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⁽¹⁾ Text with EEA relevance.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2023/1321 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 14 June 2023****amending Regulation (EU) 2020/2170 as regards the application of Union tariff rate quotas and other import quotas to certain steel products transferred to Northern Ireland**

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 207(2) thereof,

Having regard to the proposal from the European Commission,

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

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

Whereas:

- (1) Article 1 of Regulation (EU) 2020/2170 of the European Parliament and of the Council ⁽²⁾ provides that goods imported from outside the Union are to be eligible for treatment pursuant to Union import tariff rate quotas or other import quotas only if those goods are released for free circulation in the territories listed therein. That provision addresses the risks to the proper functioning of the Union's internal market and the integrity of the Common Commercial Policy that would arise from the possible circumvention of the Union tariff rate quotas or other import quotas. The territories set out in Article 1 of that Regulation do not include Northern Ireland.
- (2) The Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part ⁽³⁾ (the 'Trade and Cooperation Agreement'), provides for the opening by the Union of quotas with regard to imports into the Union of certain products originating in the United Kingdom. In addition, the Trade and Cooperation Agreement confers upon the Union the right to introduce tariff rate quotas or other import quotas with regard to imports of goods originating in the United Kingdom under certain circumstances, including as part of the application of multilateral safeguard measures in accordance with the WTO Agreement. It is necessary, therefore, to clarify whether goods originating in the United Kingdom and released for free circulation in Northern Ireland are eligible for treatment under those tariff rate quotas or other import quotas.

⁽¹⁾ Position of the European Parliament of 9 May 2023 (not yet published in the Official Journal) and decision of the Council of 30 May 2023.

⁽²⁾ Regulation (EU) 2020/2170 of the European Parliament and of the Council of 16 December 2020 on the application of Union tariff rate quotas and other import quotas (OJ L 432, 21.12.2020, p. 1).

⁽³⁾ OJ L 149, 30.4.2021, p. 10.

- (3) The United Kingdom is bound by the arrangements laid down in the Protocol on Ireland/Northern Ireland (the 'Protocol') to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community ⁽⁴⁾ (the 'Withdrawal Agreement'). Therefore, the legal relationship between the Union and the United Kingdom in respect of goods originating in the United Kingdom and released for free circulation in Northern Ireland is fundamentally different from that between the Union and any other third country in respect of goods originating in such a third country and released for free circulation in Northern Ireland.
- (4) The United Kingdom has provided evidence showing that certain steel products originating in the United Kingdom that are currently subject to safeguard measures under Commission Implementing Regulation (EU) 2019/159 ⁽⁵⁾ (the 'products concerned') have been transferred in significant quantities to Northern Ireland from other parts of the United Kingdom. In order to ensure the economic viability of those transfers and in view of the specific circumstances in Northern Ireland, it is appropriate to allow for the products concerned to benefit from the relevant Union tariff rate quotas when they are released for free circulation in Northern Ireland.
- (5) In order to limit the risk of circumvention of the Union tariff rate quotas applicable to the products concerned by imports of the same products originating in other countries, when such products are released for free circulation in Northern Ireland, the products concerned should be consigned directly from other parts of the United Kingdom.
- (6) Moreover, the United Kingdom has undertaken to take the necessary measures, in accordance with the Protocol, to ensure that the transfers of the products concerned using Union tariff rate quotas are counted against those quotas, as soon as such products are released for free circulation in Northern Ireland, in the same way as if those goods were imported into the Union.
- (7) Since the need for importation into Northern Ireland of the products concerned might vary over time, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in order to adjust the list of the products concerned should be delegated to the Commission. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ⁽⁶⁾. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (8) Regulation (EU) 2020/2170 should therefore be amended accordingly.
- (9) By virtue of Article 5(3) and (4) of the Protocol, in conjunction with Article 13(3) thereof, this Regulation would also apply to and in the United Kingdom in respect of Northern Ireland.
- (10) In order to avoid any potential disruption in the transfers of the products concerned from other parts of the United Kingdom to Northern Ireland, this Regulation should enter into force as soon as possible,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2020/2170

Regulation (EU) 2020/2170 is amended as follows:

⁽⁴⁾ OJ L 29, 31.1.2020, p. 7.

⁽⁵⁾ Commission Implementing Regulation (EU) 2019/159 of 31 January 2019 imposing definitive safeguard measures against imports of certain steel products (OJ L 31, 1.2.2019, p. 27).

⁽⁶⁾ OJ L 123, 12.5.2016, p.1.

- (1) in Article 1, the following second paragraph is added:

'Goods listed in the Annex originating in the United Kingdom and being subject to safeguard measures under Commission Implementing Regulation (EU) 2019/159 (*) that are brought into Northern Ireland by direct transport from other parts of the United Kingdom shall also be eligible for treatment pursuant to Union import tariff rate quotas if those goods are released for free circulation in the territory of Northern Ireland.

(*) Commission Implementing Regulation (EU) 2019/159 of 31 January 2019 imposing definitive safeguard measures against imports of certain steel products (OJ L 31, 1.2.2019, p. 27).;

- (2) the following Articles are inserted:

Article 1a

The Commission is empowered to adopt delegated acts, in accordance with Article 1b, amending this Regulation in order to add to the list set out in the Annex certain categories of goods originating in the United Kingdom and being subject to safeguard measures under Implementing Regulation (EU) 2019/159, that are brought into Northern Ireland by direct transport from other parts of the United Kingdom provided that the United Kingdom has demonstrated to the satisfaction of the Union a need for those goods to be released for free circulation in Northern Ireland.

Article 1b

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 1a shall be conferred on the Commission for a period of five years from 1 July 2023. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
3. The delegation of power referred to in Article 1a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making (*).
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 1a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

(*) OJ L 123, 12.5.2016, p. 1.;

- (3) the text set out in the Annex to this Regulation is added as Annex.

Article 2

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 Strasbourg, 14 June 2023.

For the European Parliament
The President
R. METSOLA

For the Council
The President
J. ROSWALL

ANNEX

‘ANNEX

Tariff Rate Quota (TRQ) Description	Combined Nomenclature (CN) Codes ⁽¹⁾
Steel category 7	7208 51 20, 7208 51 91, 7208 51 98, 7208 52 91, 7208 90 20, 7208 90 80, 7210 90 30, 7225 40 12, 7225 40 40, 7225 40 60, 7225 99 00
Steel category 17	7216 31 10, 7216 31 90, 7216 32 11, 7216 32 19, 7216 32 91, 7216 32 99, 7216 33 10, 7216 33 90

⁽¹⁾ As defined in Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).’

REGULATION (EU) 2023/1322 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 27 June 2023
on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006

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 168(5) thereof,

Having regard to the proposal from the European Commission,

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

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

After consulting the Committee of the Regions,

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

Whereas:

- (1) The European Monitoring Centre for Drugs and Drug Addiction (the 'EMCDDA') was established by Council Regulation (EEC) No 302/93 ⁽³⁾. That Regulation was recast in 2006 by Regulation (EC) No 1920/2006 of the European Parliament and of the Council ⁽⁴⁾.
- (2) The EMCDDA was established to provide the Union, Member States and participating third countries with factual, objective, reliable and comparable information concerning drugs, drug addiction and their consequences at European level in order to help provide them with an overall view of that information for the purpose of informing policymaking and guiding initiatives to tackle drugs and, thus, giving such initiatives added value when, in their respective areas of competence, they take measures or decide on action to address the drugs phenomenon. The establishment and functioning of the EMCDDA has manifestly improved the availability of information on drugs and drug addiction, and their consequences, across the Union and internationally.
- (3) While its general objective is still valid and should be retained, Regulation (EC) No 1920/2006 no longer provides an adequate framework for addressing current and future drug challenges. Therefore, the mandate of the EMCDDA should be revised in order, amongst other things, to replace and strengthen it. The EMCDDA should be renamed the European Union Drugs Agency (EUDA) (the 'Agency'). Since substantial amendments to Regulation (EC) No 1920/2006 are needed to accommodate the common approach on Union decentralised agencies adopted on 19 July 2012 by the European Parliament, the Council and the Commission and to take account of the developments of the drugs phenomenon, in the interest of clarity and efficiency, that Regulation should be repealed and replaced by this Regulation.
- (4) The main focus of Regulation (EC) No 1920/2006 was on health-related issues. While it is essential to maintain that focus, as health- and supply-related issues regarding the drugs phenomenon are intrinsically linked, it is also necessary to address drug supply in order to reduce the availability of drugs in the Union and curb drug demand and, thus, to contribute to addressing related safety and security concerns. In order to provide factual, objective, reliable, comparable and Union-wide significant data and analysis, the Agency should address the drugs phenomenon, taking an evidence-based, integrated, balanced and multidisciplinary approach to drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences. The Agency's approach should incorporate human rights, gender and gender equality, age, health, health equity and social perspectives.

⁽¹⁾ OJ C 323, 26.8.2022, p. 88.

⁽²⁾ Position of the European Parliament of 13 June 2023 (not yet published in the Official Journal) and decision of the Council of 27 June 2023.

⁽³⁾ Council Regulation (EEC) No 302/93 of 8 February 1993 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction (OJ L 36, 12.2.1993, p. 1).

⁽⁴⁾ Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (OJ L 376, 27.12.2006, p. 1).

- (5) The work of the Agency should be carried out with due regard to the respective powers of the Union and its Member States in the area of drugs. It should cover the various facets of the drugs phenomenon and the solutions applied. In particular, the Agency should consider all aspects related to the protection and improvement of health, including physical and mental aspects, and the potential impact on public health. The Agency should also look into social aspects, including considerations linked to stigmatisation, marginalisation and the reintegration of people who use drugs. In doing so, the Agency should be guided by Union drug-related strategic documents.
- (6) In pursuing its activities, the Agency should cooperate with other relevant Union bodies, offices and agencies within their respective mandates and should take account of their activities in order to avoid duplication. In particular, with due regard for their respective mandates, the Agency should cooperate with the European Union Agency for Law Enforcement Cooperation (Europol), established by Regulation (EU) 2016/794 of the European Parliament and of the Council ⁽⁵⁾, in order to ensure the collection of data, and the monitoring of trends, on drug supply, including illicit production and trafficking and other related crimes, on the use of new technologies and on new psychoactive substances. The Agency should also cooperate at international level with relevant authorities and bodies in third countries, in particular in candidate countries, and in support of Union and Member State action at the level of the United Nations. It is necessary that such cooperation comply with human rights norms.
- (7) In order to attain maximum efficiency in addressing the drugs phenomenon, the Agency should have exchanges with relevant stakeholders and, in particular, with the scientific community, including academia, and civil society organisations, including organisations of people who use drugs and of communities affected by the consumption and sale of drugs or drug-related crime. Given the particular relevance of the experience of civil society organisations in the Agency's area of competence, the Agency should maintain cooperation on its activities with civil society organisations, such as those active in the relevant Commission expert groups on drugs composed of civil society organisations. The Agency should dedicate the necessary means to consult, exchange information and pool knowledge with those organisations, including in the area of new psychoactive substances. Where appropriate, the Agency should organise dedicated consultations on the topics within its mandate.
- (8) With a view to disseminating reliable information on drugs and the drug situation, the Agency should engage in communication activities on topics within its mandate. However, communication to the wider public in the area of drugs can sometimes have unintended negative consequences. As part of its communication activities and where appropriate, the Agency should, therefore, consider disseminating its reports, including initial reports and risk assessment reports on new psychoactive substances, to the scientific community and civil society organisations with a view to minimising possible drug-related harm. Where the Agency is prevented from disseminating its reports, in particular due to the presence of classified or sensitive non-classified information, it could consider publishing summaries of those reports with a view to minimising possible drug-related harm.
- (9) In its work, the Agency should pay due regard to poly-substance use because such use is becoming increasingly common.
- (10) The Agency should develop its activities around three main areas of competence, namely monitoring, leading to better informed policies; preparedness, leading to better informed actions; and competence development, leading to stronger Union and Member State responses to the drugs phenomenon.
- (11) The collection, analysis and dissemination of data should continue to be the main task of the Agency. When collecting, analysing or disseminating data, the Agency should comply with the legal framework on the processing of personal data and should not disseminate or transmit any data which would make it possible to identify individuals or small groups of individuals. Standard data are collected through national focal points, which should remain the primary data providers for the Agency. The Agency could also use additional sources and organise meetings of experts, including virtual meetings. In addition, closer to real-time data sources are increasingly

⁽⁵⁾ Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

available through innovative data collection methods. Therefore, the Agency should have access to relevant available data to obtain a holistic picture of the drugs phenomenon in the Union and the external factors influencing it. With a view to ensuring that each national focal point remain informed of the situation in its Member State, it should be informed on a regular basis of data concerning its Member State that are collected from additional sources of information and of the activities of the network of forensic and toxicological laboratories set up by this Regulation.

- (12) The national focal points are key players in the Union's drug monitoring and reporting system. They collect information and produce comparable and scientifically sound data on the national drug situation, which feed into monitoring the situation across the Union. The national focal points are also key in the process of improving data collection methodologies and tools and of developing relevant guidelines for their implementation. In addition, the national focal points participate in an early warning system and report on new trends in the use of existing psychoactive substances. It is therefore essential that the Agency and the national focal points have a mutually reinforcing relationship. The data requirements of the Agency should be mirrored in the national focal points. The national focal points should be empowered within the Member States to receive all relevant data from the different national authorities. While avoiding any harmonisation measures and leaving the decisions as to the governance, structure or basic tasks of the national focal points in respect of other national competent authorities to the Member States, in line with the Treaties, the mandate of the Agency should enable a streamlining of data collection in the Member States as far as possible so as to avoid double reporting and duplication of efforts.
- (13) It is necessary to establish the foundations of a relationship of mutual trust and continuous dialogue between the Agency and the national focal points, based on a clear and effective functioning mechanism and a set of rules. The Agency should therefore be empowered to financially support the national focal points and contribute to their effective functioning, including by providing an assessment of each national focal point relating directly to its contribution to coordinated Union action in the field of drugs.
- (14) With the aim of supporting effective Union action in the field of drugs and contributing to the work of the Agency, the national focal points should, *inter alia*, assume a coordinating role in activities related to ensuring coherent drug-related data collection and monitoring, communication with the Agency and promotion of evidence-based decision making, ensuring a cross-sectoral and comprehensive national view of the drug situation, including any relevant information on new trends and challenges, and contributing to the establishment of relevant indicators. In addition, and in line with national competence, the national focal points have a key role in promoting and supporting evidence-based decision-making, supporting systems of collaboration, assessing the information needs of relevant stakeholders and compiling an up-to-date inventory of national drug information sources.
- (15) In order to facilitate and structure data collection and information exchange, both qualitative and quantitative, and to support the establishment of an integrated and interoperable monitoring system enabling real-time monitoring, the Agency should develop and apply the appropriate digital solutions necessary for the performance of its tasks.
- (16) In order to enable the Agency to make better use of the information available to it, for example to take more proactive measures such as threat assessments, strategic intelligence reports and alerts, and to enhance the Union's preparedness for future developments, the monitoring and analytical capacity of the Agency should be strengthened as compared to that of the EMCDDA.
- (17) In order to improve the Union's preparedness, it is necessary to have a holistic picture of potential future developments of the drugs phenomenon. To prepare itself and to better equip policymakers for such future developments, the Agency should conduct regular foresight exercises taking into account megatrends, that is to say long-term driving forces that are currently observable and will most likely have a significant influence on the future, with the aim of identifying new challenges and opportunities for responding to drug problems.
- (18) The drugs phenomenon is becoming increasingly technology-enabled, as was shown during the COVID-19 pandemic where a greater adoption of new technologies to facilitate drug distribution was observed. It is estimated that about two-thirds of the offers on darknet markets are drug-related. Drug trading uses different platforms, including social media networks and mobile applications. That development is mirrored in responses to the drugs phenomenon, with an increased use of internet communications and online interventions, including mobile

applications and e-health interventions. The Agency, together with other relevant Union bodies, offices and agencies and while avoiding duplication of efforts, should monitor such developments as part of its holistic approach to the drugs phenomenon.

