, Subsection 2, and Article 155(2) of that Regulation, respectively, has not been incurred in conformity with Union law, the Commission shall use its own findings and shall take into account the information made available by the Member States during the conformity clearance procedure carried out in accordance with Article 55 of Regulation (EU) 2021/2116.

2. The Commission shall base the exclusion on the identification of the amounts unduly spent only if those amounts may be identified with proportionate effort. Where the amounts unduly spent cannot be identified by the Commission with proportionate effort, Member States may, within the time-periods set by the Commission during the conformity clearance procedure, submit data concerning the verification of those amounts on the basis of an examination of all individual cases potentially affected by the non-conformity. The verification shall cover the entire expenditure incurred in breach of applicable law and charged to the Union budget. The data submitted shall include all individual amounts which are ineligible due to that non-conformity.

3. Where the amounts unduly spent cannot be identified in accordance with paragraph 2, the Commission may determine the amounts to be excluded by applying extrapolated corrections. To enable the Commission to determine the relevant amounts, Member States may, within the time-periods set by the Commission during the conformity clearance procedure, submit a calculation of the amount to be excluded from Union financing by extrapolating through statistical means the results of checks carried out on a representative sample of those cases. The sample shall be drawn from the population for which the identified non-conformity is reasonably expected to occur.

4. In order to take into consideration the results submitted by Member States as referred to in paragraphs 2 and 3, the Commission shall be in a position to:

- (a) assess the methods used for identifying or extrapolating, which shall be clearly described by the Member States;
- (b) check the representativeness of the sample referred to in paragraph 3;
- (c) check the content and results of the identification or extrapolation submitted to it;
- (d) obtain sufficient and relevant audit evidence regarding the underlying data.

5. When applying extrapolated corrections as foreseen in paragraph 3, the Member States may use the paying agencies' control statistics as confirmed by the certification body, or such body's assessment of the level of error in the context of its audit referred to in Article 12 of Regulation (EU) 2021/2116, provided that:

- (a) the Commission is satisfied with the work carried out by the certification bodies, both in terms of audit strategy and concerning the content, extent and quality of the actual audit work;
- (b) the scope of the certification bodies' work is consistent with the scope of the conformity clearance enquiry in question, in particular with regard to the measures or schemes;
- (c) the amount of the penalties that should have been applied was taken into account in the assessments.

6. Where the conditions for determining the amounts to be excluded from Union financing as referred to in paragraphs 2 and 3 are not met or the nature of the case is such that the amounts to be excluded cannot be determined on the basis of those paragraphs, the Commission shall apply the appropriate flat-rate corrections, taking into account the nature and gravity of the infringement and its own estimation of the risk of financial damage caused to the Union budget.

The level of flat-rate correction shall be established by taking into consideration in particular the type of non-conformity identified. To this effect, control deficiencies shall be divided between those relating to key and ancillary controls as follows:

- (a) key controls shall be the administrative and on-the-spot checks necessary to determine the eligibility of the aid and the relevant application of reductions and penalties;
- (b) ancillary controls shall be all other administrative operations required to correctly process claims.

If, in the framework of the same conformity clearance procedure, different non-conformities which would individually lead to distinct flat-rate corrections are established, then only the highest flat-rate correction shall apply.

7. When establishing the level of flat-rate corrections, the Commission shall specifically take into account one or more of the following circumstances demonstrating a higher gravity of the deficiencies revealing a greater risk of loss for the Union budget:

- (a) one or more key controls are not applied or are applied so poorly or so infrequently that they are deemed ineffective in determining the eligibility of the claim or in preventing irregularities;
- (b) three or more deficiencies are detected with respect to the same control system;
- (c) the Member State's application of a control system is found to be absent or gravely deficient, and there is evidence of wide-spread irregularity and negligence in countering irregular or fraudulent practices;
- (d) similar deficiencies in the same sector are detected in a Member State in an enquiry that follows an enquiry in which they have been first detected and communicated to the Member State, account taken however of the corrective or compensating measures already taken by the Member State.

8. Where a Member State submits certain objective elements, which do not fulfil the requirements laid down in paragraphs 2 and 3 of this Article, but which demonstrate that the maximum loss for the EAGF and the EAFRD is limited to a sum lower than what would derive from the application of the flat-rate proposed, the Commission shall use that lower flat rate to decide on the amounts to be excluded from Union financing pursuant to Article 55 of Regulation (EU) 2021/2116.

9. Amounts effectively recovered from the beneficiaries and credited to the EAGF and the EAFRD before a relevant date, to be established by the Commission in the course of the conformity clearance procedure, shall be deducted from the amount that the Commission decides to exclude from Union financing pursuant to Article 55 of Regulation (EU) 2021/2116.

Article 15

Criteria and methodology for applying corrections in the framework of the conformity procedure for expenditure within the scope of Regulation (EU) 2021/2115

1. For the purpose of adopting the decision on the amounts to be excluded from Union financing pursuant to Article 55(1) of Regulation (EU) 2021/2116, the Commission shall use its own findings and shall take into account the information made available by the Member States during the conformity procedure carried out in accordance with Article 55(3) of that Regulation. The amount to be excluded from Union financing shall as much as possible correspond to the actual financial loss or risk for the Union budget.

2. Where the Commission finds that the expenditure has not been effected in conformity with Union law, the Commission may determine the amounts to be excluded by applying flat-rate corrections, taking into account the nature and gravity of the infringement and its own estimation of the risk of financial damage caused to the Union.

The level of flat-rate correction shall be established by taking into consideration in particular the type of serious deficiency identified. To this effect, account shall be taken of the elements of the governance systems affected by the serious deficiencies.

If, in the framework of the same conformity procedure, different serious deficiencies which would individually lead to distinct flat-rate corrections are established, then only the highest flat-rate correction shall apply.

3. When establishing the level of flat-rate corrections, the Commission shall specifically take into account one or more of the following circumstances demonstrating a higher gravity of the deficiencies, revealing a greater risk of loss for the Union budget:

- (a) serious deficiencies in one or more elements of the governance systems;
- (b) the Member State's application of an element of the governance system is found to be absent, and there is evidence of wide-spread irregularity and negligence in countering irregular or fraudulent practices;

(c) similar deficiencies in the same sector are detected in a Member State in an enquiry that follows an enquiry in which they have been first detected and communicated to the Member State, account taken however of the corrective or compensating measures already taken by the Member State.

4. Where a Member State demonstrates that the maximum loss for the EAGF and the EAFRD is limited to a sum lower than what would derive from the application of the flat-rate proposed, the lower flat-rate may be applied or the certification body's assessment of the governance systems in the context of its audit referred to in Article 12 of Regulation (EU) 2021/2116 may be used by the Commission in order to determine the amounts to be excluded from Union financing during the conformity procedure referred to in Article 55 of that Regulation.

5. Where appropriate, Member States may, within the time-periods set by the Commission during the conformity procedure, submit data concerning the verification of those amounts on the basis of an examination of all individual cases potentially affected by the deficiency. The verification shall cover the entire expenditure incurred in breach of Union law and charged to the Union budget. The data submitted shall include all amounts, which are ineligible due to that non-conformity with Union law. Alternatively, Member States may provide an assessment of the risk, based on a statistically valid and representative sample of the population affected by the deficiency, provided the Member States cannot calculate the amounts unduly spent with proportionate effort. The certification body shall confirm the Member State's assessment of the deficiency.

6. In order to take into consideration the results submitted by Member States as referred to in paragraph 5, the Commission shall assess the method, content and results of the verification or extrapolation submitted. Where the Commission is satisfied with the method, content and results of the verification or extrapolation submitted, it shall use the results submitted by Member States pursuant to paragraph 5, in order to determine the amounts to be excluded from Union financing pursuant to Article 55 of Regulation (EU) 2021/2116.

7. Amounts effectively recovered from the beneficiaries and credited to the EAGF and the EAFRD before a relevant date, to be established by the Commission in the course of the conformity procedure, shall be deducted from the amount that the Commission decides to exclude from Union financing pursuant to Article 55 of Regulation (EU) 2021/2116.

CHAPTER IV

Securities

Section 1

Scope and use of terms

Article 16

Scope

This Chapter shall apply in all cases where the sectoral agricultural legislation provides for a security whether or not the particular term 'security' is used.

This Chapter shall not apply to securities given to ensure payment of import and export duties referred to in Regulation (EU) No 952/2013 of the European Parliament and of the Council ⁽¹⁾.

⁽¹⁾ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

*Article 17***Terms used in this Chapter**

For the purposes of this Chapter:

- (a) 'competent authority' means either a party authorised to accept a security or a party authorised to decide in accordance with the relevant regulation if a security is to be released or forfeited;
- (b) 'block security' means a security made available to the competent authority with the purpose of ensuring that more than one obligation is met;
- (c) 'the relevant part of the sum secured' means the part of the sum secured corresponding to the quantity for which a requirement has been breached.

*Section 2***Requirement of a security***Article 18***Responsible party**

A security shall be given by or on behalf of the party responsible for paying the sum of money due if an obligation is not met.

*Article 19***Waiver of a security requirement**

1. The competent authority may waive the security requirement where the party responsible for meeting the obligation is either:
 - (a) a public body responsible for executing the duties of a public authority; or
 - (b) a private body executing duties referred to in point (a) under State supervision.
2. The competent authority may waive the security requirement where the value of the sum secured is less than EUR 500. In that case, the party concerned shall undertake in writing to pay a sum equal to the security waived if the corresponding obligation is not met.

In applying the first subparagraph, the value of the security shall be calculated as comprising all the relevant obligations linked with a same operation.

*Article 20***Conditions applying to securities**

1. The competent authority shall refuse to accept or shall require the replacement of any security which it considers inadequate or unsatisfactory or which does not provide cover for a sufficient period.
2. Where cash is deposited by transfer, it shall not be regarded as establishing a security until the competent authority is satisfied that it has the amount at its disposal.
3. A cheque for a sum whose payment is guaranteed by a financial institution recognised for that purpose by the Member State of the competent authority concerned shall be treated as a cash deposit. The competent authority need not to present such a cheque for payment until the period for which it is guaranteed is about to expire.

A cheque, other than as referred to in the first subparagraph, shall constitute a security only when the competent authority is satisfied that it has the amount at its disposal.

4. Any charges by a financial institution shall be borne by the party giving the security.
5. No interest shall be paid to the party giving a security in the form of a cash deposit.

Article 21

Use of euro

1. Securities shall be constituted in euro.
2. If the security is accepted in a Member State which has not adopted the euro, the amount of the security in euro shall be converted into the applicable national currency in accordance with Chapter V. The undertaking corresponding to the security and any amount withheld in the event of irregularities or breaches shall remain fixed in euro.

Article 22

The guarantor

1. The guarantor shall have his officially registered residence or an establishment in the Union and, subject to the provisions of the Treaty concerning freedom to supply services, be approved by the competent authority of the Member State in which the security is given. The guarantor shall be bound by a written guarantee.
2. The written guarantee shall state at least:
 - (a) the obligation or, in the case of a block security, the type(s) of obligation against whose fulfilment it guarantees the payment of a sum of money;
 - (b) the maximum liability to pay that the guarantor accepts;
 - (c) that the guarantor undertakes jointly and severally with the party responsible for meeting the obligation to pay, within 30 days upon demand by the competent authority, any sum, within the limit of the guarantee, due once a security is declared forfeit.
3. Where a written block security has already been given, the competent authority shall determine the procedure to be followed by which all or part of the block security shall be allocated to a particular obligation.

Article 23

Application of *force majeure*

Any person responsible for an obligation covered by a security claiming that the non-respect of the obligation is due to *force majeure* shall prove to the satisfaction of the competent authorities that *force majeure* applies. If the competent authority recognises a case of *force majeure*, the obligation is cancelled for the sole purpose of releasing the security.

Section 3

Release and forfeiture of securities other than those referred to in Section 4

Article 24

Forfeiting of securities

1. The obligation referred to in Article 64(1) of Regulation (EU) 2021/2116 is the requirement to perform or to refrain from performing an action, basic to the purposes of the Regulation imposing it.
2. If an obligation is not fulfilled and no time limit for fulfilment has been given, the security shall be forfeited when the competent authority establishes that it was not fulfilled.

3. If the fulfilment of an obligation is subject to a certain time limit, and the fulfilment took only place beyond that time limit, the security shall be forfeited.

In such case the security shall be forfeited for 10 % at once and further an additional percentage over the remaining balance shall be applied for:

- (a) 2 % per calendar day exceeding the time limit if the obligation concerns the importing of products into a third country;
- (b) 5 % per calendar day exceeding the time limit if the obligation concerns the leaving of products of the customs territory of the Union.

4. If an obligation is fulfilled timely, and the presentation of the proof of fulfilment is subject to a fixed time limit, the security covering that obligation shall be forfeited for each calendar day exceeding that time limit according to the formula $0,2/\text{time limit in days}$ set and taking account of Article 27.

If the proof referred to in the first subparagraph consists of the submission of a used or expired import or export licence, the security to be forfeited shall be 15 % if that proof is submitted after the fixed time limit referred to in the first subparagraph but at the latest on the 730th calendar day after the expiry date of the licence. After those 730 calendar days, the remaining security shall be forfeited in whole.

5. The amount of security to be forfeited shall be rounded to the first lower amount in whole euro or the applicable national currency.

Article 25

Releasing of securities

1. Once the proof as laid down by the specific Union rules that an obligation has been fulfilled, or the security has been partially forfeited in accordance with Article 64(2) of Regulation (EU) 2021/2116 and Article 24 of this Regulation, the security, or where applicable, the remainder of the security shall be released without delay.

2. A security shall on request be released in part where the relevant evidence has been furnished in relation to part of a quantity of product, provided that that part is not less than any minimum quantity specified in the regulation requiring the security, or, in the absence, as specified by the Member State.

3. Where no time-period is laid down for producing the evidence needed to release a sum secured, such period shall be 365 calendar days from the time limit specified for respecting the obligation for which the security was lodged. Where no time limit is specified for respecting the obligation for which the security was lodged, the period for producing the evidence needed to release a sum secured shall be 365 calendar days from the date by which all obligations have been fulfilled.

The period laid down in the first subparagraph shall not exceed 1 095 calendar days from the time the security was assigned to a particular obligation.

Article 26

Thresholds

1. The total sum forfeited shall not exceed 100 % of the relevant part of the sum secured.

2. The competent authority may waive the forfeiture of an amount less than EUR 100, provided that similar national provisions for comparable cases are laid down by law, regulation or administrative action.

Section 4

Securities with respect to advance payments

Article 27

Scope

This Section shall apply in cases where specific Union rules, other than rules on sectoral interventions, provide that a sum may be advanced before the obligation established to obtain any aid or advantage has been met.

Article 28

Release of securities

1. The security shall be released:
 - (a) either when final entitlement to the sum granted as an advance has been established;
 - (b) or when the sum granted, plus any addition provided for in the specific Union rules, has been repaid.
2. Once the deadline for proving final entitlement to the sum granted has passed without production of evidence of entitlement, the competent authority shall immediately follow the procedure for forfeiting the security.

However, where specific Union rules so provide, evidence may still be produced after that date against partial repayment of the security.

CHAPTER V

Use of euro

Article 29

Trade with third countries

1. For amounts relating to imports and for export taxes, fixed in euro by Union law relating to the common agricultural policy and applicable by the Member States in national currency, the conversion rate shall be specifically equal to the rate applicable pursuant to Article 53(1) of Regulation (EU) No 952/2013.
2. For prices and amounts expressed in euro in Union agricultural legislation regarding trade with third countries, the operative event for the exchange rate shall be the acceptance of the customs declaration.
3. For the purpose of calculating the standard import value of fruit and vegetables, in order to determine the entry price, the operative event for the exchange rate for the representative prices used to calculate that standard value and the amount of the reduction shall be the day to which the representative prices relate.

Article 30

Specific types of aid

1. For aid granted by quantity of marketed product or product to be used in a specific way, without prejudice to Articles 32 and 33, the operative event for the exchange rate shall be the first operation which guarantees, after the products are taken over by the operator concerned, the appropriate use of the products in question and entails grant of the aid.

2. For private storage aid the operative event for the exchange rate shall be the first day of the period in respect of which the aid relating to one and the same contract is granted.
3. For aid other than that referred to in paragraphs 1 and 2 of this Article, and in Articles 32 and 33, the operative event for the exchange rate shall be the deadline for the submission of applications.

Article 31

Wine sector

1. The operative event for the exchange rate shall be the first day of the financial year in which the support is granted for the following:
 - (a) restructuring and conversion of vineyards referred to in Article 58(1), first subparagraph, point (a), of Regulation (EU) 2021/2115;
 - (b) temporary and degressive assistance to cover administrative costs of setting-up of mutual funds referred to in Article 58(1), first subparagraph, point (l), of Regulation (EU) 2021/2115;
 - (c) harvest insurance against income losses resulting from adverse climatic events assimilated to natural disasters, adverse climatic events, damages caused by animals, plant diseases or pest infestations referred to in Article 58(1), first subparagraph, point (d), of Regulation (EU) 2021/2115.
2. For the green harvesting operations referred to in Article 58(1), first subparagraph, point (c), of Regulation (EU) 2021/2115, the operative event for the exchange rate shall be the day on which the green harvesting operation takes place
3. For the distillation of by-products of wine-making carried out in accordance with the restrictions laid down in Part II, Section D, of Annex VIII to Regulation (EU) No 1308/2013, referred to in Article 58(1), first subparagraph, point (g), of Regulation (EU) 2021/2115, the operative event for the exchange rate shall be the first day of the financial year in which the by-product is delivered.
4. For the investments referred to in Article 58(1), first subparagraph, points (b), (e) and (m), of Regulation (EU) 2021/2115, the operative event for the exchange rate shall be 1 January of the year in which the decision to grant the aid is taken.
5. For the types of intervention referred to in Article 58(1), first subparagraph, points (f), (h), (i), (j) and (k), of Regulation (EU) 2021/2115 the operative event for the exchange rate shall be the last-but-one exchange rate established by the European Central Bank before the month in respect of which the expenditure or assigned revenue is declared.

Article 32

Amounts and payments of aid linked to the implementation of the school scheme

For aid granted for the implementation of the school scheme referred to in Part II, Title I, Chapter II, Section I, of Regulation (EU) No 1308/2013, the operative event for the exchange rate shall be 1 January preceding the school year concerned.

Article 33

Support of structural or environmental character

For rural development support paid in accordance with Title III, Chapter IV, of Regulation (EU) No 2021/2115, as well as for payments relating to measures approved under Regulation (EU) No 1305/2013, the operative event for the exchange rate shall be 1 January of the year in which the decision to grant the aid is taken.

However, where, under Union rules, payment of the amounts referred to in the first subparagraph is staggered over several years, the operative event for the exchange rate for each of the annual instalments shall be 1 January of the year for which the instalment in question is paid.

Article 34

Other amounts and prices

For prices or amounts other than those referred to in Articles 30 to 33, or amounts linked to those prices, expressed in euro in Union legislation, or expressed in euro by a tendering procedure, the operative event for the exchange rate shall be the day on which one of the following legal acts occurs:

- (a) for purchases, when the valid offer has been received;
- (b) for sales, when the valid offer has been received;
- (c) for withdrawals of products the day on which the withdrawal takes place;
- (d) for non-harvesting and green harvesting operations the day on which the non-harvesting and green harvesting operation takes place;
- (e) for costs of transport, processing or public storage and for amounts allocated to studies as part of a tendering procedure, the final day for the submission of tenders;
- (f) for the recording of prices, amounts or tenders on the market, the day in respect of which the price, amount or tender is recorded;
- (g) for penalties linked to non-compliance with agricultural legislation, the date of the act of the competent authority which establishes the facts.

Article 35

Payment of advances

For advances, the operative event for the exchange rate shall be the operative event applicable to the price or amount to which the advance relates, where this event has occurred by the time the advance is paid, or, in other cases, the date of setting in euro of the advance or, failing that, the date of payment of the advance. The operative event for the exchange rate shall be applied to advances without prejudice to the application to the entire price or amount in question of the operative event for that price or amount.

Article 36

Securities

For securities, the operative event for the exchange rate shall be the date on which the security is lodged.

However, the following exceptions shall apply:

- (a) for securities relating to advances, the operative event for the exchange rate shall be the operative event as defined for the amount of the advance, where that event has occurred by the time the security is paid;
- (b) for securities relating to the submission of tenders, the operative event for the exchange rate shall be the day on which the tender is submitted;
- (c) for securities relating to the performance of tenders, the operative event for the exchange rate shall be the closing date of the invitation to tender.

*Article 37***Determination of the exchange rate**

When an operative event is fixed under Union legislation, the exchange rate to be used shall be the most recent rate set by the European Central Bank prior to the first day of the month in which the operative event occurs.

However, the exchange rate to be used shall be:

- (a) for the cases referred to in Article 29(2) of this Regulation in which the operative event for the exchange rate is the acceptance of the customs declaration, the rate referred to in Article 53(1) of Regulation (EU) No 952/2013;
- (b) for intervention expenditure incurred in the context of public storage operations, the rate resulting from the application of Article 3(2) of Commission Delegated Regulation (EU) No 906/2014 ⁽¹²⁾.

*Article 38***Scrutiny of transactions**

The amounts in euro resulting from the application of Title IV, Chapter III, of Regulation (EU) 2021/2116 shall be converted, where appropriate, into national currencies by applying the rate of exchange operating on the first working date of the year when the scrutiny period begins and as published in the C series of the *Official Journal of the European Union*.

*CHAPTER VI****Transitional and final provisions****Article 39***Transitional provisions**

Where a paying agency, accredited in accordance with Regulation (EU) No 1306/2013, assumes responsibility for expenditure for which it was not previously responsible, it shall be accredited with the new responsibilities before 1 January 2023.

*Article 40***Repeal**

Delegated Regulation (EU) No 907/2014 is repealed with effect from 1 January 2023.

However:

- (a) Article 5a, Article 7(3) and (4), Article 11(1), second subparagraph, and (2) and Article 13 of that Regulation shall continue to apply as regards the EAFRD in relation to expenditure incurred by the beneficiaries and payments effected by the paying agency in the framework of the implementation of rural development programmes pursuant to Regulation (EU) No 1305/2013 and as regards the EAGF to the operational programmes approved under Regulation (EU) No 1308/2013;
- (b) Article 13 of that Regulation shall continue to apply for ongoing recoveries launched under Article 54 of Regulation (EU) No 1306/2013.

⁽¹²⁾ Commission Delegated Regulation (EU) No 906/2014 of 11 March 2014 supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to public intervention expenditure (OJ L 255, 28.8.2014, p. 1).

*Article 41***Entry into force and application**

This Regulation shall enter into force on the 7th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2023.

However, Article 39 shall apply from the date of entry into force of this Regulation.

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

Done at Brussels, 7 December 2021.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

Accreditation criteria for paying agencies referred to in Article 1(2)**1. INTERNAL ENVIRONMENT****(A) Organisational structure**

The paying agency's organisational structure shall allow it to execute the following main functions in respect of EAGF and EAFRD expenditure:

- (i) authorisation and control of payments to establish that the amount to be paid to a beneficiary is in conformity with Union rules, which shall include, in particular, administrative and on-the-spot controls;
- (ii) execution of payments of the authorised amount to beneficiaries (or their assignees) or, in the case of rural development, the Union co-financing part;
- (iii) accounting to record all payments in the paying agency's separate accounts for EAGF and EAFRD expenditure, in the form of an information system, and the preparation of periodic summaries of expenditure, including the monthly (for the EAGF), quarterly (for the EAFRD) and annual declarations to the Commission. The paying agency's accounts shall also record the assets financed by the EAGF and the EAFRD, in particular concerning intervention stocks, uncleared advances, securities and debtors;
- (iv) as regards types of intervention referred to in Regulation (EU) 2021/2115, the paying agency's organisational structure shall also ensure the execution of the performance reporting on output indicators for the purposes of the annual performance clearance referred to in Article 54 of Regulation (EU) 2021/2116 and the performance reporting on result indicators for the multiannual performance monitoring referred to in Article 134 of Regulation (EU) 2021/2115, demonstrating that Article 37 of Regulation (EU) 2021/2116 is complied with.

The paying agency's organisational structure shall provide for clear assignment of authority and responsibility at all operational levels and for separation of the functions referred to in the first paragraph, points (i), (ii) and (iii), the responsibilities of which shall be defined in an organisational chart that includes the reporting lines. It shall include the technical services and the internal audit service referred to in point 4.

(B) Human-resource standard

The paying agency shall demonstrate a commitment to integrity and ethical values. All management levels shall respect integrity and ethical values in their instructions, actions and behaviour. The integrity and ethical values shall be set out in standards of conduct and understood at all levels of the organisation, as well as by outsourced service providers and beneficiaries. Processes shall be in place to assess whether individuals and entities are aligned with the standards of conduct and to address deviations in a timely manner. The paying agency shall also demonstrate a commitment to attract, develop, and retain competent individuals in alignment with its objectives.

In particular, the agency shall ensure that:

- (i) appropriate human resources are allocated to carry out operations and existence of appropriate technical skills as required at different operational levels;
- (ii) the division of duties is such that no official has responsibility for more than one of the responsibilities for authorising, paying or accounting of sums charged to the EAGF or to the EAFRD, and no official performs any of those tasks without supervision;
- (iii) the responsibilities of each official are defined in a written job description, including the setting of financial limits to his/her authority. The latter may be defined in the system;

- (iv) staff training is appropriate at all operational levels, including fraud awareness, and there is a policy for rotating staff in sensitive positions, or alternatively for increased supervision;
- (v) appropriate measures are taken to avoid and detect a possible risk of conflict of interests within the meaning of Article 61 of Regulation (EU, Euratom) 2018/1046 as regards implementing paying agency's functions vis-a-vis people with influence and sensitive positions inside and outside the paying agency. Where there is a risk of a conflict of interests, measures shall be in place to ensure that that Article is applied.

(C) Risk assessment

The paying agency shall ensure:

- (i) the identification of objectives of the paying agency to enable the identification and assessment of risks relating to those objectives;
- (ii) the identification of the risks, including potential irregularities or fraud, to the achievement of its objectives and the analysis of those risks as a basis for determining how the risk should be managed;
- (iii) as regards the risk of potential fraud, an anti-fraud strategy, which shall include measures to counter fraud and any illegal activities affecting the financial interests of the Union. These measures shall include the prevention and detection of, and conditions for investigating fraud; and reparation and deterrence measures, with proportionate and dissuasive sanctions;
- (iv) the implementation of measures to prevent and mitigate the risks;
- (v) the identification and assessment of changes that could significantly impact the internal control system;
- (vi) the regular review of the risk assessment and of the measures put in place to prevent or mitigate the identified risks.

(D) Delegation

(D.1) If the paying agency delegates any of its tasks to another body in accordance with Article 9(1) of Regulation (EU) 2021/2116 the following conditions shall be fulfilled:

- (i) a written agreement must be concluded between the paying agency and that body specifying, apart from the delegated tasks, the nature of the information and the supporting documents to be submitted to the paying agency and the time limit within which they must be submitted. The agreement must enable the paying agency to comply with the accreditation criteria;
- (ii) the paying agency shall in all cases remain responsible for the efficient management of the funds concerned. It remains fully responsible for the legality and regularity of the underlying transactions, including protecting the Union's financial interest, as well as for declaring the corresponding expenditure to the Commission and for preparing the accounts accordingly;
- (iii) the responsibilities and obligations of the other body, notably concerning the control and verification of the compliance with Union rules, shall be clearly defined;
- (iv) the paying agency shall ensure that the other body has effective systems for ensuring that it fulfils its tasks in a satisfactory manner;
- (v) the other body shall explicitly confirm to the paying agency that it fulfils its tasks and shall describe the means employed;
- (vi) the paying agency shall regularly review the tasks delegated to confirm that the work performed is of satisfactory standard and that it is in compliance with Union rules.

(D.2) The conditions set out in points (D.1)(i), (ii), (iii) and (v) shall apply *mutatis mutandis* in the cases where paying agency functions are performed by another body as part of its regular tasks on the basis of national legislation.

2. CONTROL ACTIVITIES

(A) Procedures for authorising claims

The paying agency shall adopt procedures to comply with the following rules:

- (i) the paying agency shall lay down detailed procedures for the receipt, recording and processing of claims, including a description of all documents and the information system to be used;
- (ii) each official responsible for authorisation shall have at his/her disposal a detailed checklist of the verifications to be carried out, and shall attest in the supporting documents of the claim that those checks have been carried out. That attestation may be made by electronic means. There shall be evidence of systematic, such as sample, system or plan based review of the work by a senior staff member;
- (iii) a claim shall be authorised for payment only after sufficient checks have been carried out to ensure compliance with Union rules.
- (iv) the checks shall include those required by the relevant regulation governing the specific measure under which aid is claimed, and those required pursuant to Article 59 of Regulation (EU) 2021/2116 to prevent and detect fraud and irregularity with particular regard to the risks incurred. For the EAFRD, there shall in addition be procedures for verifying that the conditions for the granting of aid, including contracting, have been respected and that all applicable Union rules, including those fixed in the CAP Strategic Plan, have been complied with;
- (v) the management of the paying agency shall, at an appropriate level, be informed on a regular and timely basis of the results of administrative and on-the-spot checks carried out, so that the sufficiency of those controls may always be taken into account before a claim is settled;
- (vi) the work performed shall be detailed in a report accompanying each claim, batch of claims or, if appropriate, in a report covering one marketing year. The report shall be accompanied by an attestation of the eligibility of the approved claims and of the nature, scope and limits of the work done. This may be made by electronic means. In addition, for the EAFRD there shall be an assurance that the criteria for the granting of aid, including contracting, have been respected and that all applicable Union rules, including those fixed in the CAP Strategic Plan, have been complied with. If any physical or administrative checks are not exhaustive, but performed on a sample of claims, the claims selected shall be identified, the sampling method described, the results of all inspections and the measures taken in respect of discrepancies and irregularities reported upon. The supporting documents (in paper or electronic form) shall be sufficient to provide assurance that all the required checks on the eligibility of the authorised claims have been performed;
- (vii) where documents (in paper or electronic form) relating to the claims authorised and controls made are retained by other bodies, both those bodies and the paying agency shall set up procedures to ensure that those documents or electronic data records are kept and available to the paying agency.

(B) Procedures for payment

The paying agency shall adopt the necessary procedures to ensure that payments are made only to bank accounts belonging either to beneficiaries or to their assignees. The payment shall be made by the paying agency's bank, or, as appropriate, a governmental payments office, within 5 working days of the date of charge to the EAGF or to the EAFRD. Procedures shall be adopted to ensure that all payments for which transfers are not executed are not declared to the EAGF or to the EAFRD for reimbursement. If such payments have already been declared to the EAGF or to the EAFRD, these should be re-credited to those Funds via the next monthly/quarterly declarations or in the annual accounts at the latest. No payments shall be made in cash. The approval of the authorising official and/or his/her supervisor may be made by electronic means, provided an appropriate level of security over those means is ensured, and the identity of the signatory is entered into the electronic records.

(C) Procedures for accounting

The paying agency shall adopt the following procedures:

- (i) accounting procedures shall ensure that monthly (for the EAGF), quarterly (for the EAFRD) and annual declarations are complete, accurate and timely, and that any errors or omissions are detected and corrected, in particular through checks and reconciliations performed at regular intervals;
- (ii) the accounting for intervention storage shall ensure that the quantities and associated costs are correctly and promptly processed and recorded per identifiable lot and in the correct account at each stage from the acceptance of an offer to the physical disposal of the product, in compliance with the applicable regulations, and ensure that the quantity and nature of stocks at every location may be determined at any time.

(D) Procedures for the performance reporting

As regards types of intervention referred to in Regulation (EU) 2021/2115, the paying agency shall ensure that an information system is in place to collect, record and store in computerised form data on each claim and operation. In addition, the system shall provide a breakdown of data on all relevant output indicators per intervention to guarantee that the annual performance reporting shows that the expenditure was made in accordance with Article 37 of Regulation (EU) 2021/2116, as well as the data for the result indicators, including targets and milestones.

(E) Procedures for advances and securities

Procedures shall be adopted to ensure that:

- (i) payments of advances are separately identified in the accounting or subsidiary records;
- (ii) guarantees are obtained only from financial institutions which fulfil the conditions of Chapter IV of this Regulation and which are approved by the appropriate authorities and which remain valid until cleared or called upon, on the simple request of the paying agency;
- (iii) The advances are cleared within the stipulated time limits and those overdue for clearing are promptly identified and the guarantees promptly called upon.

(F) Procedures for debts

All the criteria provided for in sections (A) to (E) shall apply, *mutatis mutandis*, to levies, forfeited guarantees, reimbursed payments, assigned revenues etc. which the paying agency is required to collect on behalf of the EAGF and of the EAFRD.

The paying agency shall set up a system for the recognition of all amounts due and for the recording in a single debtor's ledger of all such debts prior to their receipt. The debtor's ledger shall be inspected at regular intervals and action shall be taken to collect debts that are overdue.

(G) Audit trail

The information regarding documentary evidence of the authorisation, accounting and payment of claims, performance reporting and handling of advances, securities and debts shall be available in the paying agency to ensure at all times a sufficiently detailed audit trail.

3. INFORMATION AND COMMUNICATION

(A) Communication

The paying agency shall adopt the necessary procedures to ensure that every change in the Union's regulations, and in particular the rates of aid applicable, are recorded and the instructions, databases and checklists updated in good time.

(B) Information systems security

The information systems security shall be certified in accordance with International Standards Organisation 27001: Information Security management systems – Requirements (ISO).

Member States may certify, provided it is authorised by the Commission, the information systems security in accordance with other accepted standards if those standards guarantee a level of security at least equivalent to that provided by ISO 27001.

The first and second paragraphs shall not apply to paying agencies responsible for the management and control of a yearly expenditure not higher than EUR 400 million, if the Member State concerned has informed the Commission of its decision to apply one of the following standards instead:

- International Standards Organisation 27002: Code of practice for Information Security controls (ISO);
- Bundesamt für Sicherheit in der Informationstechnik: IT-Grundschutzhandbuch/IT Baseline Protection Manual (BSI);
- Information Systems Audit and Control Association: Control objectives for Information and related Technology (COBIT).

4. MONITORING

(A) Ongoing monitoring via internal control activities

The internal control activities shall cover at least the following areas:

- (i) monitoring of the technical services and delegated bodies responsible for carrying out the controls and other functions to ensure a proper implementation of regulations, guidelines and procedures;
- (ii) initiating of system changes in order to improve control systems in general;
- (iii) reviewing claims and requests submitted to the paying agency as well as other information providing suspicion of irregularities;
- (iv) monitoring procedures to prevent and detect fraud and irregularity with particular regard to those areas of CAP expenditure under the paying agency's competence which are exposed to a significant risk of fraud or other serious irregularities.

Ongoing monitoring shall be built into the normal, recurring operating activities of the paying agency. At all levels the daily operations and controls activities of the agency shall be monitored on an ongoing basis to ensure a sufficiently detailed audit trail.

(B) Separate evaluations via an internal audit service

The paying agency shall adopt procedures to comply with the following rules:

- (i) the internal audit service shall be independent of the paying agency's other departments and shall report directly to the paying agency's director;
 - (ii) the internal audit service shall verify that procedures adopted by the agency are adequate to ensure that compliance with Union rules is verified and that the accounts are accurate, complete and timely. Verifications may be limited to selected measures and to samples of transactions provided that an audit plan ensures that all significant areas, including the departments responsible for authorisation, are covered over a period not exceeding 5 years;
 - (iii) the internal audit service's work shall be performed in accordance with internationally accepted standards, shall be recorded in working papers and shall result in reports and recommendations addressed to the agency's top management.
-

ANNEX II

Accreditation criteria for coordinating bodies referred to in Article 2(3) as regards the compilation of the Annual Performance Report**1. INFORMATION AND COMMUNICATION****(A) Communication**

The coordinating body shall adopt the necessary procedures to ensure that every change in the Union's regulations are recorded and the instructions and databases updated in good time.

(B) Information systems security

The information systems security shall be certified in accordance with International Standards Organisation 27001: Information Security management systems – Requirements (ISO).

Member States may certify, provided it is authorised by the Commission, the information systems security in accordance with other accepted standards if those standards guarantee a level of security at least equivalent to that provided by ISO 27001. When a paying agency acts as a coordinating body, its certification fulfils this condition.

ANNEX III

Obligations of the paying agencies referred to in Article 3(1)**I. OBLIGATIONS OF THE PAYING AGENCIES****A. Checks****1. Frequency and representativeness**

Each storage point shall be inspected at least once every year in accordance with the rules set out in part II, to ascertain in particular:

- (a) the procedure for collecting information on public storage;
- (b) whether the accounting data held on the spot by the storer tallies with the information sent to the paying agency;
- (c) physical presence shall be established by a sufficiently representative physical inspection, covering at least the percentages set out in part II and making it possible to conclude that the entire quantities listed in the stock accounts are actually present.
- (d) checks on quality shall comprise visual, olfactory and/or organoleptic checks and, if there are any doubts, in-depth analyses.

2. Additional checks

If an anomaly is detected during the physical inspection, a further percentage of the quantities in intervention storage shall be inspected using the same method. If necessary, inspection may extend to weighing all the products in the lot or store being inspected.

B. Inspection reports

- 1. The internal inspection body of the paying agency or the body authorised by the latter shall draw up a report on each of the checks or physical inspections carried out.
- 2. The report shall contain at least the following information:
 - (a) the name of the storer, the address of the store visited and the description of the lots inspected;
 - (b) the date and time when the inspection began and ended;
 - (c) the place where the inspection took place and a description of the conditions of storage, packaging and accessibility;
 - (d) the full identity of the persons conducting the inspection, their status and the terms of their authorisation;
 - (e) the inspection measures undertaken and procedures used to establish volume, such as measuring methods, calculations, interim and final results, and the conclusions drawn;
 - (f) for each lot or quality stored, the quantity in the paying agency's books, the quantity in the store's books and any discrepancies between the two sets of books;
 - (g) for each lot or quality physically inspected, the information referred to in point (f) and the quantity verified on the spot and any discrepancies, the lot or quality number, the pallets, boxes, silos, vats or other receptacles involved and the weight (both net and gross if appropriate) or volume;
 - (h) the statements made by the storer where there are discrepancies or differences;
 - (i) the place, date and signature of the person drawing up the report and of the storer or representative;
 - (j) any extended inspection conducted in the case of anomalies, specifying the percentage of the stored quantities covered by the extended inspection, discrepancies found and explanations given.

3. The reports shall be sent immediately to the head of the department responsible for keeping the accounts of the paying agency.

Immediately after receipt of the report, the paying agency's accounts shall be corrected in the light of the discrepancies and differences detected.

4. The reports shall be available to Commission staff and persons authorised by the Commission.

5. A summary document shall be drawn up by the paying agency listing:

- (a) the checks carried out, clearly indicating which are physical inspections (inventory checks);
- (b) the quantities checked;
- (c) the anomalies detected in relation to the monthly and annual statements, and the reasons for those anomalies.

The quantities checked and the anomalies detected shall be indicated for each product concerned, in terms of weight or volume and as a percentage of the total quantities held.

This summary document shall list separately the checks to verify the quality of the products stored. It shall be sent to the Commission at the same time as the annual accounts referred to in Article 9(3), first subparagraph, point (a), of Regulation (EU) 2021/2116.

II. PHYSICAL INSPECTION PROCEDURE BY SECTOR OF THE CAP FOR THE CHECKS PROVIDED FOR IN PART I

A. Butter

1. The sample of the lots to be checked shall represent at least 5 % of the total quantity in public storage. The lots to be checked shall be selected prior to the visit to the store on the basis of the paying agency's accounting data, but the storer shall not be informed.
2. The presence of the lots selected and their composition shall be verified on the spot by:
 - (a) identifying the control numbers of the lots and boxes on the basis of purchase or entry notes;
 - (b) weighing the pallets (one in 10) and the boxes (one per pallet);
 - (c) visually checking the contents of a box (one in five pallets);
 - (d) checking the condition of the packaging.
3. A description of the lots physically inspected and any shortcomings noted shall be included in the inspection report.

B. Skimmed-milk powder

1. The sample of the lots to be checked shall represent at least 5 % of the quantity in public storage. The lots to be checked shall be selected prior to the visit to the store on the basis of the paying agency's accounting data, but the storer shall not be informed.
2. The presence of the lots selected and their composition shall be verified on the spot by:
 - (a) identifying the control numbers of the lots and bags on the basis of purchase or entry notes;
 - (b) weighing the pallets (one in 10) and bags (one in 10);
 - (c) visually checking the contents of a bag (one in five pallets);
 - (d) checking the condition of the packaging.
3. A description of the lots physically inspected and any shortcomings noted shall be included in the inspection report.

C. Cereals and rice

1. Physical inspection procedure

The inspection shall be carried out as follows:

- (a) Selection of bins or storerooms to be checked, representing at least 5 % of the total quantity of cereals or rice in public storage.

Selection shall be based on the paying agency's stock records, but the storer shall not be informed.

(b) Physical inspection:

- (i) verification of the presence of cereals or rice in the selected bins or storerooms,
- (ii) identification of the cereals or rice;
- (iii) inspection of storage conditions and check on the quality of the products stored in the conditions provided for in Commission Delegated Regulation (EU) 2016/1238 ⁽¹⁾;
- (iv) comparison of the place of storage and identity of the cereals or rice with the store's records;
- (v) evaluation of the quantities stored by a method previously approved by the paying agency, a description of which shall be lodged at its head office.

2. Procedure where discrepancies are found

Some tolerance is permitted when verifying the volume.

The rules laid down in Annex IV, section II, shall thus apply where the weight of the products stored as recorded during the physical inspection differs from the book weight by 5 % or more for cereals and for rice in the case of storage in silos or on-floor storage.

Where cereals or rice are stored in a warehouse, the quantities weighed on entry into storage may be recorded instead of those resulting from a volume assessment if the latter does not provide an adequate degree of accuracy and provided the difference between the two figures is not excessive.

The paying agency shall make use of this option where justified by circumstances, on a case-by-case basis and on its own responsibility. It shall indicate that it has done so in its inspection report, based on the following indicative model:

CEREALS – STOCK INSPECTION

Product:	Storer: Store, silo: Cell number:	Date:
Lot	Quantity stated in stock accounts	

(a) Stocks in silo

Chamber No	Volume stated in specification m ³ (A)	Free volume recorded m ³ (B)	Volume of stored cereals m ³ (A-B)	Specific gravity recorded kg/hl = 100	Weight of cereals or rice

Total (a): ...

⁽¹⁾ Commission Delegated Regulation (EU) 2016/1238 of 18 May 2016 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to public intervention and aid for private storage (OJ L 206, 30.7.2016, p. 15).

(b) Stocks in on-floor storage

	Storeroom No		Storeroom No		Storeroom No	
Area covered ...	...	...	...	...	...	...
Height ...	m ²	...	m ²	...	m ²	...
	...	m ³	...	m ³	...	m ³
	...	...	...	...	...	...
	... m		... m		... m	
Corrections ...	... m ³		... m ³		... m ³	
Volume ...	... m ³		... m ³		... m ³	
Specific gravity ...	... kg/hl		... kg/hl		... kg/hl	
Total weight	... tonnes		... tonnes		... tonnes	

Total (b): ...

Total weight in the store: ...

Difference from book weight: ...

In %: ...

..., [date]

... (Stamp and signature)

Paying agency inspector:

D. Beef and veal

1. The sample of the lots to be checked shall represent at least 5 % of the total quantity in public storage. The lots to be checked shall be selected prior to the visit to the store on the basis of the paying agency's accounting data, but the storer shall not be informed.
2. On-the-spot verification of the presence of the lots selected and of their composition. Verification shall comprise:
 - (a) for bone-in meat:
 - (i) identification of the lots and verification of the number of pieces;
 - (ii) verification, for each type of cut and/or quality, of the weight of 20 % of the pieces;
 - (iii) visual check on the condition of the packaging.
 - (b) for boned meat:
 - (i) identifying the lots and pallets and verifying the number of boxes;
 - (ii) checking the weight of 10 % of the pallets or containers;
 - (iii) checking the weight of 10 % of the boxes from each pallet weighed;
 - (iv) visually checking the contents of the boxes and the condition of the packaging in each box.

The pallets shall be chosen having regard to the different cuts in store.

3. A description of the lots physically inspected and any shortcomings noted shall be included in the inspection report.

ANNEX IV

Obligations and general principles relating to storers' responsibilities, to be included in storage contracts concluded between paying agencies and storers referred to in Article 3(2)**I. GENERAL OBLIGATIONS OF STORERS**

Storers shall be responsible for ensuring that the products covered by Union intervention measures are properly conserved. They shall bear the financial consequences of any failure to do so.

They shall keep available a plan of the warehouse and the measurements for each silo or storeroom at each storage point.

The cereals or rice shall be stored in such a way that their volume may be verified.

II. QUALITY OF PRODUCTS

Where the quality of intervention products in storage deteriorates as a result of poor or inappropriate storage conditions, the losses shall be borne by the storer and entered in the public storage accounts as a loss resulting from deterioration of the product due to storage conditions.

III. MISSING QUANTITIES

1. The storer shall be responsible for all discrepancies between the quantities in store and the details given in the stock statements sent to the paying agency.
2. Where the missing quantities exceed those allowed under the relevant tolerance limit(s), in accordance with Article 4, Annex III, part II, section C, point 2, and Annex V, or under sectoral agricultural legislation, the entire amount shall be charged to the storer as an unidentifiable loss. Storers contesting the missing quantities may require the product to be weighed or measured, in which case they shall bear the costs of the operation unless it is found that the quantities declared are actually present or the difference does not exceed the relevant tolerance limit(s), in which case the costs of weighing or measuring shall be charged to the paying agency.

The tolerance limits set out in Annex III, part II, section C, point 2, shall apply without prejudice to the other tolerances referred to in the first paragraph of this point.

IV. SUPPORTING DOCUMENTS AND MONTHLY AND ANNUAL DECLARATIONS**1. Supporting documents and monthly declarations**

- (a) The documents relating to the entry, storage and removal of products used to draw up the annual accounts must be in the storer's possession and contain at least the following information:
 - (i) place of storage (with identification of the bin or vat where relevant);
 - (ii) quantity carried over from the previous month;
 - (iii) entries and removals by lot;
 - (iv) stock at the end of the period.

These documents shall permit precise identification of the quantities in store at any time, and shall take account of purchases and sales that have been agreed but for which the corresponding entries or removals of stock have not yet occurred.

- (b) The documents relating to the entry, storage and removal of products shall be sent by the storer to the paying agency at least once a month, in support of a summary monthly stock statement. They shall must be in the paying agency's possession before the tenth day of the month following that to which the stock statement relates.
- (c) A specimen summary monthly stock statement (indicative model) is set out below. It shall be made available to storers in electronic form by the paying agencies.