- (19) New psychoactive substances which pose public health and social risks across the Union should be adequately addressed. It is therefore necessary to monitor new psychoactive substances and, in order to enable a quick response, to maintain the early warning system set up under Regulation (EC) No 1920/2006. The provisions of that Regulation relating to the exchange of information on, and the early warning system for, new psychoactive substances, including initial reports and risk assessments on new psychoactive substances, were amended recently and should remain unchanged in this Regulation.
- (20) Based on strengthened monitoring by the Agency and the experience gained in the risk assessment of new psychoactive substances, the Agency should develop general health and security threat assessment capabilities. Greater capacity to proactively and rapidly identify new threats and inform the development of counter-measures is urgently needed as the current dynamic nature of the drugs phenomenon means that related challenges can rapidly spread across borders.
- (21) As dangerous substances and certain consumption patterns might lead to harm for health, the Agency should be able to issue alerts complementing and without prejudice to the relevant national alert systems. To support that function, the Agency should develop a European drug alert system which is accessible by national authorities. That system should facilitate the rapid exchange of information that might require rapid actions to safeguard health, social aspects, safety and security. The Agency should, under the conditions laid down in this Regulation, be able to develop an alert system to make information on identified risks available to people who use or potentially use specific drugs.
- (22) Drug precursors are substances necessary for the production of drugs such as amphetamines, cocaine and heroin. As illegal drug production in the Union is increasing, the prevention of diversion and trafficking of drug precursors from legal channels to illegal drug production should be strengthened. To support that effort, the Agency should have a role in monitoring the diversion and trafficking of drug precursors and in assisting the Commission in the implementation of Union law on drug precursors.
- (23) As there is a growing need for forensic and toxicological data and specialist expertise, matched by a need for better coordination between laboratories in the Member States, a network of forensic and toxicological laboratories knowledgeable in the area of drugs and drug-related harm should be set up. That network should enable the Agency to have access to relevant information, increase the Agency's capacities in that area and support knowledge exchange between the relevant laboratories in the Member States, without the Agency incurring the high costs of creating and running its own laboratory.
- (24) The network of forensic and toxicological laboratories should be representative of the Member States in that each of them should be allowed to appoint up to three laboratories to the network, covering toxicological and forensic expertise. In order to ensure the broadest coverage possible, experts from other laboratories relevant for the work of the Agency, including from the Customs Laboratories European Network, should also be given the possibility to participate in the network. Such cooperation would enable all laboratories involved to learn from each other across different domains, support the sharing of information between relevant laboratories and decrease the costs for individual laboratories.
- (25) To further knowledge in the area covered by the mandate of the Agency and support Member States, the Agency should identify and finance relevant projects, such as the development of reference standards on new drugs, the elaboration of toxicological or pharmacological studies, the implementation of innovative approaches to research, and drug profiling. The projects that the Agency finances should be included in the Agency's consolidated annual activity report and be made public.

- (26) The Agency will be in a position to access data and gain necessary scientific experience to develop and promote evidence-based interventions and best practices, to raise awareness about the adverse effects of drugs, prevention, risk and harm reduction measures, treatment, care, rehabilitation and recovery, and, where relevant, to take a gender-sensitive approach and to take into account the age dimension. The Agency should promote the implementation and updating of existing quality standards for drug prevention (European Drug Prevention Quality Standards) and of a curriculum providing decision- and policy-makers with the knowledge about the most effective evidence-based prevention interventions and approaches (European Union Prevention Curriculum), including how to reach high-risk populations.
- (27) Given its Union-wide perspective, the Agency should be able to assess national measures and training, for example on prevention, including gender-sensitive and age-appropriate prevention, treatment, harm reduction, recovery and other related measures, in order to determine whether they reflect the latest scientific state of play and whether they have proven effective. A positive assessment of national measures could serve as a quality label.
- (28) Considering that the Agency will be in a unique position at Union level that allows it to compare data and best practices, the Agency should be able to offer support, including, where so required by Member States, assisting with the evaluation and drafting of national drug strategies in a more structured way across Member States. In addition, the Agency's role in providing training and support to Member States in the implementation of quality standards and good practices should be strengthened in light of the expertise it will develop in those areas.
- (29) International cooperation should be part of the core tasks of the Agency with responsibilities established in clear terms in order to allow it to fully engage in such activities and respond to requests from international organisations and other bodies and from third countries. The Agency should be able to offer adequate scientific and evidence-based tools for the development and implementation of the external dimension of the Union's drugs policy and for the important role of the Union at multilateral level, in accordance with the Treaties, as a means to ensure the efficient and coherent implementation of the Union's drugs policy internally and at international level. Work in that area should be based on an international cooperation framework developed by the Agency. The international cooperation framework should be in accordance with the Treaties and the Union priorities on international cooperation and guided by the relevant United Nations instruments. The Agency should revise the international cooperation framework on a regular basis in order to ensure that it adequately reflects international developments and priorities.
- (30) In order to help Union funding for security and health research to develop its full potential and address what is required by a drugs policy, the Agency should assist the Commission in identifying key research themes and in drawing up and implementing the Union framework programmes for research and innovation that are relevant to the Agency's objectives. Where the Agency assists the Commission in identifying key research themes or in drawing up and implementing a Union framework programme, it should not receive funding from that programme and should take all necessary measures in order to avoid conflicts of interest. The Agency should participate in Union-wide initiatives addressing research and innovation to ensure that technologies necessary for its activities are developed and available for use. Planned research and innovation activities should be set out in the single programming document containing the Agency's multiannual and annual work programme.
- (31) The Commission and the Member States should be represented on the Management Board of the Agency to effectively supervise its work. The members and the alternate members of the Management Board should be appointed taking into account their relevant managerial, administrative and budgetary skills. Alternate members should act as members in the absence of the relevant members. Alternate members may also attend meetings in the presence of the relevant members without their presence entailing additional costs for the Agency and without taking part in the votes.
- (32) The Management Board should be given the necessary powers, in particular to adopt the budget, the appropriate financial rules and planning documents, and the consolidated annual activity report. In order to ensure the independent functioning and integrity of the Agency, the Management Board should also adopt rules for the prevention and management of conflicts of interest in respect of its members, the members of the Executive Board,

the members of the Scientific Committee, the members of a European Information Network on Drugs and Drug Addiction (the 'Reitox network'), seconded national experts and other staff not employed by the Agency. In so doing, it is important that the Agency give due consideration to the recommendations and guidelines on that matter, in particular those of the European Ombudsman and the Commission Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies of 10 December 2013. The Management Board should exercise the appointing authority powers vis-à-vis the staff of the Agency, including the Executive Director.

- (33) It is important that all parties represented on the Management Board endeavour to multiply perspectives and experiences represented in and contributing to its work, while ensuring the continuity of its work. All parties should aim to achieve gender-balanced representation on the Management Board.
- (34) The Management Board should be assisted by an Executive Board to prepare its decisions. The Agency should be headed by an Executive Director. A Scientific Committee should assist the Management Board and the Executive Director with regard to relevant scientific matters.
- (35) The Management Board should appoint the Executive Director following an open and transparent selection procedure organised and managed by the Commission. In line with the practice followed in the appointment of executive directors to the EMCDDA, the Commission should consider including a representative of the Management Board as an observer in the appointment procedure. The assessment by the Commission at the end of the initial five-year term of office of the Executive Director should include prior input from the Management Board on the performance of the Executive Director.
- (36) It is important that the Agency be adequately resourced to carry out its tasks, objectives and responsibilities under this Regulation and be granted an autonomous budget reflecting its mission. It should be mainly financed by a contribution from the general budget of the Union. The Union budgetary procedure should be applicable as far as the Union contribution and any other subsidies chargeable to the general budget of the Union are concerned. The Court of Auditors should audit the Agency's accounts.
- (37) In order to further support Member States and other stakeholders in understanding and addressing the drugs phenomenon, the possibility for the Agency to deliver additional services, beyond its core tasks laid down in this Regulation, against the payment of fees should be introduced. The method by which fees levied by the Agency are calculated should be transparent. The fees levied by the Agency should cover the full cost of providing the activities related to the services delivered, including staff and operational costs. Where fees have been levied in a financial year, the Agency's provisional accounts should be accompanied by a report on those fees. Such reports would also be subject to audit by the Court of Auditors. Fees should be set at a level that avoids a deficit or a significant accumulation of surplus and should be revised where that is not the case.
- (38) The Executive Director should present the annual report of the Agency to the European Parliament and the Council. Furthermore, the European Parliament and the Council should be able to invite the Executive Director to report on the performance of her or his duties.
- (39) Regulation (EC) No 1049/2001 of the European Parliament and of the Council ⁽⁶⁾ should apply to the Agency. The Agency should be as transparent as possible about its activities, without jeopardising the attainment of the objective of its operations.
- (40) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council ⁽⁷⁾ and the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-Fraud Office (OLAF) ⁽⁸⁾, to which the EMCDDA acceded, should apply to the Agency.

⁽⁶⁾ 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).

⁽⁷⁾ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

⁽⁸⁾ OJ L 136, 31.5.1999, p. 15.

- (41) The Agency processes data that require particular protection, in particular European Union Classified Information (EUCI) and sensitive non-classified information. The Agency should draw up rules on the confidentiality and processing of such information. The rules on the protection of EUCI should be consistent with Commission Decisions (EU, Euratom) 2015/443 ⁽⁹⁾ and (EU, Euratom) 2015/444 ⁽¹⁰⁾. In accordance with those legal acts, the Agency should refrain from publishing sensitive data. It should also refrain from disclosing the confidential business information of third parties.
- (42) In order to control and ensure the performance of the Agency and to ensure that its mandate allows it to carry out the necessary activities required by developments in drug markets and policy, an external evaluation of the Agency's work should be conducted on a regular basis and its mandate adapted accordingly, if needed.
- (43) The Agency should cooperate closely, in full compliance with fundamental rights, with relevant international organisations and other governmental and non-governmental bodies, including relevant technical bodies, from inside and outside the Union in the implementation of its work programme, in accordance with the relevant Treaty provisions and Member State competences, in particular to avoid duplication of work and to ensure access to all data and tools needed for carrying out its mandate.
- (44) The Agency should replace and succeed the EMCDDA. It should therefore be the legal successor of all EMCDDA's contracts, including employment contracts, liabilities and properties. International agreements concluded by the EMCDDA before 2 July 2024 should remain in force.
- (45) Since the objective of this Regulation, namely the establishment of an agency to address the drugs phenomenon, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and 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 (TEU). In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

Objectives and tasks of the Agency

Article 1

Establishment of the Agency

1. This Regulation establishes the European Union Drugs Agency (EUDA) (the 'Agency').
2. The Agency replaces and succeeds the European Monitoring Centre for Drugs and Drug Addiction (the 'EMCDDA') established by Regulation (EC) No 1920/2006.

Article 2

Legal status and seat

1. The Agency shall be a body of the Union with legal personality.
2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It shall, in particular, be able to acquire or dispose of movable and immovable property and be a party to legal proceedings.

⁽⁹⁾ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

⁽¹⁰⁾ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

3. The seat of the Agency shall be Lisbon, Portugal.

Article 3

Definitions

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

- (1) 'drug' means any of the following:
 - (a) a substance covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances;
 - (b) any of the substances listed in the Annex to Council Framework Decision 2004/757/JHA ⁽¹¹⁾;
- (2) 'new psychoactive substance' means new psychoactive substance as defined in Article 1, point 4, of Framework Decision 2004/757/JHA;
- (3) 'poly-substance use' means the use of one or more psychoactive substances or types of psychoactive substance, whether illicit or licit, in particular medicinal products, alcohol and tobacco, at the same time as the use of drugs or sequentially within a short period of time of the use of drugs;
- (4) 'drug precursor' means a substance that is controlled and monitored in accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council ⁽¹²⁾ and with Council Regulation (EC) No 111/2005 ⁽¹³⁾;
- (5) 'participating country' means a Member State or a third country which has concluded an agreement with the Union in accordance with Article 54 of this Regulation;
- (6) 'international organisation' means an organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries;
- (7) 'United Nations Drug Conventions' means the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the 1971 United Nations Convention on Psychotropic Substances and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances
- (8) 'United Nations system' means the control mechanism system established by the United Nations Drug Conventions.

Article 4

General task of the Agency

1. The Agency shall:
 - (a) provide the Union and the Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration, recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences; and
 - (b) recommend appropriate and concrete evidence-based actions on how to address, in an efficient and timely manner, the challenges relating to drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration, recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences.

⁽¹¹⁾ Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).

⁽¹²⁾ Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

⁽¹³⁾ Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Union and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).

2. In carrying out its tasks, the Agency shall ensure full compliance with fundamental rights and data protection rules and shall take an evidence-based, integrated, balanced and multidisciplinary approach to the drugs phenomenon. That approach shall incorporate human rights, gender and gender equality, age, health, health equity and social perspectives.

Article 5

Specific tasks

1. In order to carry out the general task set out in Article 4(1), the Agency shall have the following specific tasks:

(a) monitoring tasks that include:

- (i) the collection and analysis of information and data pursuant to Article 6(1);
- (ii) the dissemination of information, data and results of analyses pursuant to Article 6(5); and
- (iii) the monitoring of the drugs phenomenon, encompassing the health, human rights, social, safety and security aspects thereof pursuant to Article 7;

(b) preparedness tasks that include:

- (i) the exchange of information on, and the early warning system for, new psychoactive substances, including the preparation of initial reports and risk assessments pursuant to Articles 8 to 11;
- (ii) health and security threat assessment and preparedness pursuant to Article 12;
- (iii) the establishment and operation of a European drug alert system pursuant to Article 13;
- (iv) the monitoring of developments related to the diversion and trafficking of drug precursors and contributing to the implementation of Union law on drug precursors pursuant to Article 14;
- (v) the establishment and operation of a network of forensic and toxicological laboratories pursuant to Article 15;

(c) competence development tasks that include:

- (i) the development and promotion of evidence-based interventions, best practices and awareness-raising activities pursuant to Article 16;
- (ii) the assessment of national measures pursuant to Article 17;
- (iii) support to Member States pursuant to Article 18;
- (iv) training pursuant to Article 19;
- (v) international cooperation and technical assistance pursuant to Article 20;
- (vi) research and innovation activities pursuant to Article 21.

2. The Agency shall establish and coordinate, in consultation and cooperation with the competent authorities and organisations in the participating countries, the European Information Network on Drugs and Drug Addiction referred to in Article 32 (the 'Reitox network').

3. The Agency shall act in a transparent, objective, impartial and scientifically rigorous manner when carrying out the specific tasks set out in paragraph 1.

4. The Agency shall support, and improve coordination between, national and Union action in its areas of activity. The Agency shall facilitate the exchange of information between decision-makers, researchers, specialists and those involved in drug-related issues in governmental and non-governmental organisations.

5. The Agency shall support the Commission, Member States and other relevant stakeholders identified in the applicable Union drugs-related strategic documents in the implementation of those strategic documents, where appropriate.

6. In carrying out the specific tasks set out in paragraph 1, the Agency may:

- (a) organise meetings of experts;
- (b) set up ad hoc working groups; and
- (c) finance projects, as necessary.

Where the Agency organises meetings, sets up working groups or finances projects under the first subparagraph, it shall keep the Reitox network informed.

7. In order to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon, the Agency shall, in carrying out the specific tasks set out in paragraph 1, cooperate actively with relevant stakeholders, including:

- (a) other relevant Union bodies, offices and agencies, within the limits of their mandates, in particular Europol, the European Union Agency for Criminal Justice Cooperation (Eurojust), established by Regulation (EU) 2018/1727 of the European Parliament and of the Council ⁽¹⁴⁾, the European Union Agency for Fundamental Rights, established by Council Regulation (EC) No 168/2007 ⁽¹⁵⁾, the European Union Agency for Law Enforcement Training (CEPOL), established by Regulation (EU) 2015/2219 of the European Parliament and of the Council ⁽¹⁶⁾, the European Medicines Agency, established by Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽¹⁷⁾, the European Centre for Disease Prevention and Control, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council ⁽¹⁸⁾, and the European Foundation for the Improvement of Living and Working Conditions (Eurofound), established by Regulation (EU) 2019/127 of the European Parliament and of the Council ⁽¹⁹⁾;
- (b) other international bodies, offices and agencies, in particular the United Nations Office on Drugs and Crime (UNODC), the United Nations Economic and Social Council and the International Narcotics Control Board (INCB); and
- (c) the scientific community and civil society organisations.

8. The Agency shall engage in communication activities on its own initiative within its mandate. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the specific tasks set out in paragraph 1. The Agency shall carry out communication activities in accordance with relevant communication strategies and dissemination plans adopted by the Management Board. The Agency may involve relevant stakeholders, including the scientific community and civil society organisations, in the development of those strategies and plans.

⁽¹⁴⁾ Regulation (EU) 2018/1727 of the European Parliament and of the Council of 14 November 2018 on the European Union Agency for Criminal Justice Cooperation (Eurojust), and replacing and repealing Council Decision 2002/187/JHA (OJ L 295, 21.11.2018, p. 138).