Monthly stock statement

Products:		Storer: Store: No: Address:		Month:	
Lot	Description	Quantity (kg, tonnes, boxes, items, etc.)		Date	Comments
		Entry	Exit		
	Quantity carried over				
	Quantity to be carried over				

(Stamp and signature)

Place and date:

Name:

2. Annual declaration

- (a) The storer shall prepare an annual stock declaration on the basis of the monthly statements described in point 1. It shall be sent to the paying agency no later than the 15 October following the closure of the accounting year.
- (b) The annual stock declaration shall give a summary of the quantities in store, broken down by product and place of storage, and shall give for each product the quantities in store, the lot numbers (except in the case of cereals), the year of their entry into store and an explanation of any anomalies detected.
- (c) A specimen summary annual stock declaration (indicative model) is set out below.

It shall be made available to storers in electronic form by the paying agencies.

Annual stock statement

Products:		Storer: Store: No: Address:	Year:
Lot	Description	Quantity and/or weight booked	Comments

(Stamp and signature)

Place and date:

Name:

V. COMPUTERISED STOCK ACCOUNTS AND AVAILABILITY OF INFORMATION

Public storage contracts concluded between the paying agency and the storer shall contain provisions which make it possible to guarantee compliance with Union legislation.

They shall require the following:

- (a) the keeping of computerised intervention stock accounts;
- (b) direct, immediate availability of a permanent inventory;

- (c) availability at all times of all the documents relating to the entry, storage and removal of stock and the accounting documents and records drawn up in accordance with this Regulation and held by the storer;
- (d) permanent access to those documents for staff of the paying agency and the Commission, and for any person duly authorised by them.

VI. FORM AND CONTENT OF THE DOCUMENTS SENT TO THE PAYING AGENCY

The form and content of the documents referred to in section IV shall be established in accordance with Article 92 of Regulation (EU) 2021/2116.

VII. KEEPING OF DOCUMENTS

Supporting documents relating to all public storage operations shall be kept by the storer for the full period required under the rules adopted based on Article 92 of Regulation (EU) 2021/2116 for the clearance of accounts procedures, without prejudice to the relevant national provisions.

ANNEX V

Tolerance limits referred to in Article 4(2)

1. For quantity losses resulting from normal storage operations carried out in accordance with the rules, the following tolerance limits shall apply for each agricultural product which is the subject of a public storage measure:
 - (a) cereals 0,2 %;
 - (b) paddy rice, maize 0,4 %;
 - (c) skimmed-milk powder 0,0 %;
 - (d) butter 0,0 %;
 - (e) beef and veal 0,6 %.
 2. The percentage for allowable losses during boning of beef shall be 32. This percentage shall apply to all quantities boned during the accounting year.
 3. The tolerance limits referred to in point 1 shall be fixed as a percentage of the actual weight, without packaging, of the quantities entering storage and taken over during the accounting year in question, plus the quantities in storage at the beginning of that year.

These tolerances shall apply during the physical stock inspections. They shall be calculated, for each product, on the basis of all the quantities stored by a paying agency.

The actual weight at entry and removal shall be the recorded weight minus the standard packaging weight, as laid down in the conditions of entry or, where no such conditions have been laid down, minus the average packaging weight used by the paying agency.
 4. The tolerance shall not cover losses in terms of number of packages or number of registered pieces.
 5. Losses arising from theft or other identifiable losses shall not be included in the calculation of tolerance limits provided for in points 1 and 2.
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COMMISSION IMPLEMENTING REGULATION (EU) 2022/128**of 21 December 2021****laying down rules for the application of Regulation (EU) 2021/2116 of the European Parliament and of the Council on paying agencies and other bodies, financial management, clearance of accounts, checks, securities and transparency**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/2116 of the European Parliament and of the Council of 2 December 2021 on the financing, management and monitoring of the common agricultural policy and repealing Regulation (EU) No 1306/2013 ⁽¹⁾, and in particular Articles 11(2), 12(4), 32(9) and 39(4), Article 41(1), fourth subparagraph, Article 42(1), second subparagraph, Articles 43(2), 47(2), 51(3), 53(2), 54(5) and 55(7), Article 58, Articles 59(9) and 64(4), Articles 82 and 92, Article 95(1) and Article 100 thereof,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽²⁾, and in particular Article 223(3) thereof,

Whereas:

- (1) Regulation (EU) 2021/2116 lays down the basic rules on the financing, management and monitoring of the common agricultural policy, including on the accreditation of paying agencies and coordinating bodies, financial management and clearance procedures, including scrutiny of transactions, securities and transparency. In order to ensure that the new legal framework established by that Regulation functions smoothly and applies uniformly, the Commission has been empowered to adopt certain rules in those areas by means of implementing acts. The new rules should replace the relevant provisions of Commission Implementing Regulation (EU) No 908/2014 ⁽³⁾.
- (2) Paying agencies should only be accredited by Member States if they comply with certain minimum accreditation criteria established at Union level, as referred to in Article 1(2) of Commission Delegated Regulation (EU) 2022/127 ⁽⁴⁾ and set out in Annex I to that Regulation. Rules should be laid down regarding the procedures for issuing, reviewing and withdrawing the accreditation of paying agencies and coordination bodies.
- (3) Member States should keep their paying agencies under constant supervision. They should establish a system for the exchange of information to report and keep the competent authorities informed on suspected cases of non-compliance. A procedure should be put in place by which Member States are to deal with such cases, which should include the obligation to draw up a plan to remedy any identified deficiencies within a set time limit. In respect of expenditure effected by paying agencies whose accreditation is maintained by their Member State even though they have failed to implement such a plan within the set time limit the Commission should have the possibility to decide to pursue the deficiencies through the conformity procedure provided for in Article 55 of Regulation (EU) 2021/2116.

⁽¹⁾ OJ L 435, 6.12.2021, p. 187.

⁽²⁾ OJ L 347, 20.12.2013, p. 671.

⁽³⁾ Commission Implementing Regulation (EU) No 908/2014 of 6 August 2014 laying down rules for the application of Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to paying agencies and other bodies, financial management, clearance of accounts, rules on checks, securities and transparency (OJ L 255, 28.8.2014, p. 59).

⁽⁴⁾ Commission Delegated Regulation (EU) 2022/127 of 7 December 2021 supplementing Regulation (EU) 2021/2116 of the European Parliament and of the Council with rules on paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro (see page 131 of this Official Journal).

- (4) Pursuant to Article 9(3), first subparagraph, point (d), of Regulation (EU) 2021/2116, the persons in charge of accredited paying agencies are required to draw up management declarations as to the completeness and accuracy of the information provided, the proper functioning of the governance systems put in place, as well as to the fact that the expenditure was made in accordance with Article 37 of Regulation (EU) 2021/2116. Rules should be laid down as regards the content and format of such management declarations.
- (5) The rules for the functioning of the coordinating bodies referred to in Article 10 of Regulation (EU) 2021/2116, as well as the tasks of the certification bodies referred to in Article 12 of that Regulation should be laid down. In addition, the content of the certificates and reports to be drawn up by the certification bodies should be specified in order to ensure that they are of assistance to the Commission in the clearance of accounts procedure.
- (6) In order to ensure the proper management of the appropriations entered in the budget of the Union for the European Agricultural Guarantee Fund (EAGF) and the European Agricultural Fund for Rural Development (EAFRD) (hereinafter together referred to as 'the Funds'), paying agencies should keep separate accounts relating exclusively to payments made and revenues assigned from and to each of the Funds. To this end, the accounts kept by paying agencies should clearly show, for each of the Funds, the expenditure effected and revenue assigned under Article 5(2) and Articles 6 and 45 of Regulation (EU) 2021/2116, and allow this expenditure and revenue to be linked to the resources made available to them under the Union budget.
- (7) The common agricultural policy is financed in euro, while allowing Member States which have not adopted the euro to make payments to beneficiaries in their national currency. To enable all the expenditure and revenue to be consolidated, it is therefore necessary to provide that relevant paying agencies must be able to provide data relating to the expenditure and revenue in both euro and the currency in which the expenditure was incurred and the revenue received.
- (8) The expenditure co-financed by the Union budget and the national budgets as support for rural development under the EAFRD is based on CAP Strategic Plans specifying different types of intervention and specific contribution rates. In accordance with the principle of sound financial management, that expenditure should be monitored and entered into the accounts on this basis so that all operations can be identified by CAP Strategic Plan, types of intervention and specific contribution rates. Doing so will ensure that correspondence between the expenditure effected and the financial resources assigned can be verified. In that context, the elements to be taken into account by the paying agencies should be specified. In particular, paying agencies should clearly show the origin of public and Union funds in the accounts in relation to the financing effected. In addition, the amounts to be recovered from beneficiaries and the amounts which have been recovered should be identified and shown in relation to the original operations.
- (9) Member States mobilise the resources needed to finance EAGF expenditure referred to in Article 5 of Regulation (EU) 2021/2116 before the Commission finances that expenditure in the form of monthly reimbursements of the expenditure effected. Alternatively, Member States receive an advance payment for EAFRD expenditure to be later cleared with the annual financial clearance pursuant to Article 53 of Regulation (EU) 2021/2116. In order to ensure sound management of financial flows, Member States should gather the information necessary to demonstrate the completeness, accuracy and veracity of the expenditure effected for these monthly and interim reimbursements and keep it at the Commission's disposal as and when expenditure and revenue are effected, or transmit it to the Commission at regular intervals. The information should be provided to the Commission by Member States at intervals adapted to the management method of each of the Funds. Providing information at such intervals should not affect the obligation of the Member States to keep the complete information gathered for the proper monitoring of expenditure at the Commission's disposal for verification.
- (10) The general obligations on paying agencies regarding the keeping of accounts cover the data required for the management and control of Union funds. However, those obligations do not cover requirements as regards the reimbursement of expenditure and the details that have to be provided to the Commission in order to obtain such reimbursement. The information and details relating to expenditure to be financed by the Funds, which have to be sent to the Commission at regular intervals, should therefore be specified. Notifications of information by Member States to the Commission have to enable it to use the information sent directly and as effectively as possible for the management of the Funds' accounts and the relevant payments. To achieve this objective, all information to be made available or to be communicated between the Member States and the Commission should be sent electronically.

- (11) Pursuant to Article 90(1), point (c), of Regulation (EU) 2021/2116, for interventions and measures relating to operations financed by the Funds, declarations of expenditure, which also act as payment requests, are also to be sent to the Commission accompanied by the requisite information within the deadlines set. To allow Member States, the accredited coordinating bodies and the paying agencies to draw up those declarations of expenditure in accordance with harmonised rules, and to allow the Commission to take payment requests into consideration, the conditions under which that expenditure may be taken into account under the respective EAGF and EAFRD budgets should be laid down. Such conditions should specify the rules that apply to the recording of expenditure and revenue, in particular the assigned revenue and any corrections to be made, and to their actual declaration.
- (12) Where, on the basis of the declarations of expenditure received from the Member States under the EAGF, the total advance commitments which could be authorised under Article 11(2), point (b), of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽⁹⁾ exceeds 75 % of the appropriations for the current financial year, the Commission is required to reduce those amounts. In accordance with the principle of sound financial management, that reduction has to be shared among all Member States proportionally, on the basis of the declarations of expenditure received from them. To allocate the available appropriations fairly among the Member States, provision should be made for monthly payments under the EAGF to be reduced by a percentage of the declarations of expenditure submitted by each Member State and for the balance not used in a given month to be reallocated by Commission decisions in subsequent monthly payments.
- (13) After approving the monthly payments, the Commission should place at the Member States' disposal the resources necessary to cover expenditure to be financed by the Funds, in accordance with practical arrangements and conditions to be laid down on the basis of information communicated to the Commission by Member States and the information systems set up by the Commission.
- (14) A condition for the reimbursement of public intervention expenditure incurred by paying agencies is the inclusion in their declarations of expenditure, of the values and amounts booked during the month following the month to which the public storage operations relate. In order to ensure that the reimbursement procedure runs smoothly, it is necessary to specify how such information, which is necessary to calculate costs and expenditure, is to be notified to the Commission.
- (15) In accordance with Article 3(3) of Delegated Regulation (EU) 2022/127, public intervention stock accounting must make it possible to ascertain both the amount of Union financing paid out and the situation of intervention stocks. To that end, paying agencies should be required to keep separate stock accounts and financial accounts, containing the elements necessary to monitor stocks and ensure the financial management of expenditure and revenue generated by public intervention measures.
- (16) With respect to public intervention storage measures, paying agencies are required to record in their accounts elements relating to quantities, values and certain averages. However, there exist circumstances in which certain operations and expenditure should not be entered in the accounts, or should be booked in accordance with specific rules. In order to ensure equal treatment and protect the Union's financial interests, such circumstances should be specified, including where applicable the arrangements for entering the operations and expenditure in the accounts.
- (17) The date on which the different elements of expenditure and revenue resulting from public intervention storage measures are to be entered in the accounts depends on the type of operation to which they relate and can be determined under the applicable sectoral agricultural legislation. In this context, it is necessary to adopt a general rule specifying the different elements that are to be entered in the accounts on the date on which the physical operation resulting from the intervention measure takes place, and specifying the special cases to be taken into consideration.

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

- (18) In the interest of sound financial management, Member States should provide the Commission with forecasts of the amounts still to be funded by the EAFRD for an agricultural financial year and estimates of funding requests for the following financial year. That information should be sent to the Commission in sufficient time to enable it to meet its obligations, and in any event twice a year, not later than 31 January and 31 August each year.
- (19) In accordance with Article 32(9) of Regulation (EU) 2021/2116, the deadlines for drawing up the declarations of expenditure under the EAFRD are to be set. In view of the specific characteristics of the accounting rules which apply to the EAFRD, the use of prefinancing and the financing of the interventions, measures and technical assistance by calendar year, provision should be made for that expenditure to be declared at intervals adapted to these specific conditions.
- (20) Member States have to declare to the Commission all EAFRD expenditure they have paid under their own responsibility to the beneficiaries prior to the approval of a CAP Strategic Plan in the first declaration of expenditure following that approval. The same rule applies *mutatis mutandis* in case of amendment of a CAP Strategic Plan. For the purpose of accounting, it is necessary to clarify that the declaration concerning expenditure paid by the paying agencies prior to the approval of a CAP Strategic Plan or prior to the amendment of a CAP Strategic Plan should correspond to the relevant declaration periods. Furthermore, all expenditure paid by paying agencies during the period in which the approval of a CAP Strategic Plan or its amendment takes place should be declared by the deadline set for the corresponding period. It is also necessary to clarify that in the case of amendments to the CAP Strategic Plan, that rule should not apply for financing plan adjustments.
- (21) In accordance with Article 80 of Regulation (EU) 2021/2115 of the European Parliament and of the Council ⁽⁶⁾, support in the form of financial instruments, as laid down in Article 58 of Regulation (EU) 2021/1060 of the European Parliament and of the Council ⁽⁷⁾, may be granted under the types of intervention referred to in Articles 73 to 78 of Regulation (EU) 2021/2115. Therefore, it is appropriate to lay down that expenditure has to be declared in the financial year in which the conditions as referred to in Article 32(3) and (4) of Regulation (EU) 2021/2116 are met and it had been effected by the paying agency before the end of the financial year.
- (22) This Regulation should establish how to calculate the Union contribution to be paid in respect of expenditure declared based on contribution rate or flat rate. It should be clarified that the relevant provision applies to the payments related to the EAFRD under the CAP Strategic plan and mentioned in the financing plan, in particular the EAFRD expenditures referred to in Article 6 of Regulation (EU) 2021/2116 and to certain eligible types of expenditure, referred to in Articles 155 and 157 of Regulation (EU) 2021/2115, based on the EAFRD contribution rate and technical assistance, as a flat rate.
- (23) Exchanges of information and documents between Member States and the Commission, and the provision and notification of information from the Member States to the Commission are generally carried out electronically. In order to improve the way such exchanges of information relating to the Funds are dealt with and to extend their use, information systems were developed. Such systems should continue to be used and further implemented after informing the Member States via the Committee on the Agricultural Funds.

⁽⁶⁾ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).

⁽⁷⁾ Regulation (EU) 2021/1060 of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy (OJ L 231, 30.6.2021, p. 159).

- (24) The conditions under which information is processed by those information systems and the form and content of documents which have to be communicated pursuant to Regulation (EU) 2021/2116 have to be adjusted frequently in line with changes to the applicable rules or management requirements. To achieve those objectives and to simplify procedures and ensure that the information systems concerned can be made operational rapidly, the form and content of the documents should be laid down on the basis of standardised models and protocols, which should be adapted and updated by the Commission after informing the Committee on the Agricultural Funds.
- (25) Pursuant to Article 59 of Regulation (EU) 2021/2116, Member States through their paying agencies are responsible for the management and control of the Funds' expenditure. The data on financial operations should therefore be communicated or entered in the information systems and updated under the responsibility of the paying agencies, by the paying agencies themselves or the bodies to which that function has been delegated, where applicable via the accredited coordinating body. Each Member State should notify the Commission of the name or number of the account(s) in accordance with the format made available to it by the Commission.
- (26) The electronic signatures or approvals used in the procedure for the declaration of expenditure and management declaration need to be in compliance with the requirements laid down in Regulation (EU) No 910/2014 of the European Parliament and of the Council ⁽⁸⁾. Therefore, a provision for the implementation of those requirements is needed.
- (27) Detailed rules should be laid down on the structure of action plans referred to in Article 42 of Regulation (EU) 2021/2116 as it is necessary to ensure that Member States clearly indicate the remedial actions and the timeline for their implementation. The Commission should provide a template to guide Member States on the expected structure of the action plans. That template should be used for exchanges in electronic form to facilitate the communication between the Commission and the Member States concerned. In relation to a specific case of action plans stemming from deficiencies detected under the remedial actions referred to in Articles 68, 69 and 70 of that Regulation, the efforts already undertaken to remedy the deficiencies should be taken into account.
- (28) Pursuant to Article 59(1), point (e), of Regulation (EU) 2021/2116, Member States through their paying agencies are responsible for recovering undue payments plus interest. In order to ensure an effective and proper application of those provisions, it is appropriate to lay down rules as regards off-setting. Without prejudice to national *de minimis* amounts for non-recovery, the obligation for the Member States to recover undue amounts can be executed in different ways. Without prejudice to any other enforcement action provided for in national law, an effective and cost-efficient means of debt recovery is to deduct any outstanding amounts from future payments to the debtor, once the debt has been established in accordance with national legislation. It should therefore be compulsory for Member States to apply that debt recovery method. Common conditions for its application should be laid down.
- (29) Detailed provisions should be laid down for the procedure for the clearance of accounts provided for in Article 53 of Regulation (EU) 2021/2116, the performance clearance provided for in Article 54 of that Regulation and the conformity procedure provided for in Article 55 of that Regulation, including a mechanism whereby the resulting amounts are, as the case may be, deducted from or added to one of the subsequent payments made to Member States by the Commission.
- (30) With respect to the clearance of accounts procedure provided for in Article 53 of Regulation (EU) 2021/2116, it is necessary to specify the content of the paying agencies' annual accounts and to establish a date for the transmission of those accounts and other relevant documents to the Commission. The period during which paying agencies must keep the supporting documents regarding all expenditure and assigned revenues at the disposal of the Commission should also be specified.

⁽⁸⁾ Regulation (EU) No 910/2014 of the European parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).

- (31) In order to ensure that the performance clearance decision is adopted within the deadline provided for in Article 54(1) of Regulation (EU) 2021/2116, it is appropriate to lay down specific time periods for the exchange of information to be respected by the Commission and Member States. In addition, the performance clearance procedure should give Member States the right to provide justifications as to any differences encountered and should properly assess the information necessary for a reduction of expenditure.
- (32) In order to ensure that in normal cases the conformity procedure is concluded within a reasonable period of time, it is appropriate to lay down specific time periods for the different stages of the procedure to be respected by the Commission and Member States. At the same time, however, it should be possible for the Commission to extend those time periods, where necessary, in view of the complexity of a case under investigation. The conformity procedure should give Member States the right to adversarial proceedings and properly assess the information necessary for the Funds' risk evaluation.
- (33) In view of supplementing and reinforcing their checks on the CAP expenditure, including on the identification of groups, it should be provided that Member States may use a single data-mining tool made available by the Commission.
- (34) It is further appropriate to lay down rules concerning the performance by Member States of the scrutiny of transactions pursuant to Article 77 of Regulation (EU) 2021/2116, in particular the selection of undertakings, rate and the timescale for the scrutiny, mutual assistance and the content of control plans and reports.
- (35) Delegated Regulation (EU) 2022/127 lays down rules supplementing the legal framework on securities, in particular as regards the requirement to lodge a security, the conditions applying to securities, as well as rules on lodging, releasing and forfeiting a security. To ensure a uniform application of those rules, provisions should be laid down on the form and the procedures for lodging and releasing a security, as well as on the exchange of information and the communications required in that respect.
- (36) In accordance with Title V, Chapter IV, of Regulation (EU) 2021/2116 on transparency, Member States are required to publish annually the beneficiaries of the Funds, and, *inter alia*, the amounts received by each beneficiary under each of the Funds. To that end, and in accordance with Article 98 of that Regulation, the form of that publication should be laid down. That publication should not go further than what is necessary in order to reach the transparency objectives pursued.
- (37) Pursuant to Article 98(2) of Regulation (EU) 2021/2116, the amounts of payment corresponding to each operation financed by the Funds received by a beneficiary are to be published. In addition, to achieve a greater transparency and to be able to identify larger recipients of Union funds, Member States should publish the total amount of payments received by a beneficiary.
- (38) In order to contribute to a greater transparency regarding distribution of the Funds, Member States should collect and publish information that allows for the identification of groups of undertakings as referred to in Article 59(4) of Regulation (EU) 2021/2116.
- (39) Pursuant to Article 49(4) of Regulation (EU) 2021/1060, the information is to be published on a website in an open, machine-readable format. Those formats could be CVS and XLXS. In order to achieve common standards and to facilitate the access to the published information, Member States should use a unified table format presenting data on all beneficiaries. A web search tool should ensure that the public at large is able to consult the information on beneficiaries in an easily accessible form.

- (40) Article 98(2) of Regulation (EU) 2021/2116 provides that the publication requirements referred to in Article 49(3) and (4) of Regulation (EU) 2021/1060 are to apply where relevant. The start date and end dates of the types of intervention in the form of direct payments, rural development interventions in the form of payments for natural or other area-specific constraints and area-specific disadvantages resulting from certain mandatory requirements, as well as measures laid down in Regulations (EU) No 228/2013 ⁽⁹⁾ and (EU) No 229/2013 of the European Parliament and of the Council ⁽¹⁰⁾ are considered not to be relevant as those operations are annual. Therefore, it should be provided that Member States may decide not to publish that information.
- (41) In view of protecting individuals with regard to the processing of their personal data, Article 98(4) of Regulation (EU) 2021/2116 provides that Member States are not to publish the names of beneficiaries receiving an amount equal to or less than EUR 1 250. To provide information on the operation concerned, the Member State should instead use a code. For the same reason, where it would be possible to identify a small beneficiary residing or registered in a municipality where the number of beneficiaries is limited, the Member State should instead publish the next larger administrative entity to which that municipality belongs.
- (42) To comply with applicable data protection requirements, beneficiaries of the Funds should be informed of the publication of their data before the publication takes place. The information should be provided to the beneficiaries through the application forms for aid or when the data are collected.
- (43) In order to facilitate public access to the data published, Member States are to establish single websites in accordance with Article 98(4) of Regulation (EU) 2021/2116. In view of the different organisational structures within Member States, it should be decided at national level which body is responsible for setting up and maintaining the single website and publishing the data. The Commission should set up a website that contains links to the Member States' websites.
- (44) The Union is required to make certain notifications to the World Trade Organization (WTO) in accordance with Article 18(2) of the WTO Agreement on Agriculture ⁽¹¹⁾, as further detailed in paragraph 4 of WTO document G/AG/2 of 30 June 1995. In order to comply with those requirements, the Commission should require certain information from Member States, notably information relating to domestic support.
- (45) In order to simplify and reduce the notification requirements for Member States in relation to the transmission of data for the Union's WTO domestic support notification obligations, it is appropriate that Member States submit the amounts concerning expenditure paid from national sources at the same time as the annual accounts are submitted.
- (46) In the interest of clarity and legal certainty, Implementing Regulation (EU) No 908/2014 should be repealed. However, Articles 21 to 24 and Articles 27 to 34 of that Regulation should continue to apply to the implementation of rural development programmes pursuant to Regulation (EU) No 1305/2013 of the European Parliament and of the Council ⁽¹²⁾ and to the operational programmes approved under Regulation (EU) No 1308/2013, while Article 59 of Implementing Regulation (EU) No 908/2014 should continue to apply to payments made for financial years 2021, 2022 and 2023. In addition, Annexes II and III to Implementing Regulation (EU) No 908/2014 should continue to apply to certain data to be included in the annual accounts.

⁽⁹⁾ Regulation (EU) No 228/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 (OJ L 78, 20.3.2013, p. 23).

⁽¹⁰⁾ Regulation (EU) No 229/2013 of the European Parliament and of the Council of 13 March 2013 laying down specific measures for agriculture in favour of the smaller Aegean islands and repealing Council Regulation (EC) No 1405/2006 (OJ L 78, 20.3.2013, p. 41).

⁽¹¹⁾ OJ L 336, 23.12.1994, p. 22.

⁽¹²⁾ Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).

- (47) This Regulation should apply from the same date as Regulation (EU) 2021/2116. However, in order to provide for continuity of reporting within the same financial year, the relevant provisions of this Regulation should apply to expenditure incurred and assigned revenue received by Member States as from 16 October 2022.
- (48) Also, in order to ensure consistency in the treatment of ongoing conformity procedures, the time periods provided for in this Regulation should not apply to procedures for which the communication in accordance with Article 34(1) of Implementing Regulation (EU) No 908/2014 is sent before 1 January 2024.
- (49) Finally, since Title VII, Chapter IV, of Regulation (EU) 2021/2116 on transparency applies to payments made from the financial year 2024 onwards, the relevant provisions of this Regulation should apply to those payments.
- (50) The measures provided for in this Regulation are in accordance with the opinion of the Committee on the Agricultural Funds,

HAS ADOPTED THIS REGULATION:

CHAPTER I

Paying agencies and other bodies

Article 1

Procedure for the accreditation of paying agencies

1. Member States shall designate an authority at ministerial level responsible for:
 - (a) the issuing, reviewing and withdrawing of accreditation of paying agencies;
 - (b) carrying out the tasks assigned to the competent authority pursuant to this Chapter.
2. The competent authority shall, by way of a formal act, decide on the issuing or, after review, the withdrawal of the accreditation of the paying agency on the basis of an examination of the accreditation criteria referred to in Article 1(2) and (3) of Delegated Regulation (EU) 2022/127. The competent authority shall inform the Commission of accreditations and withdrawals of accreditations without delay.
3. The competent authority shall appoint an audit body to carry out an examination before any accreditation is issued (pre-accreditation review). The audit body shall be an audit authority, or other public or private organisation or organisational unit of an authority with the requisite proficiency, skills and capacity to carry out audits. The audit body shall be independent from the paying agency to be accredited.
4. The examination (pre-accreditation review) to be carried out by the audit body shall cover, in particular:
 - (a) the procedures and systems in place for the authorisation and execution of payments and for the execution of the annual performance reporting;
 - (b) the division of duties and the adequacy of internal and external control in respect of transactions financed by the European Agricultural Guarantee Fund (EAGF) and the European Agricultural Fund for Rural Development (EAFRD), hereinafter together referred to as 'the Funds';
 - (c) the extent to which the procedures and systems put in place are apt to safeguard the Union budget including risk-based anti-fraud measures;
 - (d) the security of information systems;
 - (e) the maintenance of accounting records.

The audit body shall prepare a report detailing the audit work carried out, the results of that work and its assessment as to whether the paying agency complies with the accreditation criteria. The report shall be provided to the competent authority which shall then assess the results and issue the accreditation act where it is satisfied that the paying agency complies with the accreditation criteria.

5. Where the competent authority considers that the paying agency does not comply with the accreditation criteria, it shall inform the paying agency of the specific conditions it is required to fulfil before accreditation may be issued.

Pending the implementation of any necessary changes in order to fulfil such specific conditions, accreditation may be issued provisionally for a period to be determined taking into account the severity of the problems identified, which shall not exceed 12 months. In duly justified cases, the Commission may, upon request of the Member State concerned, grant an extension of that period.

6. The information provided for in Article 90(1), first subparagraph, point (a), of Regulation (EU) 2021/2116 shall be communicated immediately after the paying agency is first accredited and in any case before any expenditure effected by it is charged to the Funds. That information shall be accompanied by declarations and documents concerning:

- (a) the responsibilities vested in the paying agency;
- (b) the allocation of responsibilities between the departments of the paying agency;
- (c) the relationship of the paying agency with other bodies, public or private, which are responsible for implementing any measures under which the paying agency charges expenditure to the Funds;
- (d) the procedures by which claims by beneficiaries are received, verified, and validated, and by which expenditure is authorised, paid and accounted for;
- (e) the provisions concerning the security of information systems;
- (f) the report of the pre-accreditation review carried out by the audit body referred to in paragraph 3.

7. The Commission shall inform the Committee on the Agricultural Funds of paying agencies accredited in each Member State.

Article 2

Review and withdrawal of accreditation of paying agencies

1. The competent authority shall keep the paying agencies for which it is responsible under constant supervision, on the basis of, in particular, the certificates and reports drawn up by the certification body referred to in Article 12 of Regulation (EU) 2021/2116, and shall follow-up on any deficiencies identified.

Every 3 years, the competent authority shall report in writing to the Commission on its supervision of paying agencies and monitoring of their activities. The report shall include a review of the paying agencies' continuous compliance with the accreditation criteria, together with a summary of the actions taken to remedy the deficiencies. The competent authority shall confirm whether a paying agency for which it is responsible continues to comply with the accreditation criteria.

2. Member States shall establish a system that ensures that any information suggesting that a paying agency does not comply with the accreditation criteria is communicated to the competent authority without delay.

3. Where the competent authority has determined that an accredited paying agency no longer respects one or more of the accreditation criteria in a manner that is liable to hinder the fulfilment of the tasks set out in Article 1(1) of Delegated Regulation (EU) 2022/127, the competent authority shall put the paying agency's accreditation under probation without delay. It shall draw up a plan including actions and deadlines to remedy the deficiencies found within a period to be determined according to the severity of the problem, which shall not exceed 12 months from the date on which the accreditation is put under probation. In duly justified cases, the Commission may, upon request of the Member State concerned, grant an extension of that period.

4. The competent authority shall inform the Commission of its decision to place a paying agency's accreditation under probation, of the plan drawn up pursuant to paragraph 3 and, subsequently, of the progress in the implementation of such plans.

5. If the accreditation is withdrawn, the competent authority shall without delay accredit another paying agency which fulfils the conditions laid down in Article 9(2) of Regulation (EU) 2021/2116 to ensure that payments to beneficiaries are not interrupted.

6. Where the Commission finds that the competent authority has not complied with its obligation to draw up a remedial plan pursuant to paragraph 3 or that the paying agency continues to be accredited without having fully implemented such a plan within the determined period, it shall request the competent authority to withdraw the accreditation of that paying agency unless the necessary changes are made within a period to be determined by the Commission according to the severity of the problem. In such a situation, the Commission may decide to pursue the deficiencies through the conformity procedure in accordance with Article 55 of Regulation (EU) 2021/2116.

Article 3

Procedure for issuing, reviewing and withdrawing the accreditation of the coordinating body

1. Member States shall designate an authority at ministerial level responsible for the issuing, reviewing and withdrawing of the accreditation of the coordinating body referred to in Article 10 of Regulation (EU) 2021/2116 (hereinafter “the competent authority”).

2. The competent authority shall, by way of a formal act, designate and decide on the issuing or, after review, the withdrawal of the accreditation of the coordinating body on the basis of an examination of the accreditation criteria referred to in Article 2 of Delegated Regulation (EU) 2022/127. This examination on the compliance with the accreditation criteria shall be carried out by the competent authority and it may rely on an examination performed by an audit body. The competent authority shall inform the Commission of issuing and withdrawing the accreditation of the coordinating body without delay.

3. The coordinating body referred to in Article 10 of Regulation (EU) 2021/2116 shall act as the Commission's sole interlocutor for the Member State concerned for all questions relating to the Funds as regards its tasks.

4. A paying agency may act as a coordinating body provided that the two functions are kept separate.

5. In performing its tasks, the coordinating body may, in accordance with national procedures, call on other administrative bodies or departments, particularly on those with accounting or technical expertise.

6. The confidentiality, integrity and availability of all computer data held by the coordinating body shall be ensured by measures adapted to the administrative structure, staffing and technological environment of each coordinating body. The financial and technological effort shall be proportionate to the actual risks incurred.

7. The communication of information provided for in Article 90, first subparagraph, point (a), of Regulation (EU) 2021/2116 shall be made immediately after the coordinating body is first accredited and, in any case, before any expenditure for which it is responsible is charged to the Funds. That information shall be accompanied by declarations and documents concerning:

- (a) the responsibilities vested in the coordinating body;
- (b) the allocation of responsibilities within the coordinating body;
- (c) the relationship of the coordinating body with other bodies, public or private, which are responsible to collaborate with it on the performance of its tasks;
- (d) the procedures and systems in place to ensure the performance of its tasks;

- (e) the provisions concerning the security of information systems;
- (f) the result of the examination on the compliance with the accreditation criteria referred to in paragraph 2.

8. Where the competent authority considers that the coordinating body does not comply with the accreditation criteria, it shall inform the coordinating body of the requirements to be complied with.

Pending the implementation of any necessary changes in order to meet the accreditation criteria, accreditation may be:

- (a) issued provisionally for a new coordinating body;
- (b) put under probation for an existing coordinating body provided that an action plan is followed to remedy the situation.

The accreditation shall be withdrawn if the accreditation criteria have not been fulfilled and the competent authority considers that the coordinating body cannot fulfil its tasks.

Article 4

Management declarations

1. The management declarations referred to in Article 9(3), first subparagraph, point (d), and Article 10(3) of Regulation (EU) 2021/2116 shall be drawn up in due time for the certification body to issue the opinion referred to in Article 12(1) of that Regulation.

The management declarations shall be in the forms set out in Annexes I and II respectively to this Regulation and may be qualified by reservations quantifying the potential financial impact. In the event that reservations are expressed, the declaration shall include a remedial action plan and a precise a time frame for its implementation.

2. The management declarations shall be based on an effective supervision of the management and control system in place throughout the year.

Article 5

Certification

1. The competent authority shall designate the certification body provided for in Article 12 of Regulation (EU) 2021/2116.

Where there is more than one certification body in a Member State, that Member State may designate a public certification body at the national level to be responsible for coordination.

2. The certification body shall organise its work in an effective and efficient manner, and carry out its checks within an appropriate time frame, taking into account the nature and the timing of the transactions for the financial year concerned.

3. The opinion to be provided by the certification body in accordance with Article 12(1) of Regulation (EU) 2021/2116 shall be drawn up annually.

That opinion shall be based on the audit work to be carried out in accordance with Articles 6 and 7 of this Regulation.

4. The certification body shall draw up a report of its findings. The report shall also cover the delegated functions of the paying agency in accordance with Section 1.(D) of Annex I to Delegated Regulation (EU) 2022/127. The report shall state whether, for the period covered by the report:

- (a) the paying agency complied with the accreditation criteria;
- (b) the paying agency's procedures were such as to give reasonable assurance that the expenditure charged to the Funds was effected in compliance with Union rules, thus ensuring that:

- (i) as regards the types of intervention referred to in Regulation (EU) 2021/2115, the expenditure has corresponding reported output and that it has been effected in accordance with the applicable governance systems, and that recommendations for improvements, if any, have been followed up;
- (ii) the underlying transactions were legal and regular, as regards the measures laid down in Regulations (EU) No 228/2013, (EU) No 229/2013, (EU) No 1308/2013 and Regulation (EU) No 1144/2014 of the European Parliament and of the Council ⁽¹³⁾, as well as for the crop-specific payment for cotton and support for early retirement under Title III, Chapter II, Section 3, Subsection 2, and Article 155(2), respectively, of Regulation (EU) 2021/2115, and that recommendations for improvements, if any, have been followed up;
- (c) the performance reporting on output indicators for the purpose of the annual performance clearance referred to in Article 54 of Regulation (EU) 2021/2116 and the performance reporting on result indicators for the multiannual performance monitoring referred to in Article 134 of Regulation (EU) 2021/2115, demonstrating that Article 37 of Regulation (EU) 2021/2116 is complied with, was correct;
- (d) the annual accounts referred to in Article 33 of this Regulation were kept in accordance with the books and records of the paying agency;
- (e) the statements of expenditure and of public intervention operations were a materially true, complete and accurate record of the operations charged to the Funds;
- (f) the financial interests of the Union were properly protected as regards advances paid, guarantees obtained, intervention stocks and amounts to be collected.

The report shall include information on the number and qualifications of staff conducting the audit, the work done, the systems examined, the level of materiality and confidence obtained where applicable, any weaknesses found and recommendations made for improvement and the operations of both the certification body and other audit bodies, internal and external to the paying agency, from which all or part of the certification body's assurance on the matters reported was gained.

Article 6

Audit principles

1. The certification audit shall be carried out in accordance with internationally accepted auditing standards.
2. The certification body shall prepare an audit strategy that sets the scope, timing and direction of the certification audit, the audit methods and the sampling methodology, while distinguishing types of intervention referred to in Regulation (EU) 2021/2115 from measures laid down in Regulations (EU) No 228/2013, (EU) No 229/2013, (EU) No 1308/2013 and (EU) No 1144/2014. An audit plan shall be developed in respect of each financial year audited based on the estimated audit risk. Upon request, the certification body shall provide the Commission with the audit strategy and the audit plan.
3. The reasonable level of audit assurance to be achieved from auditing shall be obtained as to the proper functioning of the governance systems, the correctness of the performance reporting, the true and fair view of the annual accounts and the legality and regularity of the underlying transactions as regards the measures laid down in Regulations (EU) No 228/2013, (EU) No 229/2013, (EU) No 1308/2013 and (EU) No 1144/2014, as well as for the crop-specific payment for cotton and support for early retirement under Title III, Chapter II, Section 3, Subsection 2, and Article 155(2), respectively, of Regulation (EU) 2021/2115, for which reimbursement has been requested from the Commission.

⁽¹³⁾ Regulation (EU) No 1144/2014 of the European Parliament and of the Council of 22 October 2014 on information provision and promotion measures concerning agricultural products implemented in the internal market and in third countries and repealing Council Regulation (EC) No 3/2008 (OJ L 317, 4.11.2014, p. 56).

This shall be done through system audit and compliance testing as regards the functioning of governance system, completeness and accuracy testing and analytical procedures for the performance reporting system.

As regards the audit of annual accounts substantive testing of expenditure shall be applied, including test of details. As regards the audit of the legality and regularity of the underlying transactions as referred to in the first subparagraph, the testing shall include verification on-the-spot.

4. The Commission shall establish guidelines, which contain, in particular:
 - (a) further clarification and guidance in respect of the certification audit to be performed;
 - (b) the determination of the reasonable level of audit assurance to be achieved from auditing.

Article 7

Audit methods

1. The audit methods relevant to the certification audit shall be defined in the audit strategy provided for in Article 6(2).
 2. To achieve the audit objectives and to issue the opinion as laid down in Article 12(2) of Regulation (EU) 2021/2116, the audit steps shall include systems audits, substantive testing, where necessary, and the verification of reconciliations on financial and management declarations.
 3. As regards the auditing of governance systems, the certification body shall perform systems audits that may include compliance testing and also testing of IT general controls and application controls, for the purpose of verification of the system design and implementation.
 4. Substantive testing of expenditure shall cover the verification of legality and regularity of the underlying transactions at the level of the final beneficiaries as regards the measures laid down in Regulations (EU) No 228/2013, (EU) No 229/2013, (EU) No 1308/2013 and (EU) No 1144/2014 as well as for the crop-specific payment for cotton and support for early retirement under Title III, Chapter II, Section 3, Subsection 2, and Article 155(2), respectively, of Regulation (EU) 2021/2115. For those purposes, the certification body may accompany the paying agency when it carries out secondary level on-the-spot checks. The certification body may not accompany the paying agency when it carries out initial on-the-spot checks, with the exception of those situations, where it would be physically impossible to re-verify the initial check carried out by the paying agency.
 5. As regards auditing of the performance reporting system, the certification body shall apply testing of records, databases to verify if reported performance output and result indicators are correctly reported and match the expenditure financed by the Union or objectives of intervention, respectively. Justifications provided for the differences between the annual expenditure declared for an intervention and the amount corresponding to the relevant reported output indicator in accordance with Article 54(2) of Regulation (EU) 2021/2116 shall be verified and confirmed by the certification body. The certification body's work shall also include the verification of the calculation of the indicators.
 6. The certification body may rely on the audit results of the external auditors of the bodies implementing financial instruments for the purpose of the overall assurance and on this basis, the certification body may decide to limit its own audit work.
- In the context of guarantee funds, the certification body may conduct audits of the bodies providing new underlying loans only when either one or both of the following situations occur:
- (a) supporting documents, providing evidence of the support from the financial instrument to final recipients, are not available at the level of the managing authority or at the level of the bodies implementing the financial instrument;
 - (b) there is evidence that the documents available at the level of the managing authority or at the level of the bodies implementing the financial instrument do not represent a true and accurate record of the support provided.

The Member State shall define the arrangements to ensure the audit trail for financial instruments in accordance with the template set out in Annex III, demonstrating the fulfilment of conditions or achievement of results.

7. The European Investment Bank (EIB), or other international financial institutions in which a Member State is a shareholder implementing financial instruments, shall by the end of each calendar year provide the Member States with the annual audit report referred to in the third subparagraph of Article 12(2) of Regulation (EU) 2021/2116 prepared by their external auditors covering the elements included in Annex IV to this Regulation.

8. The Commission shall provide further conditions and guidance on designing the audit procedures, sampling integration, planning and carrying out the on-the-spot re-verification of transactions, where necessary, through the guidelines as referred to in Article 6(4).

CHAPTER II

Financial management of the Funds

Section 1

General provisions

Article 8

Paying agencies' accounts

1. Each paying agency shall keep a set of accounts covering only the expenditure and revenue referred to in Article 5(1) and Articles 6 and 45 of Regulation (EU) 2021/2116 and the use of the funds made available to it to defray the corresponding expenditure. Those accounts shall enable the financial data for the Funds to be distinguished and provided separately.

Member States shall make available for the Commission the information of the expenditure effected and assigned revenue received on its request.

2. The paying agencies of the Member States which have not adopted the euro shall keep accounts covering the amounts expressed in the currency in which the expenditure was incurred and the revenue received. However, to enable all their expenditure and revenue to be consolidated, they must be able to provide the corresponding data in national currency and in euro.

3. As regards the EAFRD, each paying agency shall keep accounts enabling all the operations for each plan and each intervention to be identified. Such accounts shall include in particular:

- (a) the amount of public expenditure and the amount of the Union contribution paid for each operation;
- (b) the amounts to be recovered from beneficiaries for irregularities or negligence found;
- (c) the amounts recovered, with an indication of the original operation.

Section 2

EAGF accounts

Article 9

Establishment of the declaration of expenditure

1. The amount of the payment to be granted to a beneficiary under the EAGF shall be determined by the Member States in the framework of the control systems as referred to in Title IV of Regulation (EU) 2021/2116.
2. The expenditure effected and to be declared to the EAGF shall take account of penalties applied in the framework of Member States' control systems in case of non-compliances.
3. The amount resulting from the application of paragraph 2 shall serve for types of intervention in the form of direct payments referred to in Article 16 of Regulation (EU) 2021/2115 and the programmes for the outermost regions of the Union and the smaller Aegean islands as laid down in Regulation (EU) No 228/2013 and Regulation (EU) No 229/2013, respectively, as a basis for the reduction of payments referred to in Article 17 of Regulation (EU) 2021/2115 and for the application of financial discipline referred to in Article 17 of Regulation (EU) 2021/2116.
4. The amount resulting from the application of paragraph 2 and in the specific case of direct payments and the programmes referred to in paragraph 3, the amount resulting from the application of paragraphs 2 and 3 shall constitute the amount to be declared to the Commission.
5. The expenditure declared to the EAGF shall serve as a basis for the verification of the financial ceilings set by Union law.
6. The amount resulting from the application of paragraphs 2 and 3 shall serve as a basis for the calculation of administrative penalties in relation to conditionality as referred to in Title IV, Chapters IV and V, of Regulation (EU) 2021/2116.
7. By way of derogation from paragraph 3, Member States may pay advances for direct payments without applying the adjustment rate for financial discipline referred to in Article 17 of Regulation (EU) 2021/2116 to beneficiaries in respect of the aid applications for a given year. The balance payment to be granted to beneficiaries as from 1 December shall take into account the adjustment rate for financial discipline applicable at that time for the total amount of direct payments in the corresponding calendar year.

Article 10

Communication of information by Member States

1. In accordance with Article 90(1), point (c)(i) and (ii), of Regulation (EU) 2021/2116, Member States shall send to the Commission, electronically and by the seventh day of each month at the latest, the information and documents on expenditure and assigned revenue referred to in Articles 11 and 12 of this Regulation, and in particular the declaration of expenditure drawn up in accordance with paragraph 2 of this Article.

However, the communication on expenditure effected and assigned revenue received between 1 and 15 October shall be sent by 25 October at the latest.

All relevant information shall be provided on the basis of the model made available by the Commission to Member States through information systems.

2. The declaration of expenditure referred to in paragraph 1 shall consist of at least:
 - (a) a statement, drawn up by each paying agency, broken down according to the nomenclature of the Union budget and by expenditure and assigned revenue, based on a detailed nomenclature made available within the information systems to the Member States covering:
 - (i) the expenditure effected and assigned revenue received during the preceding month;

- (ii) total expenditure effected and assigned revenue received from the beginning of the financial year until the end of the preceding month;
- (iii) estimates of expenditure and assigned revenue covering separately the next three months and, as appropriate, the total of estimates of expenditure and assigned revenue to the end of the financial year.

Where the estimates for the next three months, as referred to in the first subparagraph, point (iii), fall in the next financial year, only the total per month needs to be provided;

- (b) the accounts evidencing expenditure and revenue relating to public intervention.

3. All the financial information required under this Article shall be communicated in euro.

Article 11

General rules on the declaration of expenditure and on assigned revenue

1. Without prejudice to the special provisions on declarations of expenditure and revenue relating to public storage referred to in Article 12, expenditure and assigned revenue declared by paying agencies in respect of a given month shall correspond to payments and receipts actually effected during that month.

That expenditure and assigned revenue shall be entered in the accounts of the EAGF budget in respect of the corresponding financial year.

However:

- (a) expenditure which may be paid prior to the implementation of the provision permitting it to be wholly or partially borne by the EAGF may be declared only:

- (i) in respect of the month during which the provision in question was implemented; or
- (ii) in respect of the month following implementation of that provision;

- (b) revenue assigned to the EAGF shall be declared in respect of the month during which the time limit for payment of the corresponding amounts, laid down in Union legislation, expires. Where corrections to assigned revenue lead, at paying agency level, to the declaration of negative revenue assigned for a budget line, surplus corrections shall be carried over to the following month.

2. Expenditure and assigned revenue shall be taken into consideration on the date on which the account of the paying agency was debited or credited. However, for payments, the date to be taken into consideration may be the date on which the agency concerned issued the payment document and sent it to a financial institution or to the beneficiary. Each paying agency shall use the same method throughout the financial year.

3. Payment orders which are not executed and payments debited to the account, then re-credited, shall be shown in the accounts as deductions from expenditure in respect of the month during which the failure to execute or the cancellation is reported to the paying agency.

4. Where payments due under the EAGF are encumbered by claims, they shall be deemed to have been effected in their entirety for the purpose of applying paragraph 1:

- (a) on the date of the payment of the sum due to the beneficiary, if the claim is less than the expenditure settled;
- (b) on the date of set-off, if the expenditure is less than or equal to the claim.

*Article 12***Special rules on declarations of expenditure relating to public storage**

1. The operations to be taken into consideration for drawing up declarations of expenditure relating to public storage shall be those entered at the end of a given month in the accounts of the paying agency, which have taken place from the beginning of the accounting year within the meaning of Article 3(3), first subparagraph, point (a) of Delegated Regulation (EU) 2022/127 up to the end of that month.
2. Such declarations of expenditure shall comprise the values and amounts determined in accordance with Articles 17 and 18 of this Regulation and Article 4 of Commission Delegated Regulation (EU) No 906/2014 ⁽¹⁴⁾ entered in the accounts by paying agencies during the month following that to which the operations relate.

However:

- (a) in the case of operations carried out in the course of September, the values and amounts shall be entered in the accounts by paying agencies by 15 October at the latest;
- (b) in the case of the overall depreciation amounts referred to in Article 3(1), point (e), of Delegated Regulation (EU) No 906/2014, the amounts shall be entered in the accounts on the date laid down in the decision providing for them.

*Article 13***Payment decision by the Commission**

1. On the basis of the data sent in accordance with Article 10(1) of this Regulation, the Commission shall decide to make the monthly payments pursuant to Article 21(3) of Regulation (EU) 2021/2116, without prejudice to the corrections which may be made by means of subsequent decisions in accordance with Articles 53, 54 and 55 of that Regulation, and taking into account the reductions and suspensions decided in accordance with Articles 39 to 42 of that Regulation.
2. If the total expenditure declared by Member States for the following financial year exceeds three quarters of the EAGF total appropriations for the current financial year, the advance commitments referred to in Article 11(2), point (b), of Regulation (EU, Euratom) 2018/1046 and the corresponding monthly payments shall be granted in proportion to the declarations of expenditure, up to a maximum of 75 % of the appropriations for the current financial year. The Commission shall take the balance of amounts not reimbursed to Member States into account in decisions on subsequent reimbursements.

*Article 14***Making resources available to Member States**

By deciding to make the monthly payments, the Commission shall place at the disposal of the Member States, within the framework of the budget appropriations, the resources needed to cover expenditure to be financed by the EAGF, less the corresponding amount of assigned revenue, in the account opened by each Member State.

When the amount established by the Commission for the application of Article 13(1) is negative for a Member State in total or for a given budget line, the effective offsetting may be deferred to the following months.

*Article 15***Communication under public intervention**

1. Paying agencies shall transmit to the Commission:

⁽¹⁴⁾ Commission Delegated Regulation (EU) No 906/2014 of 11 March 2014 supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to public intervention expenditure (OJ L 255, 28.8.2014, p. 1).

- (a) at the Commission's request, the documents and information referred to in Article 3(7) of Delegated Regulation (EU) 2022/127 and the additional national administrative provisions adopted for the application and management of intervention measures;
 - (b) by the day provided for in Article 10(1), of this Regulation, the information on public storage, on the basis of the models made available by the Commission to Member States through information systems.
2. The relevant information systems referred to in Article 25 shall be used to perform the notifications and information exchanges and to draw up the documents relating to public intervention expenditure.

Article 16

Content of the public storage accounts to be kept by paying agencies

1. The stock accounts provided for in Article 3(3), first subparagraph, point (a), of Delegated Regulation (EU) 2022/127 shall contain the following categories of elements, shown separately:
- (a) the quantities of products recorded on entry into and removal from storage, with or without physical movement;
 - (b) the quantities used for free distribution to the most deprived persons under the Fund for European Aid to the Most Deprived, and accounted for under Article 4(3) of Delegated Regulation (EU) No 906/2014, distinguishing those which are the subject of a transfer to another Member State;
 - (c) quantities taken as samples, distinguishing samples taken by purchasers;
 - (d) the quantities which, after checking by visual examination in the context of the annual stock-taking or during the inspection after taking into intervention, may no longer be repackaged and are the subject of direct sales;
 - (e) quantities missing, for identifiable or unidentifiable reasons, including those corresponding to the legal tolerance limits;
 - (f) quantities which have deteriorated;
 - (g) surplus quantities;
 - (h) missing quantities exceeding the tolerance limits;
 - (i) quantities which have entered into storage and been found not to meet the requirements and for which taking-over has therefore been refused;
 - (j) net quantities in storage at the end of each month or accounting year, which are carried forward to the next month or accounting year.
2. The financial accounts provided for in Article 3(3), first subparagraph, point (a), of Delegated Regulation (EU) 2022/127 shall contain:
- (a) the value of the quantities referred to in paragraph 1, point (a), of this Article, showing separately the value of the quantities bought in and of the quantities sold;
 - (b) the book value of the quantities used or taken into account under the free distribution arrangements referred to in paragraph 1, point (b), of this Article;
 - (c) the financing costs referred to in Article 3(1), point (a), of Delegated Regulation (EU) No 906/2014;
 - (d) expenditure on physical operations as referred to in Article 3(1), points (b) and (c), of Delegated Regulation (EU) No 906/2014;
 - (e) amounts resulting from depreciation as referred to in Article 3(1), point (e), of Delegated Regulation (EU) No 906/2014;
 - (f) the amounts collected or recovered from sellers, purchasers and storers, other than those referred to in Article 21 of this Regulation;

- (g) the amount from direct sales carried out after the annual stock-taking or following checks after products are taken into intervention storage;
- (h) losses and gains on removals of products, taking account of depreciation as referred to in point (e) of this paragraph;
- (i) other debits and credits, in particular those corresponding to the quantities referred to in paragraph 1, points (c) to (g), of this Article;
- (j) the average book value, expressed per tonne.

Article 17

Accounting related to public intervention

1. The elements referred to in Article 16 shall be booked for the quantities, values, amounts and averages actually recorded by paying agencies or for the values and amounts calculated on the basis of the standard amounts established by the Commission.
2. The records and calculations referred to in paragraph 1 shall be made subject to the application of the following rules:
 - (a) the removal costs relating to quantities for which quantitative losses or deterioration have been recorded, in accordance with the rules laid down in Annexes VI and VII to Delegated Regulation (EU) No 906/2014, shall be entered in the accounts only for the quantities actually sold and removed from storage;
 - (b) quantities recorded as missing on transfer between Member States shall not be deemed to have entered storage in the Member State of destination and shall not be covered by standard entry costs;
 - (c) the standard entry and removal costs fixed for transport and transfer shall be entered in the accounts if those costs are not considered, under the Union rules, to be an integral part of the transport costs;
 - (d) unless specific Union rules provide otherwise, amounts accruing from sales of products which have deteriorated and any other amounts received in this context shall not be entered in the EAGF account records;
 - (e) any surplus quantities recorded shall be entered in the accounts as a negative amount, in the missing quantities in the stock situation and movements. Those quantities shall be included when determining the quantities exceeding the tolerance limit;
 - (f) samples other than those taken by purchasers shall be entered in the accounts in accordance with point 2(a) of Annex VII to Delegated Regulation (EU) No 906/2014.
3. Corrections made by the Commission, as regards the elements referred to in Article 16 for the current accounting year, shall be notified to the Committee on the Agricultural Funds. They may be notified to the Member States on the occasion of a monthly payment decision or, failing that, at the time of the decision on the clearance of accounts. They shall be entered in the accounts by paying agencies under the terms of that decision.

Article 18

Dates for entering expenditure and revenue and product movements in the accounts for public intervention

1. The various items of expenditure and revenue shall be entered in the accounts on the date on which the physical operation under the public intervention measure takes place and by using the exchange rate as referred to in Article 3(2) of Delegated Regulation (EU) No 906/2014.

However, the following dates shall apply in the cases set out below:

- (a) the date of receipt, in the case of amounts received or recovered, as referred to in Article 16(2), points (f) and (g), of this Regulation;
- (b) the date of actual payment of costs relating to physical operations, where such costs are not covered by standard amounts.

2. The various elements relating to the physical movement of products and the management of stocks shall be entered in the accounts on the date on which the physical operation under the intervention measure takes place.

However, the following dates shall apply in the cases set out below:

- (a) the date of taking-over of products by the paying agency, in accordance with Article 22(2) of Commission Implementing Regulation (EU) 2016/1240 ⁽¹⁵⁾, for quantities entering public storage without any change in the place of storage;
- (b) regarding missing or deteriorated and surplus quantities, the date of the finding as to the facts in the case of missing or deteriorated and surplus quantities;
- (c) the date of actual removal from storage, in the case of direct sales of products remaining in storage which can no longer be repackaged after visual examination in the context of the annual stock-taking or during the inspection after taking into intervention;
- (d) the last day of the accounting year, for any losses exceeding the tolerance limit referred to in Article 4(2) of Delegated Regulation (EU) 2022/127.

Article 19

Amount financed under public intervention

1. The amount to be financed under the intervention measures referred to in Article 2 of Delegated Regulation (EU) No 906/2014 shall be determined on the basis of the accounts drawn up and kept by paying agencies in accordance with Article 3(3), first subparagraph, point (a) of Delegated Regulation (EU) 2022/127, and to which the various items of expenditure and revenue referred to in Article 16 of this Regulation are debited and credited, respectively, taking account where necessary of amounts of expenditure fixed under the sectoral agricultural legislation.

2. Paying agencies or coordinating bodies as appropriate shall transmit to the Commission, each month and each year, by electronic means, on the basis of the models made available by the Commission to Member States through information systems, the information needed for the financing of public storage expenditure and the accounts evidencing expenditure and revenue relating to public storage in the form of tables, by the day provided for in Article 10(1) and by the date provided for in Article 33(2).

Article 20

Declarations of public intervention expenditure and revenue

1. Financing by the EAGF under the intervention measures referred to in Article 2 of Delegated Regulation (EU) No 906/2014 shall be equal to the expenditure, calculated on the basis of the information notified by the paying agency, after deduction of any revenue accruing from the intervention measures, validated by the information system set up by the Commission and included by the paying agency in its declaration of expenditure drawn up in accordance with Article 12 of this Regulation.

2. Sums recovered in accordance with Article 53 of Regulation (EU) 2021/2116 and amounts received or recovered from sellers, purchasers and storers, which meet the criteria laid down in Article 45 of that Regulation shall be declared to the EAGF budget in accordance with Article 10(2), point (a), of this Regulation.

⁽¹⁵⁾ Commission Implementing Regulation (EU) 2016/1240 of 18 May 2016 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to public intervention and aid for private storage (OJ L 206, 30.7.2016, p. 71).

Section 3

EAFRD accounts

Article 21

Forecast of funding requirements

For each CAP Strategic Plan as referred to in Article 118 of Regulation (EU) 2021/2115, and in accordance with Article 90(1), first subparagraph, point (c)(ii), of Regulation (EU) 2021/2116, Member States shall send to the Commission, twice per year, by 31 January and 31 August at the latest, their forecasts of the amounts to be funded by the EAFRD for the financial year. In addition, Member States shall send an updated estimate of their funding requests for the following financial year.

Those forecasts and that updated estimate shall be sent on the basis of the model made available by the Commission to Member States through information systems.

Article 22

Declarations of expenditure

1. Paying agencies shall declare expenditure and recovered amount for each rural development type of intervention and technical assistance under the CAP Strategic Plan as referred to in Article 118 of Regulation (EU) 2021/2115 for each of the reference periods, referred to in paragraph 2 of this Article, on the basis of the model made available by the Commission to Member States through information systems.

For each CAP Strategic Plan, paying agencies shall specify in a declaration of expenditure at least the following:

- (a) the amount of eligible public expenditure, excluding additional national financing as referred to in Article 115(5) of Regulation (EU) 2021/2115, for which the paying agency has actually paid the corresponding EAFRD contribution during each of the reference periods referred to in paragraph 2 of this Article;
- (b) the information on financial instruments as referred to in Article 32(4) and (5) of Regulation (EU) 2021/2116;
- (c) the additional information on advances paid to beneficiaries as referred to in Article 44(3) of Regulation (EU) 2021/2116;
- (d) the amount recovered during the current period as referred to in paragraph 2 of this Article, in respect of the CAP Strategic Plan;
- (e) the amount recovered during the current period as referred to in paragraph 2 of this Article in respect of the EAFRD rural development programmes from 2007 onwards, for which Member States is no more obliged to send interim declaration of expenditure;
- (f) the amounts related to technical assistance.

The expenditure effected and to be declared to the EAFRD shall take account of penalties applied in the framework of Member States' management and control system in case of non-compliance.

2. Once the Commission has approved a CAP Strategic Plan, Member States shall send to the Commission, in accordance with Article 90(1), first subparagraph, point (c)(i), of Regulation (EU) 2021/2116, their declarations of expenditure by the following deadlines:

- (a) by 30 April at the latest in the case of expenditure in the period 1 January to 31 March;
- (b) by 31 July at the latest in the case of expenditure in the period 1 April to 30 June;
- (c) by 10 November at the latest in the case of expenditure in the period 1 July to 15 October;
- (d) by 31 January at the latest in the case of expenditure in the period 16 October to 31 December.

If in a Member State the CAP Strategic Plan is implemented by more than one paying agency, the coordinating body shall ensure that the declarations of expenditure are transmitted on the same day.

However, all expenditure paid by paying agencies to the beneficiaries in accordance with Article 86 of Regulation (EU) 2021/2115 until the end of the last period, as specified in the first subparagraph of this paragraph, prior to the approval of a CAP Strategic Plan as referred to in Article 118 of that Regulation, is made under the Member States' responsibility and shall be declared to the Commission in the first declaration of expenditure following the approval of that plan. Recovered amounts for the corresponding period, as referred to in paragraph 1, second subparagraph, points (d) and (e), of this Article shall also be declared in that declaration. The same rule shall apply *mutatis mutandis* in case of amendment of a CAP Strategic Plan as referred to in Article 119 of Regulation (EU) 2021/2115, except for financing plan adjustments as referred to in Article 23 of this Regulation.

As regards financial instruments set up in accordance with Article 58 of Regulation (EU) 2021/1060 and Article 80 of Regulation (EU) 2021/2115, the expenditure shall be declared in the financial year when the conditions as referred to in Article 32(3) and (4) of Regulation (EU) 2021/2116 are met and it had been effected by the paying agency before the end of the financial year.

All the financial information required under this Article shall be communicated in euro.

Article 23

Calculation of the amount to be paid

1. The Union contribution to be paid in respect of the eligible public expenditure, excluding additional national financing as referred to in Article 115(5) of Regulation (EU) 2021/2115, shall be mentioned in the financing plan in force on the first day of the reference period and calculated as regards the CAP Strategic Plans referred to in Article 118 of that Regulation as follows:

- (a) for each reference period referred to in Article 22(2) of this Regulation on the basis of the EAFRD contribution rate as provided for in Article 91 of Regulation (EU) 2021/2115 and approved by the Commission in accordance with Article 118 of that Regulation;
- (b) for certain eligible types of expenditure, referred to in Article 155 of Regulation (EU) 2021/2115 in the period 2023–2027, on the basis of the contribution rate of the intervention set in the CAP Strategic Plan, subject to the conditions in that Article;
- (c) technical assistance on the basis of a flat rate, as referred to in Article 94(2) of Regulation (EU) 2021/2115.

The calculation shall take account of the corrections to the Union contribution as declared in the declaration of expenditure for that period.

2. Without prejudice to the ceiling provided for in Article 30(2) of Regulation (EU) 2021/2116, where the combined total of the Union contribution paid to the CAP Strategic Plan exceeds the contribution to a type of intervention, as regards the EAFRD, the amount to be paid shall be reduced to the amount programmed for that type of intervention. Any Union contribution excluded as a result may be paid later provided that an adjusted financing plan has been submitted by the Member State and approved by the Commission.

Article 24

Automatic decommitment

In case a Member State does not submit a revised financing plan, as provided for in Article 34(6) of Regulation (EU) 2021/2116, and the related amendment of the CAP Strategic Plan by 30 June, the Commission shall reduce the amounts allocated to each type of intervention pro rata, by amending the decision approving the Member State's CAP Strategic Plan no later than 30 September.

Section 4

Common provisions for the Funds

Article 25

Electronic exchange of information and documents

1. The Commission shall define the information systems enabling electronic exchanges of documents and information between it and the Member States for the communications and consultation of information provided for in Article 90 of Regulation (EU) 2021/2116 and the necessary arrangements for their application. It shall inform the Member States of the general conditions for implementing those systems via the Committee on the Agricultural Funds.

2. The information systems referred to in paragraph 1 shall be able to process in particular:

- (a) the data required for financial transactions, in particular those relating to the annual accounts of paying agencies, declarations of expenditure and assigned revenue and the transmission of information and documents referred to in Article 3 of Delegated Regulation (EU) 2022/127 and Articles 8, 10, 11, 12, 14, 18, 19, 21, 22, 23 and 32 of this Regulation;
- (b) documents of common interest enabling the monthly and interim declarations of expenditure and annual accounts to be monitored and the information and documents which paying agencies must make available to the Commission to be consulted;
- (c) the Union texts and Commission guidelines on the financing of the Common Agricultural Policy by authorities accredited and designated under Regulation (EU) 2021/2116, and the guidelines on the harmonised application of the relevant legislation.

3. The form and content of the documents referred to in Articles 10, 18, 19, 21, 22, 23 and 32 shall be made available by the Commission to Member States by way of models through information systems.

Those models shall be adapted and updated by the Commission, after having informed the Committee on the Agricultural Funds.

4. The information systems referred to in paragraph 1 may contain the tools required for storing the data and for managing the accounts of the Funds by the Commission.

5. Data on financial transactions shall be communicated, entered and updated in the information systems referred to in paragraph 1 under the responsibility of paying agencies, by paying agencies themselves or by bodies to which that function has been delegated, where applicable via the coordinating bodies accredited in accordance with Article 9(4) and Article 10 of Regulation (EU) 2021/2116.

6. Where a document sent pursuant to Article 90(1), point (c), (i) and (iii), of Regulation (EU) 2021/2116 or a procedure in the information systems require the signature or the approval of an authorised person at one or more of the stages of that procedure, that compulsory electronic signature or approval shall be done in compliance with Regulation (EU) No 910/2014.

7. The electronic and digitised documents shall be kept for the whole of the period provided for in Article 3(3), first subparagraph, point (a), of Delegated Regulation (EU) 2022/127.

8. Where there is a malfunction in an information system or no stable connection, the Member State may, with the prior approval of the Commission, send the documents in another form, under the conditions laid down by the Commission.

*Article 26***Requirements for the reimbursement of expenditure for the Funds**

1. Declarations of expenditure for the Funds shall be entered in the form of structured data by accredited paying agencies or the accredited coordinating body on the basis of the model made available by the Commission to Member States through information systems.
2. EAGF and EAFRD expenditure and EAGF assigned revenue declared in respect of a period may contain corrections to data declared in respect of the preceding declaration periods of the same financial year.
3. EAGF and EAFRD expenditure and assigned revenue to be charged to the financial year not introduced respectively in the monthly and interim declarations may be corrected only in the annual accounts to be sent to the Commission in accordance with Article 90(1), first subparagraph, point (c)(iii), of Regulation (EU) 2021/2116.
4. The Union contribution shall be paid by the Commission, subject to resource availability, into the account(s) opened by each Member State.
5. Each Member State shall notify the Commission of the name or number of the account(s) in accordance with the format made available to it by the Commission.

*Article 27***Suspension of payments**

The implementing acts determining the monthly payments referred to in Article 21(3) of Regulation (EU) 2021/2116 or the interim payments referred to in Article 32 of that Regulation shall take account of the suspension of payments decided in accordance with Articles 40(1) and (2), 41(2) and 42(2) of that Regulation.

*Article 28***Action plans in relation to the multi-annual performance monitoring**

1. Following the assessment of the justification submitted by the Member State in the context of the performance review referred to in Article 135 of Regulation (EU) 2021/2115, the Commission may ask the Member State concerned to submit an action plan as referred to in Article 41 of Regulation (EU) 2021/2116. The Member State shall submit an action plan within 2 months after receiving the Commission request. In that action plan the Member State shall propose concrete remedial actions to address the shortcomings and identify the interventions, which affect the performance of the CAP Strategic Plan, in particular as regards deviations from milestones set to achieve the specific objectives laid down in Article 6(1) of Regulation (EU) 2021/2115. The remedial actions shall be described in sufficient detail to enable the Commission assessing whether the action plan is appropriate to remedy these shortcomings, including, where relevant, the actions to improve the performance of the concerned interventions.
2. For each of the actions the Member State shall set the planned implementation deadline which shall not be later than 2 years from the time the action plan is launched. In order to enable the review of the expected timeframe for execution of the action plan, Member State shall also set up progress indicators towards that deadline which shall be at least every 3 months throughout the duration of the action plan.
3. Within a period of 2 months after receipt of the action plan from the Member State concerned, the Commission shall, where appropriate, inform that Member State in writing of its objections to the submitted action plan and request its modification. The Member State concerned shall provide further clarifications or submit an updated action plan within 2 months after receiving the Commission comments.

4. Following the period referred to in paragraph 3, the Commission shall inform the Member State in writing within a period of 2 months, whether it considers that the action plan is sufficient to address the shortcomings affecting the performance of the CAP Strategic Plan. In case of a positive assessment, the receipt of that assessment by the Member State shall be considered as the date of launching the implementation of the action plan. The launching date is without prejudice to the possibility for the Member State concerned to start implementing remedial actions earlier. In case of a negative assessment, the Commission shall inform the Member State concerned of its intention concerning the suspension of payments, referred to in Article 41(2) of Regulation (EU) 2021/2116.

5. Member States shall prepare the action plans and report on the progress in their implementation in line with the respective template provided by the Commission at the moment of the submission of the annual performance report, in accordance with Article 9(3), first subparagraph, point (b), of Regulation (EU) 2021/2116. The template shall be available and used in electronic form.

Article 29

Action plans in relation to deficiencies in the governance systems

1. Member State shall submit the action plan referred to in Article 42 of Regulation (EU) 2021/2116 within 2 months after receiving the Commission request. In its action plan, the Member State concerned shall propose concrete actions to address each of the serious deficiencies indicated by the Commission. The corrective actions shall be adequately described so as to enable the Commission to assess whether the action plan is sufficient to remedy the deficiencies.

2. For each of the actions Member State shall set the planned implementation deadline which shall not be later than 2 years from the date of the launching of the action plan. In order to enable the review of progress indicators, Member State shall also set milestones towards that deadline which shall be at least every 3 months throughout the duration of the action plan.

3. Within 2 months after receipt of the action plan from the Member State concerned, the Commission shall, where appropriate, inform that Member State in writing of its objections to the submitted action plan and request its modification. The Member State concerned shall provide further clarifications or submit an updated action plan within 2 months after receiving the Commission comments. In duly justified cases, this period may be extended.

4. Following the exchanges referred to in paragraph 3, and not later than 2 months after receiving the latest communication from the Member State, the Commission shall inform the Member State in writing of its assessment. In case of a positive assessment, the receipt of that assessment by the Member State shall be considered as the date of launching the implementation of the action plan. The launching date is without prejudice to the possibility for the Member State concerned to start implementing remedial actions earlier. In case of a negative assessment due to a manifestly insufficient action plan, the Commission shall inform the Member State concerned of its intention concerning the suspension of payments, referred to in Article 42(2) of Regulation (EU) 2021/2116.

5. Where there is insufficient progress in the implementation of the action plan or it has not been submitted in accordance with the written request of the Commission, the Commission shall inform the Member State concerned of its intention concerning the suspension of payments, referred to in Article 42(2) of Regulation (EU) 2021/2116.

6. For recurrent serious deficiencies revealed in the quality assessment reports referred to in Articles 68(3), 69(6) and 70(2) of Regulation (EU) 2021/2116, the Commission shall request an action plan in accordance with Article 42 (1) of that Regulation, if the same deficiencies are detected without any improvement in the second consecutive year.

7. Member States shall prepare the action plans and report on the progress in their implementation in accordance with the respective template provided by the Commission. The template shall be available and used in electronic form.

*CHAPTER III****Clearance of accounts***

Section 1

Recovery of debts*Article 30***Recovery of undue payments**

1. For any undue payment following the occurrence of irregularity or negligence, Member States shall set up a system ensuring a recovery request from the beneficiaries within a reasonable time frame after where applicable, the paying agency or body responsible for the recovery received a control report or similar document, stating that an irregularity has taken place. The system shall ensure that the corresponding amounts are recorded at the time of the recovery request in the debtors' ledger of the paying agency.
2. The Member States shall have a system in place to ensure that the recovery procedures, including calculation of interest in accordance with the applicable national laws, regulations and administrative provisions referred to in Article 59(1) of Regulation (EU) 2021/2116, off-setting and enforcement of unduly paid amounts, are launched and followed up in a timely manner. The follow up of a debt according to the applicable national recovery procedure shall be ensured and the recovered amounts shall be reimbursed to the Funds in due time.
3. The correction of a debt towards the Funds shall only take place if the absence of any irregularity is recorded by an administrative or legal instrument of a final nature.
4. The Member States shall properly justify the write-off of a debt and the decision not to pursue the recovery of a debt in accordance with the applicable national rules.

*Article 31***Recovery by offsetting**

Without prejudice to any other enforcement action provided for by national law, Member States shall offset any undue amount arising from a pending irregularity of a beneficiary established in accordance with national law against any future payments in favour of that beneficiary, to be made by the paying agency responsible for the recovery of the debt.

Section 2

Clearance*Article 32***Content of the annual accounts**

1. The annual accounts referred to in Article 90(1), first subparagraph, point (c)(iii), of Regulation (EU) 2021/2116 shall include:
 - (a) the assigned revenue referred to in Article 45 of that Regulation;
 - (b) the expenditure of the EAGF after deduction of any undue payments not recovered at the end of the financial year other than those referred to in point (f) of this paragraph, including any interests thereon, summarised by item and sub-item of the Union budget;

- (c) the expenditure of the EAFRD, by programme, measure or type of intervention as applicable and specific contribution rate. The annual statement of expenditure shall also include information on the amounts recovered. Once a programme or CAP Strategic Plan is closed, any undue payments not recovered other than those referred to in point (f) of this paragraph, including any interests thereon, shall be deducted from the expenditure of the financial year in question;
- (d) a table of differences by item and sub-item or, in the case of the EAFRD by programme, measure or by type of intervention as applicable and by specific contribution rate and focus area where applicable, between the expenditure and the assigned revenue declared in the annual accounts and that declared for the same period in the documents referred to in Article 10(2) of this Regulation, as far as the EAGF is concerned, and Article 22(2) of this Regulation, as far as the EAFRD is concerned, accompanied by an explanation for every difference;
- (e) separately, the amounts to be borne by, respectively, the Member State concerned and the Union in accordance with Article 54(2), first subparagraph, and (3) of Regulation (EU) No 1306/2013 of the European Parliament and of the Council ⁽¹⁶⁾ in relation to:
 - (i) expenditure incurred and payments made for support schemes under Regulation (EU) No 1307/2013 of the European Parliament and of the Council ⁽¹⁷⁾ in respect of calendar year 2022 and before;
 - (ii) measures laid down in Regulations (EU) No 228/2013, (EU) No 229/2013, (EU) No 1308/2013 and (EU) No 1144/2014 until 31 December 2022;
 - (iii) aid for operational programmes of recognised producer organisations or their associations in the fruit and vegetables sector and support programmes in the wine sector as referred to in Article 5(6) and (7), respectively, of Regulation (EU) 2021/2117 of the European Parliament and of the Council ⁽¹⁸⁾ in relation to expenditure incurred and payments made for operations implemented pursuant to Regulation (EU) No 1308/2013 after 31 December 2022 until the end of the operational programmes or the support programmes in accordance with Article 5(6)(c) and (7), respectively, of Regulation (EU) 2021/2117;
 - (iv) revenue declared in the framework of the implementation of rural development programmes approved by the Commission pursuant to Regulation (EU) No 1305/2013, Council Regulation (EC) No 1698/2005 ⁽¹⁹⁾ and Commission Regulation (EC) No 27/2004 ⁽²⁰⁾;
- (f) an extract of the undue payments yet to be recovered at the end of the financial year as a consequence of irregularities within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95 ⁽²¹⁾, including any penalties provided for by the applicable sectoral Union rules and the interest thereon, to be presented in a table in accordance with the model set out in Annex V to this Regulation. For expenditure referred to point (e) of this paragraph, an extract of the undue payments shall be presented in a table in accordance with the model set out in Annex II to Implementing Regulation (EU) No 908/2014;

⁽¹⁶⁾ Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

⁽¹⁷⁾ Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

⁽¹⁸⁾ Regulation (EU) 2021/2117 of the European Parliament and of the Council of 2 December amending Regulations (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products, (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs, (EU) No 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union (OJ L 435, 6.12.2021, p. 262).

⁽¹⁹⁾ Council Regulation (EC) No 1698/2005 of 20 September 2005 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) (OJ L 277, 21.10.2005, p. 1).

⁽²⁰⁾ Commission Regulation (EC) No 27/2004 of 5 January 2004 laying down transitional detailed rules for the application of Council Regulation (EC) No 1257/1999 as regards the financing by the EAGGF Guarantee Section of rural development measures in the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia (OJ L 5, 9.1.2004, p. 36).

⁽²¹⁾ Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

- (g) an extract from the debtors ledger of the amounts to be recovered and credited to either the EAGF or the EAFRD other than those referred to in point (b), (c), (e) and (f) of this paragraph, including any penalties and interest thereon, to be presented in a table in accordance with the model set out in Annex III to Implementing Regulation (EU) No 908/2014 in respect of expenditure referred to in point (e) of this paragraph;
- (h) a summary of intervention operations and a statement of the quantity and location of stocks at the end of the financial year;
- (i) confirmation that expenditure, assigned revenue and the details of each movement of intervention storage is held on the paying agency's files and accounting records;
- (j) the closing balance at the end of the financial year of unused/un-cleared cumulated advances paid by Member States to beneficiaries, detailed for the EAGF by intervention and for the EAFRD by programme, or by type of intervention as applicable and for the latter, including the financial instruments. For the financial instruments, the closing balance concerns amounts paid as advances by the Commission in accordance with Article 32(4) point (a), of Regulation (EU) 2021/2116 that have neither been used by Member States for payments to or for the benefit of final recipients, nor have been committed for guarantee contracts or paid as management fees and costs in accordance with Article 80(5) of Regulation (EU) 2021/2115.

2. The annual accounts shall be the basis for the Annual Performance Report to be submitted pursuant to Article 134 of Regulation (EU) 2021/2115.

Article 33

Transmission of information

1. For the purpose of the clearance of accounts pursuant to Articles 53 and 54 of Regulation (EU) 2021/2116, each Member State shall send to the Commission:

- (a) the items included in the annual accounts, as referred to in Article 32 of this Regulation;
- (b) the annual performance report referred to in Article 54(1) of Regulation (EU) 2021/2116 and Article 134 of Regulation (EU) 2021/2115;
- (c) the opinion and reports established by the certification body or bodies, as referred to in Article 5(3) and (4) of this Regulation;
- (d) the management declarations referred to in Article 3 of this Regulation;
- (e) an annual summary of the final audit reports and of controls carried out, including an analysis of the nature and extent of errors and weaknesses identified in systems, as well as corrective action taken or planned, as provided for in Article 63(5), point (b), of Regulation (EU, Euratom) 2018/1046 and Article 9(3), first subparagraph, point (c), of Regulation (EU) 2021/2116, submitted with the Paying Agency management declaration referred to in Article 3 of this Regulation.

Upon request by the Commission, the Member State shall provide the complete records of all the accounting information required for statistical and control purposes, related to expenditure as regards the measures laid down in Regulations (EU) No 228/2013, (EU) No 229/2013, (EU) No 1308/2013 and (EU) No 1144/2014. The form and content of the accounting information shall be specified by the Commission.

2. The documents referred to in paragraph 1 shall be sent to the Commission by 15 February at the latest, of the year following the end of the financial year to which they relate. The documents shall be submitted electronically in accordance with the format and under the conditions established by the Commission pursuant to Article 25.

Those documents shall bear a compulsory electronic signature within the meaning of Regulation (EU) No 910/2014.

3. At the request of the Commission or on the initiative of a Member State, further information concerning the clearance of accounts may be addressed to the Commission within a time period determined by the Commission, taking into account the amount of work required for providing that information. In the absence of such information, the Commission may clear the accounts on the basis of the information in its possession.

4. In duly justified cases, the Commission may accept a request for late submission of information, if that request is addressed to it before the submission deadline.

Article 34

Conservation of accounting information

1. The supporting documents regarding the expenditure financed and the assigned revenues to be collected by the EAGF shall be kept at the Commission's disposal for at 3 years following the year in which the Commission clears the accounts of the financial year concerned pursuant to Article 53 of Regulation (EU) 2021/2116.

2. The supporting documents regarding the expenditure financed and the assigned revenues to be collected by the EAFRD shall be kept at the Commission's disposal for at least 3 years following the year in which the final payment by the paying agency has taken place.

3. In the case of irregularities or negligence, the supporting documents referred to in paragraphs 1 and 2 shall be kept at the Commission's disposal for at least 3 years following the year in which the sums are entirely recovered from the beneficiary and credited to the Funds.

4. The supporting documents regarding the outputs corresponding to the expenditure declared under the EAGF pursuant to Regulation (EU) 2021/2115 and under the EAFRD shall be kept at the Commission's disposal for at least 3 years following the year in which the final expenditure under the CAP Strategic Plans pursuant to Regulation (EU) 2021/2115 is declared.

5. In the case of a conformity procedure provided for in Article 55 of Regulation (EU) 2021/2116, the supporting documents referred to in paragraphs 1 and 2 of this Article shall be kept at the Commission's disposal for at least 1 year following the year in which that procedure has been concluded or, if a conformity decision is the subject of legal proceedings before the Court of Justice of the European Union, for at least 1 year following the year in which those proceedings are concluded.

6. The supporting documents referred to in paragraphs 1 to 5 shall be kept at the Commission's disposal either in paper form, in electronic form and/or in both forms.

Documents may only be kept exclusively in electronic form if the national law of the Member State concerned permits the use of electronic documents as evidence of the underlying transactions in national court proceedings.

If the documents are kept in electronic form only, the system for doing so shall comply with Section 3.(B) of Annex I to Delegated Regulation (EU) 2022/127.

Article 35

Financial clearance

1. The Commission's decision on the clearance of accounts referred to in Article 53 of Regulation (EU) 2021/2116 shall determine the amounts of expenditure effected in each Member State during the financial year concerned which shall be recognised as being chargeable to the Funds on the basis of the accounts referred to in Article 32 of this Regulation and any reductions and suspensions pursuant to Articles 39, 40 and 41 of Regulation (EU) 2021/2116.

For the EAFRD, the amount determined by the clearance of accounts decision shall include the funds which are re-usable by reallocation by the Member State concerned pursuant to Article 57 of Regulation (EU) 2021/2116.

2. As regards the EAGF, the amount which, as a result of the clearance of accounts decision, is recoverable from or payable to each Member State shall be established by deducting the monthly payments in respect of the financial year concerned from the expenditure recognised for the same year in accordance with paragraph 1. The Commission shall deduct that amount from or add it to the monthly payment relating to the expenditure effected in the second month following the clearance of accounts decision.

As regards the EAFRD, the amount which, as a result of the clearance of accounts decision, is recoverable from or payable to each Member State shall be established by deducting the intermediate payments in respect of the financial year concerned from the expenditure recognised for the same year in accordance with paragraph 1.

The Commission shall deduct that amount from or add it to the first payment for which the declaration of expenditure is submitted by the Member State after the decision pursuant to Article 53 of Regulation (EU) 2021/2116 has been adopted.

3. The Commission shall communicate to the Member State concerned the results of its verification of the information supplied, together with any amendments it proposes, by 30 April following the end of the financial year at the latest.

4. If, for reasons attributable to the Member State concerned, the Commission is unable to clear the accounts of a Member State before 31 May of the following year, the Commission shall notify that Member State of the additional inquiries it proposes to undertake pursuant to Article 49 of Regulation (EU) 2021/2116.

5. Paragraphs 1 to 4 shall apply, *mutatis mutandis*, to the assigned revenue referred to Article 45 of Regulation (EU) 2021/2116.

Article 36

Performance clearance

1. When determining what amounts are to be reduced from Union financing, when finding that expenditure does not have a corresponding output as reported in the annual performance report referred to in Article 54(1) of Regulation (EU) 2021/2116 and in Article 134 of Regulation (EU) 2021/2115, the Commission shall use its own findings and the findings of the certification body, and shall take into account the information made available by Member States, provided that the latter information is provided within the time limits set by the Commission in the framework of the annual performance clearance procedure carried out in accordance with Article 54 of Regulation (EU) 2021/2116 and in conformity with this Article.

2. When, as a result of the annual clearance documents submitted by the Member State and in the absence of sufficient justifications, the Commission considers that expenditure does not have a corresponding output, it shall communicate its findings to the Member State concerned, specifying the difference found. The communication shall make reference to this Article.

The Member State shall reply within a deadline to be fixed in the communication, which shall not be less than 30 calendar days of receipt of the communication. In its reply, the Member State shall have the opportunity, in particular, to:

- (a) provide comments and justifications as to the differences established;
- (b) demonstrate to the Commission that the actual difference found or the amount not having corresponding outputs is less than what was indicated by the Commission;
- (c) inform the Commission of the corrective measures it has undertaken to ensure correct reporting of outputs or to ensure that expenditure has a corresponding output and the effective date of their implementation.

The communication referred to in the first and second subparagraphs may be made via electronic means.

3. The Commission, after having assessed the Member States' justifications in accordance with paragraph 2 of this Article, shall adopt, where appropriate, a decision under Article 54 of Regulation (EU) 2021/2116 in order to reduce from Union financing expenditure which does not have a corresponding output for the financial year in question.

4. As regards the EAGF, the reductions from the Union financing shall be made by the Commission from the monthly payments relating to the expenditure effected in the second month following the decision pursuant to Article 54 of Regulation (EU) 2021/2116.

5. As regards the EAFRD, the reductions from Union financing shall be made by the Commission from the payment for which the declaration of expenditure is submitted by the Member State after the decision pursuant to Article 54 of Regulation (EU) 2021/2116 has been adopted.

6. Paragraphs 1 to 5 shall apply, *mutatis mutandis*, to the assigned revenue referred to in Article 45 of Regulation (EU) 2021/2116.

Article 37

Conformity procedure

1. In order to determine what amounts are to be excluded from Union financing, when finding that expenditure has not been effected in conformity with Union rules, the Commission shall use its own findings and shall take into account the information made available by Member States, provided that the latter information is provided within the time limits set by the Commission in the framework of the conformity procedure carried out in accordance with Article 55 of Regulation (EU) 2021/2116 and in conformity with this Article. For interventions under the integrated administration and control system, referred to in Article 65 of that Regulation, the Commission shall also take into account the assessment reports on the quality of the identification system for agricultural parcels, of the geo-spatial application and of the area monitoring system.

2. When, as a result of any inquiry, the Commission considers that expenditure was not effected in compliance with Union rules, it shall communicate its findings to the Member State concerned, specifying the corrective measures needed to ensure future compliance with those rules, and indicating the provisional level of financial correction which at that stage of the procedure it considers corresponds to its findings. That communication shall also schedule a bilateral meeting within 5 months after expiry of the period for reply by the Member State. The communication shall make reference to this Article.

The Member State shall reply within 2 months of receipt of the communication. In its reply the Member State shall have the opportunity, in particular, to:

- (a) demonstrate to the Commission that the actual extent of the non-compliance or the risk for the Funds is less than what was indicated by the Commission;
- (b) inform the Commission of the corrective measures it has undertaken to ensure compliance with Union rules and the effective date of their implementation.

In justified cases, the Commission may, upon reasoned request of the Member State, authorise an extension of the 2-month period by a maximum of 2 months. The justified reason may be the certification body's assessment of the Member State's calculation. The request shall be addressed to the Commission before the expiry of that period.

If the Member State considers that a bilateral meeting is not required, it shall inform the Commission accordingly in its reply to the communication.

3. In the bilateral meeting both parties shall endeavour to come to an agreement as to the measures to be taken as well as to the evaluation of the gravity of the infringement and of the financial damage caused to the Union budget.

The Commission shall within 30 working days of the bilateral meeting draw up the minutes and send them to the Member State. The Member State may send its observations to the Commission within 15 working days after receipt of the minutes.

The Commission shall within 6 months after sending the minutes of the bilateral meeting formally communicate its conclusions to the Member State on the basis of the information received in the framework of the conformity procedure. That communication shall evaluate the expenditure to be excluded from Union financing under Article 55 of Regulation (EU) 2021/2116 and Articles 14 and 15 of Delegated Regulation (EU) 2022/127. The communication shall make reference to Article 43(1) of this Regulation.

If a Member State notifies the Commission that a bilateral meeting is not required, the 6-month period starts from the date of receipt by the Commission of the notification.

4. Where the Member State has made use of the conciliation procedure referred to in Article 43, the Commission shall communicate its conclusions to the Member State no later than 6 months after:

- (a) the receipt of the conciliation body report; or
- (b) the receipt of additional information from the Member State within the deadline referred to in Article 43(3), second subparagraph, provided that the conditions set out in paragraph 6 of this Article are met.

5. In order to apply paragraphs 3 and 4 within the respective time periods, the Commission shall have available all information relevant at that particular step of the procedure. Where the Commission deems it lacks information, it may at any time within the time periods set out in those paragraphs:

- (a) ask for additional information from the Member State, to which the Member State shall reply within 2 months of receipt of the communication; and/or
- (b) inform the Member State of its intention to carry out an additional audit mission to conduct the necessary verifications.

In that case, the time periods referred to in paragraphs 3 and 4 shall start again either on the receipt by the Commission of the requested additional information or from the last day of the additional audit mission.

Where the time periods referred to in paragraphs 2, 3 and 4 and in this paragraph include fully or partially the month of August, the running of those time periods will be suspended during that month.

6. When evaluating the expenditure to be excluded from Union financing, the information communicated by the Member State after the Commission's formal communication referred to in paragraph 3, third subparagraph, may only be taken into account:

- (a) where it is necessary to avoid the gross overestimation of the financial damage caused to the Union budget; and
- (b) if the late transmission of the information is duly justified by external factors and does not jeopardise the timely adoption by the Commission of the decision pursuant to Article 55 of Regulation (EU) 2021/2116.

7. The Commission, after having communicated its conclusions to the Member States in accordance with paragraph 3 or 4 of this Article, shall adopt, where appropriate, one or more decisions under Article 55 of Regulation (EU) 2021/2116 in order to exclude from Union financing expenditure affected by the non-compliance with Union rules. The Commission may pursue consecutive conformity procedures until the Member State has actually implemented the corrective measures.

8. As regards the EAGF, the deductions from the Union financing shall be made by the Commission from the monthly payments relating to the expenditure effected in the second month following the decision pursuant to Article 55 of Regulation (EU) 2021/2116.

As regards the EAFRD, the deductions from Union financing shall be made by the Commission from the payment for which the declaration of expenditure is submitted by the Member State after the decision pursuant to Article 55 of Regulation (EU) 2021/2116 has been adopted.

However, at the Member State's request and after consultation of the Committee on the Agricultural Funds, the Commission may adopt an implementing decision setting a different date for the deductions or authorising their reimbursement in not more than three instalments where this is warranted by the materiality of the deductions included in an implementing act adopted on the basis of Article 55 of Regulation (EU) 2021/2116. This request for instalments shall be submitted by the Member State to the Commission not later than 5 days after the consultation of the Committee on the Agricultural Funds on the decision pursuant to Article 55 of that Regulation.

9. For Member States which are subject to financial assistance under Council Regulation (EC) No 332/2002 ⁽²²⁾, Council Regulation (EU) No 407/2010 ⁽²³⁾ and the Treaty establishing the European Stability Mechanism, the Commission may, at the Member State's request and after consultation of the Committee on the Agricultural Funds, adopt an implementing decision deferring, for a period not exceeding 24 months from the date of its adoption, the execution of decisions adopted after 1 May 2025 pursuant to Article 55 of Regulation (EU) 2021/2116 ('deferral decision').

The deferral decision shall authorise the deductions to be made after the end of the deferral period in three annual instalments. Where the total amount subject to the deferral decision represents more than 0,02 % of the Member State's gross domestic product, the Commission may authorise the reimbursement in maximum five annual instalments.

The Commission may decide, at the Member State's request and after consultation of the Committee on the Agricultural Funds, to extend once, for a period not exceeding 12 months, the time period of deferral referred to in the first subparagraph.

The Member State benefitting from a deferral decision shall ensure that the deficiencies which have been the reasons for the deductions and which persist at the time of adoption of the deferral decision are being remedied on the basis of an action plan, established in consultation with the Commission, including deadlines and clear progress indicators. The Commission shall amend or repeal the deferral decision, taking into account the principle of proportionality, in one of the following cases:

- (a) the Member State fails to take the necessary actions to remedy the deficiencies as foreseen in the action plan;
- (b) the progress of the remedial actions is not sufficient according to the progress indicators; or
- (c) the outcome of the actions is not satisfactory.

10. The implementing decisions referred to in paragraphs 8 and 9 shall be adopted in accordance with the advisory procedure referred to in Article 102(2) of Regulation (EU) 2021/2116.

11. In duly justified cases to be notified to the Member State concerned, the Commission may extend the time periods set out in paragraphs 2 to 5.

12. The communications referred to in this Article may be made via electronic means.

13. Paragraphs 1 to 11 shall apply, *mutatis mutandis*, to the assigned revenue referred to in Article 45 of Regulation (EU) 2021/2116.

Article 38

Decision not to start or pursue a conformity inquiry

1. The Commission may decide not to start or pursue a conformity inquiry in accordance with Article 55 of Regulation (EU) 2021/2116 where it expects that the possible financial correction, for the non-compliance identified as a result of an inquiry referred to in Article 37(2) of this Regulation, would not exceed EUR 50 000 and 2 % of the relevant expenditure or the amounts to be recovered.

2. Where the Commission reduces the monthly payments in accordance with Article 39(1) and (2) of Regulation (EU) 2021/2116, it may decide not to start or pursue a conformity inquiry in accordance with Article 55 of that Regulation, provided that the Member State concerned has not expressed its objection to the application of this paragraph in the framework of the procedure provided for in Article 39(1) and (2) of that Regulation.

⁽²²⁾ Council Regulation (EC) No 332/2002 of 18 February 2002 establishing a facility providing medium-term financial assistance for Member States' balances of payments (OJ L 53, 23.2.2002, p. 1).