⁽¹⁵⁾ Council Regulation (EC) No 168/2007 of 15 February 2007 establishing a European Union Agency for Fundamental Rights (OJ L 53, 22.2.2007, p. 1).

⁽¹⁶⁾ Regulation (EU) 2015/2219 of the European Parliament and of the Council of 25 November 2015 on the European Union Agency for Law Enforcement Training (CEPOL) and replacing and repealing Council Decision 2005/681/JHA (OJ L 319, 4.12.2015, p. 1).

⁽¹⁷⁾ 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 use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

⁽¹⁸⁾ 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).

⁽¹⁹⁾ Regulation (EU) 2019/127 of the European Parliament and of the Council of 16 January 2019 establishing the European Foundation for the improvement of living and working conditions (Eurofound), and repealing Council Regulation (EEC) No 1365/75 (OJ L 30, 31.1.2019, p. 74).

CHAPTER II

Monitoring*Article 6***Collection and dissemination of information and data**

1. The Agency shall:

- (a) collect relevant information and data, including information and data which have been communicated by the national focal points, which result from research, which are available from open sources, and which emanate from Union sources, non-governmental sources and competent international organisations and bodies;
- (b) collect information and data needed in order to monitor poly-substance use and its consequences pursuant to Article 7(1), point (d);
- (c) collect the information and data available from national focal points, in cooperation with Europol, on new psychoactive substances and communicate that information without undue delay to the national focal points, the Europol national units and the Commission;
- (d) collect and analyse information and data on drug precursors and on the diversion and trafficking of drug precursors;
- (e) conduct and commission research and monitoring studies, surveys, feasibility studies and pilot projects necessary to accomplish its tasks;
- (f) ensure improved comparability, objectivity and reliability of information and data at Union level by establishing, in cooperation with the national focal points, indicators and non-binding common standards with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Union; the Agency may recommend compliance with such non-binding common standards;
- (g) cooperate closely with relevant Union bodies, offices and agencies and international organisations and bodies, in particular the UNODC and the INCB, in order to facilitate notifications and avoid unnecessary burdens on Member States.

2. The Agency shall collect relevant national data through the national focal points. Prior to collecting the data, the Agency and the national focal points shall discuss and agree on the national reporting package. The Agency may use additional sources of information for national data. Where the Agency uses such additional sources, it shall keep the national focal point concerned duly informed. The data collected shall, where possible, be disaggregated by sex and, where possible, by gender. Such data shall take into account the gender-sensitive aspects of drugs policy.

3. The Agency shall develop, within its mandate, data collection methods and approaches, including through projects with external partners.

4. The Agency shall develop the necessary digital solutions for the purpose of collecting, validating, analysing, reporting, managing and exchanging information and data, including in an automated manner.

5. The Agency shall disseminate information and data by:

- (a) making the information it produces available to the Union, the Member States and other interested parties, including as regards new developments and changing trends;
- (b) ensuring wide dissemination of its analyses, conclusions and reports, including to the scientific community, civil society organisations and affected communities, including people who use drugs, with the exception of classified and sensitive non-classified information as referred to in Article 49;
- (c) publishing, on the basis of data which it collects, a regular report on the state of the drugs phenomenon and emerging trends;
- (d) setting up and making available open scientific documentation resources;

- (e) providing information on quality standards, evidence-based best practices, innovative approaches and implementable research results in the Member States and facilitating the exchange of information on, and the implementation of, such standards and practices.
- 6. Where relevant, the Agency may disseminate information and data which have been disaggregated, in particular by Member State, sex, gender, age, disability and socio-economic status, in accordance with relevant Union law, in particular on data protection.
- 7. When disseminating information and data under paragraph 5, the Agency shall include references to the sources thereof.
- 8. The Agency shall not disseminate or transmit any information and data from which it is possible to identify individuals or small groups of individuals.

Article 7

Monitoring of the drugs phenomenon and sharing of best practices

1. The Agency shall monitor:
 - (a) the drugs phenomenon in the Union in a holistic manner, using epidemiological and other indicators, covering the health, human rights, social, safety and security aspects thereof, including the implementation of the applicable Union drug-related strategic documents;
 - (b) evidence-based best practices and innovative approaches regarding health, human rights, social, safety or security responses;
 - (c) drug use, drug use disorders, drug addictions and related health risks, drug-related harm, risk behaviours associated with drug use and emerging trends in those fields;
 - (d) poly-substance use and its consequences, in particular the increased risks of health and social problems, the social determinants of drug use, drug use disorders and addictions, and the implications for policies and responses;
 - (e) drug and poly-substance use and its consequences from an age and gender perspective, in particular its impact on gender-based violence;
 - (f) emerging trends in the drugs phenomenon in the Union and internationally in so far as they impact the Union; monitoring under this point shall include the monitoring of drug supply, including illicit production, trafficking and other related crimes and the use of new technologies, without prejudice to the mandates of other Union bodies, offices and agencies;
 - (g) in cooperation with Europol and with the support of the national focal points and the Europol national units, all new psychoactive substances that have been reported by Member States;
 - (h) drug precursors and the diversion and trafficking of drug precursors;
 - (i) the implementation of Union and national drugs policies, including with a view to supporting the development and independent evaluation of such policies.
2. Based on its monitoring activities under paragraph 1, the Agency shall identify, support and, where appropriate, co-develop evidence-based best practices and innovative approaches. The Agency shall share such best practices and approaches with the Member States and facilitate the exchange of such best practices and approaches between them.
3. The Agency shall develop tools and instruments to help Member States monitor and evaluate their national policies, in cooperation with the national focal points, and to help the Commission monitor and evaluate Union policies.
4. The Agency shall undertake regular foresight exercises, taking into account the information available. It shall develop, on that basis, relevant scenarios for the development of future drugs policy.

CHAPTER III

Preparedness*Article 8***The exchange of information on, and the early warning system for, new psychoactive substances**

1. Each Member State shall ensure that its national focal point and its Europol national unit provide the Agency and Europol, taking into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay. That information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances.

2. The Agency, in cooperation with Europol, shall collect, collate, analyse and assess information on new psychoactive substances. It shall communicate that information in a timely manner to the national focal points, the Europol national units and the Commission with a view to providing them with any information required for the purposes of early warning.

The Agency shall draw up initial reports or combined initial reports pursuant to Article 9 based on the information collected pursuant to the first subparagraph.

*Article 9***Initial report**

1. Where the Agency, the Commission or a majority of Member States considers that information on a new psychoactive substance collected in one or more Member States and shared with it or them gives rise to concerns that the new psychoactive substance might pose health or social risks at Union level, the Agency shall draw up an initial report on the new psychoactive substance.

For the purposes of the first subparagraph, Member States shall inform the Commission and the other Member States of their wish that an initial report be drawn up. Where a majority of Member States has so informed the Commission, the Commission shall instruct the Agency accordingly and shall inform the Member States thereof.

2. An initial report as referred to in paragraph 1 shall contain:

- (a) a preliminary indication of the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance might potentially be involved and the patterns of use of the new psychoactive substance;
- (b) a preliminary indication of the chemical and physical description of the new psychoactive substance and the methods and precursors used to manufacture or extract it;
- (c) a preliminary indication of the pharmacological and toxicological description of the new psychoactive substance;
- (d) a preliminary indication of the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance;
- (e) information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;
- (f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use, and its use for scientific research and development purposes;
- (g) information on whether the new psychoactive substance is subject to any restrictive measures in any Member State;
- (h) information on whether the new psychoactive substance is currently or has been under assessment within the United Nations system;
- (i) other relevant information, where available.

3. For the purpose of an initial report as referred to in paragraph 1, the Agency shall use the information which is at its disposal.

4. Where the Agency considers it necessary, it shall request the national focal points to provide additional information on a new psychoactive substance. The national focal points shall provide such information within two weeks of receipt of such a request.

5. The Agency shall, without undue delay after it starts drawing up an initial report pursuant to paragraph 1, request the European Medicines Agency to provide information on whether, at Union or national level, the new psychoactive substance is an active substance in:

- (a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council ⁽²⁰⁾, Regulation (EC) No 726/2004 or Regulation (EU) 2019/6 of the European Parliament and of the Council ⁽²¹⁾;
- (b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;
- (c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;
- (d) an unauthorised medicinal product for human use as referred to in Article 5(1) and (2) of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously in accordance with Article 112(1), point (c), of Regulation (EU) 2019/6;
- (e) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC of the European Parliament and of the Council ⁽²²⁾.

Where information provided under the first subparagraph relates to marketing authorisations granted by Member States, the Member States concerned shall provide the European Medicines Agency with such information upon its request.

6. The Agency shall, without undue delay after it starts drawing up an initial report pursuant to paragraph 1, request Europol to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods and trafficking of the new psychoactive substance, and on any use of the new psychoactive substance.

7. The Agency shall, without undue delay after it starts drawing up an initial report pursuant to paragraph 1, request the European Chemicals Agency, established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽²³⁾, and the European Centre for Disease Prevention and Control and the European Food Safety Authority, established by Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽²⁴⁾, to provide the information and data at their disposal on the new psychoactive substance.

8. The details of the cooperation between the Agency and the Union agencies referred to in paragraphs 5, 6 and 7 of this Article shall be set out in working arrangements. Such working arrangements shall be concluded in accordance with Article 53(2).

⁽²⁰⁾ 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).

⁽²¹⁾ 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).

⁽²²⁾ Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

⁽²³⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

⁽²⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

9. The Agency shall respect the conditions on the use of information, which are communicated to the Agency, including conditions on access to documents and information, data security and the protection of confidential data, including the sensitive data and confidential business information of third parties.

10. The Agency shall submit an initial report as referred to in paragraph 1 to the Commission and the Member States within five weeks of making the requests for information referred to in paragraphs 5, 6 and 7.

11. Where the Agency collects information on several new psychoactive substances that it considers to be of a similar chemical structure, it shall submit to the Commission and the Member States an individual initial report as referred to in paragraph 1 for each of those new psychoactive substances, or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks of making the requests for information referred to in paragraphs 5, 6 and 7.

Article 10

Risk assessment procedure and report

1. Within two weeks of receipt of an initial report as referred to in Article 9(10), the Commission may request the Agency to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report, where there are indications in the initial report to believe that the new psychoactive substance might pose severe public health risks and, where applicable, severe social risks. The risk assessment shall be carried out by the Scientific Committee.

2. Within two weeks of receipt of individual initial reports or a combined initial report as referred to in Article 9(11), the Commission may request the Agency to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where there are indications in the combined initial report to believe that those new psychoactive substances might pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.

3. A risk assessment report or combined risk assessment report shall contain:

- (a) available information on the chemical and physical properties of the new psychoactive substance or substances and the methods and the precursors used to manufacture or extract it or them;
- (b) available information on the pharmacological and toxicological properties of the new psychoactive substance or substances;
- (c) an analysis of the health risks associated with the new psychoactive substance or substances, in particular with respect to its or their acute and chronic toxicity, abuse liability, dependence-producing potential, and physical, mental and behavioural effects;
- (d) an analysis of the social risks associated with the new psychoactive substance or substances, in particular its or their impact on social functioning, public order and criminal activities, and of the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance or substances;
- (e) available information on the extent and patterns of use of the new psychoactive substance or substances and its or their availability and potential for diffusion within the Union;
- (f) available information on the commercial and industrial use of the new psychoactive substance or substances, the extent of such use, as well as its or their use for scientific research and development purposes;
- (g) other relevant information, where available.

4. The Scientific Committee shall carry out a risk assessment in order to assess the risks posed by the new psychoactive substance or group of new psychoactive substances. For each such risk assessment, the Commission, the Agency, Europol and the European Medicines Agency shall each have the right to appoint two observers.

5. The Scientific Committee shall carry out risk assessments as referred to in paragraph 4 on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Agency shall organise the risk assessment procedure, including identifying future information needs and relevant studies.
6. The Agency shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within six weeks of receipt of the request from the Commission to draw up a risk assessment report pursuant to paragraph 1 or a combined risk assessment report pursuant to paragraph 2.
7. Upon receipt of a duly reasoned request of the Agency, the Commission may extend the period for completion of the risk assessment or combined risk assessment set out in paragraph 6 to allow for additional research and data collection to take place. Such a request shall contain information on the period of time needed to complete the risk assessment or combined risk assessment.
8. The Agency shall provide timely rapid risk assessments, in accordance with Article 20 of Regulation (EU) 2022/2371 of the European Parliament and of the Council ⁽²⁵⁾, in the case of a threat as referred to in Article 2(1), point (b), of that Regulation, where the threat falls under the mandate of the Agency.

Article 11

Exclusion from risk assessment

1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organization's Expert Committee on Drug Dependence has published its critical review together with a written recommendation, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report for that substance.
2. No risk assessment shall be carried out where, following an assessment within the United Nations system, it has been decided not to schedule the new psychoactive substance, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report for that substance.
3. No risk assessment shall be carried out where the new psychoactive substance is an active substance in:
 - (a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC, Regulation (EC) No 726/2004 or Regulation (EU) 2019/6;
 - (b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;
 - (c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;
 - (d) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC.

Article 12

Health and security threat assessment and preparedness

1. The Agency shall develop a strategic evidence-based health and security threat assessment capability to identify at an early stage new developments of the drugs phenomenon that have the potential to impact negatively on health, social matters, safety or security in the Union and, by doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in an effective and timely manner.

⁽²⁵⁾ Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).

2. The Agency may launch a health and security threat assessment on its own initiative based on an internal appraisal of signals arising from routine monitoring, research or other appropriate information sources. The Agency may also launch a health and security threat assessment at the request of the Commission or of a Member State, provided that the criteria set out in paragraph 1 are met.
3. A health and security threat assessment shall consist of a rapid evaluation of existing information and, where necessary, the collection of new information through the Agency's information networks. The Agency shall develop appropriate scientific rapid assessment methods.
4. Where, following a health and security threat assessment, the Agency draws up a health and security threat assessment report, that report shall describe the identified threat, the current situation based on available evidence and the potential outcomes in the event of no action. The health and security threat assessment report shall set out options for preparedness and response that can be adopted to mitigate and to respond to the threat identified, including, where possible, evidence-based interventions on demand reduction, risk and harm reduction and recovery. The health and security threat assessment report may also contain potential follow-up measures. The Agency shall send the health and security threat assessment report to the Commission and, as appropriate, to the Member States.
5. The Agency shall cooperate closely with Member States, other Union bodies, offices and agencies and international organisations in carrying out a health and security threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism, the Agency shall not carry out a health and security threat assessment.
6. With the agreement of the Commission, the Agency shall conduct health and security threat assessments on drug-related threats emerging from outside the Union, which have the potential to impact health, social matters, safety or security within the Union.
7. The Agency shall monitor the evolution of the situation and, where necessary, update the health and security threat assessments accordingly.

Article 13

European drug alert system

1. The Agency shall set up and manage a rapid European drug alert system, complementing and without prejudice to the relevant national alert systems. The European drug alert system shall be complementary to the early warning system referred to in Article 8.
2. The national focal points, in cooperation with the relevant national competent authorities, shall immediately notify the Agency of any information relating to the appearance of a serious direct or indirect drug-related risk to health, social aspects, safety or security and of any information that might be useful for coordinating a response whenever they become aware of such information, such as:
 - (a) the type and origin of the risk;
 - (b) the date and place of the event involving the risk;
 - (c) the means of exposure, transmission or dissemination;
 - (d) analytical and toxicological data;
 - (e) identification methods;
 - (f) health risks;
 - (g) social, safety and security risks;
 - (h) health measures implemented or intended to be taken at national level;
 - (i) measures other than health measures;
 - (j) any other information relevant to the serious risk to health in question.

3. The Agency shall analyse and assess the available information and data on potential serious risks to health and complement it with any scientific and technical information available from the early warning system referred to in Article 8 and other threat assessments undertaken in accordance with Article 12, from other Union bodies, offices and agencies and from international organisations, in particular the World Health Organization. The Agency shall take into account open source information and available information obtained through its data collection tools and from relevant stakeholders, including the scientific community and civil society organisations.
4. Based on the information and data received pursuant to paragraph 3, the Agency shall provide targeted rapid alert risk communications to the relevant national authorities, including the national focal points. The Agency may propose response options in such risk communications. Member States may consider such response options as part of their preparedness planning and national response activities.
5. The national focal points, in cooperation with the relevant national competent authorities, shall inform the Agency of additional information at their disposal in order to enable the Agency to further analyse and assess risks referred to in paragraph 2 and of the actions implemented or measures taken following receipt of the rapid alert risk communications referred to in paragraph 4.
6. The Agency shall cooperate closely with the Commission and the Member States to promote the necessary coherence in the risk communication process.
7. The Agency may open up participation in the European drug alert system to third countries or international organisations. That participation shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Agency.
8. In close cooperation with the relevant national competent authorities, in particular the national focal points, the Agency shall, if needed, develop an alert system to make information on a specific risk available, where appropriate, to people who use or potentially use specific drugs.
9. The Agency shall update its drug alerts, whenever necessary.