⁽²³⁾ Council Regulation (EU) No 407/2010 of 11 May 2010 establishing a European financial stabilisation mechanism (OJ L 118, 12.5.2010, p. 1).

*Article 39***Conciliation body**

For the purpose of the conformity procedure provided for in Article 55 of Regulation (EU) 2021/2116, a conciliation body shall be established. It shall perform the following tasks:

- (a) to examine any matter referred to it by a Member State which has received a formal communication from the Commission pursuant to Article 37(3), third subparagraph, of this Regulation, including an evaluation of expenditure which the Commission intends to exclude from Union financing;
- (b) to try to reconcile the divergent positions of the Commission and the Member State concerned;
- (c) at the end of its examination, to draw up a report on the results of its reconciliation efforts, making any remarks it deems useful should all or some of the points of dispute remain unresolved.

*Article 40***Composition of the conciliation body**

1. The conciliation body shall be composed of at least five members selected among eminent persons offering every guarantee of independence and who are highly qualified in matters regarding the financing of the common agricultural policy, including rural development, or in the practice of financial audit.

They must be nationals of different Member States.

2. The chairperson, the members and the substitute members shall be appointed by the Commission for an initial term of office of 3 years after consultation of the Committee on the Agricultural Funds.

The terms of office may be renewed for a year at a time only, the Committee on the Agricultural Funds having been informed. However, if the chairperson to be appointed is already a member of the Conciliation Body, the initial term of office as chairperson shall be three years.

The names of the chairperson, the members and the substitute members shall be published in the C series of the *Official Journal of the European Union*.

3. The members of the conciliation body shall be remunerated having regard to the time which they are required to dedicate to the task. Costs shall be compensated in accordance with the rules in force for Commission staff.

4. After expiry of the term of office, the chairperson and the members shall remain in office until they are replaced or their term of office is renewed.

5. The term of office of members who no longer meet the conditions required for the accomplishment of their duties with the conciliation body or who, for whatever reason, are unavailable for an indeterminate period may be terminated by the Commission after consultation of the Committee on the Agricultural Funds.

In that case, the member concerned shall be replaced for the remainder of the period for which that member was appointed by a substitute member, the Committee on the Agricultural Funds being informed.

If the chairperson's term of office is terminated, the member who is to perform the chairperson's duties for the remainder of the period for which the chairperson was appointed shall be appointed by the Commission after consultation of the Committee on the Agricultural Funds.

*Article 41***Independence of the conciliation body**

1. The members of the conciliation body shall carry out their duties independently, neither seeking nor accepting instructions from the Commission, any government or body.

The members shall not take part in the work of the conciliation body or sign a report if, in a previous office, they have been personally involved in the matter at issue.

2. Without prejudice to Article 287 of the Treaty, the members shall not disclose any information acquired by them in the course of their work for the conciliation body. Such information shall be confidential and covered by the obligation of professional secrecy.

*Article 42***Working arrangements**

1. The conciliation body shall meet at the headquarters of the Commission. The chairperson shall prepare and organise the work. In the chairperson's absence, and without prejudice to Article 40(5), first subparagraph, the most senior member shall take the chair.

The secretariat of the conciliation body shall be provided by the Commission.

2. Without prejudice to Article 41(1), second subparagraph, reports shall be adopted by an absolute majority of members present, the quorum for deliberations being three.

The reports shall be signed by the chairperson and members who have taken part in the deliberations. They shall be co-signed by the secretariat.

*Article 43***Conciliation procedure**

1. A Member State may refer a matter to the conciliation body within 30 working days of receipt of the Commission's formal communication referred to in Article 37(3), third subparagraph, by sending a reasoned request for conciliation to the secretariat of the conciliation body.

2. The procedure to be followed and the address of the secretariat shall be notified to the Member States through the Committee on the Agricultural Funds.

3. A request for conciliation shall only be admissible where the amount envisaged to be excluded from the Union financing according to the Commission's communication either:

(a) exceeds EUR 1 million;

or

(b) represents at least 25 % of the Member State's total annual expenditure under the budget items concerned.

In addition, if during the preceding discussions the Member State claimed and demonstrated that the matter is one of principle relating to the application of Union rules, the chairperson of the conciliation body may declare a request for conciliation to be admissible. However, such a request shall not be admissible if it relates solely to a matter of legal interpretation.

4. The conciliation body shall conduct its investigations as informally and promptly as possible, basing itself solely on the evidence available to the Commission at the time when formal conclusions are communicated in accordance with Article 37(3), third subparagraph, and giving the Commission and the national authorities concerned a fair hearing.

However, if the Member State considers it necessary to present in its request for conciliation information which has not yet been communicated to the Commission, the conciliation body may invite the Commission to assess that new information only if the conditions set out in Article 37(6) are met. The information shall be communicated to the Commission at the latest 2 months after the report referred to in Article 39, point (c), has been sent.

5. Where, within 4 months of a case being referred to it, the conciliation body is not able to reconcile the positions of the Commission and the Member State, the conciliation procedure shall be deemed to have failed.

6. The report referred to in of Article 39, point (c), shall state the reasons why the positions could not be reconciled. It shall indicate whether any partial agreement was reached during the proceedings and whether the conciliation body invites the Commission to assess new information in accordance with paragraph 4, second subparagraph.

7. The report shall be sent to:

- (a) the Member State concerned;
- (b) the Commission, for examination before communicating its conclusions to the Member State;
- (c) the other Member States in the framework of the Committee on the Agricultural Funds.

8. Where the time periods referred to in paragraphs 1, 4, second subparagraph, and 5 include fully or partially the month of August, the running of those time periods will be suspended during that month.

CHAPTER IV

Checks

Section 1

General rules

Article 44

Information to be collected on the identification of beneficiaries

1. Member States shall ensure that beneficiaries provide in the aid applications and payment claims the information necessary for their identification, including, where applicable, the identification of the group, as defined in Article 2(11) of Directive 2013/34/EU of the European Parliament and of the Council ⁽²⁴⁾ in which they participate as of a certain date to be set by the Member State. That information shall include at least:

- (a) name of the entity;
- (b) VAT or tax identification number;
- (c) name of the parent entity and VAT or tax identification number;
- (d) ultimate parent and VAT or tax identification number;
- (e) subsidiaries and VAT or tax identification numbers.

⁽²⁴⁾ Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013 on the annual financial statements, consolidated financial statements and related reports of certain types of undertakings, amending Directive 2006/43/EC of the European Parliament and of the Council and repealing Council Directives 78/660/EEC and 83/349/EEC (OJ L 182, 29.6.2013, p. 19).

The information referred to in the first subparagraph may be used when drawing up the check sample referred to in Article 60(1), second subparagraph, of Regulation (EU) 2021/2116. The information may, in particular, be used to carry out checks as regards circumvention as referred to in Article 62 of that Regulation.

2. The information on the identification of groups as referred in paragraph 1, first subparagraph, points (a), (b) and (c), shall be published ex-post by the Member State, in accordance with Article 98 of Regulation (EU) 2021/2116.

Article 45

Requirements for the data-mining tool

1. In order to make use on a voluntary basis of the data-mining tool referred to in Article 59(2) of Regulation (EU) 2021/2116 to be made available by the Commission for the checks under Article 60 of that Regulation, Member States shall ensure that:

- (a) the management and control systems, including the integrated administration and control system referred to in Article 65(1) of Regulation (EU) 2021/2116, can be linked electronically to the tool and, in order to minimise the administrative burden and manual intervention, the exchange of data shall be automatic and in machine-readable format;
- (b) the information and the checks performed with the data-mining tool can automatically be fed back to the management and control systems, and can be recorded and stored there.

2. Where the Member State decides to use the information collected under Article 44 of this Regulation when drawing up the check sample referred to in Article 60(1), second subparagraph, of Regulation (EU) 2021/2116, the information may be verified by means of that data-mining tool.

Section 2

Scrutiny of transactions

Article 46

Scrutiny by Member States

1. The systematic scrutiny of the commercial documents of undertakings referred to in Article 77(1) of Regulation (EU) 2021/2116 shall apply, for each period of scrutiny referred to in paragraph 4 of this Article, to a number of undertakings which may not be less than half the undertakings whose receipts or payments, or the sum thereof, under the system of financing by the EAGF, exceeded EUR 150 000 for the EAGF financial year preceding the beginning of the period of scrutiny in question.

2. In relation to each scrutiny period, Member States shall, without prejudice to their obligations laid down in Article 77(1) of Regulation (EU) 2021/2116, select the undertakings to be scrutinised on the basis of a risk analysis for all measures where it is practicable to do so. Member States shall communicate to the Commission the risk analysis as part of the control plan referred in Article 80(1) of that Regulation.

3. For measures for which a Member State considers the use of a risk analysis not to be practicable, it shall be compulsory to scrutinise undertakings which receive payments exceeding EUR 350 000 within the system of financing by the EAGF and which were not scrutinised in accordance with this Regulation and Title IV, Chapter III, of Regulation (EU) 2021/2116 during either of the two preceding scrutiny periods.

4. The scrutiny period shall run from 1 July to 30 June of the following year.

*Article 47***Mutual assistance**

Member States shall send a request for mutual assistance referred to in Article 79 of Regulation (EU) 2021/2116 to each Member State in which an undertaking as referred to in that Article is established. The request shall contain all the details necessary to enable the Member State of destination to identify the undertakings and to undertake its scrutiny obligations. The Member State of destination shall be responsible for the scrutiny of such undertakings in accordance with Article 77 of that Regulation.

*Article 48***Annual control plans and reports**

1. The control plan for scrutiny and the report referred to in Article 80 of Regulation (EU) 2021/2116 shall be drawn up in accordance with the specimen form set out in Annexes VI and VII to this Regulation.
2. The information to be submitted under this Article shall be communicated in electronic form.
3. The Commission shall inform annually the Member States of the results of the scrutiny.

*CHAPTER V***Securities***Section 1***Scope, information technology, force majeure***Article 49***Scope**

This Chapter shall apply in all cases where the agricultural legislation provides for a security, whether or not the particular term 'security' is used.

This Chapter shall not apply to securities lodged to ensure payment of import and export duties referred to in Regulation (EU) No 952/2013 of the European Parliament and of the Council ⁽²⁵⁾.

*Article 50***e-Administration**

Communications, documents and securities may be produced, processed, and managed by using IT systems on condition that the systems applicable are managed under the officially approved quality and security protocols fit for those systems.

If competent authorities cannot access required documents for verification because of differences in IT systems, those documents shall be printed out and certified as genuine by the authority competent for the management of those IT systems ('the issuing authority') or by an authority competent for certifying documents as genuine copies.

⁽²⁵⁾ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

Such print-outs may be replaced by an electronic message between the issuing authority and the beneficiary or the competent authority, on condition that the issuing authority provides in an officially approved certification protocol ensuring the genuineness of the message.

Article 51

Force majeure time limits

1. This Article shall apply when a specific Regulation refers to it.
2. A request for recognition of a case of *force majeure* shall not be admissible if it is received by the competent authority more than 30 calendar days after the date on which the operator was informed by the competent authority of the established non-fulfilment of the relevant obligation within the meaning of Article 24(2) of Delegated Regulation (EU) 2022/127, the expiry of the time limit for the fulfilment of the relevant obligation as referred to in Article 24(3) of that Regulation or the expiry of the time limit for the presentation of the proof for the fulfilment of the relevant obligation as referred to in Article 24(4) of that Regulation.
3. Operators shall, to the competent authority's satisfaction, provide proof of the circumstances which they consider to constitute *force majeure* within 181 calendar days of the expiry of the period in which the obligation had to be fulfilled completely. Operators may be granted further time if they are unable to produce proof within that time limit despite having acted with all due diligence.
4. Member States shall notify the Commission of the cases of *force majeure* they have recognised, providing the relevant information of each case.

Section 2

Form of securities

Article 52

Form

1. A security may be given:
 - (a) as a cash deposit as referred to in Article 20(2) and (3) of Delegated Regulation (EU) 2022/127; and/or
 - (b) by providing a guarantor in accordance with Article 22 of Delegated Regulation (EU) 2022/127.
2. At the discretion of the competent authority, a security may be given by:
 - (a) pledging cash deposits in a bank;
 - (b) pledging recognised claims against a public body or public funds, which are due and payable and against which no other claim has precedence; and/or
 - (c) pledging collateral negotiable in the Member State concerned provided they are issued or guaranteed by that Member State.
3. The competent authority may impose additional terms for accepting securities of the type listed in paragraph 2.

Article 53

Negotiable collateral

1. Collateral pledged in accordance with Article 52(2), point (c), shall, at the time the security is given, have a disposable value of at least 115 % of the value of the security required.

2. A competent authority may accept a security as referred to in Article 52(2), point (c), only if the party offering it undertakes, in writing, either to give an additional security or to replace the original security should the disposable value of the security in question have been for a period of 3 months below 105 % of the value of the security required. That written undertaking shall not be necessary where national law already so provides. The competent authority shall regularly review the value of such security.
3. The disposable value of a security as referred to in Article 52(2), point (c), shall be assessed by the competent authority, taking into account any costs of disposal.
4. The disposable value of securities shall be assessed using the last available quotation.
5. The party giving the security shall, at the request of the competent authority, provide proof of its disposable value.

Article 54

Replacement and assignment

1. Any form of security may be replaced by another.

However, the agreement of the competent authority shall be required in the following cases:

- (a) where the original security has been forfeited but not yet realised; or
- (b) where the replacement security is of a type listed in Article 52(2).

2. A block security may be replaced by another block security on condition that the new block security covers at least that part of the original block security assigned at the time of replacement to ensure fulfilment of one or more obligations still outstanding.
3. As soon as part of a block security is assigned to a particular obligation, the balance of the block security remaining shall be noted.

Section 3

Release and forfeiture

Article 55

Partial release

Where specific Union rules do not specify a minimum quantity, the competent authority may itself restrict the number of partial releases of any one security and may specify a minimum sum for any such release.

Before releasing all or part of a security the competent authority may require that a written request for release be provided.

In the case of securities covering more than 100 % of the sum required to be secured, that part of the security exceeding 100 % shall be released when the remainder of the sum secured is finally released or forfeited.

Article 56

Forfeiture

1. Once the competent authority is aware of circumstances giving rise to forfeiture of the security, in whole or in part, it shall without delay demand the party required to meet the obligation to pay the sum forfeited, allowing up to 30 days from the day of receipt of demand for payment.

Where payment has not been made at the end of that period, the competent authority shall:

- (a) without delay clear any security of the type described in Article 52(1), point (a), to the appropriate account;
- (b) without delay require the guarantor referred to in Article 52(1), point (b), to pay, allowing up to 30 days from the day of receipt of demand for payment;
- (c) without delay take steps to:
 - (i) convert the securities described in Article 52(2), points (b) and (c), into money sufficient to recover the sum due;
 - (ii) clear pledged cash deposits referred to in Article 52(2), point (a), to its own account.

The competent authority may without delay clear any security of the type described in Article 52(1), point (a), to the appropriate account without first requiring the person concerned to effect payment.

2. Without prejudice to paragraph 1:

- (a) where the decision to forfeit a security is taken but on appeal is subsequently postponed in accordance with national law, the party concerned shall pay interest on the sum actually forfeited over the period starting 30 days from the day of receipt of the demand for payment as referred to in paragraph 1 and ending on the day prior to the payment of the sum actually forfeited;
- (b) where following the outcome of the appeal procedure the party concerned is asked to pay within 30 days the sum forfeited, for the purpose of calculating interest the Member State may consider payment to be made on the 20th day following the date of such request;
- (c) the rate of interest applicable is calculated in accordance with national law, but shall in no case be lower than the interest rate applicable in case of recovery of national amounts;
- (d) paying agencies shall deduct the interest paid from EAGF or EAFRD expenditure in accordance with Regulation (EU) 2021/2116;
- (e) Member States may claim periodically an increase of the security in respect of the interest involved.

3. Where a security has been forfeited and the amount already credited to the Funds and, following the outcome of an appeal procedure, the sum forfeited in whole or in part, including interest at a rate in accordance with national law, is to be repaid, the sum to be repaid shall be borne by the Funds, unless the repayment of the security is attributable to the negligence or serious mistake of administrative authorities or other bodies of the Member State.

Section 4

Information

Article 57

Information on securities forfeiture, types of securities and guarantors

1. Member States shall keep available for the Commission, for each year, the total number and sum of securities forfeited, whatever stage of the procedure set out in Article 56 has been reached, distinguishing in either case between those credited to the national budgets and those credited to the budget of the Union. That information shall be kept in relation to all securities forfeited for an amount greater than EUR 1 000 and each Union provision requiring that a security be given. The information shall cover both sums paid directly by the interested party and sums recovered by realising a security.

2. Member States shall keep at the Commission's disposal a list of:

- (a) the types of institutions authorised to act as guarantors and the requirements laid down in that respect;
- (b) the types of security accepted pursuant to Article 52(2) and the requirements laid down in that respect.

*CHAPTER VI***Transparency***Article 58***Form and way of presentation**

1. The information referred to in Article 98 of Regulation (EU) 2021/2116 in connection to Article 49(3), first subparagraph, points (a), (b), (d), (f) to (l) , of Regulation (EU) 2021/1060 shall be published in open, machine-readable formats, such as CSV or XLXS, and contain the information specified in Annex VIII to this Regulation, including the code of the operation, as described in Annex IX to this Regulation.
2. Member States may decide not to publish the information referred to in Article 49(3), first subparagraph, points (f) and (g) of Regulation (EU) 2021/1060, in relation to the types of intervention in form of direct payments referred to in Article 16 of Regulation (EU) 2021/2115, the types of intervention for rural development referred to in Article 69, points (b) and (c) of Regulation (EU) 2021/2115 and the measures laid down in Regulations (EU) No 228/2013 and (EU) No 229/2013.
3. The information shall be accessible through a web search tool allowing the user to search for beneficiaries by either name, group of beneficiaries, municipality, amounts received or operation, or by a combination thereof, and to extract all the corresponding information as a single set of data.
4. The information shall be provided in the official language or languages of the Member State and/or in one of the three working languages of the Commission.
5. The information referred to in paragraph 1 shall be expressed in euro. A Member State that has not adopted the euro shall express the amounts in both euro and its national currency, using two separate tables in open, machine-readable formats.
6. The exchange rate specified in Article 12 of Delegated Regulation (EU) 2022/127 shall apply to the national currencies.
7. The information referred to in Article 98(2) of Regulation (EU) 2021/2116 in connection to Article 49(3), first subparagraph, point (e), of Regulation (EU) 2021/1060, shall be published in a separate document, which shall include at least the information contained in Annex IX to this Regulation.

*Article 59***Publication of beneficiaries in case of small amounts**

1. Where the amount of aid received in one year by a beneficiary is equal to or less than EUR 1 250, that beneficiary shall be identified by a code. Member States shall decide on the form of that code.
2. Where the information on beneficiaries referred to in paragraph 1 would, due to the limited number of beneficiaries residing or registered in a given municipality, allow for the identification of a natural person as a beneficiary, the Member State concerned shall publish as information, for the purposes of Article 49(3), first subparagraph, point (l), of Regulation (EU) 2021/1060, the next larger administrative entity of which the municipality in question is part of.

*Article 60***Date of publication**

The information referred to in this Chapter shall be published by 31 May each year for the preceding financial year.

*Article 61***Information of the beneficiaries**

The information to the beneficiaries referred to in Article 98 of Regulation (EU) 2021/2116 shall be provided by including it in the application forms for receiving support from the EAGF or the EAFRD, or otherwise at the time when the data are collected.

*Article 62***Cooperation between the Commission and Member States**

1. The Commission shall set up and maintain a Union website under its central internet address which includes links to the websites of Member States referred to in Article 98(4) of Regulation (EU) 2021/2116. The Commission shall provide updated internet links according to the information sent by Member States.
2. Member States shall provide the Commission with their websites' internet addresses as soon as they have been set up as well as any subsequent changes thereof having an influence on the accessibility of their websites from the Union website.
3. Member States shall nominate a body in charge of setting up and maintaining the website. They shall inform the Commission of the name and address details of that body.

*CHAPTER VII****Data for WTO notification of domestic support****Article 63***Data and transmission**

1. On the same date as the date on which the annual accounts are submitted to the Commission, Member States shall transmit data on the amounts paid from national sources for all expenditures related to the Funds as indicated in Article 32(1), points (b) and (c).
2. The data required under paragraph 1 shall be submitted in the same structure as the data to be submitted pursuant to Article 32(1), points (b) and (c). This information shall be provided on the basis of the model made available by the Commission to Member States through information systems.

*CHAPTER VIII****Final provisions****Article 64***Repeal**

Implementing Regulation (EU) No 908/2014 is repealed with effect from 1 January 2023.

However:

- (a) Articles 21 to 24 and Articles 27 to 34 of that Regulation shall continue to apply as regards the EAFRD in relation to expenditure incurred by the beneficiaries and payments effected by the paying agency in the framework of the implementation of rural development programmes pursuant to Regulation (EU) No 1305/2013 and as regards the EAGF in relation to the operational programmes approved under Regulation (EU) No 1308/2013;

- (b) Article 59 of that Regulation shall continue to apply to payments made for financial years 2021, 2022 and 2023;
- (c) Annexes II and III to that Regulation shall continue to apply for the purposes of Article 32, points (f) and (g), of this Regulation.

Article 65

Entry into force and application

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

It shall apply from 1 January 2023.

However:

- (a) Articles 9, 10 and 11 shall apply to expenditure incurred and assigned revenue received by Member States from 16 October 2022;
- (b) Article 22(1), second subparagraph, point (e), shall apply in respect of the assigned revenue recovered from 1 January 2026 for the rural development programmes approved by the Commission pursuant to Regulation (EU) No 1305/2013;
- (c) Chapter VI shall apply to payments made from the financial year 2024 onwards.

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

Done at Brussels, 21 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX II

Management declaration – coordinating body as referred to in Article 4

I, ..., Director of the ... Coordinating Body, present the annual performance report for (Member State) for the financial year 16/10/xx to 15/10/xx+1.

I declare, based on my own judgement and on the information at my disposal, including, *inter alia*, the results of work of the certification body, that:

- the annual performance report referred to in Article 54(1) of Regulation (EU) 2021/2116 and Article 134 of Regulation (EU) 2021/2115 has been compiled following the accredited procedure and systems in place at the coordinating body and based on the certified data provided by the paying agencies (.....list) in (Member State).

That assurance is, however, subject to the following reservations:

Finally, I confirm that I am not aware of any undisclosed matter, which could be damaging to the financial interest of the Union.

Signature

ANNEX III

Elements for the audit trail for financial instruments as referred to in Article 7(6)

1. documents on the establishment of the financial instrument, such as funding agreements, etc.;
 2. documents identifying the amounts contributed by the CAP Strategic Plan and under each type of intervention to the financial instrument, the expenditure that is eligible under the CAP Strategic Plan and the interest and other gains generated by support from the EAFRD and re-use of resources attributable to the EAFRD in accordance with Articles 60 and 62 of Regulation (EU) 2021/1060;
 3. documents on the functioning of the financial instrument, including those related to monitoring, reporting and control;
 4. documents concerning exits of CAP Strategic Plan contributions and the winding-up of the financial instrument;
 5. documents on the management costs and fees;
 6. application forms, or equivalent, submitted by final recipients with supporting documents, including business plans and, when relevant, previous annual accounts;
 7. checklists and reports from the bodies implementing the financial instrument;
 8. declarations made in connection with *de minimis* aid, when applicable;
 9. agreements signed in connection with the support provided by the financial instrument, including for equity, loans, guarantees or other forms of investment provided to final recipients;
 10. evidence that the support provided through the financial instrument is to be used for its intended purpose;
 11. records of the financial flows between the paying agency and the financial instrument, and within the financial instrument at all levels, down to the final recipients, and, for guarantees, proof that underlying loans were disbursed;
 12. separate records or accounting codes for a CAP Strategic Plan contribution paid or a guarantee committed by the financial instrument for the benefit of the final recipient.
-

ANNEX IV

Template for the annual audit report on financial instruments as referred to in Article 7(7)**1. Introduction**

- 1.1. Identification of the external audit firm that has been involved in preparing the report.
- 1.2. Reference period (16 October N-1 to 15 October N).
- 1.3. Identification of the financial instrument(s)/mandate(s) and CAP Strategic Plan(s) covered by the audit report. Identification of the funding agreement to which the report relates to (the 'Funding agreement').

2. Audit of internal control systems applied by the EIB/EIF or other international financial institutions

Results of the external audit of the internal control system of the EIB or other international financial institutions (IFIs), in which a Member State is a shareholder, assessing the set-up and effectiveness of this internal control system and covering the following elements:

- 2.1. Mandate acceptance process.
- 2.2. Process for the appraisal and selection of financial intermediaries: formal and quality assessment.
- 2.3. Process for the approval of transactions with financial intermediaries and signature of relevant funding agreements.
- 2.4. Processes for the monitoring of financial intermediaries relating to:
 - 2.4.1. reporting by financial intermediaries;
 - 2.4.2. maintenance of records;
 - 2.4.3. disbursements to final recipients;
 - 2.4.4. eligibility of support to final recipients;
 - 2.4.5. management fees and costs charged by the financial intermediaries;
 - 2.4.6. visibility, transparency and communication requirements;
 - 2.4.7. implementation of State aid and cumulation of aid requirements by the financial intermediaries;
 - 2.4.8. differentiated treatment of investors, where relevant;
 - 2.4.9. compliance with applicable Union law related to money laundering, terrorism financing, tax avoidance, tax fraud or tax evasion.
- 2.5. Systems for the processing of payments received from the paying agency.
- 2.6. Systems for the calculation and payment of amounts related to management costs and fees.
- 2.7. Systems for the processing of payments to financial intermediaries.
- 2.8. Systems for the processing of interest and other gains generated by support from the CAP Strategic Plan(s) to financial instruments.
- 2.9. For the annual audit report concerning the final accounting year information on the following elements shall be covered in addition to those of points 2.1 to 2.8:
 - 2.9.1. Use of differentiated treatment of investors;
 - 2.9.2. Achieved multiplier ratio compared to the agreed multiplier ratio in the guarantee agreements for financial instruments delivering guarantees;

2.9.3. Use of interest and other gains attributable to the support from the CAP Strategic Plan paid to financial instruments in line with Article 60 of Regulation (EU) 2021/1060;

2.9.4. Use of resources paid back to financial instruments, which are attributable to the support from the EAFRD, until the end of the eligibility period and arrangements put in place for the use of those resources after the end of the eligibility period in line with Article 62 of Regulation (EU) 2021/1060.

For points 2.1, 2.2 and 2.3, following the submission of the first annual audit report, only information on updates or changes to the procedures or arrangements in place need to be provided.

3. **Audit conclusions**

3.1. Conclusion as to whether the external audit firm can provide reasonable assurance on the set-up and effectiveness of the internal control system put in place by the EIB or other IFIs, in which a Member State is a shareholder, in accordance with the applicable rules, as per the elements referred to in section 2.

3.2. Findings and recommendations resulting from the audit work carried out.

Points 3.1 and 3.2 shall be based on the results of the audit work referred to in section 2 and where relevant, take account of the results of other national or Union audit work carried out in relation to the same body implementing financial instruments and/or to the same mandate for financial instruments.

Model table referred to in Article 32(1), point (f), concerning irregularities

The information referred to in Article 32(1), point (f), shall be provided per paying agency by using the following table:

a	b	c	d	e	f	g	h	i	j
Paying Agency	Fund	Currency unit	Balance 15 October N-1	Total 'new cases' (financial year N)	Total 'corrections' (financial year N)	Total 'interests' (financial year N)	Total 'recoveries' (financial year N)	Total 'irrecoverable' amounts (year N)	Amount for which recovery is ongoing (Balance 15 October N)

ANNEX VI

Control plan for scrutiny as referred to in Article 80(1) of Regulation (EU) 2021/2116 and Article 48 of this Regulation

PROPOSED CONTROL PLAN FOR THE SCRUTINY PERIOD ...

Part 1. Procedures and risk analysis

1.1. Selection procedure

A description shall be provided of the procedure to be applied in order to select the undertakings to be scrutinised.

Furthermore, a clear indication shall be made on the use of the risk analysis specifying if such procedure is complemented by random and/or manual selection.

In addition, an explanation shall be provided on how the different sectors/measures and regions will be covered in the selection of the undertakings.

1.2. Risk factors, risk values and weighting to be applied

Where risk analysis shall be applied, information shall be provided on all risk factors taken into consideration and the subsequent possible values assigned to those risk factors. That information shall be included in the tables provided below.

Where appropriate, a description shall be provided of the procedure to be applied to weight the risk factors.

Risk factors and risk values applicable to all sectors/measures subject to risk analysis			Weighting of risk factors
Risk factors	Risk values		
	Description	Values	

Specific risk factors and risk values applicable to ... (sector/measure)			Weighting of risk factors
Risk factors	Risk values		
	Description	Values	

Where applicable, additional boxes for risk factors and risk values to sector/measures shall be added.

1.3. Results of selection procedure

Information shall be provided on how the results of the risk analysis and the adopted procedures led to the selection of undertakings into the final scrutiny control plan.

Sectors/measures to be excluded shall be clearly identified and the reasons for exclusion shall be described.

Reasons to select undertakings whose receipts or payments, or the sum thereof, were less than EUR 40 000, shall be provided.

Part 2. **Control plan**2.1. *Overview of the selection*

Calculation of the minimum number of undertakings:

(A) The number of undertakings whose receipts or payments, or the sum thereof, amounted to more than EUR 150 000 for the EAGF financial year ...	
(B) The minimum number (1/2 of A).	

Population from which the selection is made:

(C) Total number	
(D) Total number whose receipts or payments, or the sum thereof, were exceeding EUR 350 000	
(E) Total number whose receipts or payments, or the sum thereof, were EUR 350 000 or less, but not less than EUR 40 000	
(F) Total number whose receipts or payments, or the sum thereof, were less than EUR 40 000	

Undertakings proposed for scrutiny:

(G) Total number	
(H) Total based upon risk analysis*	
(I) Total number whose receipts or payments, or the sum thereof, were exceeding EUR 350 000	
(J) Total number whose receipts or payments, or the sum thereof, were EUR 350 000 or less, but not less than EUR 40 000	
(K) Total number whose receipts or payments, or the sum thereof, were less than EUR 40 000	

Note on table:

* Undertakings in this category include only those selected through risk analysis and exclude those added randomly and/or manually to the control plan no subject to risk analysis.

2.2. *Selection of undertakings proposed for scrutiny*

(A) EAGF Budget Item No	(B) EAGF Budget Article	(C) Total expenditure by EAGF budget heading (EUR)	(D) Total expenditure by EAGF budget heading relating to undertakings whose receipts or payments, or the sum thereof, were above EUR 40 000 (EUR)	(E) Total expenditure by EAGF budget heading relating to undertakings included in the scrutiny control plan (EUR)	(F) Number of undertakings by EAGF budget heading included in the scrutiny control plan
Totals:					

Note on table:

Where applicable, additional rows shall be added.

ANNEX VII

Scrutiny report as referred to in Article 80(2), point (B) of Regulation (EU) 2021/2116 and Article 48 of this Regulation

REPORT FOR THE SCRUTINY PERIOD ...

1. Overview of the controls

(A) The total number of undertakings to be scrutinised:	
(B) The total number of undertakings scrutinised:	
(C) The total number of undertakings in the course of scrutiny:	
(D) The total number of undertakings not yet scrutinised	

2. Overview of controls (per budget article or item No)

(A) EAGF Budget Item No	(B) EAGF Budget Article	(C) Total expenditure relating to undertakings selected for scrutiny... (EUR) (C=E+F +G)	Scrutinised undertakings		(F) Undertak- ings in the course of scrutiny –total expenditure relating to those undertakings (EUR)	(G) Undertak- ings not scruti- nised –total expenditure relating to those undertakings (EUR)
			(D) Expendi- ture actually scrutinised (EUR)*	(E) Total expenditure related to those undertakings (EUR)		
Totals:						

Notes on table:

* Relates only to the expenditure of the invoices that have been effectively scrutinised (which are those selected for verification and/or cross-checked).

Where applicable, additional rows shall be added.

3. Potential irregularities identified

(A) EAGF Budget Article	(B) EAGF Budget Item N.	(C) The reference number of the undertaking concerned	(D) Description and nature of each potential irregularity identified	(E) Number of potential irregularities identified	(F) Estimated value of potential irregularities	(G) The OLAF reference number(s) (IMS notification numbers)	(H) Scrutiny period in which scrutiny has been planned *
Totals:							

Notes on table:

- * For preceding scrutiny periods, only those not reported in previous reports.
Each undertaking with irregularity(ies) should be reported in a separate line.
Where applicable, additional rows are to be added.

4. Execution of scrutinies relating to preceding scrutiny control plans.

Execution of scrutinies relating to preceding scrutiny control plans	(A) Number of undertakings	(B) Expenditure concerned	(C) Expenditure actually scrutinised relating to undertakings *
4.1. Undertakings declared in previous report as in the course of scrutiny (4.1 = 4.2+ 4.3)			x
4.2. Undertakings in 4.1 for which scrutinies have been completed			
4.3. Undertakings in 4.1 for which scrutinies are still in course			x
4.4. Undertakings for which scrutinies in previous report were declared as not started (4.4 = 4.5+4.6+4.7)			x
4.5. Undertakings in 4.4 for which scrutinies have been completed			
4.6. Undertakings in 4.4 for which scrutinies are still in course			x

4.7. Undertakings in 4.4 for which scrutinies have not been started			x
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Notes on table:

* Relates only to the expenditure of the invoices that has been effectively scrutinised (those selected for verification and/or cross-checked).

5. Mutual assistance

A summary of mutual assistance requests made and received under Title IV, Chapter III, of Regulation (EU) 2021/2116, shall be provided.

Information on the requests sent and the replies received shall be included in the tables provided below:

(A) Member State to whom request has been sent	(B) Date of <i>request</i>	(C) Date of <i>reply</i> and a summary of the results

Note on table:

Where applicable, additional rows shall be added.

6. Resources

The number of staff, expressed in person/years, allocated to scrutinies, per control body and, where appropriate, per region shall be provided.

7. Difficulties and suggestions for improvement

Information shall be provided on any difficulties encountered in the application of Title IV, Chapter III, of Regulation (EU) 2021/2116 and the measures taken to overcome them or proposals to that end.

Where appropriate, suggestions shall be made for the improvement of the application of Title IV, Chapter III, of Regulation (EU) 2021/2116.

Information for the purposes of transparency pursuant to Article 58

Name of the beneficiary/ Legal entity/ association	Surname of beneficiary	If belonging to a group, name of the parent entity and VAT or Tax identifica- tion number	Munici- pality	Code of the measure/ type of intervention/sector as set in Annex IX	Specific objec- tive ⁽¹⁾	Start date ⁽²⁾	End date ⁽³⁾	Amount by opera- tion under EAGF	Total of EAGF amount for that benefi- ciary	Amount by opera- tion under EAFRD	Total of EAFRD amount for that benefi- ciary	Amount by operation under co-finan- cing	Total of co-fi- nanced amount for that benefi- ciary	Total of EAFRD and co-fi- nanced amounts	Total of the EU amount for that benefi- ciary
									50		70		40	110	120
				Code A				20							
				Code B						40		25			
				Code C				30							
				Code D						30		15			

⁽¹⁾ The specific objective of the operation must correspond to one or more objectives set in the relevant Union legislation governing the operation concerned as described in Annex IX. In particular, the specific objective(s) of an operation under Regulation (EU) 2021/2115 must correspond to the specific objectives laid down in Article 6 thereof and be consistent with the CAP Plan of the Member State. Furthermore, the specific objective(s) of an operation under Regulation (EU) No 1305/2013, Regulation (EU) No 1307/2013 and Regulation (EU) No 1308/2013 must correspond to the objectives laid down in Article 110(2) of Regulation (EU) No 1306/2013 (for further guidance Member States may refer to the Technical Handbook on the Monitoring and Evaluation Framework of the Common Agricultural Policy 2014 – 2020).

⁽²⁾ The information on the start date and end date of the types of intervention in the form of direct payments, the types of interventions for rural development interventions with regard to natural or other area-specific constraints and to area-specific disadvantages resulting from certain mandatory requirements as well as of the measures under Regulation (EU) No 228/2013 and under Regulation (EU) No 229/2013 is not relevant as those measures and types of intervention operations are annual.

⁽³⁾ The information on the start date and end date of the types of interventions in the form of direct payments, the types of intervention for rural development interventions with regard to natural or other area-specific constraints and to area-specific disadvantages resulting from certain mandatory requirements as well as of the measures under Regulation (EU) No 228/2013 and under Regulation (EU) No 229/2013 is not relevant as those measures and types of intervention operations are annual.

ANNEX IX

Measure/type of intervention/sector as referred to in Article 58

Code of the measure/type of intervention/sector	Name of the measure/type of intervention/ sector	Purpose of the measure/type of intervention/sector
	Operations in the form of types of intervention for direct payments as provided for in Article 16 of Regulation (EU) 2021/2115.	
	1. Decoupled income support	
I.1	Basic income support for sustainability;	The basic income support is an area payment decoupled from production. The aim is to support viable farm income and resilience across the Union to enhance food security.
I.2	Complementary redistributive income support for sustainability;	The complementary redistributive income support for sustainability is an area payment decoupled from production. The aim is to improve the distribution of direct payments by redistributing support from larger to smaller or medium-sized farms.
I.3	Complementary income support for young farmers;	The complementary income support for young farmers is a payment decoupled from production providing enhanced income support to young farmers who are setting up for the first time. The aim is to modernise the agricultural sector by attracting young people and improving their business development.
I.4	Schemes for the climate and the environment.	Eco-schemes are a payment decoupled from production. The aim is to target income support to agricultural practices beneficial for the environment, climate and animal welfare.
I.5	Small farmer's payments	The small farmer's payments are decoupled from production and replace all other direct payments for the concerned beneficiaries. The purpose of the payments for small farmers is to promote a more balanced distribution of support and to reduce administrative burden for both beneficiaries of small amounts and managing authorities.
	2. Coupled direct payments	
I.6	Coupled income support;	Coupled income support covers payments per hectare or head linked to specific productions. The aim is to improve competitiveness, sustainability, and/or quality in certain sectors and products that are particularly important for social, economic or environmental reasons and encounter certain difficulties.
I.7	Crop-specific payment for cotton	The crop-specific payment for cotton is a coupled payment granted per hectare of eligible area of cotton. It is a mandatory scheme for cotton producer's Member States to support the cotton production in regions where it is important for the agricultural economy.

	Measures set out in Annex I to Regulation (EU) No 1307/2013	
II.1	Basic payment scheme (Title III, Chapter 1, Sections 1, 2, 3 and 5)	The basic payment scheme is an area payment decoupled from production operated on the basis of payment entitlements allocated to farmers. The aim is to support the income of farmers which is, on average, significantly below the average income in the rest of the economy.
II.2	Single area payment scheme (Article 36)	The single area payment scheme is an area payment decoupled from production paid for eligible hectares declared by a farmer. The aim is to support the income of farmers which is, on average, significantly below the average income in the rest of the economy.
II.3	Redistributive payment (Title III, Chapter 2)	The redistributive payment is a decoupled area payment. The aim is to support smaller farms by providing them an additional support on their first hectares declared under the basic payment.
II.4	Payment for agricultural practices beneficial for the climate and the environment (Title III, Chapter 3)	Greening is a decoupled area payment per hectare paid. The aim is to observe three agricultural practices in favour of the climate and the environment: crop diversification, maintenance of permanent grassland and having ecological focus area on the agricultural area
II.5	Payment for areas with natural constraints (Title III, Chapter 4)	The payment to areas with natural constraints is an area based decoupled payment, provided on top of the basic payment to farmers. The aim is to give support to farmers who are situated in areas with natural constraints.
II.6	Payment for young farmers (Title III, Chapter 5)	Payment for young farmers is a payment decoupled from production providing enhanced income support to young farmers who are newly set up for the first time. The aim is to promote the creation and development of new economic activities in the agricultural sector, which is essential for the competitiveness of the agricultural sector in the Union.
II.7	Voluntary coupled support (Title IV, Chapter 1)	The voluntary coupled support covers payments per hectare or head linked to specific productions. The aim is to improve the competitiveness and sustainability of sectors that are particularly important for economic, social or environmental reasons and undergo certain difficulties.
II.8	Crop-specific payment for cotton (Title IV, Chapter 2)	The crop-specific payment for cotton is a coupled payment granted per hectare of eligible area of cotton. It is a mandatory scheme for Member States producing cotton so as to support its production in regions where it is important for the agricultural economy.
II.9	Small farmers scheme (Title V)	The small farmers' scheme is decoupled from production and replaces all other direct payments for the concerned beneficiaries. The aim is to promote a more balanced distribution of support and to reduce administrative burden for both beneficiaries of small amounts and managing authorities.

II.10	Measures set out in Annex I to Council Regulation (EC) No 73/2009 ⁽¹⁾	The aim of these direct payments is to decouple support from the production of crops and livestock in order to improve the income support of the farmers.
	Operations in the form of sectoral interventions as provided for in Article 42 of Regulation (EU) 2021/2115.	
III.1	In the fruit and vegetables sector (Articles 49 to 53)	The aim is to support concentration of supply, competitiveness and sustainability of the f&v sector. It is done through producer organisations (PO) or their associations (APO) recognised under Regulation (EU) No 1308/2013 and running operational programmes in accordance with Regulation (EU) 2021/2115. Beneficiaries are POs and APOs. Programmes have a duration between 3 and 7 years and are managed on a financial year basis. Member States have to approve every single programme.
III.2	In the apiculture products sector (Articles 54, 55 and 56)	The aim is to support beekeepers, quality and market for apiculture products
III.3	In the wine sector (Articles 57 to 60)	The aim is to support competitiveness and sustainability of the wine sector. Programmes are run by Member States at national level as part of their Strategic Plan and are managed in a financial year basis. Beneficiaries are winegrowers as well as wine-making and wine-trading operators or their associations/organisations. Operations to be approved by Member States can be annual or multiannual.
III.4	In the hops sector (Articles 61 and 62)	The aim is to support concentration of supply, competitiveness and sustainability of the hops sector through producer organisations (PO) or their associations (APO) recognised under Regulation (EU) No 1308/2013 and running operational programmes in accordance with Regulation (EU) 2021/2115. Beneficiaries are POs or APOs. Programmes have a duration between 3 and 7 years and are managed on a financial year basis. Member States have to approve every single programme.
III.5	In the olive oil and table olives sector (Articles 63, 64 and 65)	The aim is to support concentration of supply, competitiveness and sustainability of the olive oil and table olives sector through producer organisations (PO) and their associations (APO) recognised under Regulation (EU) No 1308/2013 and running operational programmes in accordance with Regulation (EU) 2021/2115. Beneficiaries are POs or APOs. Programmes have a duration between 3 and 7 years and are managed in a financial year basis. MS have to approve every single programme.
III.6	In other sectors referred to in Article 1(2), points (a) to (h), (k), (m), (o) to (t) and (w), of Regulation (EU) No 1308/2013 and sectors covering products listed in Annex XIII of Regulation (EU) 2021/2115. (Articles 66, 67 and 68)	The aim is to support concentration of supply, competitiveness and sustainability of the related sectors through producer organisations (PO), their associations (APO) recognised under Regulation (EU) No 1308/2013, as well as Producers Groups (PG) temporarily approved by MS, and running operational programmes in accordance with Regulation (EU) 2021/2115. Beneficiaries are POs, APOs or PGs. Programmes have a duration between 3 and 7 years and are managed in a financial year basis. MS have to approve every single programme.

	Measures set out in Regulation (EU) No 1308/2013.	
IV.1	Public intervention	When market prices for certain agricultural products fall below a predetermined level, the public authorities of the Member States may intervene to stabilise the market by purchasing surplus supplies, which may then be stored until the market price increases. The entities that must be published are the ones which benefit from the aid, in other words the entities from which the product has been bought.
IV.2	Aid for private storage	The aim of the aid granted is to temporarily support producers of certain products regarding the cost of private storage.
IV.3	School fruit, vegetables and milk scheme	The aims of the aid provided is to support the distribution of agricultural products to children in nursery, primary and secondary schools with the objective to increase their fruit, vegetables and milk consumption and improve their eating habits.
IV.5	Exceptional measures	The aim of the exceptional measures granted under Articles 219(1), 220(1) and 221(1) and (2) of Regulation (EU) No 1308/2013 is to support agricultural markets in accordance with Article 5(2), point (a), of Regulation (EU) 2021/2116.
IV.6	Aid in the fruit and vegetables sector (Chapter II, Section 3)	Growers are encouraged to join producer organisations (POs). These receive aid for implementing operational programmes, based on a national strategy. The aim of the aid granted is also to mitigate income fluctuation from crises. Aid is offered for crisis prevention/management measures under operational programmes, i.e.: product withdrawal, green harvesting/non-harvesting, promotion/communication tools, training, harvest insurance, help to secure bank loans and cover administrative costs of setting up mutual funds (farmer-owned stabilisation funds).
IV.7	Support in the wine sector (Chapter II, Section 4)	The aim of the various aids granted is to ensure market balance and increase the competitiveness of Union wine: support for promotion of wine on third country markets and information on responsible consumption of wine and the Union system of PDO/PGI; co-financing of costs for restructuring and conversion of vineyards, for investments in wineries and in marketing facilities as well as for innovation; support for green harvesting, mutual funds, harvest insurance and by-product distillation.
IV.8	Support in the olive oil and table olives sector (Chapter II, Section 2)	Support granted to the three-year work programmes to be drawn up by producer organisations, associations of producer organisations or interbranch organisations in one or more of the following areas: market follow-up and management in the olive oil and table olives sector; the improvement of the environmental impact of olive cultivation; the improvement of the competitiveness of olive cultivation through modernisation; the improvement of the production quality of olive oil and table olives; the traceability system, the certification and protection of the quality of olive oil and table olives; the dissemination of

		information on measures carried out by producer organisations, associations of producer organisations or interbranch organisations to improve the quality of olive oil and table olives.
IV.9	Aid in the apiculture sector (Chapter II, Section 5)	The aim of the aid granted is to support this sector through apiculture programmes in order to improve the production and marketing of apiculture products.
IV.10	Aid in the hops sector (Chapter II, Section 6)	Aid granted to support hops producer organisations.
	Operation in the form of types of intervention for rural development as provided for in Article 69 of Regulation (EU) 2021/2115.	
V.1	Environmental, climate and other management commitments	The aim of the aid granted is to compensate farmers, forest holders and other land managers for the additional costs and income foregone related to voluntary environment, climate and other management commitments undertaken which go beyond mandatory standards and which contribute to the specific objectives of the CAP, notably in the area of environment, climate and animal welfare.
V.2	Natural or other area-specific constraints	The aim of the aid granted is to compensate farmers for all or part of the additional costs and income foregone related to the natural or other area-specific constraints in the area concerned, such as mountainous areas.
V.3	Area-specific disadvantages resulting from certain mandatory requirements	The aim of the aid granted is to compensate farmers, forest holders and other land managers for all or part of the additional costs and income foregone related to certain area-specific disadvantages in the area concerned which are imposed by requirements resulting from the implementation of the Natura 2000 Directives (Council Directive 92/43/EEC ⁽²⁾ and Directive 2009/147/EC of the European Parliament and of the Council ⁽³⁾) or, for agricultural areas, the Water Framework Directive (Directive 2000/60/EC of the European Parliament and of the Council ⁽⁴⁾).
V.4	Investments, including investments in irrigation	The aim of the aid granted is to support investments in tangible or intangible assets, including investments in irrigation, that contribute to achieving one or more of the specific objectives of the CAP.
V.5	Setting-up of young farmers, new farmers and rural business start-up	The aim of the aid granted is to support the setting-up of young farmers, new farmers and, under certain conditions, rural business start-up with the view of contributing to the achievement of one or more of the specific objectives of the CAP.
V.6	Risk management tools	The aim of the aid granted is to promote risk management tools, which help farmers manage production and income risks related to their agricultural activity which are outside their control.

V.7	Cooperation	The aim of the aid granted is to support cooperation with the view of contributing to the achievement of one or more of the specific objectives of the CAP. This includes cooperation support to: (a) prepare and implement Operational Group operations of the European Innovation Partnership for agricultural productivity and sustainability; (b) prepare and implement LEADER (c) promote and support Union and national recognised quality schemes and their use by farmers; (d) support producer groups, producer organisations or interbranch organisations; (e) prepare and implement Smart Villages strategies; (f) support other forms of cooperation.
V.8	Knowledge exchange and information	The aim of the aid granted is to support knowledge exchange and information actions that contribute to one or more of the specific objectives of the CAP, specifically targeting the protection of nature, environment and climate, including environmental education and awareness actions and the development of rural businesses and communities. Such actions may include actions to promote innovation, training and advice as well as exchange and dissemination of knowledge and information.
Measures provided for in Title III, Chapter I, of Regulation (EU) No 1305/2013		
VI.1	Knowledge transfer and information actions (Article 14)	This measure concerns training and other types of activities such as workshops, coaching, demonstration activities, information actions, short-term farm and forest exchange and visit schemes in order. The aim is to enhance the human potential of persons engaged in the agricultural, food and forestry sectors, land managers and small and medium-sized enterprises (SMEs) operating in rural areas.
VI.2	Advisory services, farm management and farm relief services (Article 15)	This measure, through the use of advisory services as well as the setting up of advisory, farm management and farm relief services, aims to improve the sustainable management and the economic and environmental performance of farm and forest holdings and SMEs operating in rural areas. It also promotes the training of advisors.
VI.3	Quality schemes for agricultural products and foodstuffs (Article 16)	The aim of this measure is to support all new entrants to the Union, national and voluntary quality schemes. Support may also cover costs arising from information and promotion activities in order to improve consumers' awareness of the existence and specifications of products produced under these Union and national quality schemes.
VI.4	Investments in physical assets (Article 17)	The aim of this measure is to improve the economic and environmental performance of agricultural holdings and rural enterprises, improve the efficiency of the agricultural products marketing and processing sector, provide infrastructure needed

		for the development of agriculture and forestry and support non-remunerative investments necessary to achieve environmental aims.
VI.5	Restoring agricultural production potential damage by natural disasters and introduction of appropriate prevention actions (Article 18)	The aim of this measure is to help farmers prevent natural disasters and catastrophic events or restore agricultural potential, which has been damaged, after its formal recognition by the competent public authorities of Member States, in order to help farm viability and competitiveness in the face of such events.
VI.6	Farm and business development (Article 19)	The aim of this measure is to support the creation and development of new viable economic activities such as new holdings run by young farmers, new businesses in rural areas, or the development of small farms. Support is also given to new or existing enterprises for investments and development of non-agricultural activities which are essential for the development and competitiveness of rural areas and of all farmers diversifying their agricultural activities. The measure provides payments for farmers eligible for the small farmers scheme who permanently transfer their holding to another farmer.
VI.7	Basic services and village renewal in rural areas (Article 20)	The aim of this measure is to support the interventions stimulating growth and promoting environmental and socio-economic sustainability of rural areas, in particular through the development of local infrastructure (including broadband, renewable energy and social infrastructure) and local basic services, as well as through the renewal of villages and activities aimed at the restoration and upgrading of the cultural and natural heritage. The measure also supports the relocation of activities and conversion of facilities with a view to improving the quality of life or increasing the environmental performance of the settlement.
VI.8	Investments in forest area development and improvement of the viability of forests (Article 21; Articles 22 to 26)	The aim of this measure is to promote investments in development of woodlands, in forest protection, in innovation in forestry, in forestry technologies and forest products, in order to contribute to the growth potential of rural areas.
VI.9	Afforestation and creation of woodland (Article 22)	The aim of this sub-measure is to provide support for operations of afforestation and creation of woodland on agricultural and non-agricultural land.
VI.10	Establishment, regeneration or renovation of agroforestry systems (Article 23)	The aim of this sub-measure is to support the establishment of agroforestry systems and practices where woody perennials are deliberately integrated with crops and/or animals on the same land unit.
VI.11	Prevention and restoration of damage to forests from forest fires, natural disasters and catastrophic events (Article 24)	This sub-measure aims at preventing and restoring (clearing and replanting) forestry potential after the occurrence of forest fires, other natural disasters including pest and disease outbreaks, as well as climate change related threats.
VI.12	Investments improving the resilience and environmental value of forest ecosystems (Article 25)	The aim of this sub-measure is to support actions that enhance the environmental value of the forest, facilitate the adaptation and mitigation of forests to climate change, provide ecosystem

		services and enhance the public amenity value of forest. The increase of the environmental value of the forest should be ensured.
VI.13	Investments in forest technologies, processing, mobilising and marketing of forest products (Article 26)	This sub-measure aims at providing support for investment in machinery and/or equipment related to harvesting, cutting, mobilising, processing the wood prior to industrial sawing of wood. The main goal of this sub-measure is to improve the economic value of forests.
VI.14	Setting up of producer groups and organisations (Article 27)	The aim of this measure is to support the setting up of producer groups and organisations, especially in the early years, when additional costs are incurred so as to face jointly market challenges and strengthening bargain power in relation to production and marketing, including in local markets.
VI.15	Agri-environment-climate (Article 28)	The aim of this measure is to encourage land managers to apply farming practices contributing to the protection of the environment, landscape, natural resources and climate mitigation and adaptation. It may concern not only environmentally beneficial improvements to farming practice but also the maintenance of existing beneficial practices.
VI.16	Organic farming (Article 29)	The aim of this measure is to focus on supporting the conversion to and/or the maintenance of organic farming practices and methods, with a view to encourage farmers to participate in such schemes, thus answering to society's demand for the use of environmentally friendly farm practices.
VI.17	Natura 2000 and Water Framework Directive payments (Article 30)	The aim of this measure is to give compensatory support to beneficiaries who suffer from particular disadvantages due to specific mandatory requirements in the areas concerned resulting from the implementation of Directives 92/43/EEC, 2009/147/EC and 2000/60/EC when compared to the situation of farmers and foresters in other areas not concerned by these disadvantages.
VI.18	Payments to areas facing natural or other specific constraints (Article 31)	The aim of this measure is to give support to beneficiaries who suffer from particular constraints due to their location in mountain areas or other areas facing significant natural constraints or specific constraints.
VI.19	Animal welfare (Article 33)	The aim of this measure is to provide payments to farmers who undertake, on a voluntary basis, to carry out operations of one or more animal welfare commitments.
VI.20	Forest-environmental and climate services and forest conservation (Article 34)	The aim of this measure is to respond to the needs of promoting the sustainable management and improvement of forests and woodland, including the maintenance and improvement of biodiversity, water and soil resources and combating climate change and also to the need to conserve the forest genetic resources, including activities such as development of different varieties of forest species in order to adapt to specific local conditions.

VI.21	Co-operation (Article 35)	The aim of this measure is to promote forms of co-operation involving at least two entities and aiming to develop (inter alia): pilot projects; new products, practices, processes and technologies in the agriculture, food and forestry sectors; tourism services; short supply chains and local markets; joint projects / practices concerning the environment / climate change; projects for the sustainable provision of biomass; non-LEADER local development strategies; forest management plans; and diversification into "social farming" activities.
VI.22	Risk management (Article 36)	This measure represents a new risk management toolkit and takes forward the possibilities that currently exist to support insurances and mutual funds via Member States' national direct payment envelopes to help farmers exposed to increasing economic and environmental risks. The measure also introduces an income stabilisation tool to provide compensation to farmers suffering a severe drop in their income.
VI.22bis	Exceptional temporary support to farmers and SMEs particularly affected by the COVID-19 crisis (Article 39b)	The aim of this measure offersis to offer to the farmers temporary support due to the Covid-19 crisis
VI.23	Financing of complementary national direct payments for Croatia (Article 40)	The aim of this measure offersis to offer to the farmers eligible for complementary national direct payments in Croatia a top-up payment under the second pillar.
VI.24	Support for LEADER local development (community-led local development) (Article 35 of Regulation (EU) No 1303/2013 of the European Parliament and of the Council ⁽³⁾)	The aim of this measure is to maintain LEADER as an integrated territorial development tool on sub-regional ("local") level which will directly contribute to the balanced territorial development of rural areas, which is one of the overall objectives of the rural development policy.
VI.25	Technical assistance (Articles 51 to 54)	The aim of this measure is to give to Member States the ability to provide a technical assistance to support actions that support administrative capacity linked to the management of ESI Funds. These actions may be addressed to the preparation, management, monitoring, evaluation, information and communication, networking, complaint resolution and control and audit of the Rural Development Programmes.
VII.1	Measures provided for in Regulation (EU) No 228/2013	POSEI measures are specific agricultural schemes aiming at taking into account the constraints of the Outermost Regions as required by Article 349 TFEU. It consists of two main elements: the specific supply arrangements and the measures to support local production. The former aims at mitigating additional costs for supplying essential products resulting from the remoteness of these regions (through aid for products from the Union and exemption from import duties for products from third countries) and the latter at assisting the development of the local agriculture sector (direct payments and market measures). POSEI also allow the financing of plant-health programmes.

VIII.1	Measures provided for in Regulation (EU) No 229/2013	The regime for the smaller Aegean Islands is similar to POSEI but does not have the same legal basis in the TFEU and operates on a smaller scale than POSEI. It includes both the specific supply arrangements (limited however to aid for products from the Union) and the measures to support the local agricultural activities consisting in top-up payments for specifically defined local products.
IX.1	Information and promotion measures provided for in Regulation (EU) No 1144/2014	Information provision and promotion measures concerning agricultural products and certain food products based on agricultural products implemented in the internal market or in third countries as listed in Regulation (EU) No 1144/2014 may be fully or partly financed by the Union budget, subject to the conditions laid down in this Regulation. These measures shall take the form of information and promotion programmes.

(¹) Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers, amending Regulations (EC) No 1290/2005, (EC) No 247/2006, (EC) No 378/2007 and repealing Regulation (EC) No 1782/2003 (OJ L 30, 31.1.2009, p. 16).

(²) Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7).

(³) Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

(⁴) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

(⁵) Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006 (OJ L 347, 20.12.2013, p. 320).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/129**of 21 December 2021****laying down rules for types of intervention concerning oilseeds, cotton and by-products of wine making under Regulation (EU) 2021/2115 of the European Parliament and of the Council and for the information, publicity and visibility requirements relating to Union support and the CAP Strategic Plans**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 ⁽¹⁾, and in particular Articles 11(2), 37(6), 59(8) and 123(5) thereof,

Whereas:

- (1) Regulation (EU) 2021/2115 lays down a new legal framework for the common agricultural policy (CAP) to improve its delivery on the Union objectives set out in the Treaty on the Functioning of the European Union. That Regulation further specifies these Union objectives to be achieved by the CAP and defines the types of intervention as well as the common Union requirements applicable to Member States, while leaving flexibility for Member States in the design of the interventions to be provided in their CAP Strategic Plans. Member States have to draw up those CAP Strategic Plans and to submit their proposals for those plans to the Commission. For that purpose, certain implementing rules have to be laid down.
- (2) Article 11(1) of Regulation (EU) 2021/2115 states that where Member States provide for area-based interventions, other than those which comply with the provisions of Annex 2 to the WTO Agreement on Agriculture, including coupled income support under that Regulation, and where those interventions concern some or all of the oilseeds referred to in the Annex to the Memorandum of Understanding between the European Economic Community and the United States of America on oil seeds under GATT ⁽²⁾, the total of the support area based upon the planned outputs included in the CAP Strategic Plans of the Member States concerned is not to exceed the maximum support area for the whole Union for the purpose of ensuring compliance with its international commitments. Therefore, the Commission has to fix an indicative reference support area for each Member State as a share of the maximum support area for the whole Union, which corresponds to 7 854 446 hectares, calculated on the basis of the average cultivation area in the Union during the years 2016 to 2020.
- (3) Title III, Chapter II, Section 3, Subsection 2, of Regulation (EU) 2021/2115 provides for a crop-specific payment for cotton, for which four Member States have to authorise the land and varieties concerned. It should be for those Member States to lay down detailed rules in this regard. However, the procedure for those authorisations should be organised in such a way that it allows the farmers concerned to receive notifications related to the authorisation in due time before the next sowing season. In addition, it is appropriate to lay down the minimum information that those notifications should contain.
- (4) In accordance with Article 58(1) of Regulation (EU) 2021/2115, certain Member States are to choose in their CAP Strategic Plans one or more types of intervention in the wine sector, including distillation of by-products of wine making. The Commission has to fix the Union financial assistance for that intervention.

⁽¹⁾ OJ L 435, 6.12.2021, p. 1.

⁽²⁾ OJ L 147, 18.6.1993, p. 25.

- (5) In accordance with Article 123(2), point (j), of Regulation (EU) 2021/2115, the managing authority is to ensure through appropriate visibility actions that beneficiaries of support financed by the European Agricultural Fund for Rural Development (EAFRD), with the exception of support under area- and animal-related interventions, acknowledge that support, including by the appropriate use of the Union emblem. In accordance with Article 123(2), point (k), of that Regulation, the managing authority is to ensure that publicity is made for the CAP Strategic Plans by carrying out communication and visibility actions for the general public, potential beneficiaries and relevant target groups. Finally, in accordance with Article 124(3), point (f), of Regulation (EU) 2021/2115, the managing authority is to make available to the monitoring committee the information necessary for the task of examining the implementation of communication and visibility actions. It is appropriate to lay down uniform conditions for the application of the information, publicity and visibility requirements referred to in those provisions.
- (6) Since Member States need to take the rules laid down in this Regulation into account when developing their CAP Strategic Plans, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Common Agricultural Policy Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down rules for the application of Regulation (EU) 2021/2115, for the purpose of drawing up and implementing the CAP Strategic Plans of the Member States in accordance with that Regulation, in relation to:

- (a) the indicative reference support area for each Member State for the purposes of area-related interventions concerning oilseeds;
- (b) the authorisation of land and varieties for the purposes of the crop-specific payment for cotton and the notification related thereto;
- (c) the amount of the support for distillation of by-products of wine making;
- (d) the use of the Union emblem in the framework of certain interventions financed by the EAFRD and the information, publicity and visibility requirements as regards the CAP Strategic Plans and the Union support received on their basis.

Article 2

Indicative reference support area

The indicative reference support area for each Member State for the purposes of area-related interventions concerning oilseeds referred to in Article 11(1) of Regulation (EU) 2021/2115 is set out in Annex I to this Regulation.

Article 3

Procedure for the authorisation of land and varieties for the crop-specific payment for cotton and notifications related thereto

1. The procedure for the authorisation of land and varieties for the purposes of the crop-specific payment for cotton pursuant to Title III, Chapter II, Section 3, Subsection 2, of Regulation (EU) 2021/2115 shall be organised in such a way that it allows the farmers concerned to receive notifications related to the authorisation in due time before the sowing season.

That notification shall include at least the following information:

- (a) the authorised varieties for sowing;
- (b) the criteria for authorising land for cotton production as established by the Member States in accordance with Article 6 of Commission Delegated Regulation (EU) 2022/126 ⁽³⁾;
- (c) the minimum cotton plant density referred to in Article 8 of Delegated Regulation (EU) 2022/126.

2. Where a Member State withdraws an existing authorisation for a variety, the farmers concerned shall be notified in due time before the sowing season of the following year.

Article 4

Union financial assistance for the distillation of by-products of wine making

1. The Union financial assistance for the distillation of by-products of wine making referred to in Article 58(1), first subparagraph, point (g), of Regulation (EU) 2021/2115 to be paid to distillers, including a lump sum amount to compensate for the collection costs referred to in Article 60(3), third subparagraph, of that Regulation, shall not exceed:

- (a) for raw alcohol obtained from marcs: EUR 1,1/% volume/hl;
- (b) for raw alcohol obtained from wine and lees: EUR 0,5/% volume/hl.

2. Member States shall fix the actual amounts to be paid as Union financial assistance based on objective and non-discriminatory criteria and by taking into account the different production typologies.

Article 5

Union emblem

The Member State and the managing authority shall use the Union emblem in accordance with the requirements laid down in Annex II when carrying out visibility, transparency and communication activities referred to in Article 123(2), point (k), of Regulation (EU) 2021/2115. The managing authority shall also ensure that beneficiaries use the emblem accordingly.

Article 6

Information, publicity and visibility requirements

Detailed rules for the application of the information, publicity and visibility requirements referred to in Article 123(2), points (j) and (k), of Regulation (EU) 2021/2115 are laid down in Annex III to this Regulation.

Article 7

Entry into force

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

⁽³⁾ Commission Delegated Regulation (EU) 2022/126 of 7 December 2021 supplementing Regulation (EU) 2021/2115 of the European Parliament and of the Council with additional requirements for certain types of intervention specified by Member States in their CAP Strategic Plans for the period 2023 to 2027 under that Regulation as well as rules on the ratio for the good agricultural and environmental condition (GAEC) standard 1 (see page 197 of this Official Journal).

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

Done at Brussels, 21 December 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Indicative reference support area referred to in Article 2

	<i>ha</i>
Belgium	7 295
Bulgaria	711 954
Czechia	300 498
Denmark	114 000
Germany	846 779
Estonia	51 620
Ireland	7 197
Greece	69 709
Spain	559 382
France	1 525 286
Croatia	117 366
Italy	302 843
Cyprus	-
Latvia	89 153
Lithuania	154 217
Luxembourg	2 270
Hungary	707 720
Malta	-
Netherlands	1 952
Austria	88 129
Poland	644 818
Portugal	7 865
Romania	1 250 509
Slovenia	4 059
Slovakia	184 603
Finland	32 342
Sweden	72 880

ANNEX II

The use and technical characteristics of the Union emblem ('the emblem')

1. The emblem shall be prominently featured on all communication materials such as printed or digital products, websites and their mobile views relating to the implementation of an operation, used for the public or for participants.
2. The statement 'Funded by the European Union' or 'Co-funded by the European Union' shall be written in full and placed next to the emblem.
3. The typeface to be used in conjunction with the emblem may be any of the following fonts: *Arial*, *Auto*, *Calibri*, *Garamond*, *Trebuchet*, *Tahoma*, *Verdana* or *Ubuntu*. Italic, underlined variations or font effects shall not be used.
4. The positioning of the text in relation to the emblem shall not interfere with the emblem in any way.
5. The font size used shall be proportionate to the size of the emblem.
6. The colour of the font shall be reflex blue, black or white depending on the background.
7. The emblem shall not be modified or merged with any other graphic elements or texts. If other logos are displayed in addition to the emblem, the emblem shall have at least the same size, measured in height or width, as the biggest of the other logos. Apart from the emblem, no other visual identity or logo must be used to highlight the support from the Union.
8. Where several operations are taking place at the same location, supported by the same or different funding instruments, or where further funding is provided for the same operation at a later date, at least one plaque or billboard shall be displayed.
9. Graphic standards for the emblem and the definition of standard colours:

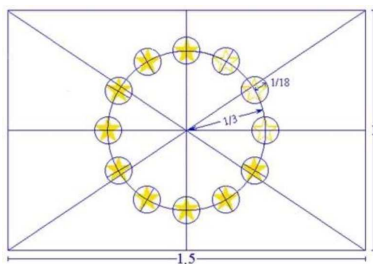
(A) SYMBOLIC DESCRIPTION

Against a background of blue sky, twelve golden stars form a circle representing the union of the peoples of Europe. The number of stars is fixed, twelve being the symbol of perfection and unity.

(B) HERALDIC DESCRIPTION

On an azure field a circle of twelve golden mullets, their points not touching.

(C) GEOMETRIC DESCRIPTION



The emblem has the form of a blue rectangular flag of which the fly is one and a half times the length of the hoist. Twelve gold stars situated at equal intervals form an invisible circle whose centre is the point of intersection of the diagonals of the rectangle. The radius of the circle is equal to one third of the height of the hoist. Each of the stars has five points which are situated on the circumference of an invisible circle whose radius is equal to one eighteenth of the height of the hoist. All the stars are upright, i.e. with one point vertical and two points in a straight line at right angles to the mast. The circle is arranged so that the stars appear in the position of the hours on the face of a clock. Their number is invariable.

(D) REGULATION COLOURS

The emblem is in the following colours: PANTONE REFLEX BLUE for the surface of the rectangle; PANTONE YELLOW for the stars.

(E) FOUR-COLOUR PROCESS

If the four-colour process is used, recreate the two standard colours by using the four colours of the four-colour process.

PANTONE YELLOW is obtained by using 100 % 'Process Yellow'.

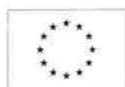
PANTONE REFLEX BLUE is obtained by mixing 100 % 'Process Cyan' and 80 % 'Process Magenta'.

INTERNET

PANTONE REFLEX BLUE corresponds in the web-palette colour RGB: 0/51/153 (hexadecimal: 003399) and PANTONE YELLOW corresponds in the web-palette colour RGB: 255/204/0 (hexadecimal: FFCC00).

MONOCHROME REPRODUCTION PROCESS

Using black, outline the rectangle in black and print the stars in black on white.



Using blue (Reflex Blue), use 100 % with the stars reproduced in negative white.



REPRODUCTION ON A COLOURED BACKGROUND

If there is no alternative to a coloured background, put a white border around the rectangle, the width of the border being 1/25th of the height of the rectangle.



The principles of the use of the emblem by third parties are set out in the Administrative agreement with the Council of Europe regarding the use of the European emblem by third parties ⁽¹⁾.

⁽¹⁾ OJ C 271, 8.9.2012, p. 5.

ANNEX III

Information, publicity and visibility requirements**1. Communication and visibility actions of the managing authority**

- 1.1. For the purposes of Article 123(2), point (k), of Regulation (EU) 2021/2115, the managing authority shall ensure that publicity is made for the CAP Strategic Plan by planning and carrying out relevant communication and visibility actions throughout the preparation and implementation of the CAP Strategic Plan for the purpose of informing the target groups referred to in that point.
- 1.2. For the purposes of Article 124(3), point (f), of Regulation (EU) 2021/2115, the managing authority shall make available to the monitoring committee the information necessary for the monitoring committee to carry out the task of examining the implementation of communication and visibility actions.
- 1.3. The managing authority shall ensure that, within 6 months of the Commission decision approving the CAP Strategic Plan, there is a website where information on the CAP Strategic Plan under its responsibility is available, covering the plan's objectives, activities, available funding opportunities as well as expected and, once available, actual achievements. The website shall target the general public as well as potential beneficiaries as referred to in Article 123(2), point (k), of Regulation (EU) 2021/2115.
- 1.4. The managing authority shall ensure the publication on the website referred to in point 1.3, a timetable of the planned calls and deadlines for applications, that is updated at least three times a year, with the following indicative data:
 - (a) geographical area covered;
 - (b) intervention and specific objective(s) concerned;
 - (c) type of eligible applicants;
 - (d) total amount of support;
 - (e) start and end date for the submission of applications.
- 1.5. The managing authority shall ensure, in accordance with Article 123(2), point (k)(i), of Regulation (EU) 2021/2115, that potential beneficiaries have access to all the information needed about funding opportunities, including eligibility conditions, selection criteria and all requirements for beneficiaries selected for funding, as well as their responsibilities.
- 1.6. The managing authority shall ensure that beneficiaries selected for funding are informed that the support is co-financed by the Union.
- 1.7. The managing authority shall ensure that communication and visibility material including at the level of beneficiaries is made available upon request to Union institutions, bodies, offices or agencies and that a royalty-free, non-exclusive and irrevocable licence to use such material and any pre-existing rights attached to it is granted to the Union in accordance with the second paragraph. This shall not require significant additional costs or a significant administrative burden for the beneficiaries or for the managing authority.

The licence on intellectual property rights referred to in the first paragraph shall grant to the Union at least the following rights:

- (a) internal use, i.e. right to reproduce, copy and make available the communication and visibility materials to Union's institutions and agencies, Member States' authorities, and their employees;
- (b) reproduction of the communication and visibility materials by any means and in any form, in whole or in part;

- (c) communication to the public of the communication and visibility materials by using any and all means of communication;
- (d) distribution to the public of the communication and visibility materials (or copies thereof) in any and all forms;
- (e) storage and archiving of the communication and visibility materials;
- (f) sub-licensing of the rights on the communication and visibility materials to third parties.

2. **Visibility of certain operations supported by the EAFRD**

For the purposes of Article 123(2), point (j), of Regulation (EU) 2021/2115, the managing authority shall, through the following measures, ensure that the beneficiaries under interventions financed by the EAFRD other than area- and animal-related interventions acknowledge support from the CAP Strategic Plan as follows:

- (a) by providing on the beneficiary's official website, where such a site exists, and official social media sites, a short description of the operation, proportionate to the level of support, including its aims and results, and highlighting the financial support from the Union;
- (b) by providing a statement highlighting the support from the Union in a visible manner on documents and communication material relating to the implementation of the operation, intended for the public or for participants, presenting also the Union emblem in accordance with the technical characteristics laid down in Annex II;
- (c) for operations consisting of the financing of infrastructure or construction operations, of which the total public expenditure, or the total cost in the case of support in the form of financial instruments, including working capital finance, exceeds EUR 500 000, by displaying durable plaques or billboards clearly visible to the public, that present the Union emblem in accordance with the technical characteristics laid down in Annex II, as soon as the physical implementation of the operations starts or purchased equipment is installed;
- (d) for operations consisting of investment in physical assets not falling under point (c), the total public support of which exceeds EUR 50 000, or in the case of support in the form of financial instruments, including working capital finance, the total cost of which exceeds EUR 500 000, by placing an explanatory plaque or equivalent electronic display with information about the project, highlighting the financial support from the Union, presenting also the Union emblem in accordance with the technical characteristics laid down in Annex II;
- (e) for operations consisting of support for LEADER operations, basic services and infrastructure not falling under point (c) and (d), the total public support of which exceeds EUR 10 000, or in the case of support in the form of financial instruments, including working capital finance, the total cost of which exceeds EUR 100 000, by displaying at a location clearly visible to the public at least one poster of a minimum size A3 or equivalent electronic display with information about the operation highlighting the support from the Union. An explanatory plaque shall also be installed in the premises of the local action groups financed by LEADER.

By way of derogation from the first paragraph, the managing authority shall ensure, to the extent possible, that in cases where the beneficiary is a natural person, appropriate information is available, highlighting the support from the funds, at a location visible to the public or through an electronic display.

The first paragraph, points (a) and (b), shall apply *mutatis mutandis* to the bodies implementing financial instruments financed by the EAFRD.

The first paragraph, points (c), (d) and (e), shall apply to the final recipients of financial instruments by means of the contractual terms provided for in the funding agreement as referred to in Article 59(5) of Regulation (EU) 2021/1060 of the European Parliament and of the Council ⁽¹⁾.

⁽¹⁾ Regulation (EU) 2021/1060 of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy (OJ L 231, 30.6.2021, p. 159).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/130**of 24 January 2022****entering a name in the register of protected designations of origin and protected geographical indications 'Bračko maslinovo ulje' (PDO)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Croatia's application to register the name 'Bračko maslinovo ulje' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Bračko maslinovo ulje' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Bračko maslinovo ulje' (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.5 – Oils and fats (butter, margarine, oil, etc.), as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 24 January 2022.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 400, 4.10.2021, p. 8.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/131**of 24 January 2022****entering a name in the register of protected designations of origin and protected geographical indications ‘Carne Ramo Grande’ (PDO)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Portugal's application to register the name ‘Carne Ramo Grande’ was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name ‘Carne Ramo Grande’ should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name ‘Carne Ramo Grande’ (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.1 – Fresh meat (and offal), as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.*Article 2*This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 24 January 2022.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 398, 1.10.2021, p. 40.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

COMMISSION REGULATION (EU) 2022/132**of 28 January 2022****amending Regulation (EC) No 1099/2008 of the European Parliament and of the Council on energy statistics, as regards the implementation of updates for the annual, monthly and short-term monthly energy statistics****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1099/2008 of the European Parliament and of the Council of 22 October 2008 on energy statistics ⁽¹⁾, and in particular Article 4(3), Article 5(3) and Article 9(2) and (3) thereof,

Whereas:

- (1) Regulation (EC) No 1099/2008 establishes a common framework for the production, transmission, evaluation and dissemination of comparable energy statistics in the Union.
- (2) Energy statistics need to evolve continuously due to the fast pace of technological progress, the evolution of Union energy policies and the importance of basing Union targets and the monitoring of progress in reaching them on official energy data. Regular updates of the European energy statistics reporting framework are therefore required to reflect growing or changing needs.
- (3) Using reliable high quality energy statistics to monitor the policy targets under the European Green Deal and the Energy Union packages should enhance the credibility of Union energy policy.
- (4) The Commission has identified several aspects of the annual and short-term monthly energy statistics that need to be updated. They concern notably greater disaggregation of the statistics on final energy consumption in services and transport, new energy carriers like hydrogen, new data on electricity generation and storage, more detailed data on renewable energy sources, new estimated data for the production of energy balances earlier and improved timeliness of the annual data collection. In addition, reporting requirements related to short-term monthly statistics for natural gas and oil and petroleum products are removed, because more complete monthly data are now available with improved timeliness. The Commission has discussed and agreed with the Member States on several technical aspects, including the scope, feasibility, production costs, confidentiality and reporting requirements.
- (5) Regulation (EC) No 1099/2008 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee, established by Article 7 of Regulation (EC) No 223/2009 of the European Parliament and of the Council ⁽²⁾,

HAS ADOPTED THIS REGULATION:

Article 1

The Annexes to Regulation (EC) No 1099/2008 are replaced by the text in the Annex to this Regulation.

⁽¹⁾ OJ L 304, 14.11.2008, p. 1.

⁽²⁾ Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).

Article 2

This Regulation shall enter into force on the twentieth day following 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, 28 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

ANNEX A

CLARIFICATIONS OF TERMINOLOGY

This annex provides explanations, geographical notes and definitions of terms that are used in the other annexes, unless specified differently in these annexes.

1. GEOGRAPHICAL NOTES

For statistical reporting purposes only, the following geographical definitions apply:

- Australia excludes its external territories,
- Denmark excludes the Faeroe Islands and Greenland,
- France includes Monaco and the French overseas departments of Guadeloupe, Martinique, Guyane, Reunion and Mayotte,
- Italy includes San Marino and the Vatican (Holy See),
- Japan includes Okinawa,
- Portugal includes the Açores and Madeira,
- Spain includes the Canary Islands, the Balearic Islands, and Ceuta and Melilla,
- Switzerland does not include Liechtenstein,
- United States includes the 50 states, the District of Columbia, the US Virgin Islands, Puerto Rico and Guam.

2. AGGREGATES

Producers of electricity and heat are classified according to the purpose of production:

- **main activity producers** are privately- or publicly owned producers that generate electricity and/or heat for sale to third parties as their principal activity,
- **autoproducers** are privately- or publicly owned producers that generate electricity and/or heat wholly or partly for their own use as an activity which supports their primary activity.

Note: the Commission may further clarify the terminology by adding relevant NACE ⁽¹⁾ references in accordance with the regulatory procedure with scrutiny referred to in Article 11(2), after a revision of the NACE classification has entered into force.

2.1. Supply

2.1.1. PRODUCTION/INDIGENOUS PRODUCTION

Quantities of fuels extracted or produced are calculated after any operation that removes inert matter. Production includes the quantities consumed by the producer during the production process (e.g. for heating or operation of equipment and auxiliaries), as well as supplies to other producers of energy for transformation or other uses.

'Indigenous production' means production from resources within a specific territory – national territory of the reporting country.

2.1.2. RECOVERED PRODUCTS

Applies to hard coal only. Slurries and waste-heap shale recovered by mines.

2.1.3. RECEIPTS FROM OTHER SOURCES

Quantities of fuels whose production is covered in other fuel reporting, but which are mixed with other fuels and consumed as a mix. Further details of this component are to be provided as:

- Receipts from other sources: Coal

⁽¹⁾ NACE Rev. 2 – Statistical Classification of Economic Activities in the European Community, Rev. 2 (2008).

- Receipts from other sources: Oil and petroleum products
- Receipts from other sources: Natural gas
- Receipts from other sources: Renewables

2.1.4. IMPORTS/EXPORTS

Unless otherwise specified, 'imports' refer to ultimate origin (the country in which the energy product was produced) for use in the country and 'exports' refer to the ultimate country of consumption of the produced energy product. Amounts are considered as imported or exported when they have crossed the political boundaries of the country, whether customs clearance has taken place or not.

If no origin or destination can be specified, 'Non-specified/Other' may be used.

2.1.5. INTERNATIONAL MARINE BUNKERS

Quantities of fuels delivered to ships of all flags that are engaged in international navigation. The international navigation may take place at sea, on inland lakes and waterways, and in coastal waters. The following are excluded:

- consumption by ships engaged in domestic navigation; the domestic/international split should be determined based on port of departure and port of arrival, and not by the flag or nationality of the ship;
- consumption by fishing vessels;
- consumption by military forces.

2.1.6. INTERNATIONAL AVIATION

Quantities of fuels delivered to aircrafts for international aviation. The domestic/international split should be determined based on departure and landing locations and not on the nationality of the airline. Excludes fuels used by airlines for their road vehicles (to be reported in 'Not elsewhere specified – Transport') and military use of aviation fuels (to be reported in 'Not elsewhere specified – Other').

2.1.7. STOCK CHANGES

The difference between the opening stock level and closing stock level for stocks held on national territory. Unless otherwise specified, a stock build is shown as a negative number and a stock draw is shown as a positive number.

2.1.8. OPENING AND CLOSING TOTAL STOCKS ON NATIONAL TERRITORY

All stocks on national territory, including stocks held by governments, by major consumers or by stockholding organisations, stocks held on board incoming ocean vessels, stocks held in bonded areas and stocks held for others, whether under bilateral government agreement or not. Opening and closing refers to the first and last day of the reporting period, respectively. Stock includes stocks held in all types of special storage facilities, either on the surface or underground.

2.1.9. DIRECT USE

Oil (Crude oil and petroleum products) used directly without being processed in petroleum refineries. Includes crude oil burned for electricity generation.

2.1.10. PRIMARY PRODUCT RECEIPTS

Includes quantities of indigenous or imported crude oil (including condensate) and indigenous NGL ^(?) used directly without being processed in a petroleum refinery, and quantities of backflows from the petrochemical industry which, although not primary fuel, are used directly.

2.1.11. GROSS REFINERY OUTPUT

Production of finished products at a refinery or blending plant. Excludes refinery losses, but includes refinery fuel.

^(?) Natural gas liquids.

2.1.12. RECYCLED PRODUCTS

Finished products that pass through the marketing network a second time, after having been delivered to final consumers (e.g. used lubricants which are reprocessed). These quantities should be distinguished from petrochemical backflows.

2.1.13. BACKFLOWS

Finished or semi-finished products which are returned from final consumers to refineries for processing, blending or sale. They are usually by-products of petrochemical manufacturing.

2.1.14. INTERPRODUCT TRANSFERS

Quantities reclassified either because their specification has changed or because they are blended into another product. A negative entry for one product is compensated by a positive entry (or several entries) for one or several products and vice versa; the total net effect should be zero.

2.1.15. PRODUCTS TRANSFERRED

Imported petroleum products which are reclassified as feedstocks for further processing in the refinery, without delivery to final consumers.

2.1.16. STATISTICAL DIFFERENCES

Calculated value, defined as difference between calculation from the supply perspective (top-down approach) and the calculation from the consumption perspective (bottom-up approach). Any major statistical differences should be explained.

2.2. **Transformation sector**

In the transformation sector, only quantities of fuels that were transformed into other fuels should be reported. Quantities of fuels used for heating, operation of equipment and as general support for transformation should be declared in the energy sector.

2.2.1. MAIN ACTIVITY PRODUCER ELECTRICITY ONLY

Quantities of fuels used by main activity producers to produce electricity in electricity-only units/plants.

2.2.2. MAIN ACTIVITY PRODUCER COMBINED HEAT AND POWER (CHP) UNITS

Quantities of fuels used by main activity producers to produce electricity and/or heat in CHP units.

2.2.3. MAIN ACTIVITY PRODUCER HEAT ONLY

Quantities of fuels used by main activity producers to produce heat in heat-only units/plants.

2.2.4. AUTOPRODUCER ELECTRICITY ONLY

Quantities of fuels used by autoproducers to produce electricity in electricity-only units/plants.

2.2.5. AUTOPRODUCER COMBINED HEAT AND POWER (CHP) UNITS

All quantities of fuels used by autoproducers to produce electricity and the proportional part of fuels used to produce heat sold in CHP units. The proportional part of fuels used to produce heat that was not sold (auto-consumed heat) is to be reported in the relevant sector of final energy consumption based on NACE classification. Heat not sold but delivered to other entities under non-financial agreements or to entities with different ownership should be reported based on the same principle as heat sold.

2.2.6. AUTOPRODUCER HEAT ONLY

The proportional part of fuels used to produce heat sold in heat-only units/plants by autoproducers. The proportional part of fuels used to produce heat that was not sold (auto-consumed heat) is to be reported in the relevant sector of final energy consumption based on NACE classification. Heat not sold but delivered to other entities under non-financial agreements or to entities with different ownership should be reported based on the same principle as heat sold.

2.2.7. PATENT FUEL PLANTS

Quantities of fuels used in patent fuel plants to produce patent fuel.

2.2.8. COKE OVENS

Quantities of fuels used in coke ovens to produce coke oven coke and coke oven gas.

2.2.9. BKB/PB PLANTS

Quantities of fuels used to produce brown coal briquettes (BKB) in BKB plants and quantities of fuels used in peat briquette plants to produce peat briquettes (PB).

2.2.10. GAS WORKS

Quantities of fuels used to produce gas work gas in gas works and in coal gasification plants.

2.2.11. BLAST FURNACE

Quantities of fuels entering the blast furnace vessel, whether through the top along with the iron ore, or through the tuyeres in the bottom along with the heated blast air.

2.2.12. COAL LIQUEFACTION

Quantities of fuel used to produce synthetic oil.

2.2.13. GAS-TO-LIQUID PLANTS

Quantities of gaseous fuels converted to liquid fuels.

2.2.14. CHARCOAL PRODUCTION PLANT

Quantities of solid biofuels converted to charcoal.

2.2.15. PETROLEUM REFINERIES

Quantities of fuels used to produce petroleum products.

2.2.16. NATURAL GAS BLENDING PLANTS (FOR BLENDED NATURAL GAS)

Quantities of gases blended with natural gas into the gas grid (gas network).

2.2.17. FOR BLENDING WITH MOTOR GASOLINE/DIESEL/KEROSENE:

Quantities of liquid biofuels blended with their fossil counterparts.

2.2.18. NOT ELSEWHERE SPECIFIED

Quantities of fuels used for transformation activities not included elsewhere. If used, what is included under this heading should be explained in the report.

2.3. **Energy sector**

Quantities consumed by the energy industry to support extraction (mining, oil and gas production) or plant operations related to transformation activities. This corresponds to NACE Rev. 2 Divisions 05, 06, 19 and 35, NACE Rev. 2 Group 09.1 and NACE Rev. 2 classes 07.21 and 08.92.

Excludes quantities of fuels transformed into another energy form (which should be reported under the transformation sector) or used to support the operation of oil, gas and coal slurry pipelines (which should be reported in the transport sector).

Includes the manufacture of chemical materials for atomic fission and fusion and the products of these processes.

2.3.1. OWN USE OF ELECTRICITY, CHP AND HEAT PLANTS

Quantities of fuels consumed as energy for support operations at plants with electricity-only, heat-only and CHP units.

2.3.2. COAL MINES

Quantities of fuels consumed as energy to support the extraction and preparation of coal within the coal mining industry. Coal burned in pithead power stations should be reported in the transformation sector.

2.3.3. PATENT FUEL PLANTS

Quantities of fuels consumed as energy for support operations at patent fuel plants.

2.3.4. COKE OVENS

Quantities of fuels consumed as energy for support operations in coke ovens (coking plants).

2.3.5. BKB/PB PLANTS

Quantities of fuels used as energy for support operations in BKP/PB plants (briquetting plants).

2.3.6. GAS WORKS/GASIFICATION WORKS

Quantities of fuels consumed as energy for support operations at gas works and coal gasification plants.

2.3.7. BLAST FURNACES

Quantities of fuels consumed as energy for support operations at blast furnaces.

2.3.8. COAL LIQUEFACTION

Quantities of fuels consumed as energy for support operations at coal liquefaction plants.

2.3.9. LIQUEFACTION (LNG)/REGASIFICATION

Quantities of fuels consumed as energy for support operations in natural gas liquefaction and regasification plants.

2.3.10. GASIFICATION PLANTS (BIOGAS)

Quantities of fuels consumed as energy for support operations in biogas gasification plants.

2.3.11. GAS-TO-LIQUID (GTL) PLANTS

Quantities of fuels consumed as energy for support operations in gas-to-liquid conversion plants.

2.3.12. CHARCOAL PRODUCTION PLANTS

Quantities of fuels consumed as energy for support operations in charcoal production plants.

2.3.13. PETROLEUM REFINERIES

Quantities of fuels consumed as energy for support operations at petroleum refineries.

2.3.14. OIL AND GAS EXTRACTION

Quantities of fuels consumed in oil and natural gas extraction facilities. Excludes pipeline losses (to be reported as distribution losses) and energy quantities used to operate pipelines (to be reported in the transport sector).

2.3.15. NOT ELSEWHERE SPECIFIED – ENERGY

Quantities of fuels related to energy activities not included elsewhere. If used, what is included under this heading should be explained in the report.

2.4. **Transmission and distribution losses**

2.4.1. TRANSMISSION LOSSES

Quantities of fuel losses that occur due to transmission, at the part of the system operated by the transmission system operator. It includes technical and non-technical losses. For electricity, it includes losses in transformers that are not considered as integral parts of power plants. For gas, it includes venting and flaring during transmission.

2.4.2. DISTRIBUTION LOSSES

Quantities of fuel losses that occur due to distribution, at the part of the system operated by the distribution system operator. It includes technical and non-technical losses. For gas, it includes venting and flaring during distribution.

2.5. **Final non-energy consumption**

Quantities of fossil fuels used for non-energy purposes – fuels not combusted.

2.6. **Final energy consumption (end-use specifications)**

2.6.1. INDUSTRY SECTOR

This refers to fuel quantities consumed by the industrial undertaking to support its primary activities.

For heat-only or CHP units, only quantities of fuels consumed for the production of heat used by the entity itself (heat auto-consumed) are to be reported. Quantities of fuels consumed for the production of heat sold and for the production of electricity should be reported under the appropriate transformation sector.

2.6.1.1. Mining and quarrying: NACE Rev. 2 Divisions 07 (excluding 07.21) and 08 (excluding 08.92); NACE Rev. 2 Group 09.9.

2.6.1.1.1. Mining of metal ores [NACE Rev. 2 Division 07; excludes NACE Rev. 2 Class 07.21 Mining of uranium and thorium ores]

2.6.1.1.2. Other mining and quarrying [NACE Rev. 2 Div. 08; excludes NACE Rev. 2 Class 08.92 Extraction of peat]

2.6.1.1.3. Mining support service activities [NACE Rev. 2 Div. 09; excludes NACE Rev. 2 Group 09.1 Support activities for petroleum and natural gas extraction]

2.6.1.2. Food, beverages and tobacco: NACE Rev. 2 Divisions 10, 11 and 12.

2.6.1.2.1. Manufacture of food products [NACE Rev. 2 Div. 10]

2.6.1.2.2. Manufacture of beverages [NACE Rev. 2 Div. 11]

2.6.1.2.3. Manufacture of tobacco products [NACE Rev. 2 Div. 12]

2.6.1.3. Textile and leather [NACE Rev. 2 Div. 13, 14 and 15; includes the Manufacture of textiles, the Manufacture of wearing apparel and the Manufacture of leather and related products]

2.6.1.4. Wood and wood products – Manufacture of wood and of products of wood and cork, except furniture; Manufacture of articles of straw and plaiting materials [NACE Rev. 2 Div. 16]

2.6.1.5. Pulp, paper and printing: NACE Rev. 2 Divisions 17 and 18.

2.6.1.5.1. Manufacture of paper and paper products [NACE Rev. 2 Div. 17]

2.6.1.5.1.1. Manufacture of pulp [NACE Rev. 2 Class 17.11]

- 2.6.1.5.1.2. Other paper and paper products [NACE Rev. 2 Class 17.12 and NACE Rev. 2 Group 17.2]
- 2.6.1.5.2. Printing and reproduction of recorded media [NACE Rev. 2 Div. 18]
- 2.6.1.6. Chemical and petrochemical: NACE Rev. 2 Divisions 20 and 21.
- 2.6.1.6.1. Manufacture of chemicals and chemical products [NACE Rev. 2 Div. 20]
- 2.6.1.6.2. Manufacture of basic pharmaceutical products and pharmaceutical preparations [NACE Rev. 2 Div. 21]
- 2.6.1.7. Non-metallic minerals [NACE Rev. 2 Div. 23]
- 2.6.1.7.1. Manufacture of glass and glass products [NACE Rev. 2 Group 23.1]
- 2.6.1.7.2. Manufacture of cement, lime and plaster (incl. Clinker) [NACE Rev. 2 Group 23.5]
- 2.6.1.7.3. Other non-metallic mineral products [NACE Rev. 2 Groups 23.2, 23.3, 23.4, 23.6, 23.7 and 23.9]
- 2.6.1.8. Iron and steel [Manufacture of basic metals A: NACE Rev. 2 Groups 24.1, 24.2 and 24.3 and Classes 24.51 and 24.52]
- 2.6.1.9. Non-ferrous metals industries [Manufacture of basic metals B: NACE Rev. 2 Group 24.4 and Classes 24.53 and 24.54]
- 2.6.1.9.1. Aluminium production [NACE Rev. 2 Class 24.42]
- 2.6.1.9.2. Other non-ferrous metals industries [NACE Rev. 2 Group 24.4 – excl. NACE Rev. 2 Class 24.42; NACE Rev. 2 Classes 24.53 and 24.54]
- 2.6.1.10. Machinery: NACE Rev. 2 Divisions 25, 26, 27 and 28.
- 2.6.1.10.1. Manufacture of fabricated metal products, except machinery and equipment [NACE Rev. 2 Div. 25]
- 2.6.1.10.2. Manufacture of computer, electronic and optical products [NACE Rev. 2 Div. 26]
- 2.6.1.10.3. Manufacture of electrical equipment [NACE Rev. 2 Div. 27]
- 2.6.1.10.4. Manufacture of machinery and equipment n.e.c. [NACE Rev. 2 Div. 28]
- 2.6.1.11. Transport equipment: Industries related to the equipment used for transport [NACE Div. 29 and 30; includes the Manufacture of motor vehicles, trailers and semi-trailers and the Manufacture of other transport equipment]
- 2.6.1.12. Not elsewhere specified – Industry: NACE Divisions 22, 31 and 32
- 2.6.1.12.1. Manufacture of rubber and plastic products [NACE Div. 22]
- 2.6.1.12.2. Manufacture of furniture [NACE Rev. 2 Div. 31]
- 2.6.1.12.3. Other manufacturing [NACE Rev. 2 Div. 32]
- 2.6.1.13. Construction [NACE Rev. 2 Div. 41, 42 and 43]
- 2.6.2. TRANSPORT SECTOR
Energy used in all transport activities irrespective of the NACE category (economic sector) in which the activity occurs. Fuels used for heating and lighting at railway stations, bus stations, shipping piers and airports should be reported under 'Commercial and Public Services' and not in the transport sector.
- 2.6.2.1. Rail
Quantities of fuels used by rail traffic, including industrial railways and rail transport as part of urban or suburban transport systems (for example trains, trams, metros).