Article 14

Drug precursors

1. The Agency shall assist the Commission in monitoring developments related to the diversion and trafficking of drug precursors and in assessing the need to add to, remove from or change the category of listed scheduled and non-scheduled substances in relation to Regulations (EC) No 273/2004 and (EC) No 111/2005, including in identifying and assessing their licit and illicit uses.
2. The Agency shall prepare, on its own initiative or at the request of the Commission, a threat assessment report on drug precursors.

Article 15

Network of forensic and toxicological laboratories

1. The Agency shall set up a network of forensic and toxicological laboratories active in forensic and toxicological investigations of drugs and drug-related harm (the 'network').
2. The network shall act primarily as a forum for:
 - (a) generating data and exchanging information on new developments and trends;
 - (b) organising training to enhance the competence of forensic drug and toxicology experts;
 - (c) supporting the implementation of quality assurance schemes; and
 - (d) supporting the further harmonisation of data collection and analytical methods.

The national focal points shall be informed on a regular basis, at least once a year, about the activities of the network. The national focal points shall have access to the information and data generated by the network.

3. Each Member State shall have the right to appoint to the network, through its representative in the Management Board, up to three laboratories specialising in forensic analysis, toxicology or other relevant fields related to drugs to act as national representative laboratories. The Agency may select additional laboratories or experts particularly active in forensic and toxicological investigations of drugs and drug-related harm for specific projects.

4. The Joint Research Centre of the Commission shall be a member of the network and represent the Commission in the network.

5. The network shall cooperate closely with existing networks and organisations active in the same areas as the network and shall take their work into account in order to avoid overlaps. The Reitox network shall be informed regularly, and at least once a year, about the work of the network.

6. The Agency shall chair the network and convene at least one meeting a year. The network may decide to create working groups, which may be chaired by members of the network.

7. The network shall enable the Agency to have access to forensic and toxicological data, generated or collected by laboratories of the network, including, where necessary, for the analysis of new psychoactive substances.

8. The Agency shall identify and finance specific projects to further the work of the network, as appropriate and based on clear and transparent rules and procedures. The Agency shall establish those rules and procedures prior to identifying such projects.

9. The Agency shall create a database to store, analyse and make available the information and data collected or generated by the network, in accordance with the relevant provisions of this Regulation, including Article 6(8) and Article 49.

CHAPTER IV

Competence development

Article 16

Evidence-based interventions, best practices and awareness raising

1. The Agency shall develop and promote evidence-based interventions and best practices with regard to, and raise awareness about, the adverse effects of drugs, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery. Where relevant, the Agency shall take a gender-sensitive approach and take into account the age dimension. Evidence-based interventions, best practices and awareness raising activities may be adapted to the national context and implemented at national level and, whenever necessary, be targeted to specific groups.

2. Evidence-based interventions, best practices and awareness raising activities referred to in paragraph 1 shall be in accordance with human rights norms and the political orientation set out in the applicable Union drug-related strategic documents.

3. The Agency shall promote the implementation of existing quality standards for drug prevention and update them as appropriate. The Agency shall provide or support training pursuant to Article 19. The Agency shall develop, where appropriate, quality standards for risk and harm reduction, treatment, recovery, care and rehabilitation.

4. The Agency may offer support to Member States and shall, subject to their prior agreement, assist them in developing national interventions in the area of its mandate.

*Article 17***Assessment scheme for national measures**

1. At the request of a national authority of a participating country, the Agency shall assess national measures in accordance with the standard operating protocol provided for in paragraph 3.
2. Before assessing a national measure, the Agency shall evaluate it and analyse whether it complies with the latest scientific state of play and whether it has proven useful in addressing its declared objectives.
3. The Agency shall develop an assessment procedure. The Agency shall set out the assessment procedure in a transparent way in a standard operating protocol. The Management Board shall approve the standard operating protocol and any changes to it before the Agency applies it.
4. The Agency shall regularly inform the Management Board of the assessments it has undertaken pursuant to this Article.

*Article 18***Support to Member States**

1. At the request of a Member State, the Agency may support the independent evaluation of its drug policies and the development of evidence-based drug policies in accordance with the applicable Union drug-related strategic documents.
2. The Agency may offer support to Member States and shall, subject to their prior agreement, assist them in implementing their national drug policies, quality standards, best practices and innovative approaches. The Agency shall facilitate the exchange of information, including on relevant law and best practices, between national authorities and experts.
3. When it supports the evaluation of drugs policies, the Agency shall act independently and shall be guided by its scientific standards and an evidence-based approach.

*Article 19***Training**

The Agency shall, within the scope of its mandate and in coordination with other Union bodies, offices and agencies:

- (a) provide specialised training and curricula in areas of Union interest and relevance;
- (b) provide training-related tools and support systems to facilitate Union-wide knowledge exchange;
- (c) assist Member States in organising training and capacity-building initiatives.

*Article 20***International cooperation and technical assistance**

1. The Agency shall:
 - (a) develop an international cooperation framework, to be approved by the Management Board subject to the prior approval of the Commission, which shall guide the activities of the Agency in the area of international cooperation;
 - (b) cooperate actively with the organisations and bodies referred to in Article 53(1);
 - (c) support the exchange and dissemination of Union best practices and implementable research results at international level;

- (d) monitor developments of the international drugs phenomenon that might pose a threat to or have implications for the Union through the monitoring and analysis of information available from international bodies, national authorities, research findings and other relevant information sources;
- (e) provide data and analysis on the European drug situation in appropriate international meetings and technical fora, in close coordination with the Commission, and support the Commission and the Member States in international drugs dialogues;
- (f) promote the incorporation of all relevant data on drugs covered by this Regulation and collected in the Member States or emanating from the Union into international monitoring and drug-control programmes, particularly those established by the United Nations and its specialised agencies, without prejudice to Member States' obligations with regard to the transmission of information under the United Nations Drug Conventions;
- (g) support the Member States in reporting the relevant information and providing the required analysis to the United Nations system, including the submission of all relevant data related to new psychoactive substances to the UNODC and the World Health Organization;
- (h) support third countries, in particular candidate countries, in developing their drug policies in accordance with the principles set out in the applicable Union drug-related strategic documents, including by providing support to the independent evaluation of their policies, and encourage those third countries to support the participation and involvement of civil society in the development, implementation and evaluation of drug policies.

2. The international cooperation framework referred to in paragraph 1, point (a), shall seek to further strengthen and support third countries' efforts to address drug issues in an evidence-based, integrated, balanced and multidisciplinary manner and in full compliance with human rights norms. That international cooperation framework shall take into account the relevant policy documents of the Union and consider the developments of the drugs phenomenon. It shall set out the priority countries or regions for cooperation and the key outcomes of the cooperation. It shall take into account the experiences of and activities undertaken by the Member States. The Agency shall evaluate and review the international cooperation framework regularly.

3. The Agency shall transfer, at the request of the Commission and subject to the approval of the Management Board, its expertise and provide technical assistance to third countries, in particular candidate countries, in accordance with the international cooperation framework referred to in paragraph 1, point (a).

Technical assistance shall focus, in particular, on setting up or consolidating national focal points, national data collection systems and national early warning systems and on the promotion of best practices in the fields of prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, and subsequently assist in the creation and strengthening of structural links with the early warning system referred to in Article 8 and the Reitox network. The Agency may assess the national bodies of a third country where that third country so requests.

4. The Agency shall cooperate with international organisations and with third countries in accordance with Articles 53 and 54.

Article 21

Research and innovation

1. The Agency shall assist the Commission and the Member States in identifying key research themes and in drawing up and implementing the Union framework programmes for research and innovation activities that are relevant to achieve its general and specific tasks set out in Articles 4 and 5, respectively. The Agency shall pay due attention to intersectionality as a crosscutting principle in its research-related activities. Where the Agency assists the Commission in identifying key research themes or in drawing up and implementing a Union framework programme, the Agency shall not receive funding from that programme.

2. The Agency shall proactively monitor and contribute to research and innovation activities to achieve its general and specific tasks set out in Articles 4 and 5, respectively, support related activities of Member States, and implement its research and innovation activities regarding matters covered by this Regulation, including the development, training, testing and validation of algorithms for the development of tools. The Agency shall disseminate the results of such research and innovation activities to the European Parliament, the Member States and the Commission in accordance with the security rules provided for in Article 49.
3. The Agency shall contribute to and participate in the activities carried out in the framework of the research and innovation cycle, such as the EU Innovation Hub for Internal Security and the Health Emergency Preparedness and Response Authority, established by the Commission Decision of 16 September 2021 ⁽²⁶⁾.
4. The Agency may plan and implement pilot projects regarding matters covered by this Regulation.
5. The Agency shall take all necessary measures to avoid conflicts of interest in the implementation of the pilot projects referred to in paragraph 4. It shall make public information on its research projects, including demonstration projects. Such information shall include the cooperation partners involved and the project budget.
6. The Agency shall create a database to store, analyse and make available drug-related research programmes.

CHAPTER V

Organisation of the Agency

Article 22

Administrative and management structure

1. The Agency's administrative and management structure shall comprise:
 - (a) a Management Board, which shall exercise the functions set out in Article 24;
 - (b) an Executive Board, which shall exercise the functions set out in Article 28;
 - (c) an Executive Director, who shall exercise the responsibilities set out in Article 30;
 - (d) a Scientific Committee, which shall exercise the functions set out in Article 31; and
 - (e) the Reitox network.
2. The members of the Agency's administrative and management structure shall not have any financial or other interests that could affect their impartiality. They shall act in the public interest and carry out their activities in an independent, impartial and transparent manner. They shall make an annual declaration of their interests, which may be accessible upon request.

Article 23

Composition of the Management Board

1. The Management Board shall be composed of:
 - (a) one representative from each Member State, with the right to vote;
 - (b) two representatives from the Commission, with the right to vote.

⁽²⁶⁾ Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02 (OJ C 393 I, 29.9.2021, p. 3).

2. The Management Board shall also include:
 - (a) two independent experts designated by the European Parliament, who are particularly knowledgeable in the field of drugs, with the right to vote;
 - (b) one representative from each third country which has concluded an agreement with the Union in accordance with Article 54, without the right to vote.
3. Each member of the Management Board shall have an alternate. The alternate shall represent the member in her or his absence and may attend the meetings of the Management Board.
4. Members of the Management Board and their alternates shall be appointed in light of their knowledge in the fields set out in Article 4(1), point (a), taking into account relevant managerial, administrative and budgetary skills. All parties represented on the Management Board shall make efforts to limit the turnover of their representatives in order to ensure continuity in the work of the Management Board. All parties shall aim to achieve gender-balanced representation on the Management Board.
5. The Management Board may invite, as observers, representatives of international organisations with which the Agency cooperates in accordance with Article 53.
6. The term of office for members and their alternates shall be four years. That term shall be renewable.

Article 24

Functions of the Management Board

1. The Management Board shall:
 - (a) provide the general orientation for the Agency's activities;
 - (b) adopt the draft single programming document referred to in Article 36 before its submission to the Commission for its opinion;
 - (c) having obtained the opinion of the Commission, adopt the Agency's single programming document by a majority of two-thirds of members with the right to vote;
 - (d) adopt, by a majority of two-thirds of members with the right to vote, the annual budget of the Agency and exercise other functions in respect of the Agency's budget in accordance with Chapter VI;
 - (e) assess and adopt, by a majority of two-thirds of members with the right to vote, the consolidated annual activity report on the Agency's activities, send both the report and its assessment thereof by 1 July each year to the European Parliament, the Council, the Commission and the Court of Auditors, and ensure that the consolidated annual activity is made public;
 - (f) adopt the financial rules applicable to the Agency in accordance with Article 42;
 - (g) adopt an anti-fraud strategy, proportionate to fraud risks, taking into account the costs and benefits of the measures to be implemented;
 - (h) adopt a strategy for achieving efficiency gains and synergies with other Union bodies, offices and agencies;
 - (i) adopt rules for the prevention and management of conflicts of interest in respect of its members, the members of the Executive Board, the members of the Scientific Committee and the members of the Reitox network, and of seconded national experts and other staff not employed by the Agency as referred to in Article 44, and shall publish annually on the Agency's website the declarations of interests of the Management Board members;
 - (j) approve the standard operating protocol referred to in Article 17(3);
 - (k) approve the international cooperation framework referred to in Article 20(1), point (a), and the technical assistance programmes referred to in Article 20(3);
 - (l) approve the level of co-financing referred to in Article 33(5);
 - (m) adopt and regularly update the communication strategies and dissemination plans referred to in Article 5(8), based on an analysis of needs;

- (n) adopt and make publicly available its rules of procedure, including rules for the prevention and management of conflicts of interest;
- (o) in accordance with paragraph 2 of this Article, exercise, with respect to the staff of the Agency, the powers conferred by the Staff Regulations of Officials of the European Union (the 'Staff Regulations') on the appointing authority and by the Conditions of Employment of Other Servants of the European Union (the 'Conditions of Employment of Other Servants') on the authority empowered to conclude a contract of employment, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68 ⁽²⁷⁾, (the 'appointing authority powers');
- (p) in agreement with the Commission, adopt implementing rules for giving effect to the Staff Regulations and the Conditions of Employment of Other Servants in accordance with Article 110(2) of the Staff Regulations;
- (q) appoint the Executive Director and, where relevant, decide on an extension of the term of office or on a removal from office in accordance with Article 29;
- (r) appoint an accounting officer, subject to the Staff Regulations and the Conditions of Employment of Other Servants, who shall be independent in the performance of her or his duties;
- (s) appoint the members of the Scientific Committee;
- (t) approve the list of experts to be used to extend the Scientific Committee in accordance with Article 31(6);
- (u) take decisions following the assessment of the national focal points in accordance with Article 35;
- (v) set the method for calculating fees and the way fees are paid in accordance with Article 38;
- (w) ensure adequate follow up to findings and recommendations stemming from internal or external audit reports and evaluations and from investigations of the European Anti-fraud Office (OLAF), established by Commission Decision 1999/352/EC, ECSC, Euratom ⁽²⁸⁾, and of the European Public Prosecutor's Office (EPPO), established by Council Regulation (EU) 2017/1939 ⁽²⁹⁾, as referred to in Article 48 of this Regulation;
- (x) take all decisions on the establishment and, where necessary, modification of the Agency's internal structures, taking into consideration the Agency's activity needs and having regard to sound budgetary management;
- (y) adopt working arrangements in accordance with Article 53.

2. The Management Board shall adopt, in accordance with Article 110 of the Staff Regulations, a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the Conditions of Employment of Other Servants, delegating relevant appointing authority powers to the Executive Director and setting out the conditions under which that delegation of powers can be suspended. The Executive Director shall be authorised to sub-delegate those powers.

Where exceptional circumstances so require, the Management Board may, by way of a decision, temporarily suspend the delegation of the appointing authority powers to the Executive Director and those sub-delegated by the Executive Director and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director.

Article 25

Chairperson of the Management Board

1. The Management Board shall elect a Chairperson and a Deputy Chairperson from among its members with the right to vote. The Chairperson and the Deputy Chairperson shall be elected by a majority of two-thirds of the members of the Management Boards with the right to vote.

⁽²⁷⁾ OJ L 56, 4.3.1968, p. 1.

⁽²⁸⁾ Commission Decision 1999/352/EC, ECSC, Euratom of 28 April 1999 establishing the European Anti-fraud Office (OLAF) (OJ L 136, 31.5.1999, p. 20).

⁽²⁹⁾ Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283, 31.10.2017, p. 1).

2. The Deputy Chairperson shall automatically replace the Chairperson if she or he is prevented from attending to her or his duties.
3. The term of office of the Chairperson and the Deputy Chairperson shall be four years. Their term of office may be renewed once. If, however, their membership of the Management Board ends at any time during their term of office, their term of office shall automatically expire on that date.
4. The detailed procedure for the election of the Chairperson and the Deputy Chairperson shall be set out in the rules of procedure of the Management Board.

Article 26

Meetings of the Management Board

1. The Chairperson shall convene the meetings of the Management Board.
2. The Executive Director shall take part in the deliberations of the Management Board.
3. The Management Board shall hold at least one ordinary meeting a year. In addition, it shall meet on the initiative of its Chairperson, at the request of the Commission, or at the request of at least one-third of its members.
4. The Management Board may invite any person, including representatives from civil society organisations, whose opinion may be of interest to attend its meetings as an observer.
5. The members of the Management Board may, subject to its rules of procedure, be assisted at the meetings by advisers or experts.
6. The Agency shall provide the secretariat for the Management Board.

Article 27

Voting rules of the Management Board

1. Without prejudice to Article 24(1), points (c) and (d), Article 25(1), Article 35(6), Article 29(8) and Article 53(2), the Management Board shall take decisions by a majority of its members with the right to vote.
2. Each member with the right to vote shall have one vote. In the absence of a member with the right to vote, her or his alternate shall be entitled to exercise the right to vote.
3. The Chairperson and Deputy Chairperson shall take part in the voting.
4. The Executive Director shall not take part in the voting.
5. The Management Board's rules of procedure shall establish more detailed voting arrangements, in particular the circumstances in which a member may act on behalf of another member.

Article 28

Executive Board

1. The Executive Board shall:
 - (a) decide on those matters provided for in the financial rules adopted pursuant to Article 42 that are not reserved to the Management Board by this Regulation;
 - (b) ensure adequate follow up to the findings and recommendations stemming from internal or external audit reports and evaluations, and from investigations by OLAF and by EPPO, as referred to in Article 48;

(c) without prejudice to the responsibilities of the Executive Director, set out in Article 30, monitor and supervise the implementation of the decisions of the Management Board, with a view to reinforcing supervision of administrative and budgetary management.

2. Where necessary, because of urgency, the Executive Board may take certain provisional decisions instead of the Management Board, in particular on administrative management matters, including the suspension of the delegation of the appointing authority powers and budgetary matters. The conditions for taking such provisional decisions shall be set out in the rules of procedure of the Management Board.

3. The Executive Board shall be composed of the Chairperson and the Deputy Chairperson of the Management Board, two other members appointed by the Management Board from among its members with the right to vote and the two representatives of the Commission to the Management Board.

The Chairperson of the Management Board shall also be the Chairperson of the Executive Board.

The Executive Director shall take part in the meetings of the Executive Board as an observer. The Executive Board may invite other observers to attend its meetings.

4. The term of office of members of the Executive Board shall be four years. Their term of office may be renewed once. If, however, their membership of the Management Board ends at any time during their term of office, their term of office in the Executive Board shall automatically expire on that date.

5. The Executive Board shall hold at least two ordinary meetings a year. In addition, it shall meet on the initiative of its Chairperson or at the request of its members.

6. The Executive Board shall take its decision by consensus among its members. If the Executive Board is not in a position to take a decision by consensus, the matter shall be referred to the Management Board.

7. The Management Board shall lay down the rules of procedure of the Executive Board.

Article 29

Executive Director

1. The Executive Director shall be engaged as a temporary agent of the Agency under Article 2, point (a), of the Conditions of Employment of Other Servants.

2. The Management Board shall appoint the Executive Director from a list of at least three candidates proposed by the Commission on the basis of an open and transparent selection procedure. The selection procedure shall include the publication of a call for expressions of interest in the *Official Journal of the European Union* and in other appropriate media. The Commission shall consult the Management Board on the draft call for expressions of interest. The Commission may include a representative of the Management Board as an observer in the selection procedure.

Before appointment by the Management Board to the post of Executive Director, the shortlisted candidates proposed by the Commission may be invited, without delay, to make a statement before the competent committee or committees of the European Parliament and answer questions from the committee members. After hearing the statement and the responses, the European Parliament may adopt an opinion setting out its views and submit it to the Management Board.

3. For the purpose of concluding the contract with the Executive Director, the Agency shall be represented by the Chairperson of the Management Board.

4. The term of office of the Executive Director shall be five years. By the end of that period, the Commission shall undertake an assessment that takes into account an evaluation of the Executive Director's performance, including prior input from the Management Board, and the Agency's future tasks and challenges.

5. The Management Board, acting on a proposal from the Commission that takes into account the assessment referred to in paragraph 4, may extend the term of office of the Executive Director once for a period of no more than five years.

The Management Board shall inform the European Parliament if it intends to extend the Executive Director's term of office. Before the Management Board takes a decision to extend the Executive Director's term of office, the Executive Director may be invited to make, without delay, a statement before the competent committee or committees of the European Parliament and answer questions from the committee members.

6. An Executive Director whose term of office has been extended shall not participate in another selection procedure for the same post at the end of the overall period.

7. The Executive Director may be removed from office only upon a decision of the Management Board acting on a proposal from the Commission. The European Parliament and the Council shall be informed, in a manner that complies with the applicable confidentiality requirements, about the reasons for such a decision.

8. The Management Board shall reach decisions on the appointment, extension of the term of office or removal from office of the Executive Director on the basis of a two-thirds majority of its members with the right to vote.

Article 30

Responsibilities of the Executive Director

1. The Executive Director shall be responsible for the management of the Agency. The Executive Director shall be accountable to the Management Board.

2. Without prejudice to the powers of the Commission, of the Management Board and of the Executive Board, the Executive Director shall be independent in the performance of her or his duties and shall neither seek nor take instructions from any government or from any other body.

3. The Executive Director shall report to the European Parliament on the performance of her or his duties when invited to do so. The Council may invite the Executive Director to report on the performance of her or his duties.

4. The Executive Director shall be the legal representative of the Agency.

5. The Executive Director shall be responsible for the implementation of the Agency's specific tasks set out in Article 5. In particular, the Executive Director shall be responsible for:

- (a) the day-to-day administration of the Agency;
- (b) preparing and implementing the decisions adopted by the Management Board;
- (c) preparing the single programming document referred to in Article 36 and submitting it to the Management Board after consulting the Commission;
- (d) implementing the single programming document and reporting to the Management Board on its implementation;
- (e) preparing the Agency's consolidated annual activity report and presenting it to the Management Board for assessment and adoption;
- (f) proposing to the Management Board the level of co-financing referred to in Article 33(5), where such co-financing is to be granted to the national focal points;
- (g) proposing to the Management Board the method for calculating fees and the way fees are paid in accordance with Article 38;
- (h) preparing a follow-up action plan in relation to the conclusions of internal or external audit reports and evaluations, and to investigations by OLAF and EPPO, as referred to in Article 48, and reporting on progress twice a year to the Commission and regularly to the Management Board and the Executive Board;

- (i) protecting the financial interests of the Union by applying preventive measures against fraud, corruption and any other illegal activities, without prejudicing the investigative competence of OLAF and EPPO, by effective checks and, if irregularities are detected, by recovering amounts wrongly paid and, where appropriate, by imposing effective, proportionate and dissuasive administrative penalties and by reporting any criminal conduct to the EPPO in accordance with Article 24 of Regulation (EU) 2017/1939 in respect of which the EPPO could exercise its competence;
- (j) preparing an anti-fraud strategy and efficiency gains and synergies strategies for the Agency and presenting them to the Management Board for approval;
- (k) preparing the draft for the financial rules applicable to the Agency;
- (l) preparing the Agency's draft statement of estimates of revenue and expenditure and implementing its budget.

6. The Executive Director may decide to post one or more liaison officers to the Union institutions and to relevant Union bodies, offices and agencies for the purpose of carrying out the Agency's tasks in an efficient and effective manner. The Executive Director shall obtain the prior consent of the Commission and the Management Board. Decisions to post liaison officers shall specify, in a manner that avoids unnecessary costs and a duplication of the administrative functions of the Agency, the scope of the activities to be carried out by the liaison officers.

7. Where called upon by the European Parliament or by the Council, the Executive Director shall attend, without undue delay, meetings organised by the European Parliament or the Council, as the case may be, on any subject related to the Agency's mandate.

Article 31

Scientific Committee

1. The Scientific Committee shall be composed of no less than seven and no more than 15 scientists appointed by the Management Board in view of their scientific excellence and their independence, following the publication of a call for expressions of interest in the *Official Journal of the European Union* and in other appropriate media. The Agency shall inform the competent committee or committees of the European Parliament of appointments to the Scientific Committee and about its work. The procedure for selecting members of the Scientific Committee shall ensure that the specialist fields of the members of the Scientific Committee cover the most relevant fields linked to the objectives of the Agency. The parties involved in appointing members to the Scientific Committee shall aim to achieve gender-balanced representation in the Scientific Committee.

2. The members of the Scientific Committee shall be appointed in their personal capacity for a four-year period, which shall be renewable once.

3. The members of the Scientific Committee shall be independent and shall act in the public interest. They shall neither seek nor take instructions from any government or from any other body.

4. Where a member no longer meets the criteria of independence, she or he shall inform the Management Board. Alternatively, the Management Board may declare, on a proposal of at least one-third of its members or of the Commission, that there is a lack of independence on the part of a member and revoke the appointment of that member. The Management Board shall appoint a new member for the remaining term of office of that member in accordance with the ordinary procedure for the appointment of members.

5. The Scientific Committee shall deliver an opinion where provided for in this Regulation or on any scientific matter concerning the Agency's activities which the Management Board or the Executive Director may submit to it. The opinions of the Scientific Committee shall be published on the Agency's website.

6. For the purpose of assessing the risks posed by a new psychoactive substance or a group of new psychoactive substances, the Scientific Committee may be extended as considered necessary by the Executive Director, acting on the advice of the Chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks posed by the new psychoactive substance or the group of new psychoactive substances. The Executive Director shall designate those experts from a list of experts. The Management Board shall approve the list of experts every four years.

7. The Scientific Committee shall elect a Chairperson and a Deputy Chairperson for the duration of the mandate of the Scientific Committee. The Chairperson may participate as an observer in the meetings of the Management Board.
8. The Scientific Committee shall meet at least once a year.
9. The list of members of the Scientific Committee shall be made public and shall be updated by the Agency on its website.

Article 32

The European Information Network on Drugs and Drug Addiction

1. Through the European Information Network on Drugs and Drug Addiction (the 'Reitox network') the Member States shall contribute to the Agency's task of collecting and reporting consistent and standardised information on the drugs phenomenon across the Union. The Reitox network shall consist of the national focal points designated in accordance with Article 33 and a focal point for the Commission.
2. The Reitox network shall elect a Spokesperson and between one and three Deputy Spokespersons from among its members. The Spokesperson shall represent the Reitox network in relation to the Agency and shall be allowed to participate as an observer in the meetings of the Management Board.
3. The Reitox network shall hold at least one ordinary meeting a year. The Agency shall convene and chair the meetings. In addition, the Reitox network shall meet on the initiative of its Spokesperson or at the request of at least one-third of its members.

Article 33

National focal point

1. Each participating country shall designate a single national focal point, set up through appropriate national legal or administrative measures on a permanent basis and with a clear mandate. The designation of a national focal point and the appointment of the head of a national focal point, as well as any changes to those appointments, shall be communicated to the Agency through the national member of the Management Board.
2. The responsible national authority shall ensure that the national focal point is entrusted with the tasks set out in Article 34(2). The head of the national focal point or an alternate shall represent the national focal point in the Reitox network.
3. National focal points shall be scientifically independent and ensure the quality of their data.
4. National focal points shall plan their activities in advance and shall have adequate budgetary and human resources allocated by national budgets and co-financed by the Agency in accordance with paragraph 5 of this Article to fulfil their mandate and carry out their tasks set out in Article 34(2), and shall have sufficient equipment and facilities to support their daily activities.
5. The core costs of the national focal point of each Member State shall be co-financed through a grant provided by the Agency provided that it complies with the conditions set out in paragraphs 1 to 4. In order to receive that co-financing, the national focal point shall sign a grant agreement with the Agency on an annual basis. The level of co-financing shall be proposed by the Executive Director, approved by the Management Board and regularly reviewed. The Agency may provide additional funding to national focal points on an ad hoc basis for the participation in and delivery of specific projects.
6. The Agency shall assess national focal points in accordance with Article 35.

*Article 34***Tasks of the national focal points**

1. The national focal points shall form the interface, and support interactions, between the participating countries and the Agency.
2. With a view to supporting the Agency in achieving its general and specific tasks set out in Articles 4 and 5, respectively, thus contributing to coordinated Union action, each national focal point shall carry out the following tasks:
 - (a) for the purpose of communicating those data to the Agency, coordinate at national level the activities related to drug-related data collection and monitoring;
 - (b) collect relevant national data and information in the areas covered by Article 4 in accordance with the national reporting package referred to in Article 6(2) and transmit it to the Agency; in doing so, the national focal point shall bring together experience from different sectors, in particular health, justice and law enforcement, and shall, wherever relevant, cooperate with experts and national organisations, the scientific community, civil society organisations and other relevant stakeholders active in the field of drugs policy;
 - (c) contribute to monitoring drugs and drug use and reporting thereon, including to international organisations;
 - (d) support, as appropriate, the development of new epidemiological data sources to further the timely reporting of trends in substance use;
 - (e) support ad hoc and targeted data collection exercises in relation to new health and security threats;
 - (f) provide the Agency with information on new trends and challenges in the use of existing psychoactive substances or new combinations of psychoactive substances which pose a potential risk to health and with information on possible measures related to health;
 - (g) contribute to the exchange of information on, and the early warning system for, new psychoactive substances, in accordance with Chapter III;
 - (h) contribute to the establishment of relevant indicators and other relevant datasets, including guidelines for their implementation, with a view to obtaining reliable and comparable information at Union level, in accordance with Article 6;
 - (i) nominate, when requested by the Agency, national experts for specific discussions on relevant indicators and for other ad hoc and targeted data collection exercises;
 - (j) promote the use of the internationally agreed data collection protocols and standards to monitor drugs and drug use in the country;
 - (k) present an annual report of its activities to the Agency and other relevant stakeholders;
 - (l) implement quality assurance mechanisms to ensure the reliability of the data and information it obtains.
3. In accordance with their capacity, the national focal points shall monitor, analyse and interpret relevant information in the areas covered by Article 4. The national focal points shall provide that information and information on policies and solutions applied to the Agency.
4. The national focal points shall establish and maintain the necessary cooperation with relevant national and regional authorities, bodies, agencies and organisations for the collection of the information they need to carry out their tasks pursuant to paragraph 2.
5. When collecting data pursuant to this Article, the national focal points shall ensure, where possible, that the data collected are disaggregated by sex or gender. The national focal points shall consider the gender-sensitive aspects of drugs policy when collecting and presenting data pursuant to this Article. The national focal points shall not transmit any data which would make it possible to identify individuals or small groups of individuals. They shall refrain from transmitting any information relating to specific individuals.

*Article 35***Assessment of the national focal points**

1. The Agency shall assess whether each national focal point, by carrying out the tasks set out in Article 34(2), contributes to the achievement of the tasks of the Agency. Such assessments shall not concern other functions of the body hosting the national focal point or the overall structure in which the national focal point is embedded.
2. The assessment referred to in paragraph 1 shall be based on relevant information to be provided by the national focal point. If necessary, the Agency may visit the national focal point.
3. The Agency shall present each assessment it carries out pursuant to paragraph 1 to the national focal point and national competent authority concerned. Assessments may include recommendations for carrying out the tasks set out in Article 34(2), set a timeline for their implementation and offer support from the Agency to national focal points for the purposes of capacity building.
4. Where recommendations, together with a timeline for their implementation, have been issued pursuant to paragraph 3, the national focal point concerned shall either inform the Agency that it has accepted the recommendations or, in the event of disagreement, provide the Agency with a written reasoned opinion.
5. The Agency shall inform the Management Board of the outcome of assessments carried out pursuant to paragraph 1 at its first meeting following the completion of the assessment by the Agency. In the event of disagreement between the Agency and the national focal point as referred to in paragraph 4 of this Article, the Agency shall submit the assessment, the recommendations and the timeline for their implementation for the approval of the Management Board at its next meeting by a majority of its members with the right to vote in accordance with Article 23. The representative of the Member State concerned shall not take part in that vote.
6. If, by the time specified in an assessment as referred to in paragraph 1, the national focal point does not fulfil the tasks set out in Article 34(2), the Management Board shall take a decision, at its first meeting following the time specified in the assessment by a majority of two-thirds of members with the right to vote, in accordance with Article 23, as to whether not to provide co-financing until the national focal point carries out the tasks set out in Article 34(2). The representative of the Member State concerned shall not take part in that vote.
7. The first assessment pursuant to paragraph 1 of each national focal point shall be carried out by the Agency by 3 July 2026. Thereafter, the Agency shall assess national focal points at regular intervals, as necessary.