- 2.6.2.1.1. High-speed rail
Energy used by trains running on lines where speed can exceed 200 kilometres per hour.
- 2.6.2.1.2. Conventional rail
Energy used by rail traffic, excluding high-speed rail and metro and tram.
- 2.6.2.1.2.1. Passenger transport by conventional rail
Energy used by rail for the transport of passengers, meaning for the movement of passengers using railway vehicles between the place of embarkation and the place of disembarkation. passenger is any person excluding members of the train crew, who makes a trip by rail.
- 2.6.2.1.2.2. Freight transport by conventional rail
Energy used by rail for the transport of goods, meaning for the movement of goods using railway vehicles between the place of loading and the place of unloading.
- 2.6.2.1.3. Metro and tram
Energy used by metro, tram, light rail and other elevated or underground urban railway systems.
- 2.6.2.2. Domestic navigation
Quantities of fuels delivered to vessels of all flags not engaged in international navigation (see international marine bunkers). The domestic/international split should be determined based on the port of departure and port of arrival and not by the flag or nationality of the ship.
- 2.6.2.3. Road
Quantities of fuels used in road vehicles. Includes fuel used by agricultural vehicles on highways and lubricants for use in road vehicles.

Excludes energy used in stationary engines (see 'Other sector'), for non-highway use in tractors (see 'Agriculture'), military use in road vehicles (see 'Other sector – Not elsewhere specified'), bitumen used in road surfacing and energy used in engines at construction sites (see 'Industry' sub-sector 'Construction').
- 2.6.2.3.1. Heavy-duty vehicles carrying freight
Quantities of fuels used in trucks over 3,5 t load capacity, carrying freight (categories N2 and N3 vehicles according to the European classification for vehicle category, based on UNECE standards).
- 2.6.2.3.2. Collective transport
Quantities of fuels used in large vehicles, carrying passengers, such as buses, coaches, large vans, etc. (categories M2 and M3 vehicles according to the European classification for vehicle category, based on UNECE standards).
- 2.6.2.3.3. Cars and vans
Quantities of fuels used in small vehicles, such as cars and vans, carrying passengers or freight (categories N1 and M1 vehicles according to the European classification for vehicle category, based on UNECE standards).
- 2.6.2.3.4. Other road transport:
Quantities of fuels used in all forms of road transport aside from heavy-duty vehicles carrying freight, collective transport and cars and vans.
- 2.6.2.4. Pipeline transport
Quantities of fuels used as energy to support the operation of pipelines transporting gases, liquids, slurries and other commodities. Includes energy used for pump stations and for pipeline maintenance. Excludes energy used for the pipeline distribution of natural or manufactured gas, hot water or steam from the distributor to final users (to be reported in the energy sector), energy used for the final distribution of water to households, industrial, commercial and other users (to be included in Commercial and public services) and losses occurring during the transport between distributor and final users (to be reported as distribution losses).

2.6.2.5. Domestic aviation

Quantities of fuels delivered to aircraft for domestic aviation. Includes fuel used for purposes other than flying, e.g. the bench testing of engines. The domestic/international split should be determined based on departure and landing locations and not on the nationality of the airline. This includes journeys of considerable length between two airports in a country with overseas territories. Excludes fuels used by airlines for their road vehicles (to be reported in 'Not elsewhere specified – Transport') and military use of aviation fuels (to be reported in 'Not elsewhere specified – Other').

2.6.2.6. Not elsewhere specified – Transport

Quantities of fuels used for transport activities not included elsewhere. Includes fuels used by airlines for their road vehicles and fuels used in ports for ships' unloaders, various types of cranes. If used, what is included under this heading should be explained in the report.

2.6.3. OTHER SECTORS

This category covers quantities of fuels used in sectors not specifically mentioned or not belonging to transformation, energy, industry or transport.

2.6.3.1. Commercial and public services

Quantities of fuels consumed by business and offices in the public and private sectors. NACE Rev. 2 Divisions 33, 36, 37, 38, 39, 45, 46, 47, 52, 53, 55, 56, 58, 59, 60, 61, 62, 63, 64, 65, 66, 68, 69, 70, 71, 72, 73, 74, 75, 77, 78, 79, 80, 81, 82, 84 (excluding Class 84.22), 85, 86, 87, 88, 90, 91, 92, 93, 94, 95, 96 and 99. Fuels used for heating and lighting at railway, bus stations, shipping piers and airports should be reported in this category. This includes fuels used for all non-transport activities of NACE Rev. 2 Division 49, 50 and 51.

2.6.3.1.1. Repair and installation of machinery and equipment [NACE Rev. 2, Section C division 33]

2.6.3.1.2. Water supply; sewerage, waste management and remediation activities [NACE Rev. 2, Section E]

2.6.3.1.3. Wholesale and retail trade; repair of motor vehicles and motorcycles [NACE Rev. 2, Section G]

2.6.3.1.3.1. Wholesale trade [NACE Rev. 2, Section G, Division 46]

2.6.3.1.3.2. Retail trade [NACE Rev. 2, Section G, Division 47]

2.6.3.1.4. Warehousing and support activities for transportation [NACE Rev. 2, Section H, Division 52]

2.6.3.1.5. Postal and courier activities [NACE Rev. 2, Section H, Division 53]

2.6.3.1.6. Accommodation and food service activities [NACE Rev. 2, Section I]

2.6.3.1.6.1. Accommodation [NACE REV. 2, Section I, Division 55]

2.6.3.1.6.2. Food service activities [NACE Rev. 2, Section I, Division 56]

2.6.3.1.7. Information and communication [NACE Rev. 2, Section J]

2.6.3.1.8. Financial and insurance activities and Real estate activities [NACE Rev. 2, Section K and NACE Rev. 2, Section L]

2.6.3.1.9. Administrative and support service activities [NACE Rev. 2, Section N]

2.6.3.1.10. Public administration and defence; compulsory social security [NACE Rev. 2, Section O]

2.6.3.1.11. Education [NACE Rev. 2, Section P]

2.6.3.1.12. Human health and social work activities [NACE Rev. 2, Section Q]

2.6.3.1.12.1. Hospital activities [NACE Rev. 2, Section Q, Group 86.1]

2.6.3.1.13. Arts, entertainment and recreation [NACE Rev. 2, Section R]

2.6.3.1.13.1. Sports activities [NACE Rev. 2, Section R, Division 93]

2.6.3.1.14. Activities of extra-territorial organisations and bodies [NACE Rev. 2, Section U]

2.6.3.1.15. Professional, scientific and technical activities and Other services [NACE Rev. 2, Section M and NACE Rev. 2, Section S]

2.6.3.1.16. Data centres. A data centre is defined as a structure or a group of structures used to house, connect and operate computer systems/servers and associated equipment for data storage, processing and/or distribution, as well as related activities.

2.6.3.2. Households

Quantities of fuels consumed by all households including 'households with employed persons'. NACE Rev. 2 Divisions 97 and 98.

The following specific definitions apply for the households sector:

A household is a person living alone, a family, or a group of people living together in the same private dwelling and sharing utilities and other essential living expenses. The households sector, also known as the residential or domestic sector, is therefore a collective pool of all households in a country.

Collective residences, either permanent (e.g. prisons) or temporary (e.g. hospitals), should be excluded as they are covered under consumption in the service sector. Energy used in transport activities should be reported in the transport sector and not in the households sector.

Energy consumption associated with significant economic activities carried out by households should also be excluded from total household energy consumption. Such activities include agricultural economic activities on small farms and other economic activities carried out in a household's residence and should be reported in the appropriate sector of final consumption.

2.6.3.2.1. Space heating

This energy service refers to the use of energy to provide heat in an interior area of a dwelling.

2.6.3.2.2. Space cooling

This energy service refers to the use of energy for cooling in a dwelling, by a refrigeration system and/or unit.

Fans, blowers and other appliances not connected to a refrigeration unit are excluded from this section, but should be covered in the 'Lighting and electrical appliances' section.

2.6.3.2.3. Water heating

This energy service refers to the use of energy to heat water for hot running water, bathing, cleaning and other non-cooking applications.

Swimming pool heating is excluded, but should be covered in the 'Other end uses' section.

2.6.3.2.4. Cooking

This energy service refers to the use of energy to prepare meals.

Appliances for auxiliary cooking (microwave ovens, kettles, coffee makers, etc.) are excluded and should be covered in the 'Lighting and electrical appliances' section.

2.6.3.2.5. Lighting and electrical appliances (electricity only):

Use of electricity for lighting and any other electrical appliances in a dwelling not considered within other end uses.

2.6.3.2.6. Other end uses

Any other energy consumption in households, such as use of energy for outdoor and any other activities not included into the five energy end uses mentioned above (e.g. lawn mowers, swimming pool heating, outdoor heaters, outdoor barbecues, saunas etc.).

2.6.3.3. Agriculture

Quantities of fuels consumed by users classified as crop and animal production, hunting and related service activities; NACE Rev. 2, Division 01.

2.6.3.4. Forestry

Quantities of fuels consumed by users classified as forestry and logging; NACE Rev. 2, Division 02.

2.6.3.5. Fishing

Quantities of fuels delivered for inland, coastal and deep-sea fishing. Fishing should cover fuels delivered to ships of all flags that have refuelled in the country (including international fishing) and energy used in the fishing industry. NACE Rev. 2, Division 03.

2.6.3.6. Not elsewhere specified – Other

Quantities of fuels used for activities not included elsewhere (such as NACE Rev. 2, Class 84.22). This category includes military fuel use for all mobile and stationary consumption (e.g. ships, aircraft, road and energy used in living quarters), regardless of whether the fuel delivered is for the military of that country or for the military of another country. If used, what is included under this heading should be explained in the report.

3. **PRODUCTS**

3.1. **COAL (solid fossil fuels and manufactured gases)**

3.1.1. HARD COAL

Hard coal is a product aggregate equal to the sum of anthracite, coking coal and other bituminous coal.

3.1.2. ANTHRACITE

High rank coal used for industrial and household applications. It generally has less than 10 % volatile matter and a high carbon content (about 90 % fixed carbon). Its gross calorific value is greater than 24 000 kJ/kg on an ash-free but moist basis.

3.1.3. COKING COAL

Bituminous coal with a quality that allows the production of a coke (coke oven coke) suitable to support a blast furnace charge. Its gross calorific value is greater than 24 000 kJ/kg on an ash-free but moist basis.

3.1.4. OTHER BITUMINOUS COAL

Coal used for steam raising purposes and includes all bituminous coal that is not included under coking coal nor anthracite. It is characterised by higher volatile matter than anthracite (more than 10 %) and lower carbon content (less than 90 % fixed carbon). Its gross calorific value is greater than 24 000 kJ/kg on an ash-free but moist basis.

3.1.5. BROWN COAL

Brown coal is a product aggregate equal to the sum of sub-bituminous coal and lignite.

3.1.6. SUB-BITUMINOUS COAL

Refers to non-agglomerating coal with a gross calorific value between 20 000 kJ/kg and 24 000 kJ/kg containing more than 31 % volatile matter on a dry mineral matter free basis.

3.1.7. LIGNITE

Non-agglomerating coal with a gross calorific value less than 20 000 kJ/kg and greater than 31 % volatile matter on a dry mineral matter free basis.

3.1.8. PATENT FUEL

A composition fuel manufactured from hard coal fines with the addition of a binding agent. The amount of patent fuel produced may, therefore, be slightly higher than the actual amount of coal consumed in the transformation process.

3.1.9. COKE OVEN COKE

The solid product obtained from the carbonisation of coal, principally coking coal, at high temperature; it is low in moisture and volatile matter. Coke oven coke is used mainly in the iron and steel industry, acting as an energy source and chemical agent.

Coke breeze and foundry coke are to be reported in this category.

Semi-coke (a solid product obtained from the carbonisation of coal at a low temperature) should be included in this category. Semi-coke is used as a heating fuel or by the transformation plant itself.

This heading also includes coke, coke breeze and semi-coke made from lignite.

3.1.10. GAS COKE

By-product of hard coal used for production of town gas in gas works. Gas coke is used for heating purposes.

3.1.11. COAL TAR

A result of the destructive distillation of bituminous coal. Coal tar is the liquid by-product of the distillation of coal to make coke in the coke oven process or is produced from brown coal ('low-temperature tar').

3.1.12. BKB (BROWN COAL BRIQUETTES)

BKB is a composition fuel manufactured from lignite or sub-bituminous coal, produced by briquetting under high pressure without the addition of a binding agent, including dried lignite fines and dust.

3.1.13. MANUFACTURED GASES

Manufactured gases is a product aggregate equal to the sum of gas works gas, coke oven gas, blast furnace gas and other recovered gases.

3.1.14. GAS WORKS GAS

Covers all types of gases produced in public utility or private plants whose main purpose is the manufacture, transport and distribution of gas. It includes gas produced by carbonisation (including gas produced by coke ovens and transferred to gas works gas), by total gasification with or without enrichment with oil products (LPG, residual fuel oil, etc.), and by reforming and simple mixing of gases and/or air, including blending with natural gas which will be distributed and consumed through the natural gas grid. The amount of gas resulting from transfers of other coal gases to gas works gas should be reported as the production of the gas works gas.

3.1.15. COKE OVEN GAS

Coke oven gas is a gas obtained as a by-product of the manufacture of coke oven coke for the production of iron and steel.

3.1.16. BLAST FURNACE GAS

Blast furnace gas is produced during the combustion of coke in blast furnaces in the iron and steel industry. It is recovered and used as a fuel partly within the plant and partly in other steel industry processes or in power stations equipped to burn it.

3.1.17. OTHER RECOVERED GASES

By-product of the production of steel in an oxygen furnace, recovered on leaving the furnace. The gases are also known as converter gas, LD gas or BOS gas. The quantity of recuperated fuel should be reported on a gross calorific value basis. Also covers non-specified manufactured gases not mentioned above, such as combustible gases of solid carbonaceous origin recovered from manufacturing and chemical processes not defined elsewhere.

3.1.18. PEAT

Peat is a combustible soft, porous or compressed, sedimentary deposit of plant origin with high water content (up to 90 % in the raw state), easily cut, of light to dark brown colour. Peat includes sod peat and milled peat. Peat used for non-energy purposes is not included.

3.1.19. PEAT PRODUCTS

Products such as peat briquettes derived directly or indirectly from sod peat and milled peat.

3.1.20. OIL SHALE AND OIL SANDS

Oil shale and oil sands are sedimentary rock that contains organic matter in the form of kerogen. Kerogen is a waxy hydrocarbon-rich material regarded as a precursor of petroleum. Oil shale may be burned directly or processed by heating to extract shale oil. Shale oil and other products derived from liquefaction should be reported as other hydrocarbons within petroleum products.

3.2. Natural gas**3.2.1. NATURAL GAS**

Natural gas comprises gases occurring in underground deposits, whether liquefied or gaseous, consisting mainly of methane, independent from the extraction method (conventional and non-conventional). It includes both 'non-associated' gas originating from fields producing hydrocarbons only in gaseous form, and 'associated' gas produced in association with crude oil, as well as methane recovered from coal mines (colliery gas) or from coal seams (coal seam gas). Natural gas does not include biogas or manufactured gases. Transfers of these products to the natural gas network are to be reported separately from natural gas. Natural gas includes liquefied natural gas (LNG) and compressed natural gas (CNG).

3.3. Electricity and heat**3.3.1. ELECTRICITY**

Electricity refers to the transfer of energy through the physical phenomenon involving electric charges and their effects when at rest and in motion. All electricity that is used, produced and consumed is to be reported, including off-grid and self-consumed. Off-grid electricity is produced by installations that are disconnected from the grid from the production perspective; the installation cannot inject electricity produced into the grid. Self-consumed electricity is electricity consumed by the producer before it is injected in the grid.

3.3.2. HEAT (DERIVED HEAT)

Heat refers to the energy obtained from the translational, rotational and vibrational motion of the constituents of matter as well as changes in its physical state. All heat produced, except for heat produced by autoproducers for their own use and not sold, is to be reported; all other forms of heat are reported as use of products from which the heat was produced.

3.4. OIL (Crude oil and petroleum products)**3.4.1. CRUDE OIL**

Crude oil is a mineral oil of natural origin comprising a mixture of hydrocarbons and associated impurities, such as sulphur. It exists in the liquid state under normal surface temperature and pressure and its physical characteristics (density, viscosity, etc.) are highly variable. This category includes field or lease condensate

recovered from associated and non-associated gas where it is commingled with the commercial crude oil stream. Quantities should be reported independently from the extraction method (conventional and non-conventional). Crude oil excludes NGL.

3.4.2. NATURAL GAS LIQUIDS (NGL)

NGL are liquid or liquefied hydrocarbons recovered from natural gas in separation facilities or gas processing plants. NGL include ethane, propane, butane (normal and iso-), (iso) pentane and pentanes plus (sometimes referred to as natural gasoline or plant condensate).

3.4.3. REFINERY FEEDSTOCKS

A refinery feedstock is a processed oil destined for further processing (e.g. straight run fuel oil or vacuum gas oil) excluding blending. With further processing, it will be transformed into one or more components and/or finished products. This definition also covers returns from the petrochemical industry to the refining industry (e.g. pyrolysis gasoline, C4 fractions, gasoil and fuel oil fractions).

3.4.4. ADDITIVES/OXYGENATES

Additives are non-hydrocarbon compounds added to or blended with a petroleum products to modify their properties (octane, cetane, cold properties, etc.). Additives include oxygenates (such as alcohols (methanol, ethanol), ethers (methyl tertiary butyl ether (MTBE), ethyl tertiary butyl ether (ETBE), tertiary amyl methyl ether (TAME), etc.), esters (rapeseed oil or dimethylester, etc.), chemical compounds (such as tetramethyl lead (TML), tetraethyl lead (TEL) and detergents). Quantities of additives/oxygenates (alcohols, ethers, esters and other chemical compounds) reported in this category should relate to the quantities blended with fuels or for fuel use. This category includes biofuels that are blended with liquid fossil fuels.

3.4.5. BIOFUELS IN ADDITIVES/OXYGENATES

Quantities of liquid biofuels reported in this category relate to blended liquid biofuels and refer only to the liquid biofuel portion and not to the total volume of liquids into which the liquid biofuels are blended. Excludes all liquid biofuels that have not been blended.

3.4.6. OTHER HYDROCARBONS

Synthetic crude oil from tar sands, shale oil, etc., liquids from coal liquefaction, output of liquids from natural gas conversion into gasoline, hydrogen and emulsified oils (e.g. orimulsion); excludes oil shale; includes the shale oil (secondary product).

3.4.7. PETROLEUM PRODUCTS

Petroleum products are a product aggregate equal to the sum of refinery gas, ethane, liquefied petroleum gases, naphtha, motor gasoline, aviation gasoline, gasoline type jet fuel, kerosene type jet fuel, other kerosene, gas/diesel oil, fuel oil, white spirit and SPB, lubricants, bitumen, paraffin waxes, petroleum coke and other products.

3.4.8. REFINERY GAS

Refinery gas includes a mixture of non-condensed gases mainly consisting of hydrogen, methane, ethane and olefins obtained during the distillation of crude oil or treatment of oil products (e.g. cracking) in refineries. This also includes gases which are returned from the petrochemical industry.

3.4.9. ETHANE

A naturally gaseous straight-chain hydrocarbon, (C₂H₆) extracted from natural gas and refinery gas streams.

3.4.10. LIQUEFIED PETROLEUM GASES (LPG)

LPG are light paraffinic hydrocarbons derived from refinery processes, crude oil stabilisation and natural gas processing plants. They consist mainly of propane (C_3H_8) and butane (C_4H_{10}) or a combination of the two. They could also include propylene, butylene, isopropylene and isobutylene. LPG are normally liquefied under pressure for transportation and storage.

3.4.11. NAPHTHA

Naphtha is a feedstock destined for either the petrochemical industry (e.g. ethylene manufacture or aromatics production) or for gasoline production by reforming or isomerisation within the refinery. Naphtha comprises material in the 30 °C and 210 °C distillation range or part of this range.

3.4.12. MOTOR GASOLINE

Motor gasoline consists of a mixture of light hydrocarbons distilling at between 35 °C and 215 °C. It is used as a fuel for land-based spark ignition engines. Motor gasoline may include additives, oxygenates and octane enhancers, including lead compounds. Includes motor gasoline blending components (excluding additives/oxygenates), e.g. alkylates, isomerate, reformate, cracked gasoline destined for use as finished motor gasoline. Motor gasoline is a product aggregate equal to the sum of blended biogasoline (biogasoline in motor gasoline) and non-biogasoline.

3.4.12.1. Blended biogasoline (biogasoline in motor gasoline)

Biogasoline that was blended in motor gasoline.

3.4.12.2. Non-biogasoline

The remaining part of motor gasoline – motor gasoline excluding blended biogasoline (this is mostly motor gasoline of fossil origin).

3.4.13. AVIATION GASOLINE

Motor spirit prepared especially for aviation piston engines, with an octane number suited to the engine, a freezing point of – 60 °C and a distillation range usually between 30 °C and 180 °C.

3.4.14. GASOLINE TYPE JET FUEL (NAPHTHA TYPE JET FUEL OR JP4)

This includes all light hydrocarbon oils for use in aviation turbine power units, distilling at between 100 °C and 250 °C. They are obtained by blending kerosenes and gasoline or naphthas in such a way that the aromatic content does not exceed 25 % in volume, and the vapour pressure is between 13,7 kPa and 20,6 kPa.

3.4.15. KEROSENE TYPE JET FUEL

Distillate used for aviation turbine power units. It has the same distillation characteristics at between 150 °C and 300 °C (generally not above 250 °C) and flash point as kerosene. In addition, it has particular specifications (such as freezing point) which are established by the International Air Transport Association. Includes kerosene blending components. Kerosene type jet fuel is a product aggregate equal to the sum of blended bio jet kerosene (bio jet kerosene in kerosene type jet fuel) and non-bio jet kerosene.

3.4.15.1. Blended bio jet kerosene (bio jet kerosene in kerosene type jet fuel)

Bio jet kerosene that was blended in kerosene type jet fuel.

3.4.15.2. Non-bio jet kerosene

The remaining part of kerosene type jet fuel – kerosene type jet fuel excluding blended bio jet kerosene (this is mostly kerosene type jet fuel of fossil origin).

3.4.16. OTHER KEROSENE

Refined petroleum distillate used in sectors other than aircraft transport. It distils at between 150 °C and 300 °C.

3.4.17. GAS/DIESEL OIL (DISTILLATE FUEL OIL)

Gas/diesel oil is primarily a medium distillate distilling at between 180 °C and 380 °C. Includes blending components. Several grades are available depending on uses. Gas/diesel oil includes on-road diesel oil for diesel compression ignition engines of cars and trucks. Gas/diesel oil includes light heating oil for industrial and commercial uses, marine diesel and diesel used in rail traffic, other gas oil including heavy gas oils which distil at between 380 °C and 540 °C and which are used as petrochemical feedstocks. Gas/diesel oil is a product aggregate equal to the sum of blended biodiesels (biodiesels in gas/diesel oil) and non-biodiesels.

3.4.17.1. Blended biodiesels (biodiesels in gas/diesel oil)

Biodiesels that were blended in gas/diesel oil.

3.4.17.2. Non-biodiesels

The remaining part of gas/diesel oil – gas/diesel oil excluding blended biodiesels (this is mostly gas/diesel oil of fossil origin).

3.4.18. FUEL OIL (HEAVY FUEL OIL)

All residual (heavy) fuel oils (including those obtained by blending). Kinematic viscosity is above 10 cSt at 80 °C. The flash point is always above 50 °C and density is always more than 0.90 kg/l. Fuel oil is a product aggregate equal to the sum of low sulphur fuel oil and high sulphur fuel oil.

3.4.18.1. Low sulphur fuel oil (LSFO)

Fuel oil with sulphur content lower than 1 %.

3.4.18.2. High sulphur fuel oil (HSFO)

Fuel oil with sulphur content of 1 % or higher.

3.4.19. WHITE SPIRIT AND SBP

White spirit and SBP are defined as refined distillate intermediates with a distillation in the naphtha/kerosene range. They include industrial spirit (also called SBP; light oils distilling at between 30 °C and 200 °C in 7 or 8 grades of industrial spirit, depending on the position of the cut in the distillation range – the grades are defined according to the temperature difference between the 5 % volume and 90 % volume distillation points, which is not more than 60 °C) and white spirits (industrial spirit with a flash point above 30 °C and the distillation range between 135 °C and 200 °C).

3.4.20. LUBRICANTS

Hydrocarbons produced from distillate by-product. They are mainly used to reduce friction between bearing surfaces. Includes all finished grades of lubricating oil, from spindle oil to cylinder oil, and those used in greases, motor oils and all grades of lubricating oil base stocks.

3.4.21. BITUMEN

Solid, semi-solid or viscous hydrocarbon with a colloidal structure, being brown to black in colour, obtained as a residue in the distillation of crude oil, by vacuum distillation of oil residues from atmospheric distillation. Bitumen is often referred to as asphalt and is primarily used for the construction of roads and for roofing material. Includes fluidised and cut back bitumen.

3.4.22. PARAFFIN WAXES

These are saturated aliphatic hydrocarbons. They are residues extracted when dewaxing lubricant oils. They have a crystalline structure which is more or less fine depending on the grade. Their main characteristics are as follows: they are colourless, odourless and translucent, with a melting point above 45 °C.

3.4.23. PETROLEUM COKE

Black solid by-product, obtained mainly by cracking and carbonising petroleum derived feedstock, vacuum bottoms, tar and pitches in processes such as delayed coking or fluid coking. It consists mainly of carbon (90-95 %) and has a low ash content. It is used as a feedstock in coke ovens for the steel industry, for heating purposes, for electrode manufacture and for the production of chemicals. The two most important qualities are 'green coke' and 'calcinated coke'. Includes 'catalyst coke' deposited on the catalyst during refining processes; this coke is not recoverable and is usually burned as refinery fuel.

3.4.24. OTHER PRODUCTS

All other products not specifically mentioned above, for example: tar and sulphur. Includes aromatics (e.g. BTX or benzene, toluene and xylene) and olefins (e.g. propylene) produced within refineries.

3.5. **Renewables and waste**

3.5.1. HYDRO

Potential and kinetic energy of water converted into electricity in hydroelectric plants. Hydro is a product aggregate equal to the sum of pure hydro plants, mixed hydro plants and pure pumped storage plants.

3.5.1.1. Pure hydro plants

Hydro plants that only use direct natural water inflow and have no capacity for hydro pump storage (pumping water uphill).

3.5.1.2. Mixed hydro plants

Hydro plants with natural water inflow into an upper reservoir where part or all equipment can be used for pumping water uphill; the electricity generated is a consequence of both natural water inflow and water previously pumped uphill.

3.5.1.3. Pure pumped storage plants

Hydro plants with no natural water inflow into the upper reservoir; the vast majority of water that generates electricity was previously pumped uphill; excluding rainfall and snowfall.

3.5.2. GEOTHERMAL

Energy available as heat emitted from within the earth's crust, usually in the form of hot water or steam; excluding ambient heat captured by ground source heat pumps. Geothermal energy production is the difference between the enthalpy of the fluid produced in the production borehole and that of the fluid eventually disposed of.

3.5.3. SOLAR

Solar is a product aggregate equal to the sum of solar photovoltaic and solar thermal.

3.5.3.1. Solar photovoltaic

Sunlight converted into electricity by the use of solar cells which when exposed to light will generate electricity. All electricity produced is to be reported (including small-scale production and off-grid installations).

3.5.3.1.1. Rooftop

Report here the quantity of energy produced by solar photovoltaic panels located on building structures that have another primary purpose than energy production. It also includes BIPV (building integrated PV), where the PV panels are not on the roof, but e.g. attached to the building. Solar PV panels are not be considered rooftop if they are placed on a wide area, on the ground, such as consuming extra space (e.g. agricultural areas).

3.5.3.1.2. Off-grid

Report here off-grid as defined in Annex A, 3.3.1.

3.5.3.2. Solar thermal

Heat from solar radiation (sunlight) exploited for useful energy purposes. This includes, for example, solar thermal-electric plants and active systems for producing sanitary hot water or for space heating of buildings. This energy production is the heat available to the heat transfer medium, i.e. the incident solar energy less the optical and collectors losses. Solar energy captured by passive systems for heating, cooling and lighting of buildings is not to be included; only solar energy in relation to the active systems is to be included.

3.5.4. TIDE, WAVE, OCEAN

Mechanical energy derived from tidal movement, wave motion or ocean current and exploited for electricity generation.

3.5.5. WIND

Kinetic energy of wind exploited for electricity generation in wind turbines. Wind is a product aggregate equal to the sum of on-shore wind and offshore wind.

3.5.5.1. On-shore wind

Production of electricity by wind in locations on-shore (inland, including lakes and other bodies of water located inland).

3.5.5.2. Offshore wind

Production of electricity in offshore locations (e.g. sea, ocean and artificial islands). For offshore wind production outside of the territorial waters of the concerned territory, all installations located in a country's exclusive economic zone should be taken into account.

3.5.6. INDUSTRIAL WASTE (NON-RENEWABLE PORTION)

Report waste of industrial non-renewable origin combusted directly at specific installations for meaningful energy purposes. The quantity of fuel used should be reported on a net calorific value basis. Waste incinerated without any energy recovery is excluded. The renewable portion of industrial waste should be reported in the biofuels category that best describes it.

3.5.7. MUNICIPAL WASTE:

Wastes produced by households, hospitals and the tertiary sector (in general all waste that resembles household waste), combusted directly at specific installations for meaningful energy purposes. The quantity of fuel used should be reported on a net calorific value basis. Waste incinerated without any energy recovery is excluded. Municipal waste is a product aggregate equal to the sum of renewable municipal waste and non-renewable municipal waste.

3.5.7.1. Renewable municipal waste

The portion of municipal waste which is of biological origin.

3.5.7.2. Non-renewable municipal waste

The portion of municipal waste which is of non-biological origin.

3.5.8. BIOFUELS

Biofuels is a product aggregate equal to the sum of solid biofuels, biogas and liquid biofuels. Biofuels used for non-energy purposes are excluded from the scope of energy statistics (for example wood used for construction or as furniture, biolubricant for engine lubrication and biobitumen used for road surface).

3.5.8.1. Solid biofuels

Covers solid organic, non-fossil material of biological origin (also known as biomass) which may be used as fuel for heat production or electricity generation. Solid biofuels is a product aggregate equal to the sum of charcoal, fuelwood, wood residues and by-products, black liquor, bagasse, animal waste, other vegetal materials and residuals and renewable fraction of industrial waste.

3.5.8.1.1. Charcoal

Charcoal is a manufactured fuel from solid biofuels – the solid residue of the destructive distillation and pyrolysis of wood and other vegetal material.

3.5.8.1.2. Fuelwood, wood residues and by-products

Fuelwood or firewood (in log, brushwood, pellet or chip form) obtained from natural or managed forests or isolated trees. Included are wood residues used as fuel and in which the original composition of wood is retained; wood pellets are included. Charcoal and black liquor are excluded. The quantity of fuel used should be reported on a net calorific value basis.

3.5.8.1.2.1. Wood pellets

Wood pellets are a cylindrical product which has been agglomerated from wood residues by compression.

3.5.8.1.3. Black liquor

Energy from the alkaline-spent liquor obtained from the digesters during the production of sulphate or soda pulp required for paper manufacture. The quantity of fuel used should be reported on a net calorific value basis.

3.5.8.1.4. Bagasse

Fuel obtained from the fibre which remains after juice extraction in sugar cane processing. The quantity of fuel used should be reported on a net calorific value basis.

3.5.8.1.5. Animal waste

Energy from excreta of animals, meat and fish residues which when dry is used directly as a fuel. This excludes waste used in anaerobic fermentation plants. Fuel gases from these plants are included under biogases. The quantity of fuel used should be reported on a net calorific value basis.

3.5.8.1.6. Other vegetal materials and residuals

Biofuels not specified elsewhere and including straw, vegetable husks, ground nut shells, pruning brushwood, olive pomace and other wastes arising from the maintenance, cropping and processing of plants. The quantity of fuel used should be reported on a net calorific value basis.

3.5.8.1.7. Renewable portion of industrial waste

Solid renewable portion of industrial waste combusted directly at specific installations for meaningful energy purposes (for example but not only, the portion of natural rubber in waste rubber tires or the portion of natural fibres in textile waste – from waste categories 07.3 and 07.6, respectively, as defined in Regulation (EC) No 2150/2002 on waste statistics). The quantity of fuel used should be reported on a net calorific value basis.

3.5.8.2. Biogas

A gas composed principally of methane and carbon dioxide produced by anaerobic digestion of biomass or by thermal processes from biomass, including biomass in waste. The quantity of fuel used should be reported on a net calorific value basis. Biogas is a product aggregate equal to the sum of landfill gas, sewage sludge gas, other biogases from anaerobic digestion and biogases from thermal processes.

3.5.8.2.1. Landfill gas

Biogas produced from the anaerobic digestion of landfill waste.

3.5.8.2.2. Sewage sludge gas

Biogas produced from the anaerobic fermentation of sewage sludge.

3.5.8.2.3. Other biogases from anaerobic digestion

Biogas produced from the anaerobic fermentation of animal slurries and of waste in abattoirs, breweries and other agro-food industries.

3.5.8.2.4. Biogases from thermal processes

Biogas produced from thermal processes (by gasification or pyrolysis) of biomass.

3.5.8.3. Liquid biofuels

This category includes all liquid fuels of natural origin (e.g. produced from biomass and/or the biodegradable fraction of waste) suitable to be blended with or to replace liquid fuels of fossil origin. The quantities of liquid biofuels reported in this category should include the quantities of pure biofuel that were not blended with fossil fuels. In the particular case of imports and exports of liquid biofuels, only trade of quantities that have not been blended with transport fuels (i.e. in their pure form) is relevant; trade of liquid biofuels blended into transport fuels should be reported within the oil category of products. Only liquid biofuels used for energy purposes – combusted directly or blended with fossil fuels – are to be reported. Liquid biofuels is a product aggregate equal to the sum of biogasoline, biodiesels, bio jet kerosene and other liquid biofuels.

3.5.8.3.1. Biogasoline

Liquid biofuels suitable to be blended with or to replace motor gasoline from fossil origin.

3.5.8.3.1.1. Bioethanol

Ethanol as part of biogasoline.

3.5.8.3.2. Biodiesels

Liquid biofuels suitable to be blended with or to replace gas/diesel oil from fossil origin.

3.5.8.3.3. Bio jet kerosene

Liquid biofuels suitable to be blended with or to replace jet kerosene from fossil origin.

3.5.8.3.4. Other liquid biofuels

Liquid biofuels not included in any of the previous categories.

3.5.9. AMBIENT HEAT

Heat energy at a useful temperature level, extracted (captured) by means of heat pumps that need electricity or other auxiliary energy to function. This heat energy can be stored in the ambient air, beneath the surface of solid earth or in surface water. Values should be reported using the same methodology as the one used for reporting heat energy captured by heat pumps under Directive 2009/28/EC and Directive (EU) 2018/2001, but all heat pumps must be included regardless of their performance level.

3.6. **Hydrogen**

Hydrogen used as a feedstock, a fuel or an energy carrier/storage must be reported. All hydrogen must be reported, regardless whether it is sold or not sold. When in a mixture, hydrogen should be reported only when it is the main component with a high degree of purity.

ANNEX B

ANNUAL ENERGY STATISTICS

This annex describes the scope, units, reported period, frequency, deadline and transmission arrangements for the annual collection of energy statistics.

Unless otherwise specified, the following provisions apply to all data collections specified in this annex:

- a) Reported period: The reported period of declared data will be a calendar year (1 January to 31 December), starting at reference year 2022.
- b) Frequency: Data should be declared on an annual basis.
- c) Deadline for transmission of data: Data should be submitted by 31 October of the year following the reported year, unless otherwise specified.
- d) Transmission format: The transmission format should conform to the relevant interchange standard specified by Eurostat.
- e) Transmission method: Data should be sent in or uploaded by electronic means to Eurostat's single entry point for data.

Annex A provides explanations of terms not explained in this annex.

1. **SOLID FOSSIL FUELS AND MANUFACTURED GASES**

1.1. **Applicable energy products**

Unless otherwise specified, this data collection applies to all energy products listed in Annex A, Chapter 3.1 COAL (solid fossil fuels and manufactured gases).

1.2. **List of aggregates**

The following list of aggregates must be declared for all energy products listed in the previous paragraph unless otherwise specified.

1.2.1. **SUPPLY**

1.2.1.1. **Production**

1.2.1.1.1. **Underground production**

Applicable only for anthracite, coking coal, other bituminous coal, sub-bituminous coal and lignite.

1.2.1.1.2. **Surface production**

Applicable only for anthracite, coking coal, other bituminous coal, sub-bituminous coal and lignite.

1.2.1.2. **Receipts from other sources**

This consists of two components:

- recovered slurries, middlings and other low-grade coal products, which cannot be classified according to type of coal, including coal recovered from waste piles and other waste receptacles,
- receipts from other sources.

1.2.1.3. **Receipts from other sources: from oil products**

Not applicable for anthracite, coking coal, other bituminous coal, sub-bituminous coal, lignite, peat, and oil shale and oil sands.

1.2.1.4. **Receipts from other sources: from natural gas**

Not applicable for anthracite, coking coal, other bituminous coal, sub-bituminous coal, lignite, peat, and oil shale and oil sands.

- 1.2.1.5. Receipts from other sources: from renewables
Not applicable for anthracite, coking coal, other bituminous coal, sub-bituminous coal, lignite, peat, oil shale and oil sands.
- 1.2.1.6. Imports
- 1.2.1.7. Exports
- 1.2.1.8. International Marine Bunkers
- 1.2.1.9. Stock changes
- 1.2.2. TRANSFORMATION SECTOR
 - 1.2.2.1. Main activity producer electricity only
 - 1.2.2.2. Main activity producer combined heat and power (CHP) units
 - 1.2.2.3. Main activity producer heat only
 - 1.2.2.4. Autoproducer electricity only
 - 1.2.2.5. Autoproducer combined heat and power (CHP) units
 - 1.2.2.6. Autoproducer heat only
 - 1.2.2.7. Patent fuel plants
 - 1.2.2.8. Coke ovens
 - 1.2.2.9. BKB/PB plants
 - 1.2.2.10. Gas works
 - 1.2.2.11. Blast furnaces
 - 1.2.2.12. Coal liquefaction
 - 1.2.2.13. For blended natural gas
 - 1.2.2.14. Not elsewhere specified – Transformation
- 1.2.3. ENERGY SECTOR
 - 1.2.3.1. Electricity, CHP and heat plants
 - 1.2.3.2. Coal mines
 - 1.2.3.3. Patent fuel plants
 - 1.2.3.4. Coke ovens
 - 1.2.3.5. BKB/PB plants
 - 1.2.3.6. Gas works
 - 1.2.3.7. Blast furnaces
 - 1.2.3.8. Petroleum refineries
 - 1.2.3.9. Coal liquefaction
 - 1.2.3.10. Not elsewhere specified – Energy
- 1.2.4. TRANSMISSION AND DISTRIBUTION LOSSES
- 1.2.5. NON-ENERGY USE
 - 1.2.5.1. Industry, transformation and energy sectors

- Non-energy use in all industry, transformation and energy sub-sectors, e.g. coal used to make methanol or ammonia.
- 1.2.5.1.1. Chemical and petrochemical sector
NACE Rev. 2, Divisions 20 and 21; non-energy use of coal includes use as feedstocks to produce fertiliser and as feedstocks for other petrochemical products.
- 1.2.5.2. Transport sector
Non-energy use in all transport sub-sectors.
- 1.2.5.3. Other sectors
Non-energy use in Commercial and public services, households, agriculture and not elsewhere specified – Other.
- 1.2.6. FINAL ENERGY CONSUMPTION – INDUSTRY SECTOR
- 1.2.6.1. Iron and steel
- 1.2.6.2. Chemical and petrochemical
- 1.2.6.3. Non-ferrous metals
- 1.2.6.4. Non-metallic minerals
- 1.2.6.5. Transport equipment
- 1.2.6.6. Machinery
- 1.2.6.7. Mining and quarrying
- 1.2.6.8. Food, beverages and tobacco
- 1.2.6.9. Pulp, paper and printing
- 1.2.6.10. Wood and wood products
- 1.2.6.11. Construction
- 1.2.6.12. Textile and leather
- 1.2.6.13. Not elsewhere specified – Industry
- 1.2.7. FINAL ENERGY CONSUMPTION – TRANSPORT SECTOR
- 1.2.7.1. Rail
- 1.2.7.2. Domestic Navigation
- 1.2.7.3. Not Elsewhere Specified – Transport
- 1.2.8. FINAL ENERGY CONSUMPTION – OTHER SECTORS
- 1.2.8.1. Commercial and public services
- 1.2.8.2. Households
- 1.2.8.3. Agriculture
- 1.2.8.4. Forestry
- 1.2.8.5. Fishing
- 1.2.8.6. Not elsewhere specified – Other

1.2.9. IMPORTS BY COUNTRY OF ORIGIN AND EXPORTS BY COUNTRY OF DESTINATION

Imports by country of origin and exports by country of destination should be reported. Applicable to anthracite, coking coal, other bituminous coal, sub-bituminous coal, lignite, patent fuel, coke oven coke, coal tar, BKB, peat, peat products and oil shale and oil sands.

1.2.10. CALORIFIC VALUES

Applicable for anthracite, coking coal, other bituminous coal, sub-bituminous coal, lignite, patent fuel, coke oven coke, gas coke, coal tar, BKB, peat, peat products, oil shale and oil sands.

Both gross and net calorific values are to be declared for the following aggregates:

1.2.10.1. Production

1.2.10.2. Imports

1.2.10.3. Exports

1.2.10.4. Used in coke ovens

1.2.10.5. Used in blast furnaces

1.2.10.6. Used in main activity producer electricity only, heat only and CHP units

1.2.10.7. Used in industry

1.2.10.8. For other uses

1.3. **Units of measurement**

Reported quantities must be declared in kt (kilo-tonnes), except for manufactured gases (gas works gas, coke oven gas, blast furnace gas, other recovered gases), where the reported quantity must be declared in TJ GCV (tera-joules based on gross calorific values).

Calorific values must be declared in MJ/t (mega-joules per tonne).

1.4. **Derogations and exemptions**

Not applicable.

2. **NATURAL GAS**

2.1. **Applicable energy products**

This chapter covers the reporting of natural gas.

2.2. **List of aggregates**

The following list of aggregates must be declared for natural gas.

2.2.1. SUPPLY SECTOR

Declared quantities for the supply sector must be expressed in both volume and energy units, and must include the gross and net calorific values.

2.2.1.1. Indigenous production

Includes offshore production.

2.2.1.1.1. Associated gas

Natural gas produced in association with crude oil.

2.2.1.1.2. Non-associated gas

Natural gas originating from fields producing hydrocarbons only in gaseous form.

2.2.1.1.3. Colliery gas

Methane produced at coal mines or from coal seams, piped to the surface and consumed at collieries or transmitted by pipeline to consumers.

- 2.2.1.2. Receipts from other sources
- 2.2.1.2.1. Receipts from other sources: Oil and petroleum products
- 2.2.1.2.2. Receipts from other sources: Coal
- 2.2.1.2.3. Receipts from other sources: Renewables
- 2.2.1.3. Imports
- 2.2.1.4. Exports
- 2.2.1.5. International marine bunkers
- 2.2.1.6. Stock changes
- 2.2.1.7. Inland consumption (Observed)
- 2.2.1.8. Recoverable gas

Opening and closing stock levels should be declared separately, as stocks on national territory and stocks held abroad, respectively. 'Stock level' means the quantity of gas available for delivery during any input-output cycle. This refers to recoverable natural gas stored in special storage facilities (depleted gas and/or oil field, aquifer, salt cavity, mixed caverns, or other), as well as stored liquefied natural gas. Cushion gas should be excluded. The requirement of declaring calorific values is not applicable here.
- 2.2.1.9. Gas vented

The volume of gas released into the air on the production site or at the gas processing plant. The requirement of declaring calorific values is not applicable here.
- 2.2.1.10. Gas Flared

The volume of gas burned in flares on the production site or at the gas processing plant. The requirement of declaring calorific values is not applicable here.
- 2.2.2. TRANSFORMATION SECTOR
- 2.2.2.1. Main activity producer Electricity Only
- 2.2.2.2. Autoproducer electricity only
- 2.2.2.3. Main activity producer CHP units
- 2.2.2.4. Autoproducer CHP units
- 2.2.2.5. Main activity producer heat only
- 2.2.2.6. Autoproducer heat only
- 2.2.2.7. Gas works
- 2.2.2.8. Coke ovens
- 2.2.2.9. Blast furnaces
- 2.2.2.10. Gas to liquids
- 2.2.2.11. Non specified – Transformation
- 2.2.3. ENERGY SECTOR
- 2.2.3.1. Coal mines
- 2.2.3.2. Oil and gas extraction
- 2.2.3.3. Inputs to oil refineries

- 2.2.3.4. Coke ovens
- 2.2.3.5. Blast furnaces
- 2.2.3.6. Gas works
- 2.2.3.7. Electricity, CHP and heat plants
- 2.2.3.8. Liquefaction (LNG) or gasification
- 2.2.3.9. Gas to liquids
- 2.2.3.10. Not elsewhere specified – Energy
- 2.2.4. TRANSMISSION LOSSES
- 2.2.5. DISTRIBUTION LOSSES
- 2.2.6. TRANSPORT SECTOR
Final energy consumption and final non-energy consumption should be declared separately for the following aggregates.
- 2.2.6.1. Road
- 2.2.6.2. Pipeline transport
- 2.2.6.3. Domestic navigation
- 2.2.6.4. Not elsewhere specified – transport
- 2.2.7. INDUSTRY SECTOR
Final energy consumption and final non-energy consumption should be declared separately for the following aggregates.
- 2.2.7.1. Iron and steel
- 2.2.7.2. Chemical and petrochemical
- 2.2.7.3. Non-ferrous metals
- 2.2.7.4. Non-metallic minerals
- 2.2.7.5. Transport equipment
- 2.2.7.6. Machinery
- 2.2.7.7. Mining and quarrying
- 2.2.7.8. Food, beverages and tobacco
- 2.2.7.9. Pulp, paper and printing
- 2.2.7.10. Wood and wood products
- 2.2.7.11. Construction
- 2.2.7.12. Textile and leather
- 2.2.7.13. Not elsewhere specified – industry
- 2.2.8. OTHER SECTORS
Final energy consumption and final non-energy consumption should be declared separately for the following aggregates.
- 2.2.8.1. Commercial and public services
- 2.2.8.2. Households

2.2.8.3. Agriculture

2.2.8.4. Forestry

2.2.8.5. Fishing

2.2.8.6. Not elsewhere specified – Other

2.2.9. IMPORTS BY COUNTRY OF ORIGIN AND EXPORTS BY COUNTRY OF DESTINATION

Both the quantities of total natural gas and of the LNG part of it should be declared, per country of origin for imports and per country of destination for exports.