CHAPTER VI

Financial provisions*Article 36***Single programming document**

1. By 15 December of each year, the Management Board shall adopt a draft single programming document containing multiannual and annual programming and the documents listed in Article 32 of Commission Delegated Regulation (EU) 2019/715 ⁽³⁰⁾, based on a draft put forward by the Executive Director, after consulting the Scientific Committee, taking into account the opinion of the Commission, and, in relation to multiannual programming, after consulting the European Parliament. Where the Management Board decides not to follow elements of the opinion of the Commission or elements arising following the consultation of the European Parliament or of the Scientific Committee, it shall provide a justification. The Management Board shall forward the single programming document to the European Parliament, the Council and the Commission by 31 January of the following year.

⁽³⁰⁾ Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (OJ L 122, 10.5.2019, p. 1).

The Single Programming Document shall become final once the general budget of the Union has been definitively adopted and shall, if necessary, be adjusted accordingly.

2. The annual work programme shall comprise detailed objectives and expected results including performance indicators. It shall also contain a description of the actions to be financed and an indication of the financial and human resources allocated to each action, in accordance with the principles of activity-based budgeting and management. The annual work programme shall be coherent with the multiannual work programme referred to in paragraph 4. It shall clearly indicate tasks that have been added, changed or deleted in comparison with the previous financial year.

Multiannual or annual programming shall include information about the implementation of the international cooperation framework referred to in Article 20(1), point (a), and the actions linked to that framework. It shall also include the Agency's planned research and innovation activities referred to in Article 21.

3. The Management Board shall amend the adopted annual work programme when a new task is given to the Agency.

Any substantial amendment to the annual work programme shall be adopted by the same procedure as the initial annual work programme. The Management Board may delegate the power to make non-substantial amendments to the annual work programme to the Executive Director.

4. The multiannual work programme shall set out overall strategic programming including objectives, expected results and performance indicators. It shall also set out resource programming, including the multiannual budget and staff.

The resource programming shall be updated annually. The strategic programming shall be updated where appropriate and, in particular, to address the outcome of the evaluation referred to in Article 51.

5. The multiannual and annual work programmes shall be prepared in compliance with Article 32 of Delegated Regulation (EU) 2019/715.

Article 37

Budget

1. Estimates of all revenue and expenditure for the Agency shall be prepared each financial year, corresponding to the calendar year, and shall be shown in the Agency's budget.

2. The Agency's budget shall be balanced in terms of revenue and of expenditure.

3. Without prejudice to other resources, the Agency's revenue shall comprise:

- (a) a contribution from the Union entered in the general budget of the Union;
- (b) any voluntary financial contribution from the Member States;
- (c) the fees paid for services rendered in accordance with Article 38;
- (d) any financial contributions from the organisations and bodies and third countries referred to in Articles 53 and 54, respectively; and
- (e) Union funding under indirect management or in the form of ad hoc grants in accordance with the financial rules applicable to the Agency and with the provisions of the relevant instruments supporting the policies of the Union.

4. The amount and origin of any revenue as referred to in paragraph 3, points (b) to (e), shall be included in the annual accounts of the Agency and clearly detailed in the annual report on the Agency's budgetary and financial management referred to in Article 41(3).

5. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure expenses, and operating costs. The operating costs may include expenditure in support of the national focal points, as referred to in Article 33(5).

*Article 38***Fees**

1. The Agency may deliver upon request the following additional services:
 - (a) customised training;
 - (b) certain support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources;
 - (c) capacity-building programmes for third countries which are not covered by separate dedicated Union funding;
 - (d) assessment of national bodies set up in third countries, in particular candidate countries, pursuant to Article 20(3);
 - (e) other customised services rendered at the request of a participating country which require the investment of additional resources in the support of national activities.

The Agency shall charge fees for the delivery of services as referred to in the first subparagraph.

2. At the proposal of the Executive Director and after having consulted the Commission, the Management Board shall set, in a transparent manner, the method for calculating the fees and the way in which they are paid.
3. Fees shall be proportionate to the costs of the service delivered as provided in a cost-effective way and shall be sufficient to cover those costs. Fees shall be set at such a level as to ensure that they are non-discriminatory and that they avoid placing an undue financial or administrative burden on stakeholders.
4. Fees shall be set at such a level as to avoid a deficit or a significant accumulation of surplus in the Agency's budget. If a significant positive balance in the budget, resulting from the provision of the services covered by fees, becomes recurrent, or if a significant negative balance results from the provision of the services covered by fees, the Management Board shall revise the method for calculating the fees in accordance with the procedure set out in paragraph 2.
5. Where applicable, the Agency shall include a report on the fees levied and their impact on the Agency's budget as part of the procedure for the presentation of accounts laid down in Article 41.

*Article 39***Establishment of the budget**

1. Each year, the Executive Director shall draw up a draft statement of estimates of the Agency's revenue and expenditure for the following financial year, including the establishment plan, and send it to the Management Board.
2. The Management Board shall, based on the draft referred to in paragraph 1, adopt a provisional draft statement of estimates of the Agency's revenue and expenditure for the following financial year.
3. The provisional draft statement of estimates of the Agency's revenue and expenditure shall be sent to the Commission by 31 January each year. The Management Board shall send the final draft statement of estimates to the Commission by 31 March.
4. The Commission shall send the statement of estimates of the Agency's revenue and expenditure to the budgetary authority together with the draft general budget of the Union.
5. On the basis of the statement of estimates of the Agency's revenue and expenditure, the Commission shall enter in the draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Articles 313 and 314 of the Treaty on the Functioning of the European Union (TFEU).

6. The budgetary authority shall authorise the appropriations for the contribution to the Agency.
7. The budgetary authority shall adopt the Agency's establishment plan.
8. The Management Board shall adopt the Agency's budget by a majority of two-thirds of members with the right to vote. The budget shall become final once the general budget of the Union has been definitively adopted. Where necessary, the budget shall be adjusted accordingly.
9. Delegated Regulation (EU) 2019/715 applies to any building project likely to have significant implications for the budget of the Agency.

Article 40

Implementation of the budget

1. The Executive Director shall implement the Agency's budget.
2. Each year, the Executive Director shall send to the budgetary authority all information relevant for the evaluation procedures set out in Article 51.

Article 41

Presentation of accounts and discharge

1. By 1 March of the following financial year, the Agency's accounting officer shall send the provisional accounts to the Commission's accounting officer and the Court of Auditors.
2. By 31 March of the following financial year, the Commission's accounting officer shall send the Agency's provisional accounts, consolidated with the Commission's accounts, to the Court of Auditors.
3. By 31 March of the following financial year, the Agency shall send the report on budgetary and financial management to the European Parliament, the Council and the Court of Auditors.
4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽¹⁾, the Executive Director shall draw up the Agency's final accounts under her or his own responsibility and submit them to the Management Board for an opinion.
5. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September. The Executive Director shall also send that reply to the Management Board.
6. The Management Board shall deliver an opinion on the Agency's final accounts.
7. The accounting officer shall, by 1 July following each financial year, send the final accounts, together with the Management Board's opinion, to the European Parliament, the Council, the Commission and the Court of Auditors.
8. The final accounts shall be published in the *Official Journal of the European Union* by 15 November of the following year.
9. The Executive Director shall submit to the European Parliament, at the European Parliament's request, any information required for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 261(3) of Regulation (EU, Euratom) 2018/1046.

⁽¹⁾ 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).

10. On a recommendation from the Council acting by a qualified majority, the European Parliament shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

Article 42

Financial rules

The Management Board shall adopt the financial rules applicable to the Agency after consulting the Commission. The financial rules shall not depart from Delegated Regulation (EU) 2019/715 unless such a departure is specifically required for the Agency's operation and the Commission has given its prior consent.

CHAPTER VII

Staff

Article 43

General provision

1. The Staff Regulations and the Conditions of Employment of Other Servants and the rules adopted by agreement between the institutions of the Union for giving effect to the Staff Regulations and the Conditions of Employment of Other Servants shall apply to the staff of the Agency.
2. Where it engages staff from third countries following the conclusion of the agreements referred to in Article 54, the Agency shall comply with the Staff Regulations and the Conditions of Employment of Other Servants.

Article 44

Seconded national experts and other staff

1. The Agency may make use of seconded national experts or other staff not employed by the Agency. The Staff Regulations and the Conditions of Employment of Other Servants shall not apply to seconded national experts or other staff not employed by the Agency.
2. The Management Board shall adopt a decision laying down rules on the secondment of national experts to the Agency.

CHAPTER VIII

General and final provisions

Article 45

Privileges and immunities

Protocol No 7 on the Privileges and Immunities of the European Union annexed to the TEU and to the TFEU shall apply to the Agency and its staff.

*Article 46***Language arrangements**

Council Regulation No 1 ⁽³²⁾ shall apply to the Agency.

*Article 47***Transparency**

1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.
2. Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽³³⁾ shall apply to the processing of personal data by the Agency.
3. The Management Board shall, within six months of the date of its first meeting after 2 July 2024, establish measures for the application of Regulation (EU) 2018/1725 by the Agency, including those concerning the appointment of the Agency's data protection officer. Those measures shall be established after consultation of the European Data Protection Supervisor.

*Article 48***Combatting fraud**

1. In order to combat fraud, corruption and other unlawful activities, Regulation (EU, Euratom) No 883/2013 shall apply to the Agency.
2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by OLAF by 1 October 2023 and shall adopt appropriate provisions applicable to all employees of the Agency using the template set out in the Annex to that Agreement.
3. The Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds from the Agency.
4. OLAF and EPPO may, within the scope of their mandates, carry out investigations, which, with regard to OLAF, may also include on-the-spot checks and inspections, with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant or a contract funded by the Agency, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 and Council Regulation (Euratom, EC) No 2185/96 ⁽³⁴⁾.
5. Without prejudice to paragraphs 1 to 4 of this Article, working arrangements and agreements with international organisations and third countries as referred to in Articles 53 and 54, contracts, grant agreements and grant decisions of the Agency shall contain provisions expressly empowering the Court of Auditors and OLAF to conduct the audits and investigations referred to in paragraphs 3 and 4 of this Article, in accordance with their respective competence.

⁽³²⁾ Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

⁽³³⁾ 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).

⁽³⁴⁾ Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

*Article 49***Protection of classified and sensitive non-classified information**

1. The Agency shall adopt security rules equivalent to the Commission's security rules for protecting European Union Classified Information (EUCI) and sensitive non-classified information, as set out in Decisions (EU, Euratom) 2015/443 and (EU, Euratom) 2015/444. The security rules of the Agency shall cover, *inter alia*, provisions for the exchange, processing and storage of such information.
2. The Agency may only exchange classified information with the relevant authorities of a third country or international organisation or share EUCI with another Union body, office or agency within the framework of administrative arrangements. Administrative arrangements shall be subject to the authorisation of the Management Board after consultation of the Commission. In the absence of an administrative arrangement, any exceptional ad hoc release of EUCI to another Union body, office or agency shall be subject to a decision by the Executive Director after consultation of the Commission.

*Article 50***Liability**

1. The Agency's contractual liability shall be governed by the law applicable to the contract in question.
2. The Court of Justice of the European Union shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Agency.
3. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its departments or by its staff in the performance of their duties.
4. The Court of Justice of the European Union shall have jurisdiction in disputes over compensation for damages referred to in paragraph 3.
5. The personal liability of its staff towards the Agency shall be governed by the Staff Regulations or Conditions of Employment of Other Servants.

*Article 51***Evaluation and review**

1. By 3 July 2029, and every five years thereafter, the Commission shall assess the Agency's performance in relation to its objectives, mandate, tasks and location in accordance with Commission guidelines. Such evaluations shall, in particular, address the possible need to modify the mandate of the Agency and the financial implications of any such modification. In its first evaluation, the Commission shall pay particular attention to the changes to the Agency's mandate and tasks introduced by this Regulation.
2. On the occasion of every second evaluation, the Commission shall also assess the results achieved by the Agency having regard to its objectives, mandate and tasks, including whether the continuation of the Agency is justified with regard to those objectives, mandate and tasks.
3. The Commission shall report to the European Parliament, the Council and the Management Board on the findings of evaluations under this Article. The findings of evaluations shall be made public.

*Article 52***Administrative inquiries**

The activities of the Agency shall be subject to the inquiries of the European Ombudsman in accordance with Article 228 TFEU.

*Article 53***Cooperation with other organisations and bodies**

1. The Agency shall actively seek to cooperate with international organisations and other bodies, in particular Union, governmental and non-governmental bodies, and with technical bodies competent in matters covered by this Regulation, within the framework of working arrangements concluded with such bodies, in accordance with the TFEU and the provisions on the competence of such bodies. Such working arrangements shall not cover the exchange of classified information.
2. The Management Board shall adopt working arrangements as referred to in paragraph 1 based on drafts submitted by the Executive Director and after the Commission's prior approval. Where the Commission expresses its disagreement with such working arrangements, the Management Board shall adopt them by a three-fourths majority of members with the right to vote.
3. The Management Board shall adopt amendments or changes to existing working arrangements which are limited in scope and do not change the overall scope and intention of the working arrangements, or technical working arrangements with other technical bodies, based on drafts submitted by the Executive Director and after informing the Commission.
4. The Agency shall publish working arrangements entered into pursuant to this Article on its website.

*Article 54***Cooperation with third countries**

1. The Agency shall be open to the participation in its work of third countries that have entered into agreements with the Union to that effect.
2. Under the relevant provisions of the agreements referred to in paragraph 1, arrangements shall be developed specifying, in particular, the nature, extent and manner in which the third countries concerned are to participate in the work of the Agency, including provisions relating to participation in the initiatives undertaken by the Agency, financial contributions and staff.

As regards staff matters, arrangements as referred to in the first subparagraph shall comply with the Staff Regulations.

*Article 55***Cooperation with civil society organisations**

1. The Agency shall maintain cooperation with relevant civil society organisations active in the fields covered by this Regulation at national, Union or international level for the purposes of consultation, the exchange of information and the pooling of knowledge through the involvement of those civil society organisations. To that end, the Agency shall designate a single contact point under the authority of the Executive Director to ensure the regular provision of information to civil society organisations on its activities, including by setting up a dedicated webpage or by other relevant means. The Agency shall allow civil society organisations to submit data and information relevant to its activities.
2. When considering specific topics, the Agency shall, where relevant, conduct dedicated exchanges with civil society organisations with relevant qualifications and experiences on the topic concerned.
3. Civil society organisations as referred to in paragraphs 1 and 2 shall be registered in the Transparency Register, established by the Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register ⁽³⁵⁾. The Agency shall make the list of those civil society organisations public.

⁽³⁵⁾ OJ L 207, 11.6.2021, p. 1.

*Article 56***Headquarters Agreement and operating conditions**

1. The necessary arrangements concerning the accommodation to be provided for the Agency in the Member State in which the Agency has its seat, the facilities to be made available by that Member State and the specific rules applicable in that Member State to members of the Management Board, Agency staff, including the Executive Director, and members of their families shall be laid down in a Headquarters Agreement between the Agency and that Member State.
2. The Member State in which the Agency has its seat shall provide the best possible conditions to ensure the smooth and efficient functioning of the Agency, including multilingual, European-oriented schooling and appropriate transport connections.

*Article 57***Legal succession**

1. The Agency shall be the legal successor in respect of all contracts concluded by, liabilities incumbent upon and properties acquired by the EMCDDA.
2. This Regulation shall not affect the legal force of agreements and arrangements concluded by the EMCDDA before 2 July 2024.

*Article 58***Transitional arrangements concerning the Management Board**

1. The Management Board of the EMCDDA shall continue its work and functioning based on Regulation (EC) No 1920/2006 and the rules established thereunder until all representatives of the Management Board are appointed in accordance with Article 23 of this Regulation.
2. By 1 April 2024, the Member States shall notify the Commission of the names of the persons whom they have appointed as members and alternates of the Management Board in accordance with Article 23.
3. The Management Board established in accordance with Article 23 shall hold its first meeting by 3 August 2024. On that occasion, the Management Board may adopt its rules of procedures.

*Article 59***Transitional arrangements concerning the Executive Director**

1. The Director of the EMCDDA, appointed on the basis of Article 11 of Regulation (EC) No 1920/2006, shall, for the remaining period of her or his term of office, be assigned the responsibilities of Executive Director as provided for in Article 30 of this Regulation. The other conditions of her or his contract shall remain unchanged.

If the term of office of the Director of the EMCDDA ends between 1 July 2023 and 2 July 2024, and if that term has not already been extended under Regulation (EC) No 1920/2006, it shall be extended automatically until 3 July 2025.