2.2.10. GAS STORAGE CAPACITIES

To be reported separately as gaseous gas storage facilities and LNG terminals (to be further distinguished as LNG import terminals or LNG export terminals).

2.2.10.1. Name

Name of the site of the storage facility or the LNG terminal.

2.2.10.2. Type (for the gaseous gas storage facilities only)

Type of storage, such as depleted gas field, aquifer, salt cavern, etc.

2.2.10.3. Working capacity

For gaseous gas storage facilities: total gas storage capacity, minus the cushion gas. The cushion gas is the total volume of gas required as a permanent inventory to maintain adequate underground storage reservoir pressures and deliverability rates throughout the output cycle.

For LNG terminals: total gas storage capacity expressed in gaseous gas equivalent.

2.2.10.4. Peak output

Maximum rate at which gas can be withdrawn from the storage concerned; this corresponds to the maximum withdrawal capacity.

2.2.10.5. Regasifying or liquefying capacity (for LNG terminals only)

The regasifying capacity must be reported for import terminals and the liquefying capacity must be reported for export terminals.

2.3. **Units of measurement**

Quantities of natural gas should be declared as their energy content, i.e. in TJ, based on the gross calorific value. Where physical quantities are required, the unit is in 10^6 m³ assuming reference gas conditions (15 °C, 101 325 Pa).

Calorific values should be declared in kJ/m³, assuming reference gas conditions (15 °C, 101 325 Pa).

Working capacity should be declared in 10^6 m³, assuming reference gas conditions (15 °C, 101 325 Pa).

Peak output, regasifying capacity and liquefying capacity should be declared in 10^6 m³/day, assuming reference gas conditions (15 °C, 101 325 Pa).

3. **ELECTRICITY AND HEAT**

3.1. **Applicable energy products**

This chapter covers heat and electricity.

3.2. **List of aggregates**

The following list of aggregates should be declared for heat and electricity unless otherwise specified.

3.2.1. ELECTRICITY AND HEAT PRODUCTION

The following specific definitions apply to the electricity and heat aggregates discussed in this chapter:

- Gross electricity production: the sum of the electrical energy produced by all the generating sets concerned (including pumped storage) measured at the output terminals of the main generators.
- Gross heat production: the total heat produced by the installation, including the heat used by the installation's auxiliaries that use a hot fluid (space heating, liquid fuel heating etc.) and losses in the installation/network heat exchanges, as well as heat from chemical processes used as a primary energy form.
- Net electricity production: the gross electricity production less the electrical energy absorbed by the generating auxiliaries and the losses in the main generator transformers.
- Net heat production: the heat supplied to the distribution system as determined based on measurements of the outgoing and return flows.

Aggregates 3.2.1.1 to 3.2.1.11 must be declared separately for main activity producers and for autoproducers. Within these two types of plant, both gross and net electricity and heat production must be declared for electricity-only, heat-only and CHP units, separately wherever applicable. For gross electricity produced in CHP units, the subcategory of which in full CHP-mode should be declared. For net heat produced in CHP units, a separate item on auto-consumed heat should be declared.

3.2.1.1. Nuclear

3.2.1.2. Hydro (applicable only for electricity)

3.2.1.3. Geothermal

3.2.1.4. Solar

3.2.1.5. Tide, wave, ocean (applicable only for electricity)

3.2.1.6. Wind (applicable only for electricity)

3.2.1.7. Combustible fuels

Fuels capable of igniting or burning, i.e. reacting with oxygen to produce a significant rise in temperature, and combusted directly for the production of electricity and/or heat.

3.2.1.8. Heat pumps (applicable only for heat)

3.2.1.9. Electric boilers (applicable only for heat)

3.2.1.10. Heat from chemical processes

Heat originating from processes without input energy, such as a chemical reaction. Excludes waste heat originating from energy-driven processes, which should be reported as heat produced from the corresponding fuel.

3.2.1.11. Other sources

3.2.2. SUPPLY

For 3.2.2.1 and 3.2.2.2, quantities declared should be coherent with the values declared for aggregates 3.2.1.1 to 3.2.1.11.

3.2.2.1. Total gross production

3.2.2.2. Total net production

3.2.2.3. Imports

Amounts of electricity are considered as imported or exported when they have crossed the political boundaries of a country, whether customs clearance has taken place or not. If electricity transits through a country, the amount should be reported as both an import and an export.

- 3.2.2.4. Exports
See explanation under 3.2.2.3 'Imports'.
- 3.2.2.5. International marine bunkers
- 3.2.2.6. Used for heat pumps (applicable only for electricity)
- 3.2.2.7. Used for electric boilers (applicable only for electricity)
- 3.2.2.8. Used for pumped storage – pure pumped storage plants (applicable only for electricity)
- 3.2.2.9. Used for pumped storage – Mixed hydro plants (applicable only for electricity)
- 3.2.2.10. Used for electricity production (applicable only for heat)
- 3.2.3. TRANSMISSION LOSSES
- 3.2.4. DISTRIBUTION LOSSES
- 3.2.5. FINAL ENERGY CONSUMPTION – TRANSPORT SECTOR
Final energy consumption and final non-energy consumption should be declared separately for the following aggregates.
 - 3.2.5.1. Rail
 - 3.2.5.2. Pipeline transport
 - 3.2.5.3. Road
 - 3.2.5.4. Domestic navigation
 - 3.2.5.5. Not elsewhere specified – Transport
- 3.2.6. FINAL ENERGY CONSUMPTION – OTHER SECTORS
 - 3.2.6.1. Commercial and public services
 - 3.2.6.2. Households
 - 3.2.6.3. Agriculture
 - 3.2.6.4. Forestry
 - 3.2.6.5. Fishing
 - 3.2.6.6. Not elsewhere specified – Other
- 3.2.7. ENERGY SECTOR
Excludes plants' own use for pumped storage, heat pumps and electric boilers.
 - 3.2.7.1. Coal mines
 - 3.2.7.2. Oil and gas extraction
 - 3.2.7.3. Patent fuel plants
 - 3.2.7.4. Coke ovens
 - 3.2.7.5. BKB/PB plants
 - 3.2.7.6. Gas works

- 3.2.7.7. Blast furnaces
- 3.2.7.8. Petroleum refineries
- 3.2.7.9. Nuclear industry
- 3.2.7.10. Coal liquefaction plants
- 3.2.7.11. Liquefaction (LNG)/Regasification plants
- 3.2.7.12. Gasification plants (biogas)
- 3.2.7.13. Gas to liquids
- 3.2.7.14. Charcoal production plants
- 3.2.7.15. Not elsewhere specified – Energy
- 3.2.8. INDUSTRY SECTOR
- 3.2.8.1. Iron and steel
- 3.2.8.2. Chemical and petrochemical
- 3.2.8.3. Non-ferrous metals
- 3.2.8.4. Non-metallic minerals
- 3.2.8.5. Transport equipment
- 3.2.8.6. Machinery
- 3.2.8.7. Mining and quarrying
- 3.2.8.8. Food, beverages and tobacco
- 3.2.8.9. Pulp, paper and printing
- 3.2.8.10. Wood and wood products
- 3.2.8.11. Construction
- 3.2.8.12. Textile and leather
- 3.2.8.13. Not elsewhere specified – Industry
- 3.2.9. IMPORTS AND EXPORTS
Imports and exports of quantities of electricity and heat by country of origin and destination, respectively, have to be reported. See explanation under 3.2.2.3 'Imports'.
- 3.2.10. NET PRODUCTION FROM AUTOPRODUCERS
For the following plants or activities, net production of electricity and net generation of heat from autoproducers should be declared separately for electricity-only, heat-only and CHP units:
- 3.2.10.1. Energy sector: Coal mines
- 3.2.10.2. Energy sector: Oil and gas extraction
- 3.2.10.3. Energy sector: Patent fuel plants
- 3.2.10.4. Energy sector: Coke ovens
- 3.2.10.5. Energy sector: BKB/PB plants
- 3.2.10.6. Energy sector: Gas works

- 3.2.10.7. Energy sector: Blast furnaces
- 3.2.10.8. Energy sector: Petroleum refineries
- 3.2.10.9. Energy sector: Coal liquefaction plants
- 3.2.10.10. Energy sector: Liquefaction (LNG)/Regasification plants
- 3.2.10.11. Energy sector: Gasification plants (biogas)
- 3.2.10.12. Energy sector: Gas to liquids
- 3.2.10.13. Energy sector: Charcoal production plants
- 3.2.10.14. Energy sector: Not elsewhere specified – Energy
- 3.2.10.15. Industry sector: Iron and steel
- 3.2.10.16. Industry sector: Chemical and petrochemical
- 3.2.10.17. Industry sector: Non-ferrous metals
- 3.2.10.18. Industry sector: Non-metallic minerals
- 3.2.10.19. Industry sector: Transport equipment
- 3.2.10.20. Industry sector: Machinery
- 3.2.10.21. Industry sector: Mining and quarrying
- 3.2.10.22. Industry sector: Food, beverages and tobacco
- 3.2.10.23. Industry sector: Pulp, paper and printing
- 3.2.10.24. Industry sector: Wood and wood products
- 3.2.10.25. Industry sector: Construction
- 3.2.10.26. Industry sector: Textile and leather
- 3.2.10.27. Industry sector: Not elsewhere specified – Industry
- 3.2.10.28. Transport Sector: Rail
- 3.2.10.29. Transport Sector: Pipeline transport
- 3.2.10.30. Transport Sector: Road
- 3.2.10.31. Transport Sector: Not elsewhere specified – Transport
- 3.2.10.32. Other sectors: Households
- 3.2.10.33. Other sectors: Commercial and public services
- 3.2.10.34. Other sectors: Agriculture/Forestry
- 3.2.10.35. Other sectors: Fishing
- 3.2.10.36. Other sectors: Not elsewhere specified – Other
- 3.2.11. NET PRODUCTION OF ELECTRICITY BY SECTOR

Total net production of electricity and the part that is auto-consumed (without splitting between main activity producer and autoproducer) must be declared separately for households, commercial and public services, energy sector, industry sector and other sectors for each of the following groups of fuels:

- 3.2.11.1. Solar PV
- 3.2.11.2. Solid, liquid and gaseous biofuels
- 3.2.11.3. Other renewables
- 3.2.11.4. Natural gas
- 3.2.11.5. Other (non-renewables)

3.2.12. GROSS ELECTRICITY AND HEAT PRODUCTION FROM COMBUSTIBLE FUELS

The gross electricity produced, the heat sold and the fuel quantities used, including their corresponding total energy from the combustibles listed below, must be declared separately for main activity producers and for autoproducers. For these two types of producer, electricity and heat production must be declared separately wherever applicable for electricity-only, heat-only and CHP units.

- 3.2.12.1. Anthracite
- 3.2.12.2. Coking Coal
- 3.2.12.3. Other bituminous coal
- 3.2.12.4. Sub-bituminous coal
- 3.2.12.5. Lignite
- 3.2.12.6. Peat
- 3.2.12.7. Patent fuel
- 3.2.12.8. Coke oven coke
- 3.2.12.9. Gas coke
- 3.2.12.10. Coal tar
- 3.2.12.11. BKB (brown coal briquettes)
- 3.2.12.12. Gas works gas
- 3.2.12.13. Coke oven gas
- 3.2.12.14. Blast furnace gas
- 3.2.12.15. Other recovered gases
- 3.2.12.16. Peat products
- 3.2.12.17. Oil shale and oil sands
- 3.2.12.18. Crude oil
- 3.2.12.19. NGL
- 3.2.12.20. Refinery gas
- 3.2.12.21. LPG
- 3.2.12.22. Naphtha
- 3.2.12.23. Kerosene type jet fuel
- 3.2.12.24. Other kerosene
- 3.2.12.25. Gas/Diesel oil
- 3.2.12.26. Fuel oil

- 3.2.12.27. Bitumen
- 3.2.12.28. Petroleum coke
- 3.2.12.29. Other oil products
- 3.2.12.30. Natural gas
- 3.2.12.31. Industrial waste
- 3.2.12.32. Renewable municipal waste
- 3.2.12.33. Non-renewable municipal waste
- 3.2.12.34. Solid biofuels
- 3.2.12.35. Biogases
- 3.2.12.36. Biodiesels
- 3.2.12.37. Biogasolines
- 3.2.12.38. Other liquid biofuels

3.2.13. NET MAXIMUM ELECTRICAL CAPACITY

The capacity should be declared as on 31 December of the relevant reported year and for the fuels indicated below. Includes electrical capacity of both electricity-only and CHP units. The net maximum electrical capacity must be declared for both main activity producers and autoproducers. It is the sum of the net maximum capacities of all stations taken individually over a given period of operation. The period of operation assumed for present purposes is continuous running: in practice 15 hours or more per day. The net maximum capacity is the maximum power assumed to be solely active power that can be supplied, continuously, with the whole plant running, at the point of outlet to the network.

- 3.2.13.1. Nuclear
- 3.2.13.2. Pure hydro plants
- 3.2.13.3. Mixed hydro plants
- 3.2.13.4. Pure pumped storage plants
- 3.2.13.5. Geothermal
- 3.2.13.6. Solar photovoltaic
- 3.2.13.7. Solar thermal
- 3.2.13.8. Tide, wave, ocean
- 3.2.13.9. Wind
- 3.2.13.10. Combustible fuels
- 3.2.13.10.1. Type of generation: Steam
- 3.2.13.10.2. Type of generation: Internal combustion
- 3.2.13.10.3. Type of generation: Gas turbine
- 3.2.13.10.4. Type of generation: Combined cycle
- 3.2.13.10.5. Type of generation: Other
- 3.2.13.11. Other sources

3.2.14. NET MAXIMUM ELECTRICAL CAPACITY OF COMBUSTIBLE FUELS

Net maximum electrical capacity of combustible fuels must be declared for both main activity producers and autoproducers, and separately for each type of single-fired or multi-fired plant mentioned below. Multi-fired systems include only units which can burn more than one fuel type on a continuous basis. Stations which have separate units using different fuels should be divided into the appropriate single-fuel categories. Indications on which type of fuel is used as primary and alternate must be added for each category of multi-fired plants.

3.2.14.1. Single-fuel fired (for all categories of primary fuels)

3.2.14.2. Multi-fired solids and liquids

3.2.14.3. Multi-fired solids and natural gas

3.2.14.4. Multi-fired liquids and natural gas

3.2.14.5. Multi-fired solids, liquids and natural gas

3.2.15. NEWLY INSTALLED AND DECOMMISSIONED ELECTRICAL CAPACITY

Newly installed capacity is the net maximum electrical capacity of the generation units that become operational in the reference year. Decommissioned capacity is the net maximum electrical capacity that is no longer operational during the reference year.

For all fuels indicated under 3.2.13 and 3.2.14, the newly installed and decommissioned capacity should be reported for the reference year.

3.2.16. BATTERIES

The storage capacity or energy capacity of a battery is the total quantity of energy that the battery can store. The rated power capacity is the maximum rate of discharge that the battery can achieve, starting from a fully charged state. The information below should be declared for batteries connected to the grid and used as storing/balancing element. Only batteries with a storage capacity equal to or above 1 MWh and only exchanges with the grid need to be declared.

3.2.16.1. Storage capacity of batteries

3.2.16.2. Rated power capacity of batteries

3.2.16.3. Electricity injected in the grid from batteries

3.2.16.4. Electricity used from the grid to charge batteries

Each of the elements above should be split in the following size groups of storage capacity:

- From 1 MWh to 10 MWh
- From more than 10 MWh to 100 MWh
- More than 100 MWh.

3.3. Units of measurement

Electricity should be declared in GWh (giga-watt hours), heat in TJ (tera-joules) and capacity in MW (megawatts). For batteries, storage capacity should be declared in MWh and rated power capacity in MW.

If reporting of other fuels is required, the applicable units are defined in the relevant chapters of this annex.

4. OIL AND PETROLEUM PRODUCTS

4.1. Applicable energy products

Unless otherwise specified, this data collection applies to all energy products listed in Annex A, Chapter 3.4 OIL (crude oil and petroleum products)

4.2. **List of aggregates**

The following list of aggregates should be declared for all energy products listed in the previous paragraph, unless otherwise specified.

4.2.1. SUPPLY OF CRUDE OIL, NGL, REFINERY FEEDSTOCKS, ADDITIVES AND OTHER HYDROCARBONS

The following aggregates should be declared for crude oil, NGL, refinery feedstocks, additives/oxygenates, biofuels in additives/oxygenates and other hydrocarbons:

4.2.1.1. Indigenous production

Not applicable for refinery feedstocks and for biofuels.

4.2.1.2. Receipts from other sources.

Not applicable for crude oil, NGL and refinery feedstocks.

4.2.1.2.1. Receipts from other sources: from coal

4.2.1.2.2. Receipts from other sources: from natural gas

4.2.1.2.3. Receipts from other sources: from renewables

4.2.1.2.4. Receipts from other sources: from hydrogen

4.2.1.3. Backflows from petrochemical sector

Only applicable for refinery feedstocks.

4.2.1.4. Products transferred

Only applicable for refinery feedstocks.

4.2.1.5. Imports

Includes quantities of crude oil and products imported or exported under processing agreements (i.e. refining on account). Crude oil and NGLs should be reported as coming from the country of ultimate origin; refinery feedstocks and finished products should be reported as coming from the country of last consignment. Includes any gas liquids (e.g. LPG) extracted during the regasification of imported liquefied natural gas and petroleum products imported or exported directly by the petrochemical industry. Note: all trade of biofuels which have not been blended with transport fuels (i.e. in their pure form) should not be reported here. Re-exports of oil imported for processing within bonded areas should be included as an export of product from the processing country to the final destination.

4.2.1.6. Exports

The note for imports (4.2.1.5) also applies to exports.

4.2.1.7. Direct Use

4.2.1.8. Stock changes

4.2.1.9. Observed refinery intake

Amounts measured as input to refineries

4.2.1.10. Refinery losses

The difference between refinery intake (observed) and gross refinery output. Losses may occur during the distillation processes due to evaporation. Reported losses are positive. There may be volumetric gains but no gains in mass.

4.2.1.11. Opening total stocks on national territory

4.2.1.12. Closing total stocks on national territory

4.2.1.13. Net calorific value

4.2.1.13.1. Production (not applicable for refinery feedstocks and Biofuels in Additives/Oxygenates)

4.2.1.13.2. Imports (not applicable for biofuels in additives/oxygenates)

4.2.1.13.3. Exports (not applicable for biofuels in additives/oxygenates)

4.2.1.13.4. Overall average

4.2.2. SUPPLY OF OIL PRODUCTS

The following aggregates apply to finished products (refinery gas, ethane, LPG, naphtha, motor gasoline as well as its part of biogasoline, aviation gasoline, gasoline type jet fuel, kerosene type jet fuel as well as its bio part, other kerosene, gas/diesel oil, low and high sulphur fuel oil, white spirit and SBP, lubricants, bitumen, paraffin waxes, petroleum coke and other products). Crude oil and NGL used for direct burn should be included in deliveries of finished products and interproduct transfers.

4.2.2.1. Primary product receipts

4.2.2.2. Gross refinery output

4.2.2.3. Recycled products

4.2.2.4. Refinery fuel (petroleum refineries)

Fuels used for production at refineries of electricity and heat sold should also be included in this category.

4.2.2.4.1. Used in electricity only units/plants

4.2.2.4.2. Used in CHP units

4.2.2.4.3. Used in heat only units/plants

4.2.2.5. Imports

The note for imports in Section 4.2.1.5 also applies here.

4.2.2.6. Exports

The note for imports in Section 4.2.1.5 also applies here.

4.2.2.7. International marine bunkers

4.2.2.8. Interproduct transfers

4.2.2.9. Products transferred

4.2.2.10. Stock changes

4.2.2.11. Opening stock levels

4.2.2.12. Closing stock levels

4.2.2.13. Stock changes at main activity producers

Changes in stocks which are held by public utilities and are not included in stock levels and stock changes reported elsewhere. A stock build is shown as a negative number and a stock draw is shown as a positive number.

4.2.2.14. Average net calorific values

4.2.3. DELIVERIES TO THE PETROCHEMICAL SECTOR

The observed delivery of finished petroleum products from primary sources (e.g. refineries, blending plants, etc.) to the inland market.

- 4.2.3.1. Gross deliveries to the petrochemical sector
- 4.2.3.2. Energy use in the petrochemical sector
Quantities of oil used as fuel for petrochemical processes such as steam cracking.
- 4.2.3.3. Non-energy use in the petrochemical sector
Quantities of oil used in the petrochemical sector for the purpose of producing ethylene, propylene, butylene, synthesis gas, aromatics, butadiene and other hydrocarbon-based raw materials in processes such as steam cracking, aromatics plants and steam reforming. Excludes amounts of oil used for fuel purposes.
- 4.2.3.4. Backflows from petrochemical sector to refineries
- 4.2.4. TRANSFORMATION SECTOR
The quantities involved in both energy use and non-energy use must be declared.
 - 4.2.4.1. Main activity producer electricity only
 - 4.2.4.2. Autoproducer electricity only
 - 4.2.4.3. Main activity producer CHP units
 - 4.2.4.4. Autoproducer CHP units
 - 4.2.4.5. Main activity producer heat Only
 - 4.2.4.6. Autoproducer heat only
 - 4.2.4.7. Gas works/Gasification plants
 - 4.2.4.8. Blended natural gas
 - 4.2.4.9. Coke ovens
 - 4.2.4.10. Blast furnaces
 - 4.2.4.11. Petrochemical industry
 - 4.2.4.12. Patent fuel plants
 - 4.2.4.13. Not elsewhere specified – Transformation
- 4.2.5. ENERGY SECTOR
Both the quantities involved in energy use and non-energy use shall be declared.
 - 4.2.5.1. Coal Mines
 - 4.2.5.2. Oil and Gas Extraction
 - 4.2.5.3. Coke Ovens
 - 4.2.5.4. Blast Furnaces
 - 4.2.5.5. Gas Works
 - 4.2.5.6. Own use Electricity, CHP and heat plants.
 - 4.2.5.7. Not Elsewhere Specified – Energy
- 4.2.6. TRANSMISSION AND DISTRIBUTION LOSSES
The quantities involved both in energy use and non-energy use must be declared.
- 4.2.7. FINAL ENERGY CONSUMPTION – INDUSTRY SECTOR
The quantities involved both in energy use and non-energy use must be declared.
 - 4.2.7.1. Iron and steel

4.2.7.2. Chemical and petrochemical

4.2.7.3. Non-ferrous metals

4.2.7.4. Non-metallic minerals

4.2.7.5. Transport equipment

4.2.7.6. Machinery

4.2.7.7. Mining and quarrying

4.2.7.8. Food, beverages and tobacco

4.2.7.9. Pulp, paper and printing

4.2.7.10. Wood and wood products

4.2.7.11. Construction

4.2.7.12. Textile and leather

4.2.7.13. Not elsewhere specified – Industry

4.2.8. FINAL ENERGY CONSUMPTION – TRANSPORT SECTOR

The quantities involved in both energy use and non-energy use must be declared.

4.2.8.1. International aviation

4.2.8.2. Domestic aviation

4.2.8.3. Road

4.2.8.4. Rail

4.2.8.5. Domestic navigation

4.2.8.6. Pipeline transport

4.2.8.7. Not elsewhere specified – Transport

4.2.9. FINAL ENERGY CONSUMPTION – OTHER SECTORS

The quantities involved in both energy use and non-energy use must be declared.

4.2.9.1. Commercial and public services

4.2.9.2. Households

4.2.9.3. Agriculture

4.2.9.4. Forestry

4.2.9.5. Fishing

4.2.9.6. Not elsewhere specified – Other

4.2.10. IMPORTS BY COUNTRY OF ORIGIN AND EXPORTS BY COUNTRY OF DESTINATION

Imports should be declared by country of origin and exports by country of destination. The note for imports in Section 4.2.1.5 also applies here.

4.2.11. REFINERY CAPACITY

Report the national total refining capacity and the breakdown of annual capacity by refinery in thousand metric tons per year. The following items should be reported:

- 4.2.11.1. Name/Location
- 4.2.11.2. Atmospheric distillation
- 4.2.11.3. Vacuum distillation
- 4.2.11.4. Cracking (thermal)
 - 4.2.11.4.1. Of which visbreaking
 - 4.2.11.4.2. Of which coking
- 4.2.11.5. Cracking (catalytic)
 - 4.2.11.5.1. Of which fluid catalytic cracking (FCC)
 - 4.2.11.5.2. Of which hydro-cracking (HCK)
- 4.2.11.6. Reforming
- 4.2.11.7. Desulphurisation
- 4.2.11.8. Alkylation, polymerisation, isomeration
- 4.2.11.9. Etherification

4.3. **Units of measurement**

Reported quantities must be declared in kt (kilo-tonnes). Calorific values must be declared in MJ/t (mega-joules per tonne).

4.4. **Exemptions**

Cyprus is exempted from reporting the aggregates specified in Section 4.2.9 (Final energy consumption – Other sectors); only the total values should be reported. Cyprus is also exempted from reporting non-energy use under Sections 4.2.4 (Transformation sector), 4.2.5 (Energy sector), 4.2.7 (Industry), 4.2.7.2 (Industry sector – of which chemical and petrochemical), 4.2.8 (Transport) and 4.2.9 (Other sectors).

5. **RENEWABLE ENERGY AND ENERGY FROM WASTE**

5.1. **Applicable energy products**

Unless otherwise specified, this data collection applies to all energy products listed in Annex A, Chapter 3.5 RENEWABLES AND WASTE. Only quantities of fuels used for energy purposes (for example in electricity and heat generation, combustion with energy recovery, in mobile engines in transport and for use in stationary engines) should be reported. Quantities of renewable energy products used to replace fossil fuels for non-energy purposes should be reported in Section 5.2.9, but they should not be included in the rest of sections in this chapter. Renewable products that have not been developed to replace fossil fuels should be excluded from reporting in Section 5.2.9, such as solid biofuels used for furniture, construction and paper/cardboard production, alcohols used in food industry and cotton/natural fibres used in textile industry. Passive thermal energy should be excluded from reporting in Chapter 5 (for example, passive solar thermal heating of buildings).

5.2. **List of aggregates**

Unless otherwise specified, the following list of aggregates should be declared for all energy products listed in the previous paragraph. Ambient heat (heat pumps) only needs to be reported for the following sectors: Transformation (only for aggregates related to heat sold), Energy (only total, no subcategories), Industry total (only total, no subcategories), Commercial and public services, Households and Not elsewhere specified – Other. For ambient heat (heat pumps), the subcategories Aerothermal, Geothermal and Hydrothermal should be declared under indigenous production. For each of these three categories, the subcategory Of which from heat pumps with SPF above the threshold should be declared. The SPF (seasonal performance factor) threshold should be in accordance with Directive 2009/28/EC and Directive (EU) 2018/2001 on the promotion of the use of energy from renewable sources.

5.2.1. GROSS ELECTRICITY AND HEAT PRODUCTION

The definitions offset out in Chapter 3.2.1 apply. The aggregates 5.2.1.1 to 5.2.1.18 must be declared separately for main activity producers and for autoproducers. For these two types of plant, gross electricity and gross heat production must be declared for electricity-only, heat-only and CHP units, separately wherever applicable.

5.2.1.1. Pure hydro plants (applicable only for electricity)

5.2.1.2. Mixed hydro plants (applicable only for electricity)

5.2.1.3. Pure pumped storage plants (applicable only for electricity)

5.2.1.4. Geothermal

5.2.1.5. Solar photovoltaic (applicable only for electricity)

The following size subcategories should be declared for solar photovoltaic:

5.2.1.5.1. Less than 30 kW

5.2.1.5.2. From 30 to 1 000 kW

5.2.1.5.3. More than 1 000 kW

For 5.2.1.5.1 to 5.2.1.5.3, the subcategories rooftop and off-grid should be declared. The off-grid category is mandatory only if it accounts for 1 % or more of the photovoltaic capacity in its respective size category.

5.2.1.6. Solar thermal

5.2.1.7. Tide, wave, ocean (applicable only for electricity)

5.2.1.8. Wind (applicable only for electricity)

5.2.1.9. On-shore wind

5.2.1.10. Offshore wind

5.2.1.11. Renewable municipal waste

5.2.1.12. Non-renewable municipal waste

5.2.1.13. Solid biofuels

5.2.1.14. Biogases

5.2.1.15. Biodiesels

5.2.1.16. Biogasolines

5.2.1.17. Other liquid biofuels

5.2.1.18. Heat pumps (applicable only for heat)

5.2.2. SUPPLY

5.2.2.1. Production

5.2.2.2. Imports

5.2.2.3. Exports

5.2.2.4. International marine bunkers

5.2.2.5. Stock changes

- 5.2.3. TRANSFORMATION SECTOR
 - 5.2.3.1. Main activity producer electricity only
 - 5.2.3.2. Main activity producer combined heat and power (CHP) units
 - 5.2.3.3. Main activity producer heat only
 - 5.2.3.4. Autoproducer electricity only
 - 5.2.3.5. Autoproducer combined heat and power (CHP) units
 - 5.2.3.6. Autoproducer heat only
 - 5.2.3.7. Patent fuel plants
 - 5.2.3.8. BKB/PB plants
 - 5.2.3.9. Blast Furnaces
 - 5.2.3.10. Blended in the gas grid (e.g. Natural gas blending plants)
 - 5.2.3.11. Blended with liquid fossil fuels (e.g. motor gasoline/diesel/kerosene)
 - 5.2.3.12. Charcoal production plants
 - 5.2.3.13. Not elsewhere specified – Transformation
- 5.2.4. ENERGY SECTOR
 - 5.2.4.1. Gasification plants (biogas)
 - 5.2.4.2. Electricity, CHP and heat plants
 - 5.2.4.3. Coal mines
 - 5.2.4.4. Patent fuel plants
 - 5.2.4.5. Coke ovens
 - 5.2.4.6. Petroleum refineries
 - 5.2.4.7. BKB/PB plants
 - 5.2.4.8. Gas works
 - 5.2.4.9. Blast furnaces
 - 5.2.4.10. Charcoal production plants
 - 5.2.4.11. Not elsewhere specified – Energy
- 5.2.5. TRANSMISSION AND DISTRIBUTION LOSSES
- 5.2.6. FINAL ENERGY CONSUMPTION – INDUSTRY SECTOR
 - 5.2.6.1. Iron and steel
 - 5.2.6.2. Chemical and petrochemical
 - 5.2.6.3. Non-ferrous metals
 - 5.2.6.4. Non-metallic minerals
 - 5.2.6.5. Transport equipment
 - 5.2.6.6. Machinery

- 5.2.6.7. Mining and quarrying
- 5.2.6.8. Food, beverages and tobacco
- 5.2.6.9. Pulp, paper and printing
- 5.2.6.10. Wood and wood products
- 5.2.6.11. Construction
- 5.2.6.12. Textile and leather
- 5.2.6.13. Not elsewhere specified – Industry

5.2.7. FINAL ENERGY CONSUMPTION – TRANSPORT SECTOR

- 5.2.7.1. Rail
- 5.2.7.2. Road
- 5.2.7.3. Domestic navigation
- 5.2.7.4. Domestic aviation
- 5.2.7.5. International aviation
- 5.2.7.6. Not elsewhere specified – Transport

5.2.8. FINAL ENERGY CONSUMPTION – OTHER SECTORS

- 5.2.8.1. Commercial and public services
- 5.2.8.2. Households
- 5.2.8.3. Agriculture
- 5.2.8.4. Forestry
- 5.2.8.5. Fishing
- 5.2.8.6. Not elsewhere specified – Other

5.2.9. FINAL CONSUMPTION – NON-ENERGY USE

For the following items:

- 5.2.9.1. Transport sector
- 5.2.9.2. Industry sector
- 5.2.9.3. Other sectors

The final consumption – non-energy use should be declared for the following groups of fuels:

- 5.2.9.4. Solid biofuels
- 5.2.9.5. Liquid biofuels
- 5.2.9.6. Biogases

The first reference year to declare the elements in Section 5.2.9 is 2024. Until reference year 2027 only the aggregate total final consumption – non-energy use can be declared instead of items 5.2.9.1 to 5.2.9.3 separately. The quantities reported in 5.2.9 should not be included in 5.2.2 to 5.2.8.

5.2.10. NET MAXIMUM ELECTRICAL CAPACITY

Capacity should be declared as on 31 December of the relevant reported year. Includes the electrical capacity of both electricity-only and CHP units. The net maximum electrical capacity is the sum of the net maximum capacities of all stations taken individually over a specific period of operation. The period of operation assumed for present purposes is continuous running: in practice 15 hours or more per day. The net maximum capacity is the maximum power assumed to be solely active power that can be supplied, continuously, with the whole plant running, at the point of outlet to the network.

5.2.10.1. Pure hydro plants

5.2.10.2. Mixed hydro plants

5.2.10.3. Pure pumped storage plants

5.2.10.4. Geothermal

5.2.10.5. Solar photovoltaic

The following size subcategories should be declared for solar photovoltaic:

5.2.10.5.1. Less than 30 kW

5.2.10.5.2. Between 30 and 1 000 kW

5.2.10.5.3. More than 1 000 kW

For 5.2.10.5.1 to 5.2.10.5.3, the subcategories rooftop and off-grid should be declared. The off-grid category is mandatory only if it accounts for 1 % or more of the capacity in its respective size category.

5.2.10.6. Solar thermal

5.2.10.7. Tide, wave, ocean

5.2.10.8. On-shore wind

5.2.10.9. Offshore wind

5.2.10.10. Industrial waste

5.2.10.11. Municipal waste

5.2.10.12. Solid biofuels

5.2.10.13. Biogases

5.2.10.14. Biodiesels

5.2.10.15. Biogasolines

5.2.10.16. Other liquid biofuels

5.2.11. TECHNICAL CHARACTERISTICS

5.2.11.1. Solar collector surface

The total surface area of the installed solar collectors is to be declared. The solar collector surface relates only to solar collectors used for the production of solar thermal heat; solar collector surface used for electricity generation does not have to be reported here (solar PV and concentrated solar power). The surface area of all solar collectors should be included: glazed and unglazed collectors, flat-plate and vacuum tube with a liquid or air as the energy carrier.

5.2.11.2. Production capacity for Biogasoline

- 5.2.11.3. Production capacity for Biodiesels
- 5.2.11.4. Production capacity for Bio jet kerosene
- 5.2.11.5. Production capacity for Other liquid biofuels
- 5.2.11.6. Average net calorific value for Biogasoline
- 5.2.11.7. Average net calorific value for Bioethanol
- 5.2.11.8. Average net calorific value for Biodiesels
- 5.2.11.9. Average net calorific value for Bio jet kerosene
- 5.2.11.10. Average net calorific value for Other liquid biofuels
- 5.2.11.11. Average net calorific value for Charcoal
- 5.2.11.12. Thermal capacity of heat pumps: Aerothermal
 - 5.2.11.12.1. Thermal capacity of heat pumps: Aerothermal Air-Air
 - 5.2.11.12.2. Thermal capacity of heat pumps: Aerothermal Air-Water
 - 5.2.11.12.3. Thermal capacity of heat pumps: Aerothermal Air-Air (reversible)
 - 5.2.11.12.4. Thermal capacity of heat pumps: Aerothermal Air-Water (reversible)
 - 5.2.11.12.5. Thermal capacity of heat pumps: Aerothermal Exhaust Air-Air
 - 5.2.11.12.6. Thermal capacity of heat pumps: Aerothermal Exhaust Air-Water
- 5.2.11.13. Thermal capacity of heat pumps: Geothermal energy
 - 5.2.11.13.1. Thermal capacity of heat pumps: Geothermal energy Ground-Air
 - 5.2.11.13.2. Thermal capacity of heat pumps: Geothermal energy Ground-Water
- 5.2.11.14. Thermal capacity of heat pumps: Hydrothermal heat
 - 5.2.11.14.1. Thermal capacity of heat pumps: Hydrothermal heat Water-Air
 - 5.2.11.14.2. Thermal capacity of heat pumps: Hydrothermal heat Water-Water

For all items from 5.2.11.12 to 5.2.11.14.2, the subcategory Of which from heat pumps with SPF above the threshold should be declared. The SPF (seasonal performance factor) threshold should be in accordance with Directive 2009/28/EC and Directive (EU) 2018/2001 of the European Parliament and of the Council ⁽³⁾ on the promotion of the use of energy from renewable sources.

5.2.12. PRODUCTION OF SOLID BIOFUELS AND BIOGASES

The total production of solid biofuels (excluding charcoal) should be split among the following fuels:

- 5.2.12.1. Fuelwood, wood residues and by-products
 - 5.2.12.1.1. Wood pellets as part of Fuelwood, wood residues and by-products
- 5.2.12.2. Black liquor
- 5.2.12.3. Bagasse
- 5.2.12.4. Animal waste

⁽³⁾ Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (OJ L 328, 21.12.2018, p. 82).

5.2.12.5. Other vegetal materials and residues

5.2.12.6. Renewable fraction of industrial waste

The total production of biogas should be split among the following production methods:

5.2.12.7. Biogases from anaerobic fermentation: landfill gas

5.2.12.8. Biogases from anaerobic fermentation: sewage sludge gas

5.2.12.9. Biogases from anaerobic fermentation: other biogases from anaerobic fermentation

5.2.12.10. Biogases from thermal processes

5.2.13. IMPORTS BY COUNTRY OF ORIGIN AND EXPORTS BY COUNTRY OF DESTINATION

Imports should be reported by country of origin and exports by country of destination. Applicable to biogasolines, bioethanol, bio jet kerosene, biodiesels, other liquid biofuels, wood pellets.

5.3. Units of measurement

Electricity must be declared in GWh (giga-watt hours), heat in TJ (tera-joules) and electrical capacity in MW (megawatts).

Reported quantities must be declared in TJ NCV (tera-joules based on net calorific value), except for charcoal, biogasoline, bioethanol, bio jet kerosene, biodiesels, and other liquid biofuels which must be declared in kt (kilo-tonnes).

Calorific values must be declared in MJ/t (mega-joules per tonne).

Solar collector surface must be declared in 1 000 m².

Production capacity must be declared in kt (kilo-tonnes) per year.

6. ANNUAL NUCLEAR STATISTICS

The following data concerning the civil use of nuclear energy must be declared:

6.1. List of aggregates

6.1.1. ENRICHMENT CAPACITY

The annual separative work capacity of operational enrichment plants (isotopic separation of uranium).

6.1.2. PRODUCTION CAPACITY OF FRESH FUEL ELEMENTS

The annual production capacity of fuel fabrication plants. MOX fuel fabrication plants are excluded.

6.1.3. PRODUCTION CAPACITY OF MOX FUEL FABRICATION PLANTS

The annual production capacity of MOX fuel fabrication plants.

MOX is a fuel that contains a mixture of plutonium and uranium (mixed oxide).

6.1.4. PRODUCTION OF FRESH FUEL ELEMENTS

Production of finished fresh fuel elements in nuclear fuel fabrication plants. Rods or other partial products are not included. Fabrication plants producing MOX fuel are also excluded.

6.1.5. PRODUCTION OF MOX FUEL ELEMENTS

Production of finished fresh fuel elements in MOX fuel fabrication plants. Rods or other partial products are not included.

6.1.6. PRODUCTION OF NUCLEAR HEAT

The total amount of heat generated by nuclear reactors for the production of electricity or for other useful applications of heat.

6.1.7. ANNUAL AVERAGE BURNUP OF DEFINITELY DISCHARGED IRRADIATED FUEL ELEMENTS

Calculated average of the burnup of the fuel elements which have been definitively discharged from nuclear reactors during the reference year concerned. Excludes fuel elements which are temporarily discharged and are likely to be reloaded again later.

6.1.8. PRODUCTION OF URANIUM AND PLUTONIUM IN REPROCESSING PLANTS

Uranium and plutonium produced in reprocessing plants during the reference year.

6.1.9. CAPACITY (URANIUM AND PLUTONIUM) OF REPROCESSING PLANTS

Annual reprocessing capacity of uranium and plutonium.

6.2 **Units of measurement**

tSWU (tonnes of separative work units) for 6.1.1

tHM (tonnes of heavy metal) for 6.1.4, 6.1.5, 6.1.8

tHM (tonnes of heavy metal) per year for 6.1.2, 6.1.3, 6.1.9

TJ (tera-joules) for 6.1.6

GWd/tHM (gigawatt-day per tonne of heavy metal) for 6.1.7

7. **HYDROGEN**

The following data concerning hydrogen must be declared for the first time for reference year 2024:

7.1. **List of aggregates**

7.1.1. Indigenous production

7.1.1.1. From natural gas

7.1.1.2. From oil and petroleum products

7.1.1.3. From solid fuels

7.1.1.4. From renewables

7.1.1.5. From electrolysis

7.1.1.5.1. Of which: electricity from sustainable renewables – direct transmission line

7.1.1.5.2. Of which: electricity from nuclear – direct transmission line

7.1.1.6. From other sources

7.1.2. Imports

7.1.3. Exports

7.1.4. Stock changes

7.1.5. International marine bunkers

7.1.6. International aviation

7.1.7. Statistical differences

7.1.8. Transformation: Main activity producer electricity

7.1.9. Transformation: Autoproducer electricity

7.1.10. Transformation: Main activity producer CHP

7.1.11. Transformation: Autoproducer CHP

7.1.12. Transformation: Main activity producer heat

- 7.1.13. Transformation: Autoproducer heat
- 7.1.14. Transformation: Gas works (and other conversion to gases)
- 7.1.15. Transformation: Refineries
- 7.1.16. Transformation: Petrochemical industry
- 7.1.17. Transformation Not elsewhere specified (Transformation)
- 7.1.18. Energy sector: Coal mines
- 7.1.19. Energy sector: Oil and gas extraction
- 7.1.20. Energy sector: Coke ovens (Energy)
- 7.1.21. Energy sector: Blast furnaces (Energy)
- 7.1.22. Energy sector: Gas works (Energy)
- 7.1.23. Energy sector: Electricity, CHP and heat
- 7.1.24. Energy sector: Not elsewhere specified (Energy)
- 7.1.25. Transmission and distribution losses
- 7.1.26. Final non-energy consumption – Industry sector: Iron and steel
- 7.1.27. Final non-energy consumption – Industry sector: Chemical and petrochemical
- 7.1.28. Final non-energy consumption – Industry sector: Non-ferrous metals
- 7.1.29. Final non-energy consumption – Industry sector: Non-metallic minerals
- 7.1.30. Final non-energy consumption – Industry sector: Transport equipment
- 7.1.31. Final non-energy consumption – Industry sector: Machinery
- 7.1.32. Final non-energy consumption – Industry sector: Mining and quarrying
- 7.1.33. Final non-energy consumption – Industry sector: Food, beverages and tobacco
- 7.1.34. Final non-energy consumption – Industry sector: Paper, pulp and printing
- 7.1.35. Final non-energy consumption – Industry sector: Wood and wood products
- 7.1.36. Final non-energy consumption – Industry sector: Construction
- 7.1.37. Final non-energy consumption – Industry sector: Textiles and leather
- 7.1.38. Final non-energy consumption – Industry sector: Not elsewhere specified (Industry)
- 7.1.39. Final non-energy consumption: Other sectors
- 7.1.40. Final energy consumption – Industry sector: Iron and steel
- 7.1.41. Final energy consumption – Industry sector: Chemical and petrochemical
- 7.1.42. Final energy consumption – Industry sector: Non-ferrous metals
- 7.1.43. Final energy consumption – Industry sector: Non-metallic minerals
- 7.1.44. Final energy consumption – Industry sector: Transport equipment
- 7.1.45. Final energy consumption – Industry sector: Machinery
- 7.1.46. Final energy consumption – Industry sector: Mining and quarrying

- 7.1.47. Final energy consumption – Industry sector: Food, beverages and tobacco
- 7.1.48. Final energy consumption – Industry sector: Paper, pulp and printing
- 7.1.49. Final energy consumption – Industry sector: Wood and wood products
- 7.1.50. Final energy consumption – Industry sector: Construction
- 7.1.51. Final energy consumption – Industry sector: Textiles and leather
- 7.1.52. Final energy consumption – Industry sector: Not elsewhere specified (Industry)
- 7.1.53. Final energy consumption – Transport sector: Domestic aviation
- 7.1.54. Final energy consumption – Transport sector: Road
- 7.1.55. Final energy consumption – Transport sector: Rail
- 7.1.56. Final energy consumption – Transport sector: Domestic navigation
- 7.1.57. Final energy consumption – Transport sector: Pipeline transport
- 7.1.58. Final energy consumption – Transport sector: Not elsewhere specified (Transport)
- 7.1.59. Other sectors: Commercial and public services
- 7.1.60. Other sectors: Households
- 7.1.61. Other sectors: Agriculture
- 7.1.62. Other sectors: Forestry
- 7.1.63. Other sectors: Fishing
- 7.1.64. Other sectors: Not elsewhere specified (Other)

7.2. **Production capacity**

Hydrogen production capacity on 31 December of the reference year must be declared with the same level of details as for production (items 7.1.1.1 to 7.1.1.6).

7.3. **Units of measurement**

Quantities must be declared in TJ (GCV) and production capacity in TJ (GCV) per year.

8. **DETAILED STATISTICS ON FINAL ENERGY CONSUMPTION**

The following disaggregated data concerning final energy consumption must be declared.

8.1. **List of aggregates**

8.1.1. Industry sector

To be reported as per the definitions provided in Section 2.6.1 of Annex A.

8.1.1.1. Mining and quarrying

8.1.1.1.1. Mining of metal ores

8.1.1.1.2. Other mining and quarrying

8.1.1.1.3. Mining support service activities

8.1.1.2. Food, beverages and tobacco

8.1.1.2.1. Manufacture of food products

8.1.1.2.2. Manufacture of beverages

- 8.1.1.2.3. Manufacture of tobacco products
- 8.1.1.3. Textile and leather
- 8.1.1.4. Wood and wood products
- 8.1.1.5. Pulp, paper and printing
 - 8.1.1.5.1. Manufacture of paper and paper products
 - 8.1.1.5.1.1. Manufacture of pulp
 - 8.1.1.5.1.2. Other paper and paper products
 - 8.1.1.5.2. Printing and reproduction of recorded media
- 8.1.1.6. Chemical and petrochemical
 - 8.1.1.6.1. Manufacture of chemicals and chemical products
 - 8.1.1.6.2. Manufacture of basic pharmaceutical products and pharmaceutical preparations
- 8.1.1.7. Non-metallic minerals
 - 8.1.1.7.1. Manufacture of glass and glass products
 - 8.1.1.7.2. Manufacture of cement, lime and plaster (incl. Clinker)
 - 8.1.1.7.3. Other non-metallic mineral products
- 8.1.1.8. Iron and steel [Manufacture of basic metals A]
- 8.1.1.9. Non-ferrous metals industries [Manufacture of basic metals B]
 - 8.1.1.9.1. Aluminium production
 - 8.1.1.9.2. Other non-ferrous metals industries
- 8.1.1.10. Machinery
 - 8.1.1.10.1. Manufacture of fabricated metal products, except machinery and equipment
 - 8.1.1.10.2. Manufacture of computer, electronic and optical products
 - 8.1.1.10.3. Manufacture of electrical equipment
 - 8.1.1.10.4. Manufacture of machinery and equipment n.e.c.
- 8.1.1.11. Transport equipment
- 8.1.1.12. Not elsewhere specified – Industry
 - 8.1.1.12.1. Manufacture of rubber and plastic products
 - 8.1.1.12.2. Manufacture of furniture
 - 8.1.1.12.3. Other manufacturing
- 8.1.2. Transport sector
 - To be reported as per the definitions provided in Section 2.6.2 of Annex A.
 - 8.1.2.1. Rail
 - 8.1.2.1.1. High-speed rail
 - 8.1.2.1.2. Conventional rail
 - 8.1.2.1.2.1. Passenger transport by conventional rail

- 8.1.2.1.2.1. Freight transport by conventional rail
- 8.1.2.1.3. Metro and tram
- 8.1.2.2. Road
 - 8.1.2.2.1. Heavy-duty vehicles carrying freight
 - 8.1.2.2.2. Collective transport
 - 8.1.2.2.3. Cars and vans
 - 8.1.2.2.4. Other road transport
- 8.1.3. Commercial and public services sector
 - To be reported as per the definitions provided in Section 2.6.3.1 of Annex A.
 - 8.1.3.1. Repair and installation of machinery and equipment
 - 8.1.3.2. Water supply; sewerage, waste management and remediation activities
 - 8.1.3.3. Wholesale and retail trade; repair of motor vehicles and motorcycles
 - 8.1.3.3.1. Wholesale trade
 - 8.1.3.3.2. Retail trade
 - 8.1.3.4. Warehousing and support activities for transportation
 - 8.1.3.5. Postal and courier activities
 - 8.1.3.6. Accommodation and food service activities
 - 8.1.3.6.1. Accommodation
 - 8.1.3.6.2. Food service activities
 - 8.1.3.7. Information and communication
 - 8.1.3.8. Financial and insurance activities and real estate activities
 - 8.1.3.9. Administrative and support service activities
 - 8.1.3.10. Public administration and defence; compulsory social security
 - 8.1.3.11. Education
 - 8.1.3.12. Human health and social work activities
 - 8.1.3.12.1. Hospital activities
 - 8.1.3.13. Arts, entertainment and recreation
 - 8.1.3.13.1. Sports activities
 - 8.1.3.14. Activities of extra-territorial organisations and bodies
 - 8.1.3.15. Professional, scientific and technical activities and other services
 - 8.1.3.16. Data centres. Only data centres hosted by reporting units (regardless of their NACE code) with a total power capacity of 1 MW or more need to be declared. The first mandatory reporting for this item is reference year 2024.
- 8.1.4. Households sector
 - To be reported as per the definitions provided in Section 2.6.3.2 of Annex A.

8.1.4.1. Households: Space heating

8.1.4.2. Households: Space cooling

8.1.4.3. Households: Water heating

8.1.4.4. Households: Cooking

8.1.4.5. Households: Lighting and appliances

Only concerns electricity

8.1.4.6. Households: Other end uses

8.2. Applicable energy products

Unless otherwise specified, this data collection applies to all energy products listed in Annex A.

Eurostat will specify the actual list of energy products for which data covered by point 7 of Annex B should be reported in the reporting template, as a subset of those listed in point 3 of Annex A.

8.3. Units of measurement

Quantities of solid fossil fuels must be declared in kt (kilo-tonnes).

Quantities of crude oil and petroleum products must be declared in kt (kilo-tonnes).

Quantities of natural gas and manufactured gases (gas works gas, coke oven gas, blast furnace gas, other recovered gases) must be declared by energy content, in TJ GCV (tera-joules based on gross calorific values).

Electricity must be declared in GWh (giga-watt hours).

Quantities of heat must be declared in TJ (tera-joules based on net calorific values).

Quantities of renewables and waste must be declared in TJ NCV (tera-joules based on net calorific value), except for charcoal, biogasoline, bioethanol, bio jet kerosene, biodiesels, and other liquid biofuels, which must be declared in kt (kilo-tonnes).

Calorific values for solid fossil fuels, crude oil and petroleum products and renewables and waste must be declared in MJ/t (mega-joules per tonne).

Calorific values for natural gas and manufactured gases must be declared in kJ/m³, assuming reference gas conditions (15 °C, 101 325 Pa).

For other energy products for which reporting is required, the applicable units are defined in the relevant chapters of this annex.

8.4. Deadline for transmission of data:

Data should be submitted by 31 March of the second year following the reported year.

8.5. Exemptions

Cyprus is exempted from reporting the disaggregated final energy consumption of crude oil and petroleum products (as defined in Section 3.4 of Annex A) for all aggregates covered by Section 8.1.4 of this annex (Households).

9. PRELIMINARY ANNUAL DATA

9.1. Applicable energy products

This data collection applies to all products described in Sections 1.1, 2.1, 3.1, 4.1 and 5.1 of this annex.

9.2. List of aggregates

The following list of aggregates must be declared:

- 9.2.1. For solid fossil fuels and manufactured gases: 1.2.1.1, 1.2.1.2, 1.2.1.6, 1.2.1.7, 1.2.1.8, 1.2.1.9 as defined in Chapter 1 of this annex.
- 9.2.2. For natural gas: 2.2.1.1, 2.2.1.2, 2.2.1.3, 2.2.1.4, 2.2.1.5, 2.2.1.6 as defined in Chapter 2 of this annex.
- 9.2.3. For electricity and heat: gross production by product for all individual products, own use, total of transmission and distribution losses (3.2.3 and 3.2.4) and 3.2.2.3, 3.2.2.4, 3.2.2.5, 3.2.2.6, 3.2.2.7, 3.2.2.8, 3.2.2.9 as defined in Chapter 3 of this annex.
- 9.2.4. For oil and petroleum products: 4.2.1.1, 4.2.1.2, 4.2.1.3, 4.2.1.4, 4.2.1.5, 4.2.1.6, 4.2.1.7, 4.2.1.8, 4.2.1.9, 4.2.1.10, 4.2.2.1, 4.2.2.2, 4.2.2.3, 4.2.2.4, 4.2.2.5, 4.2.2.6, 4.2.2.7, 4.2.2.8, 4.2.2.9, 4.2.2.10 as defined in Chapter 4 of this annex.
- 9.2.5. For renewable energy and energy from waste: 5.2.2.1, 5.2.2.2, 5.2.2.3, 5.2.2.4, 5.2.10.1, 5.2.10.2, 5.2.10.3, 5.2.10.8, 5.2.10.9 as defined in Chapter 5 of this annex.

9.3. Units of measurement

Quantities must be declared in units defined in Sections 1.3, 2.3, 3.3, 4.3 and 5.3 of this annex.

9.4. Deadline for transmission of data

Data should be submitted by 31 May of the year following the reported year.

ANNEX C

MONTHLY ENERGY STATISTICS

This annex describes the scope, units, reported period, frequency, deadline and transmission arrangements for the monthly collection of energy statistics.

Annex A provides explanations of terms not explained in this annex.

The following provisions apply to all data collections specified in this annex:

- a) Reported period: The reported period of declared data will be one calendar month.
- b) Frequency: Data should be declared on a monthly basis.
- c) Transmission format: The transmission format should conform to the relevant interchange standard specified by Eurostat.
- d) Transmission method: Data should be submitted or uploaded by electronic means to the Eurostat's single entry point for data.

1. **SOLID FUELS**

1.1. **Applicable energy products**

This chapter covers the reporting of:

1.1.1. Hard coal

1.1.2. Brown coal

1.1.3. Peat

1.1.4. Oil shale and oil sands

1.1.5. Coke oven coke

1.2. **List of aggregates**

1.2.1. The following aggregates must be declared for hard coal:

1.2.1.1. Production

1.2.1.2. Recovered products

1.2.1.3. Imports

1.2.1.4. Imports from outside EU

1.2.1.5. Exports

1.2.1.6. Opening total stocks on national territory

These are the quantities held by mines, importers and consumers who import directly.

1.2.1.7. Closing total stocks on national territory

These are the quantities held by mines, importers and consumers who import directly.

1.2.1.8. Deliveries to main activity producers

1.2.1.9. Deliveries to coking plants

1.2.1.10. Deliveries to total industry

1.2.1.11. Deliveries to iron and steel industry

1.2.1.12. Other deliveries (services, households, etc.). The amount of hard coal delivered to sectors not specifically mentioned or not belonging to transformation, energy, industry or transport.

1.2.2. The following aggregates must be declared for brown coal, peat and oil shale and oil sands:

1.2.2.1. Production

1.2.2.2. Imports

1.2.2.3. Exports

1.2.2.4. Opening total stocks on national territory

These are the quantities held by mines, importers and consumers who import directly.

1.2.2.5. Closing total stocks on national territory

These are the quantities held by mines, importers and consumers who import directly.

1.2.2.6. For peat, stock changes can be declared instead of opening and closing total stocks.

1.2.2.7. Deliveries to main activity producers

1.2.3. The following aggregates must be declared for coke oven coke:

1.2.3.1. Production

1.2.3.3. Imports

1.2.3.4. Imports from outside the EU

1.2.3.5. Exports

1.2.3.6. Opening total stocks on national territory

These are the quantities held by producers, importers and consumers who import directly.

1.2.3.7. Closing total stocks on national territory

These are the quantities held by producers, importers and consumers who import directly.

1.2.3.8. Deliveries to iron and steel industry

1.3. **Units of measurement**

Reported quantities must be declared in kt (kilo-tonnes).

1.4. **Deadline for transmission of data**

Within two calendar months following the reported month.

2. **ELECTRICITY**

2.1. **Applicable energy products**

This chapter covers the reporting of electricity.

2.2. **List of aggregates**

The following aggregates must be declared for electricity:

2.2.1. Net electricity production from nuclear plants

2.2.2. Net electricity production from conventional thermal power generation using coal

2.2.3. Net electricity production from conventional thermal power generation using oil

- 2.2.4. Net electricity production from conventional thermal power generation using gas
- 2.2.5. Net electricity production from conventional thermal power generation using combustible renewables (such as solid biofuels, biogases, liquid biofuels, renewable municipal waste)
- 2.2.6. Net electricity production from conventional thermal power generation using other non-renewable combustible fuels (such as non-renewable industrial and non-renewable municipal waste)
- 2.2.7. Net electricity production from pure hydro plants
- 2.2.8. Net electricity production from mixed hydro plants
- 2.2.9. Net electricity production from pure pumped storage hydro plants
- 2.2.10. Net electricity production from wind installations on shore
- 2.2.11. Net electricity production from wind installations off shore
- 2.2.12. Net electricity production from solar PV installations
- 2.2.13. Net electricity production from solar thermal installations
- 2.2.14. Net electricity production from geothermal power generation
- 2.2.15. Net electricity production from other renewable sources (such as tide, wave, ocean and other non-combustible renewable sources)
- 2.2.16. Net electricity production from non-specified origin
- 2.2.17. Imports
 - 2.2.17.1. Of which from the EU
- 2.2.18. Exports
 - 2.2.18.1. Of which to the EU
- 2.2.19. Electricity used for pumped storage
- 2.3. **Units of measurement**
Reported quantities must be declared in GWh (giga-watt hours).
- 2.4. **Deadline for transmission of data**
Within two calendar months following the reported month.
- 3. **OIL AND PETROLEUM PRODUCTS**
 - 3.1. **Applicable energy products**
Unless otherwise specified, this data collection applies to all energy products listed in Annex A, Chapter 3.4 OIL (crude oil and petroleum products).

The 'Other products' category includes both the quantities that correspond to the definition in Annex A Chapter 3.4 and the quantities of white spirit and SBP, lubricants, bitumen and paraffin waxes; these products should not be declared separately.
 - 3.2. **List of aggregates**
The following aggregates must be declared for all energy products listed in the previous paragraph unless otherwise specified.
 - 3.2.1. **SUPPLY OF CRUDE OIL, NGL, REFINERY FEEDSTOCKS, ADDITIVES AND OTHER HYDROCARBONS**
Note for additives and biofuels: include here not only already blended volumes, but also all quantities destined for blending.

The following aggregates must be declared for crude oil, NGL, refinery feedstocks, additives/oxygenates, biofuels and other hydrocarbons:

- 3.2.1.1. Indigenous Production (not applicable for refinery feedstocks and biofuels).
- 3.2.1.2. Receipts from other sources (not applicable for crude oil, NGL, refinery feedstocks)
- 3.2.1.3. Backflows
Finished or semi-finished products final consumers return to refineries for processing, blending or sale. They are usually by-products of petrochemical manufacturing. Only applicable for refinery feedstocks.
- 3.2.1.4. Products transferred
Imported petroleum products that are reclassified as feedstocks for further processing in the refinery, without delivery to final consumers. Only applicable for refinery feedstocks.
- 3.2.1.5. Imports
- 3.2.1.6. Exports
Note for import and exports: Includes quantities of crude oil and products imported or exported under processing agreements (i.e. refining on account). Crude oil and NGLs should be reported as coming from the country of ultimate origin; refinery feedstocks and finished products should be reported as coming from the country of last consignment. Includes any gas liquids (e.g. LPG) extracted during the regasification of imported liquefied natural gas and petroleum products imported or exported directly by the petrochemical industry.
- 3.2.1.7. Direct use
- 3.2.1.8. Stock changes
A stock build is shown as a positive number and a stock draw is shown as a negative number.
- 3.2.1.9. Observed refinery intake
This is defined as the total amount of oil (including Other hydrocarbons and Additives) observed to have entered the refinery process (input to refineries).
- 3.2.1.10. Refinery losses
The difference between observed refinery intake and gross refinery output. Losses may occur during distillation processes due to evaporation. Reported losses are positive. There may be volumetric gains but no gains in mass.
- 3.2.2. SUPPLY OF FINISHED PRODUCTS
The following aggregates must be declared for Crude oil, NGL, Refinery gas, Ethane, LPG, Naphtha, Biogasoline, Non-biogasoline, Aviation gasoline, Gasoline type jet fuel, Bio jet kerosene, Non-bio jet Kerosene, Other kerosene, Biodiesels, Non-bio gas/diesel oil, LSFO, HSFO, Petroleum coke, and Other products:
 - 3.2.2.1. Primary product receipts
 - 3.2.2.2. Gross refinery output (not applicable for crude oil and NGL)
 - 3.2.2.3. Recycled products (not applicable for crude oil and NGL)
 - 3.2.2.4. Refinery Fuel (not applicable for crude oil and NGL)
Annex A Chapter 2.3 Energy sector – Petroleum refineries; Includes fuels used at the refineries for the production of electricity and heat sold.
 - 3.2.2.5. Imports (not applicable for crude oil, NGL and refinery gas)

- 3.2.2.6. Exports (not applicable for crude oil, NGL and refinery gas)
The note made for imports and exports in Section 3.2.1 also applies here.
- 3.2.2.7. International marine bunkers (not applicable for crude oil and NGL)
- 3.2.2.8. Interproduct transfers
- 3.2.2.9. Products transferred (not applicable for crude oil and NGL)
- 3.2.2.10. Stock changes (not applicable for crude oil, NGL and refinery gas)
A stock build is shown as a positive number and a stock draw is shown as a negative number.
- 3.2.2.11. Observed gross inland deliveries
The observed delivery of finished petroleum products from primary sources (e.g. refineries, blending plants, etc.) to the inland market.
- 3.2.2.11.1. International aviation (applicable only for Aviation gasoline, Gasoline type jet fuel, Bio jet kerosene, Non-bio jet kerosene)
- 3.2.2.11.2. Main activity producer power plants
- 3.2.2.11.3. Road (applicable only for LPG)
- 3.2.2.11.4. Domestic navigation and Rail (applicable only for Biodiesels, Non-bio gas/diesel oil)
- 3.2.2.12. Petrochemical
- 3.2.2.13. Backflow to refineries (not applicable for crude oil and NGL)
- 3.2.3. IMPORTS BY ORIGIN – EXPORTS BY DESTINATION
Imports should be reported by country of origin and exports by country of destination. The note made for imports and exports in Section 3.2.1 also applies here.
- 3.2.4. STOCK LEVELS
The following opening and closing stocks must be declared for all energy products, including for additives/oxygenates but except for refinery gas:
- 3.2.4.1. Stocks on national territory
Stocks in the following locations: refinery tanks, bulk terminals, pipeline tankage, barges and coastal tankers (when port of departure and destination are in the same country), tankers in a port of a member country (if their cargo is to be discharged at the port), inland ship bunkers. Excludes stocks of oil held in pipelines, in rail tanks cars, in truck tanks cars, in sea-going ships' bunkers, in service stations, in retail stores and in bunkers at sea.
- 3.2.4.2. Stocks held for other countries under bilateral government agreements
Stocks on national territory which belong to another country and to which access is guaranteed by an agreement between the respective governments.
- 3.2.4.3. Stocks with known foreign destination
Stocks not included in point 3.2.4.2 on national territory which belong to and are destined for another country. These stocks may be located inside or outside bonded areas.
- 3.2.4.4. Other stocks held in bonded areas
Includes stocks not included in point 3.2.4.2 nor 3.2.4.3 irrespective of whether they have received customs clearance or not.

3.2.4.5. Stocks held by major consumers

Include stocks which are subject to government control. This definition does not include other consumer stocks.

3.2.4.6. Stocks held on board incoming ocean vessels in port or at mooring

Stocks irrespective of whether they have been cleared by customs or not. This category excludes stocks on board vessels at high seas.

Includes oil in coastal tankers if both their port of departure and destination are in the same country. In the case of incoming vessels with more than one port of unloading, only report the amount to be unloaded in the reporting country.

3.2.4.7. Stocks held by government on national territory

Includes non-military stocks that are held by the government within the national territory, and are government-owned or controlled and held exclusively for emergency purposes.

Excludes stocks held by state oil companies or electric utilities or stocks held directly by oil companies on behalf of governments.

3.2.4.8. Stocks held by stockholding organisation on national territory

Stocks held by both public and private corporations established to maintain stocks exclusively for emergency purposes.

Excludes mandatory stocks held by private companies.

3.2.4.9. All other stocks held on national territory

All other stocks satisfying the conditions described in point 3.2.4.1 above.

3.2.4.10. Stocks held abroad under bilateral government agreements

Stocks belonging to the reporting country but held in another country, to which access is guaranteed by an agreement between the respective governments.

3.2.4.10.1. Of which: Government stocks

3.2.4.10.2. Of which: Holding organisation's stocks

3.2.4.10.3. Of which: Other stocks

3.2.4.11. Stocks held abroad designated definitely for import stocks

Stocks that are not included in category 10 and that belong to the reporting state but are held in another state and are awaiting import there.

3.2.4.12. Other stocks in bonded areas

Other stocks in the national territory not included in the above categories.

3.2.4.13. Pipeline fill

Oil (crude oil and petroleum products) contained in pipelines, necessary to maintain flow in the pipelines.

In addition, a breakdown of quantities per corresponding country must be declared for:

3.2.4.13.1. closing stocks held for other countries under official agreement, by beneficiary,

3.2.4.13.2. closing stocks held for other countries under official agreement, of which held as stock tickets, by beneficiary,

3.2.4.13.3. closing stocks with known foreign destination, by beneficiary,

3.2.4.13.4. closing stocks held abroad under official agreement, by location,

3.2.4.13.5. closing stocks held abroad under official agreement, of which held as stock tickets, by location,

- 3.2.4.13.6. closing stocks held abroad designated definitely for import into the declarer's country, by location.

'Opening stocks' means the stocks on the last day of the month preceding the reported one. 'Closing stocks' means the stocks on the last day of the reported month.

3.3. **Units of measurement**

Reported quantities must be declared in kt (kilo-tonnes).

3.4. **Deadline for transmission of data**

Within 55 days following the reported month.

3.5. **Geographical notes**

For statistical reporting purposes only, the clarifications in Annex A Chapter 1 apply with the following specific exception: Switzerland includes Liechtenstein

4. **NATURAL GAS**

4.1. **Applicable energy products**

This chapter covers the reporting of natural gas.

4.2. **List of aggregates**

The following aggregates must be declared for natural gas.

4.2.1. Indigenous production

All dry marketable production within national boundaries, including offshore production. Production is measured after purification and extraction of NGLs and sulphur. Excludes extraction losses and quantities reinjected, vented or flared. Includes quantities used within the natural gas industry, in gas extraction, pipeline systems and processing plants.

4.2.2. Imports (Entries)

4.2.3. Exports (Exits)

Note for imports and exports: Report all natural gas volumes which have physically crossed the national boundaries of the country, whether customs clearance has taken place or not. This includes quantities transiting your country; transit volumes should be included as an import and as an export. Imports of liquefied natural gas should cover only the dry marketable equivalent, including amounts used as own consumption in the regasification process. The amounts used as own consumption during regasification should be reported under Own use and losses of the natural gas industry (see Section 4.2.11). Any gas liquids (e.g. LPG) extracted during the regasification process of imported LNG should be reported under 'Receipts from other sources' of 'Other hydrocarbons' as defined in Chapter 3 of this annex (OIL AND PETROLEUM PRODUCTS).

4.2.4. Stock changes

A stock build is shown as a positive number and a stock draw is shown as a negative number.

4.2.5. Observed gross inland deliveries

This category represents deliveries of marketable gas to the inland market, including gas used by the gas industry for heating and operation of their equipment (i.e. consumption in gas extraction, in the pipeline system and in processing plants); losses in transmission and distribution should also be included.

4.2.6. Opening levels of stocks held on national territory

4.2.8. Closing levels of stocks held on national territory

4.2.9. Opening levels of stocks held abroad

4.2.10. Closing levels of stocks held abroad

Note for levels of stocks: includes natural gas stored in gaseous form as well as in liquefied form.

4.2.11. Own use and losses of the natural gas industry

Quantities used by the gas industry for heating and operation of its equipment (i.e. consumption in gas extraction, in the pipeline system and in processing plants); includes losses in transmission and distribution.

4.2.12. Imports (entries) by origin and exports (exits) by destination

Imports (entries) should be reported by country of origin and exports (exits) by country of destination. The note made for imports and exports in Section 4.2.3 also applies here. Imports and exports are to be declared only for the neighbouring country or country with a direct pipeline connection or, in the case of LNG, for the country where the gas has been loaded onto the transport ship.

4.2.13. Deliveries to power generation

4.3. **Units of measurement**

Quantities must be declared in two units:

4.3.1. in physical quantity, in million m³ (million cubic metres) assuming reference gas conditions (15 C, 101 325 Pa),

4.3.2. in energy content, in TJ (tera-joules), based on the gross calorific value.

4.4. **Deadline for transmission of data**

Within 55 days following the reported month.

ANNEX D

SHORT TERM MONTHLY STATISTICS

This annex describes the scope, units, reported period, frequency, deadline and transmission arrangements for the short-term monthly collection of statistical data.

Annex A provides explanations of terms not explained in this annex.

The following provisions apply to all data collections specified in this annex:

- a) Reported period: The reported period of declared data will be one calendar month.
- b) Frequency: Data should be declared on a monthly basis.
- c) Transmission format: The transmission format should conform to the relevant interchange standard specified by Eurostat.
- d) Transmission method: Data should be submitted or uploaded by electronic means to Eurostat's single entry point for data.

1. CRUDE OIL IMPORTS AND SUPPLY**1.1. Applicable energy products**

This chapter covers the reporting of crude oil.

1.2. Definitions**1.2.1. Imports**

Imports cover every quantity of crude oil which either enters the customs territory of the Member State or comes from another Member State for purposes other than transit. Crude oil used for stock building must be included.

Oil extracted from the seabed over which a Member State exercises exclusive rights for the purposes of exploitation and entering the customs territory of the Community should be excluded from imports.

1.2.2. Supply

Supply covers the crude oil imported and the crude oil produced in the Member State during the reference period. The provision of crude oil from previously built stocks is excluded.

1.2.3. CIF price

The CIF (cost, insurance and freight) price includes the FOB (free on board) price, which is the price actually invoiced at the port/place of loading in addition to the cost of transport, insurance and charges linked to crude oil transfer operations.

The CIF price of the crude oil produced in a Member State is to be calculated free at port of discharge or free at frontier, i.e. at the moment when the crude oil falls under the customs jurisdiction of the importing country.

1.2.4. API gravity

The API gravity is a measure of how heavy/light crude oil is compared to water. The API gravity is to be reported according to the following formula, with respect to the specific gravity (SG): $API = (141,5 \div SG) - 131,5$

1.3. List of aggregates**1.3.1. The following list of aggregates must be declared for crude oil imports split by type and geographical area of production:****1.3.1.1. the designation of the crude oil****1.3.1.2. the average API gravity****1.3.1.3. the average sulphur content**

- 1.3.1.4. the total volume imported
 - 1.3.1.5. the total CIF price
 - 1.3.1.6. the number of reporting entities.
 - 1.3.2. The following list of aggregates must be declared for crude oil supply:
 - 1.3.2.1. the volume supplied
 - 1.3.2.2. the weighted average CIF price
 - 1.4. **Units of measurement**
 - bbl (barrel) for 2.3.1.4 and 2.3.2.1
 - kt (thousand tonnes) for 2.3.2.1
 - % (percentage) for 2.3.1.3
 - ° (degrees) for 2.3.1.2
 - \$ (US Dollar) per barrel for 2.3.1.5 and 2.3.2.2
 - \$ (US Dollar) per tonne for 2.3.2.2
 - 1.5. **Applicable provisions**
 - 1. Reported period:
One calendar month.
 - 2. Frequency:
Monthly.
 - 3. Deadline for transmission of data:
Within one calendar month following the reported month.
 - 4. Transmission format:
The transmission format should conform to the relevant interchange standard specified by Eurostat.
 - 5. Transmission method:
Data should be submitted or uploaded by electronic means to Eurostat's single entry point for data.'
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DECISIONS

COUNCIL IMPLEMENTING DECISION (EU) 2022/133

of 25 January 2022

authorising France to introduce a special measure derogating from Articles 218 and 232 of Directive 2006/112/EC on the common system of value added tax

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax ⁽¹⁾, and in particular Article 395(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) By letters registered with the Commission on 12 April 2021 and 20 September 2021, France requested authorisation to introduce a special measure derogating from Articles 218 and 232 of Directive 2006/112/EC ('the special measure') to introduce mandatory electronic invoicing to all taxable persons established in the territory of France. This obligation would cover invoices issued in transactions between taxable persons. The authorisation was requested for a period from 1 January 2024 to 31 December 2026.
- (2) The Commission transmitted the request made by France to the other Member States by letters dated 29 September 2021. By letter dated 30 September 2021, the Commission notified France that it had all the information necessary for the appraisal of the request..
- (3) France submits that the introduction of a generalised electronic invoicing obligation would provide benefits in combatting value added tax (VAT) fraud and evasion. The obligation to issue electronic invoices, coupled with the transmission of additional transaction data, would enable the tax administration to check in real time whether the VAT declared and collected and the invoices issued and received are consistent, improving the capacity of the administration to prevent and counter VAT fraud. It would also increase real-time knowledge of business activity, enabling economic policy to be steered as closely as possible to the economic reality.
- (4) France considers that the obligation to issue electronic invoices would facilitate voluntary compliance with tax legislation. It would allow the simplification of taxable persons' VAT reporting obligations by introducing pre-completion of their returns. Electronic invoicing would provide other advantages to taxable persons, such as the reduction of payment times, reduction of printing costs and postal charges, reduction of costs and delays in processing billing data or the reduction of storage costs. The savings and advantages that taxable persons would obtain from the implementation of electronic invoicing would largely compensate for initial investment that they will have to incur to adapt their systems.
- (5) Given the broad scope and the novelty of the special measure, it is important to evaluate the impact of the special measure on combatting VAT fraud and evasion and on taxable persons. Therefore, where France considers that the extension of the special measure is necessary, it should submit to the Commission, together with the request for extension, a report including the assessment of the special measure concerning its effectiveness in fighting VAT fraud and evasion and in simplifying tax collection.
- (6) The special measure should not affect the right of taxable persons to receive paper invoices in case of intra-Community acquisitions.

⁽¹⁾ OJ L 347, 11.12.2006, p. 1.

- (7) The special measure should be limited in time to allow an assessment of whether it is appropriate and effective in light of its objectives.
- (8) The special measure is proportionate to the objectives pursued since it is limited in time and will be implemented gradually. As of 2024, an obligation to receive electronic invoices is to apply to all taxable persons. The obligation to issue electronic invoices is to apply in 2024 to large enterprises, in 2025 to enterprises with 250 to 4 999 employees and with a turnover below EUR 1,5 billion and in 2026 to small and medium-sized enterprises, including taxable persons benefitting from the exemption for small enterprises referred to in Article 282 of Directive 2006/112/EC. In addition, the special measure does not give rise to the risk that fraud would shift to other sectors or to other Member States.
- (9) The special measure will not negatively affect the overall amount of tax revenue collected at the stage of final consumption and will have no adverse impact on the Union's own resources accruing from VAT,

HAS ADOPTED THIS DECISION:

Article 1

By way of derogation from Article 218 of Directive 2006/112/EC, France is authorised to accept invoices which have been issued by taxable persons established in the French territory in the form of documents or messages only if those documents or messages are transferred in electronic format.

Article 2

By way of derogation from Article 232 of Directive 2006/112/EC, France is authorised to provide that the use of electronic invoices issued by taxable persons established in the French territory shall not be subject to a recipient established in the French territory accepting the use of electronic invoices.

Article 3

France shall notify the national measures implementing the special measures for derogations referred to in Articles 1 and 2 to the Commission.

Article 4

1. This Decision shall take effect on the day of its notification.
2. This Decision shall apply from 1 January 2024 until 31 December 2026.
3. Where France considers that the extension of the special measures for derogations referred to in Articles 1 and 2 is necessary, France shall submit a request for extension to the Commission, together with a report assessing the extent to which the national measures referred to in Article 3 have been effective in combatting VAT fraud and evasion and in simplifying tax collection. That report shall evaluate the impact of those measures on taxable persons and in particular whether those measures increase their administrative burdens and costs.

Article 5

This Decision is addressed to the French Republic.

Done at Brussels, 25 January 2022.

For the Council
The President
C. BEAUNE

DECISION (EU) [2022/134] OF THE EUROPEAN CENTRAL BANK**of 19 January 2022****laying down common rules on the transmission by the European Central Bank of supervisory information to authorities and bodies for the purpose of carrying out the tasks conferred on it by Council Regulation (EU) No 1024/2013 (ECB/2022/2)**

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

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

Having regard to Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions ⁽¹⁾, and in particular Article 4 thereof,

Whereas:

- (1) Article 4(3) of the Treaty on European Union provides that the Union and the Member States are, in full mutual respect, to assist each other in carrying out the tasks which flow from the Treaties, and Article 13(2) of the same Treaty requires the Union institutions to practise mutual sincere cooperation. Article 3 of Regulation (EU) No 1024/2013 requires the European Central Bank (ECB) to cooperate with other national and Union authorities and bodies.
- (2) In order for the ECB to comply with Article 3 and to carry out the tasks conferred on it by Article 4 of Regulation (EU) No 1024/2013, it is necessary for it to transmit supervisory information held by it to national, Union and international authorities and bodies.
- (3) Under Article 27(2) of Regulation (EU) No 1024/2013 the ECB may, for the purpose of carrying out the tasks conferred on it by that Regulation and within the limits and under the conditions set out in the relevant Union law, exchange information with national or Union authorities and bodies where the relevant Union law allows national competent authorities to disclose information to those entities or where the Member States may provide for such disclosure under the relevant Union law.
- (4) There are also circumstances under which the ECB transmits supervisory information to authorities and bodies pursuant to an obligation under Union law. For example, under Article 80 of Regulation (EU) No 575/2013 of the European Parliament and of the Council ⁽²⁾, competent authorities are obliged, upon request by the European Banking Authority (EBA), to forward to the EBA all information deemed relevant concerning new capital instruments issued in order to enable it to monitor the quality of own funds instruments issued by institutions across the Union.
- (5) The transmission of supervisory information to authorities and bodies presupposes an assessment, connected with the carrying out of the tasks conferred on the ECB by Regulation (EU) No 1024/2013, of the appropriateness of such transmission.
- (6) Consequently, it is necessary to lay down common rules on the transmission of supervisory information held by the ECB to authorities and bodies that may be complemented by memoranda of understanding or other forms of bilateral or multilateral instruments concerning such transmission concluded by the ECB with such authorities or bodies.
- (7) The common rules laid down in this Decision should be without prejudice to the provisions of other instruments that lay down specific rules on particular categories of transmission of supervisory information to authorities and bodies. This applies, for example, in relation to memoranda of understanding, in which the ECB exercises its policy discretion and commits to transmitting information to specific recipient authorities or bodies. Furthermore, the

⁽¹⁾ OJ L 287, 29.10.2013, p. 63.

⁽²⁾ Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).

common rules laid down in this Decision should not apply to the transmission of supervisory information governed by different legal frameworks, such as the disclosure of information to criminal investigation authorities, parliamentary enquiry committees and state auditors. However, the scope of this Decision may also cover the transmission of personal data.

- (8) This Decision and other instruments that lay down specific rules on the transmission of supervisory information involve policy discretion. Therefore, they should be adopted under the non-objection procedure laid down in Article 26(8) of Regulation (EU) No 1024/2013.
- (9) The rules laid down in this Decision and in any other instruments on particular categories of transmission of supervisory information should be applied by the staff members responsible for approval of such transmission, as determined by the Executive Board. Under Article 11.6 of the Statute of the European System of Central Banks and of the European Central Bank the Executive Board has responsibility for the current business of the ECB. In this connection, Article 10.1 and 10.2 of Decision ECB/2004/2 of the European Central Bank ^(*) provide that all ECB work units fall under the managing direction of the Executive Board. Pursuant to Article 13m.1 of Decision ECB/2004/2, the Executive Board's competence in respect of the internal structure and the staff of the ECB encompasses supervisory tasks.
- (10) This Decision is without prejudice to the rules on the transmission of supervisory information held by the ECB to other authorities and bodies or held by the national competent authorities within the meaning of Article 2(2) of Regulation (EU) No 1024/2013. The transmission of supervisory information held by the ECB to authorities and bodies that falls outside the scope of this Decision must be approved in accordance with the appropriate decision-making procedure,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

- 1. This Decision lays down common rules on the transmission of supervisory information held by the ECB to authorities and bodies as defined in Article 2(2).
- 2. This Decision shall be without prejudice to rules on the transmission of supervisory information held by the ECB to other authorities and bodies or held by the national competent authorities within the meaning of Article 2(2) of Regulation (EU) No 1024/2013.

Article 2

Definitions

For the purpose of this Decision, the following definitions apply:

- (1) 'supervisory information' means any confidential information held by the ECB, the transmission of which to authorities and bodies presupposes an assessment, connected with the carrying out of the tasks conferred on the ECB by Regulation (EU) No 1024/2013, as to the appropriateness of such transmission;
- (2) 'authorities and bodies' means national, Union and international authorities and bodies, except national competent authorities as defined in Article 2(2) of Regulation (EU) No 1024/2013, as identified in the Annex to this Decision;
- (3) 'decision to allocate tasks' means a decision by which the Executive Board allocates to a transmission clearance officer the task of applying the rules laid down in this Decision and/or, as appropriate, the specific rules laid down in instruments applicable to particular categories of transmission of supervisory information;

^(*) Decision ECB/2004/2 of the European Central Bank of 19 February 2004 adopting the Rules of Procedure of the European Central Bank (OJ L 80, 18.3.2004, p. 33).

- (4) 'transmission clearance' means the approval to transmit supervisory information to authorities and bodies given by a transmission clearance officer in applying this Decision and/or, as appropriate, instruments that lay down specific rules applicable to particular categories of transmission of supervisory information, pursuant to a decision to allocate tasks.

Article 3

Common rules on the transmission of supervisory information

1. The ECB shall transmit supervisory information to authorities and bodies if:
 - (a) the applicable law authorises the transmission of such supervisory information to those authorities and bodies and the conditions laid down for that authorisation are satisfied;
 - (b) the supervisory information is adequate, relevant and not excessive in scope in relation to the tasks of those relevant authorities or bodies; and
 - (c) there are no overriding reasons for refusing to disclose such supervisory information relating to the need to avoid any interference with the functioning and independence of the Single Supervisory Mechanism, in particular by jeopardising the accomplishment of its tasks.
2. If it appears that overriding reasons for refusing to disclose the supervisory information referred to in paragraph (1)(c) exist, the Governing Council shall decide on the transmission of supervisory information, following the procedure laid down in Article 26(8) of Regulation (EU) No 1024/2013.
3. The common rules laid down in paragraph 1 shall be without prejudice to any specific rules as referred to in Article 4.

Article 4

Instruments laying down specific rules

This decision is without prejudice to other instruments laying down specific or complementing rules on particular categories of transmission of supervisory information to authorities and bodies.

Article 5

Transmission clearance

Transmission clearance officers shall have responsibility for approving the transmission of supervisory information by the ECB and shall apply in this regard the rules laid down in this Decision and/or, as appropriate, any specific rules laid down in the instruments referred to in Article 4, pursuant to a decision to allocate tasks.

Article 6

Entry into force

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

Done at Frankfurt am Main, 19 January 2022.

The President of the ECB
Christine LAGARDE

ANNEX

Recipient authority or body	Description and legal basis
European Commission	Article 32 of the SSMR ⁽¹⁾
The European Banking Authority (EBA), European Securities and Markets Authority, European Insurance and Occupational Pensions Authority, European Systemic Risk Board	Article 53(2) of the CRD ⁽²⁾ in conjunction with Article 35(1) of the EBA Regulation ⁽³⁾ or Article 80 of the CRR ⁽⁴⁾ , Article 15 of the ESRB Regulation ⁽⁵⁾ Article 9a of the EBA Regulation
National prudential supervisory authorities in the European Union and European Economic Area (EEA) regarding qualifying holding and licensing procedures or other procedures referred to in the relevant legislation	Article 56 and Articles 16(3), 24(2), 50(4) of the CRD and equivalent provisions in Union law, in particular Articles 26 and 60 in Solvency II ⁽⁶⁾ and Articles 11 and 84 of MiFID ⁽⁷⁾
National competent and resolution authorities that participate in a prudential college under the CRD, or in arrangements under FICOD or crisis management groups This category covers the exchange of information within prudential colleges under the CRD and the FICOD and crisis management groups as well as the non-discretionary annual updates and termination of written coordination and cooperation arrangements, coordination arrangements under FICOD and cooperation arrangements for crisis management groups	Article 116 of the CRD for written coordination and cooperation arrangements; Article 11 of FICOD ⁽⁸⁾ for financial conglomerate arrangements; Articles 90, 97 and 98 of the BRRD ⁽⁹⁾ for cooperation arrangements related to crisis management groups; Articles 88 and 90 of the BRRD for resolution college written arrangements.
Authorities that are part of an AML/Countering the Financing of Terrorism (CFT) college	Article 117(5) of the CRD (for AML/CFT supervisory authorities and financial intelligence units and terms of participation concluded for the specific AML/CFT college). For exchange of information with other types of authorities participating in the college, the legal basis may differ (note: the AML/CFT colleges are regulated by joint guidelines on cooperation and information exchange for the purpose of Directive (EU) 2015/849 of the European Parliament and of the Council ⁽¹⁰⁾ between competent authorities supervising credit and financial institutions and other parties; those guidelines are not addressed to the ECB).
AML/CFT supervisory authorities that signed the Multilateral Agreement on the practical modalities for exchange of information pursuant to Article 57a(2) of Directive (EU) 2015/849 (hereinafter the 'AML Agreement')	Article 117(5) of the CRD, Article 3(4) and (5) of the AML Agreement
AML/CFT supervisory authorities and financial intelligence units of Member States	Article 117(5) of the CRD and EBA Guidelines on cooperation and information exchange between prudential supervisors, AML/CFT supervisors and financial intelligence units under Directive 2013/36/EU (EBA/GL/2021/15) ⁽¹¹⁾

National market authorities in the Union and EEA	Article 56 of the CRD
National insurance supervisors in the Union and EEA	Article 56 of the CRD
Deposit guarantee schemes, contractual or institutional protection schemes, competition authorities	Article 56 of the CRD, or national law requiring an opinion from the prudential supervisor
National resolution authorities in the Union and EEA	Article 56 of the CRD
National macroprudential supervisors for tasks outside the scope of Article 5 of the SSMR	Article 56 of the CRD
Statutory auditors of significant institutions	Article 56(f) of the CRD EBA Guidelines on communication between competent authorities supervising credit institutions and the statutory auditor(s) and the audit firm(s) carrying out the statutory audit of credit institutions (EBA/GL/2016/05) ⁽¹²⁾
National authorities responsible for the supervision of financial markets if designated under Article 24(1) in connection with Article 24(4)(h) of Directive 2004/109/EC of the European Parliament and of the Council ⁽¹³⁾ (accounting enforcers)	Article 56 of the CRD
National authorities responsible for oversight of persons charged with carrying out statutory audits of the accounts of institutions, insurance undertakings and financial institutions (audit enforcers)	Article 57 of the CRD
National authorities responsible for oversight of the bodies involved in the liquidation and bankruptcy of institutions and in other similar procedures	Article 57 of the CRD
National authorities responsible for oversight of contractual or institutional protection schemes as referred to in Article 113(7) of the CRR	Article 57 of the CRD
National authorities or bodies legally responsible for the detection and investigation of breaches of company law	Article 57 of the CRD
National authorities responsible for overseeing payment systems	Article 58 of the CRD
International bodies (the International Monetary Fund, the World Bank, the Bank of International Settlements, the Financial Stability Board)	Article 58a of the CRD, with the exception of data sharing (e. g. Implementing Technical Standards modules) for stress tests

Prudential supervisory authorities in third countries	Article 55 of the CRD Exchange of information in accordance with arrangements (memoranda of understanding (MoUs), written coordination and cooperation arrangements (WCCAs), institution-specific cross-border cooperation agreements (CoAgs) developed by crisis management groups (CMGs), resolution written arrangements (WAs) etc.) or ad hoc agreements
National market, insurance, or similar authorities in third countries	Article 55 of the CRD and applicable arrangements (MoUs, WCCAs, CoAgs, resolution WAs etc.) or ad hoc agreements
AML/CFT supervisory authorities and financial intelligence units in third countries	Article 55 of the CRD and, where relevant, MoUs or other cooperation arrangements
Resolution authorities in third countries	Article 55 of the CRD, Articles 97 and 98 of the BRRD, in connection with applicable arrangements

(¹) Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions (OJ L 287, 29.10.2013, p. 63).

(²) Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338) in conjunction with EU implementing regulations.

(³) Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

(⁴) Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).

(⁵) Regulation (EU) No 1092/2010 of the European Parliament and of the Council of 24 November 2010 on European Union macro-prudential oversight of the financial system and establishing a European Systemic Risk Board (OJ L 331, 15.12.2010, p. 1).

(⁶) Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1).

(⁷) Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (OJ L 173, 12.6.2014, p. 349).

(⁸) Directive 2002/87/EC of the European Parliament and of the Council of 16 December 2002 on the supplementary supervision of credit institutions, insurance undertakings and investment firms in a financial conglomerate and amending Council Directives 73/239/EEC, 79/267/EEC, 92/49/EEC, 92/96/EEC, 93/6/EEC and 93/22/EEC, and Directives 98/78/EC and 2000/12/EC of the European Parliament and of the Council (OJ L 35, 11.2.2003, p. 1).

(⁹) Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190).

(¹⁰) Directive (EU) 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, amending Regulation (EU) No 648/2012 of the European Parliament and of the Council, and repealing Directive 2005/60/EC of the European Parliament and of the Council and Commission Directive 2006/70/EC (OJ L 141, 5.6.2015, p. 73).

(¹¹) Available on the EBA's website at www.eba.europa.eu.

(¹²) Available on the EBA's website.

(¹³) Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC (OJ L 390, 31.12.2004, p. 38).

CORRIGENDA

Corrigendum to Commission Delegated Regulation (EU) 2022/1 of 20 October 2021 amending Regulation (EU) 2021/821 of the European Parliament and of the Council as regards the list of dual-use items*(Official Journal of the European Union L 3 of 6 January 2022)*

On page 142, in the Annex, point 3B001.f is replaced as follows:

f. Lithography equipment as follows:

1. Align and expose step and repeat (direct step on wafer) or step and scan (scanner) equipment for wafer processing using photo-optical or X-ray methods and having any of the following:
 - a. A light source wavelength shorter than 193 nm; or
 - b. Capable of producing a pattern with a 'Minimum Resolvable Feature size' (MRF) of 45 nm or less;

Technical Note:

The 'Minimum Resolvable Feature size' (MRF) is calculated by the following formula:

$$MRF = \frac{(\text{an exposure light source wavelength in nm}) \times (K \text{ factor})}{\text{numerical aperture}}$$

where the K factor = 0,35

2. Imprint lithography equipment capable of producing features of 45 nm or less;

Note: 3B001.f.2. includes:

- Micro contact printing tools
- Hot embossing tools
- Nano-imprint lithography tools
- Step and flash imprint lithography (S-FIL) tools

3. Equipment specially designed for mask making having all of the following:
 - a. A deflected focussed electron beam, ion beam or "laser" beam; and
 - b. Having any of the following:
 1. A full-width half-maximum (FWHM) spot size smaller than 65 nm and an image placement less than 17 nm (mean + 3 sigma); or
 2. Not used;
 3. A second-layer overlay error of less than 23 nm (mean + 3 sigma) on the mask;
4. Equipment designed for device processing using direct writing methods, having all of the following:
 - a. A deflected focused electron beam; and
 - b. Having any of the following:
 1. A minimum beam size equal to or smaller than 15 nm; or
 2. An overlay error less than 27 nm (mean + 3 sigma);

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