2. Where the Director appointed on the basis of Article 11 of Regulation (EC) No 1920/2006 is unwilling or unable to act in accordance with paragraph 1 of this Article, the Management Board shall designate an interim Executive Director to exercise the duties assigned to the Executive Director for a period not exceeding 18 months, pending the appointment of the Executive Director in accordance with Article 29(2).

*Article 60***Transitional arrangements concerning the national focal points**

By 1 June 2024, the members of the Management Board shall provide the Agency with the name of the institutions designated as national focal points in accordance with Article 33(1) and the name of the heads of the national focal points. For that purpose, the members of the Management Board may send an e-mail confirming the current status quo.

*Article 61***Transitional budgetary provisions**

The discharge procedure in respect of the budgets approved on the basis of Article 14 of Regulation (EC) No 1920/2006 shall be carried out in accordance with the rules established by Article 15 of that Regulation.

*Article 62***Repeal of Regulation (EC) No 1920/2006**

1. Regulation (EC) No 1920/2006 is repealed with effect from 2 July 2024. References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in the Annex.
2. Internal rules and measures adopted by the Management Board on the basis of Regulation (EC) No 1920/2006 shall remain in force after 2 July 2024, unless otherwise decided by the Management Board in the application of this Regulation.

*Article 63***Entry into force**

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*. It shall apply from 2 July 2024.

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

Done at Brussels, 27 June 2023.

For the European Parliament
The President
R. METSOLA

For the Council
The President
J. ROSWALL

ANNEX

Correlation table

Regulation (EC) No 1920/2006	This Regulation
Article 1(1)	Article 1
Article 8	Article 2
–	Article 3
Article 1(2)	Article 4
Article 2	Article 5
Article 1(3) and (5), Article 2, points (a), (b) and (c)	Article 6
Annex I	Article 7
Articles 5a to 5d	Articles 8 to 11
–	Article 12
–	Article 13
–	Article 14
–	Article 15
–	Article 16
–	Article 17
–	Article 18
–	Article 19
Article 2(d)	Article 20
–	Article 21
–	Article 22
Article 9(1)	Article 23
–	Article 24
Article 9(2)	Article 25
Article 9(3)	Article 26
Article 9(1), third subparagraph	Article 27
Article 10	Article 28
Article 11	Articles 29 and 30
Article 13	Article 31
Article 5(1)	Article 32
Article 5(3)	Article 33
Article 5(2)	Article 34
–	Article 35
Article 9(4), (5) and (6)	Article 36
Article 14(1) to (4)	Article 37
–	Article 38

Regulation (EC) No 1920/2006	This Regulation
Article 14(5) to (9)	Article 39
Article 15(1)	Article 40
Article 15(2) to (9)	Article 41
–	Article 42
Article 18	Article 43
Article 18, fifth paragraph	Article 44
Article 17	Article 45
–	Article 46
Articles 6 and 7	Article 47
Article 16	Article 48
–	Article 49
Article 19	Article 50
Article 23	Article 51
–	Article 52
Article 20	Article 53
Article 21	Article 54
–	Article 55
–	Article 56
–	Article 57
–	Article 58
–	Article 59
–	Article 60
–	Article 61
Article 24	Article 62
Article 25	Article 63

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2023/1323**of 27 June 2023****on the signing, on behalf of the Union, of the Free Trade Agreement between the European Union and New Zealand**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91(1), Article 100(2) and Article 207(4), first subparagraph, in conjunction with Article 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) On 22 May 2018, the Council authorised the Commission to negotiate a free trade agreement with New Zealand.
- (2) On 30 June 2022, the negotiations for the Free Trade Agreement between the European Union and New Zealand ('the Agreement') were successfully concluded.
- (3) The Agreement should be signed,

HAS ADOPTED THIS DECISION:

*Article 1*The signing, on behalf of the Union, of the Free Trade Agreement between the European Union and New Zealand ('the Agreement') is hereby authorised, subject to the conclusion of the said Agreement. ⁽¹⁾*Article 2*

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Union.

Article 3

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

⁽¹⁾ The text of the Agreement will be published together with the decision on its conclusion.

Done at Luxembourg, 27 June 2023.

For the Council
The President
J. ROSWALL

REGULATIONS

COUNCIL REGULATION (EU) 2023/1324

of 29 June 2023

amending Regulation (EU) 2022/109 fixing for 2022 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in Union waters and for Union fishing vessels in certain non-Union waters, and Regulation (EU) 2023/194 fixing for 2023 the fishing opportunities for certain fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, as well as fixing for 2023 and 2024 such fishing opportunities for certain deep-sea fish stocks

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Council Regulation (EU) 2023/194 ⁽¹⁾ fixes for 2023 the fishing opportunities for certain fish stocks applicable in Union waters and, for Union fishing vessels, in certain non-Union waters. The total allowable catches (TACs) and measures functionally linked to the TACs set by Regulation (EU) 2023/194 should be amended to take into account the publication of scientific advice as well as the outcomes of consultations with third countries.
- (2) Regulation (EU) 2023/194 sets at zero the TAC for anchovy (*Engraulis encrasicolus*) in International Council for the Exploration of the Sea (ICES) subareas 9 and 10 and Union waters of Committee for Eastern Central Atlantic Fisheries (CECAF) division 34.1.1 for the period from 1 July 2023 to 30 June 2024, pending the publication by ICES of its scientific advice for that stock for that period. In order to allow fishing to continue until the definitive TAC for that stock is set on the basis of that scientific advice, a provisional TAC at the level of 4 564 tonnes for the period from 1 July 2023 to 30 September 2023 should be established. That level corresponds to the catches of that stock in the third quarter of 2022.
- (3) On 12 May 2023, the Union, the United Kingdom and Norway held consultations on the level of the fishing opportunities for sprat (*Sprattus sprattus*) in ICES subarea 4 and division 3a for the period from 1 July 2023 to 30 June 2024, as well as on the level of the TACs for sprat for that period in Union and United Kingdom waters of ICES subarea 4 and division 2a and Union and Norwegian waters of ICES division 3a. Those consultations were conducted on the basis of the Union position endorsed by the Council on 4 May 2023. Those TACs should therefore be set at the levels agreed with the United Kingdom and Norway.
- (4) On 4 May 2023, the Union and the United Kingdom held consultations on the level of the TAC for sprat in Union and United Kingdom waters of ICES divisions 7d and 7e for the period from 1 July 2023 to 30 June 2024. Those consultations were conducted pursuant to Article 498(2), (4) and (6) of the Trade and Cooperation Agreement ⁽²⁾ and on the basis of the Union position endorsed by the Council on 27 April 2023. The outcome of those consultations was documented in a Written Record. That TAC should therefore be set at the level agreed with the United Kingdom.

⁽¹⁾ Council Regulation (EU) 2023/194 of 30 January 2023 fixing for 2023 the fishing opportunities for certain fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters, as well as fixing for 2023 and 2024 such fishing opportunities for certain deep-sea fish stocks (OJ L 28, 31.1.2023, p. 1).

⁽²⁾ Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part (OJ L 149, 30.4.2021, p. 10).

- (5) Given that, in relation to several stocks, either their biomass is below the limit biomass reference point ('B_{lim}') or ICES does not define conservation reference points but recommends zero catches or suspending the targeted fishery, the year-to-year flexibility pursuant to Articles 3 and 4 of Council Regulation (EC) No 847/96 ⁽³⁾ should be prohibited in 2023.
- (6) Codes for several conditions regarding Norwegian quotas under TACs included in Part B of Annex IA to Regulation (EU) 2023/194, establishing in what areas Norway may fish quantities available to it, are missing or incorrect. Annex IA to that Regulation should therefore be amended.
- (7) Articles 15 and 17 of Regulation (EU) 2022/2056 of the European Parliament and of the Council ⁽⁴⁾ prohibit to retain on board, tranship, store on a fishing vessel or land any oceanic whitetip shark (*Carcharhinus longimanus*) or any silky shark (*Carcharhinus falciformis*) whole or in part in the area covered by the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC). In order to avoid overlapping provisions on the same subject matter, it is appropriate to delete Article 45 of Regulation (EU) 2023/194.
- (8) Under several recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT), the Union may, upon request, carry over a percentage of its unused quota of stocks in the ICCAT Convention Area from the penultimate or the preceding year to a given year, according to rules for each ICCAT stock as laid down by ICCAT. Council Regulation (EU) 2022/109 ⁽⁵⁾ and Regulation (EU) 2023/194 set Union quotas for ICCAT stocks for 2022 and 2023 respectively in line with the outcome of the ICCAT annual meeting in the preceding year, which take into account the carry-overs of unused Union quotas, where applicable. It should not be possible to combine those carry-overs with the transfers of quotas under Article 4 of Regulation (EC) No 847/96 and the use of such transfers should therefore be prohibited for that period.
- (9) Five Member States transmitted modifications to their farming management plans to the Commission in accordance with Article 6(3) of Regulation (EU) 2016/1627 of the European Parliament and of the Council ⁽⁶⁾. Based on those modifications, the Commission transmitted the modified Union farming management plan for 2023 to the ICCAT Secretariat on 9 May 2023 and ICCAT published those modifications to that Union plan on 11 May 2023. The Union's maximum farming input and capacity should therefore be amended in line with those modifications.
- (10) Regulations (EU) 2023/194 and (EU) 2022/109 should therefore be amended accordingly.
- (11) In order to allow fishing to continue on 1 July 2023 and beyond, this Regulation should enter into force without delay.
- (12) The provisions of this Regulation amending certain provisions of Regulation (EU) 2023/194 should apply from 1 January 2023, in line with the application period of those amended provisions. The provisions of this Regulation concerning fishing opportunities for anchovy and sprat and the deletion of Article 45 of Regulation (EU) 2023/194 should apply from 1 July 2023. The provisions of this Regulation concerning ICCAT and amending certain provisions of Regulation (EU) 2022/109 should apply from 1 January 2022, in line with the application period of those amended provisions. Such retroactive application does not affect the principles of legal certainty and protection of legitimate expectations, as either the fishing opportunities concerned are increased by those amendments or the relevant quantities have not yet been transferred under Article 4(2) of Regulation (EC) No 847/96,

⁽³⁾ Council Regulation (EC) No 847/96 of 6 May 1996 introducing additional conditions for year-to-year management of TACs and quotas (OJ L 115, 9.5.1996, p. 3).

⁽⁴⁾ Regulation (EU) 2022/2056 of the European Parliament and of the Council of 19 October 2022 laying down conservation and management measures applicable in the Western and Central Pacific Fisheries Convention Area and amending Council Regulation (EC) No 520/2007 (OJ L 276, 26.10.2022, p. 1).

⁽⁵⁾ Council Regulation (EU) 2022/109 of 27 January 2022 fixing for 2022 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in Union waters and for Union fishing vessels in certain non-Union waters (OJ L 21, 31.1.2022, p. 1).

⁽⁶⁾ Regulation (EU) 2016/1627 of the European Parliament and of the Council of 14 September 2016 on a multiannual recovery plan for bluefin tuna in the eastern Atlantic and the Mediterranean, and repealing Council Regulation (EC) No 302/2009 (OJ L 252, 16.9.2016, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Amendment of Regulation (EU) 2023/194

Regulation (EU) 2023/194 is amended as follows:

- (a) Article 45 is deleted;
- (b) Annexes IA and ID are amended in accordance with Annex I to this Regulation;
- (c) Annex VI is amended in accordance with Annex II to this Regulation.

Article 2

Amendment of Regulation (EU) 2022/109

Annex ID of Regulation (EU) 2022/109 is amended in accordance with Annex III to this Regulation.

Article 3

Entry into force and application

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

It shall apply from 1 January 2023. However:

- (a) Article 2 shall apply from 1 January 2022;
- (b) Article 1, point (a), shall apply from 1 July 2023;
- (c) In Annex I, point 1, subpoints (a) and (b), shall apply from 1 July 2023.

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

Done at Brussels, 29 June 2023.

For the Council
The President
J. ROSWALL

ANNEX I

The Annexes to Regulation (EU) 2023/194 are amended as follows:

(1) in Annex IA:

- (a) in Part A, the table for anchovy (*Engraulis encrasicolus*) in ICES subareas 9 and 10 and Union waters of CECAF 34.1.1 is replaced by the following:

‘Species: Anchovy <i>Engraulis encrasicolus</i>		Zone: 9 and 10; Union waters of CECAF 34.1.1 (ANE/9/3411)	
Spain	2 183	(1)	Precautionary TAC
Portugal	2 381	(1)	
Union	4 564	(1)	
TAC	4 564	(1)	
(1) This quota may only be fished from 1 July 2023 to 30 September 2023.’;			

- (b) in Part B, the tables for the stocks listed below are replaced by the following:

- (i) the table for sprat and associated by-catches (*Sprattus sprattus*) in ICES division 3a is replaced by the following:

‘Species: Sprat and associated by-catches <i>Sprattus sprattus</i>		Zone: 3a (SPR/03A.)	
Denmark	17 608	(1)(2)(3)	Analytical TAC
Germany	37	(1)(2)(3)	
Sweden	6 662	(1)(2)(3)	
Union	24 307	(1)(2)(3)	
TAC	26 278	(2)	
(1) Up to 5 % of the quota may consist of by-catches of whiting and haddock (OTH/*03A.). By-catches of whiting and haddock counted against the quota pursuant to this provision and by-catches of species counted against the quota pursuant to Article 15(8) of Regulation (EU) No 1380/2013 shall, together, not exceed 9 % of the quota.			
(2) This quota may only be fished from 1 July 2023 to 30 June 2024.			
(3) Transfers of this quota may be effected to United Kingdom and Union waters of 2a and 4. However, such transfers shall be notified in advance to the Commission and to the United Kingdom.’;			

- (ii) the table for sprat and associated by-catches (*Sprattus sprattus*) in United Kingdom and Union waters of ICES subarea 4 and United Kingdom waters of ICES division 2a is replaced by the following:

'Species:	Sprat and associated by-catches <i>Sprattus sprattus</i>		Zone:	United Kingdom and Union waters of 4; United Kingdom waters of 2a (SPR/2AC4-C)
Belgium	1 221	(1)(2)	Analytical TAC	
Denmark	96 624	(1)(2)		
Germany	1 221	(1)(2)		
France	1 221	(1)(2)		
Netherlands	1 221	(1)(2)		
Sweden	1 330	(1)(2)(3)		
Union	102 838	(1)(2)		
Norway	10 000	(1)		
Faroe Islands	0	(1)(4)		
United Kingdom	4 482	(1)		
TAC	117 320	(1)		
(1)	The quota may only be fished from 1 July 2023 to 30 June 2024.			
(2)	Up to 2 % of the quota may consist of by-catches of whiting (OTH/*2AC4C). By-catches of whiting counted against the quota pursuant to this provision and by-catches of species counted against the quota pursuant to Article 15(8) of Regulation (EU) No 1380/2013 shall, together, not exceed 9 % of the quota.			
(3)	Including sandeels.			
(4)	May contain up to 4 % of by-catch of herring.;			

- (iii) the table for sprat (*Sprattus sprattus*) in ICES divisions 7d and 7e is replaced by the following:

'Species:	Sprat <i>Sprattus sprattus</i>		Zone:	7d and 7e (SPR/7DE.)
Belgium	5	(1)	Analytical TAC	
Denmark	341	(1)		
Germany	5	(1)		
France	73	(1)		
Netherlands	73	(1)		
Union	497	(1)		
United Kingdom	1 940	(1)		
TAC	2 437	(1)		
(1)	The quota may only be fished from 1 July 2023 to 30 June 2024.;			

- (c) in Parts B and F, in the tables for: (i) herring (*Clupea harengus*) in ICES divisions 7a south of 52°30'N, 7g, 7h, 7j and 7k; (ii) whiting (*Merlangius merlangus*) in ICES divisions 7b, 7c, 7d, 7e, 7f, 7g, 7h, 7j and 7k; (iii) blue ling (*Molva dypterygia*) in international waters of ICES subarea 12; (iv) blue ling in United Kingdom and international waters of ICES subarea 2 and United Kingdom and Union waters of ICES subarea 4; (v) blue ling in Union waters of ICES division 3a; (vi) northern prawn (*Pandalus borealis*) in United Kingdom and Union waters of ICES subarea 4 and United Kingdom waters of ICES division 2a; and (vii) red seabream (*Pagellus bogaraveo*) in ICES subareas 6, 7 and 8, the following is inserted:

'Article 3 of Regulation (EC) No 847/96 shall not apply.

Article 4 of Regulation (EC) No 847/96 shall not apply.';

- (d) in Part B:

- (i) in footnote 2 of the table for herring (*Clupea harengus*) in Union, United Kingdom and Norwegian waters of ICES subarea 4 north of 53°30' N, the code is replaced by the following:

'HER/*04B-C';

- (ii) in footnote 2 of the table for cod (*Gadus morhua*) in ICES subarea 4, United Kingdom waters of ICES division 2a, the part of division 3a not covered by the Skagerrak and Kattegat, at the end of the first sentence, the following code is inserted:

'(COD/*3AX4-EU);

- (iii) in footnote 2 of the table for haddock (*Melanogrammus aeglefinus*) in ICES subarea 4, United Kingdom waters of ICES division 2a, at the end of the first sentence, the following code is inserted:

'(HAD/*04-EU);

- (iv) in footnote 1 of the table for whiting (*Merlangius merlangus*) in ICES subarea 4, United Kingdom waters of ICES division 2a, at the end of the first sentence, the following code is inserted:

'(WHG/*04-EU);

- (v) in footnote 4 of the table for blue whiting (*Micromesistius poutassou*) in United Kingdom, Union and international waters of ICES zones 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 8d, 8e, 12 and 14, '2a,' is deleted and, at the end of the sentence, the following code is inserted:

'(WHB/*46AB7-EU);

- (vi) in footnote 5 of the table for blue whiting (*Micromesistius poutassou*) in United Kingdom, Union and international waters of ICES zones 1, 2, 3, 4, 5, 6, 7, 8a, 8b, 8d, 8e, 12 and 14, '2a,' is deleted and, after '12° W', the following code is inserted:

'(WHB/*46AB7);

- (vii) in footnote 1 of the table for plaice (*Pleuronectes platessa*) in ICES subarea 4, United Kingdom waters of ICES division 2a, the part of division 3a not covered by the Skagerrak and the Kattegat, at the end of the first sentence, the following code is inserted:

'(PLE/*3AX4-EU);

- (2) in Annex ID, in the tables for: (i) northern albacore (*Thunnus alalunga*) in the Atlantic Ocean, north of 5° N; (ii) southern albacore in the Atlantic Ocean, south of 5° N; (iii) bigeye tuna (*Thunnus obesus*) in the Atlantic Ocean; (iv) swordfish (*Xiphias gladius*) in the Atlantic Ocean, north of 5° N; and (v) swordfish in the Atlantic Ocean, south of 5° N, the following is inserted:

'Article 3 of Regulation (EC) No 847/96 shall not apply.

Article 4 of Regulation (EC) No 847/96 shall not apply.'.

ANNEX II

In Annex VI to Regulation (EU) 2023/194, point 6 is replaced by the following:

- ‘6. Maximum bluefin tuna farming capacity and fattening capacity for each Member State and maximum input of wild-caught bluefin tuna that each Member State may allocate to its farms in the Eastern Atlantic and Mediterranean

Table A

Maximum tuna farming capacity and fattening capacity		
	Number of farms	Capacity (in tonnes)
Greece	2	2 100,00
Spain	4	11 852,00
Croatia	4	7 880,00
Italy	2	9 370,00
Cyprus	0	0
Malta	6	16 579,65
Portugal	2	500,00

Table B

Maximum input of wild-caught bluefin tuna (in tonnes)	
Greece	649,00
Spain	8 237,93
Croatia	2 947,00
Italy	1 100,00
Cyprus	0
Malta	11 842,61
Portugal	350,00’.

ANNEX III

In Annex ID to Regulation (EU) 2022/109, in the tables for: (i) northern albacore (*Thunnus alalunga*) in the Atlantic Ocean, north of 5° N; (ii) southern albacore in the Atlantic Ocean, south of 5° N; (iii) bigeye tuna (*Thunnus obesus*) in the Atlantic Ocean; (iv) swordfish (*Xiphias gladius*) in the Atlantic Ocean, north of 5° N; and (v) swordfish in the Atlantic Ocean, south of 5° N, the following is inserted:

‘Article 3 of Regulation (EC) No 847/96 shall not apply.

Article 4 of Regulation (EC) No 847/96 shall not apply.’.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1325**of 23 June 2023****approving amendments to the specification for a Protected Designation of Origin or a Protected Geographical Indication ('Extremadura' (PGI))**

THE EUROPEAN COMMISSION,

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

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 ⁽¹⁾, and in particular Article 99 thereof,

Whereas:

- (1) The Commission has examined the application for the approval of amendments to the specification for the Protected Geographical Indication 'Extremadura', forwarded by Spain in accordance with Article 105 of Regulation (EU) No 1308/2013.
- (2) The Commission has published the application for the approval of the amendments to the specification in the *Official Journal of the European Union* ⁽²⁾, as required by Article 97(3) of Regulation (EU) No 1308/2013.
- (3) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (4) The amendments to the specification should therefore be approved in accordance with Article 99 of Regulation (EU) No 1308/2013.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Extremadura' (PGI) are hereby approved.

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*.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ C 40, 2.2.2023, p. 8.

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

Done at Brussels, 23 June 2023.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1326**of 23 June 2023****approving amendments to the specification for a Protected Designation of Origin or a Protected Geographical Indication ('Balaton / Balatoni' (PDO))**

THE EUROPEAN COMMISSION,

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

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 ⁽¹⁾, and in particular Article 99 thereof,

Whereas:

- (1) The Commission has examined the application for the approval of amendments to the specification for the Protected Designation of Origin 'Balaton / Balatoni', forwarded by Hungary in accordance with Article 105 of Regulation (EU) No 1308/2013.
- (2) The Commission has published the application for the approval of the amendments to the specification in the *Official Journal of the European Union* ⁽²⁾, as required by Article 97(3) of Regulation (EU) No 1308/2013.
- (3) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (4) The amendments to the specification should therefore be approved in accordance with Article 99 of Regulation (EU) No 1308/2013.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Balaton / Balatoni' (PDO) are hereby approved.

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*.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ C 114, 29.3.2023, p. 12.

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

Done at Brussels, 23 June 2023.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1327**of 23 June 2023****conferring protection under Article 99 of Regulation (EU) No 1308/2013 of the European Parliament
and of the Council on the name ‘Canelli’ (PDO)**

THE EUROPEAN COMMISSION,

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

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 ⁽¹⁾, and in particular Article 99 thereof,

Whereas:

- (1) In accordance with Article 97(2) and (3) of Regulation (EU) No 1308/2013, the Commission has examined the application to register the name ‘Canelli’ forwarded by Italy and has published it in the *Official Journal of the European Union* ⁽²⁾.
- (2) No statement of objection has been received by the Commission under Article 98 of Regulation (EU) No 1308/2013.
- (3) In accordance with Article 99 of Regulation (EU) No 1308/2013, the name ‘Canelli’ should be protected and entered in the register referred to in Article 104 of that Regulation.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The name ‘Canelli’ (PDO) is hereby protected.

*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, 23 June 2023.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ C 43, 6.2.2023, p. 5.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1328**of 28 June 2023****amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin**

THE EUROPEAN COMMISSION,

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

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 ⁽¹⁾, and in particular Article 183(b) thereof,

Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 ⁽²⁾, and in particular Article 5(6)(a) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1484/95 ⁽³⁾ lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.
- (2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.
- (3) Regulation (EC) No 1484/95 should therefore be amended accordingly.
- (4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 150, 20.5.2014, p. 1.

⁽³⁾ Commission Regulation (EC) No 1484/95 of 28 June 1995 laying down detailed rules for implementing the system of additional import duties and fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and repealing Regulation No 163/67/EEC (OJ L 145, 29.6.1995, p. 47).

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

Done at Brussels, 28 June 2023.

*For the Commission,
On behalf of the President,
Wolfgang BURTSCHER
Director-General
Directorate-General for Agriculture and Rural
Development*

ANNEX

‘ANNEX I

CN code	Description	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin ⁽¹⁾
0207 14 10	Fowls of the species <i>Gallus domesticus</i> , boneless cuts, frozen	243,3	17	BR

⁽¹⁾ Nomenclature laid down by Commission Implementing Regulation (EU) 2020/1470 of 12 October 2020 on the nomenclature of countries and territories for the European statistics on international trade in goods and on the geographical breakdown for other business statistics (OJ L 334, 13.10.2020, p. 2).’

COMMISSION REGULATION (EU) 2023/1329**of 29 June 2023****amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycerol polyricinoleate (E 476) and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476)****(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) and Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012 ⁽³⁾ lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) The Union lists of food additives and the specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (4) Glycerol (E 422), polyglycerol esters of fatty acids (E 475) and polyglycerol polyricinoleate (E 476) are substances authorised in accordance with Annexes II and III to Regulation (EC) No 1333/2008.
- (5) On 15 March 2017, the European Food Safety Authority ('the Authority') issued a scientific opinion on the re-evaluation of glycerol (E 422) as a food additive ⁽⁴⁾, which concluded that there was no need for a numerical acceptable daily intake and that the food additive was of no safety concern for the reported uses. The Authority recommended some modifications to the specifications for E 422 set out in Regulation (EU) No 231/2012 and that more information on the uses and use levels is made available to the Authority.
- (6) On 23 November 2018, the Commission launched a public call for technical data on the food additive glycerol (E 422), targeting the data needs identified by the Authority.
- (7) Following the data submission by interested business operators, the Commission requested the Authority to provide a scientific opinion to confirm that the technical data provided by interested business operators adequately supported an amendment to the specifications for the food additive glycerol (E 422) to bring them in line with current standards, as recommended by the Authority.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁴⁾ EFSA Journal 2017;15(3):4720.

- (8) In its scientific opinion adopted on 18 May 2022 ⁽⁵⁾, the Authority concluded that the current specifications for glycerol (E 422) were to be adapted in particular by reducing the maximum limits for toxic elements (arsenic, lead, mercury and cadmium), by deleting the identification method based on acrolein formation during heating, by deleting the test for the presence of acrolein, by including a maximum limit for acrolein and by modifying the definition of glycerol (E 422).
- (9) It is therefore appropriate to amend the specifications for glycerol (E 422). The definition of the food additive should be amended to restrict it to the manufacturing processes for which data were assessed by the Authority. The current maximum limits for toxic elements should be reduced in accordance with the scientific opinion of the Authority, taking into account the currently achievable levels by the application of good manufacturing practices. The identification method for glycerol based on acrolein formation during heating should be deleted considering that the content of glycerol in E 422 is to be determined by an appropriate analytical method. The test for the presence of acrolein should be deleted and a maximum numerical limit for acrolein should be included in accordance with the scientific opinion of the Authority and taking into account the level which is currently achievable by the application of good manufacturing practices.
- (10) Considering that the Authority did not identify an immediate health concern linked to the presence of toxic elements and acrolein, it is appropriate to allow during a transitional period the use of the food additive glycerol (E 422) lawfully placed on the market before the date of the entry into force of this Regulation.
- (11) For the same reasons, it is appropriate that foods containing the food additive glycerol (E 422) that has been lawfully placed on the market before the date of entry into force of this Regulation may continue to be placed on the market during a transitional period and to remain on the market until their date of minimum durability or 'use-by-date'.
- (12) On 20 December 2017, the Authority issued a scientific opinion on the re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive ⁽⁶⁾, which concluded that there was no need for a numerical acceptable daily intake and that the food additive was of no safety concern at the reported uses and use levels. The Authority recommended some modifications to the specifications for E 475 set out in Regulation (EU) No 231/2012.
- (13) On 23 November 2018, the Commission launched a public call for technical data on the food additive polyglycerol esters of fatty acids (E 475), targeting the data needs identified by the Authority.
- (14) Following the data submission by interested business operators, the Commission requested the Authority to provide a scientific opinion to confirm that the technical data provided by interested business operators adequately supported an amendment to the specifications for the food additive polyglycerol esters of fatty acids (E 475) to bring them in line with current standards, as recommended by the Authority.
- (15) In its scientific opinion adopted on 1 April 2022 ⁽⁷⁾, the Authority concluded that the current specifications for polyglycerol esters of fatty acids (E 475) were to be adapted in particular by reducing the maximum limits for toxic elements, by including maximum limits for impurities and constituents of safety concern and by modifying the definition of polyglycerol esters of fatty acids (E 475).
- (16) It is therefore appropriate to amend the specifications for polyglycerol esters of fatty acids (E 475). The definition of the food additive should be amended in order to restrict the use of glycerol for the production of the food additive to glycerol compliant with the specifications for the food additive (E 422). The current maximum limits for toxic elements should be reduced and maximum limits for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD), glycidyl fatty acid esters (expressed as glycidol) and erucic acid should be established in accordance with the scientific opinion of the Authority and taking into account the level which is currently achievable by the application of good manufacturing practices.

⁽⁵⁾ EFSA Journal 2022;20(6):7353.

⁽⁶⁾ EFSA Journal 2017;15(12):5089.

⁽⁷⁾ EFSA Journal 2022;20(5):7308.

- (17) As new manufacturing techniques resulting in the production of the food additive polyglycerol esters of fatty acids (E 475) with lower levels of glycidyl fatty acid esters (expressed as glycidol) are being implemented, it is appropriate to provide the manufacturers of food additives with a transitional period to reach a maximum level of 5 mg/kg for glycidyl fatty acid esters (expressed as glycidol) in the food additive (E 475). However, given that glycidyl fatty acid esters are genotoxic and carcinogenic, an intermediate maximum level of 10 mg/kg for glycidyl fatty acid esters (expressed as glycidol) should apply from the date of entry into force of this Regulation.
- (18) Considering that the Authority did not identify an immediate health concern linked to the presence of toxic elements, 3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters, erucic acid and glycidyl fatty acid esters, it is appropriate to allow during a transitional period the use of the food additive polyglycerol esters of fatty acids (E 475) lawfully placed on the market before the date of entry into force of this Regulation and to allow foods containing such food additive, to continue to be placed on the market for the same transitional period and to remain on the market until their date of minimum durability or 'use-by-date'.
- (19) For the same reasons and considering its reduced content of glycidyl fatty acid esters, the food additive polyglycerol esters of fatty acids (E 475) legally placed on the market after the date of entry into force of this Regulation and complying with the reduced intermediate maximum level for glycidyl fatty acid esters (expressed as glycidol) should be allowed to be used until the exhaustion of stocks and foods containing such food additive should be allowed to be placed on the market and to remain on the market until their date of minimum durability or 'use-by-date'.
- (20) On 24 March 2017, the Authority issued a scientific opinion on the re-evaluation of polyglycerol polyricinoleate (E 476) as a food additive ⁽⁸⁾. The Authority concluded that the data set gave reason to increase the acceptable daily intake to 25 mg/kg bw per day. The Authority recommended some modifications to the specifications for E 476 set out in Regulation (EU) No 231/2012.
- (21) On 23 November 2018, the Commission launched a public call for technical data on the food additive polyglycerol polyricinoleate (E 476), targeting the data needs identified by the Authority.
- (22) On 18 March 2020, an application was submitted for the authorisation of the use of polyglycerol polyricinoleate (E 476) as an emulsifier in edible ices for fat and oil emulsion of water-in-oil type and emulsified sauces with a fat content of more than 20 %. The application was subsequently made available to the Member States by the Commission pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (23) Polyglycerol polyricinoleate (E 476) is capable of producing stable water-in-oil emulsions with smaller droplet sizes that can be frozen to produce soft, creamy, edible ices requiring less energy in the manufacturing process and having enhanced stability in the frozen supply chain. It allows the use of low saturated fats and oils and lower amounts of sugars in edible ices. The level of polyglycerol polyricinoleate (E 476) needed to achieve the intended technological function is 4 000 mg/kg.
- (24) Polyglycerol polyricinoleate (E 476) also enables oil reduction in emulsified sauces (e.g. mayonnaise or salad dressings) without having the negative effect on mouthfeel. The currently authorised maximum level of 4 000 mg/kg is not sufficient for products with a fat content of more than 20 %. The level of use of polyglycerol polyricinoleate (E 476) needed to achieve the intended technological function in products with a fat content of more than 20 % is 8 000 mg/kg.
- (25) Following the data submission by interested business operators in response to the public call for technical data and the submission of the application on the extension of use of polyglycerol polyricinoleate (E 476), the Commission requested the Authority to provide a scientific opinion to confirm that the technical data provided by interested business operators adequately supported an amendment to the specifications for the food additive polyglycerol polyricinoleate (E 476) to bring them in line with current standards, as recommended by the Authority.

⁽⁸⁾ EFSA Journal 2017;15(3):4743.

- (26) In its scientific opinion adopted on 30 March 2022 ⁽⁹⁾, the Authority concluded that the proposed extension of use would not give rise to a safety concern. The Authority also concluded that the current specifications for polyglycerol polyricinoleate (E 476) were to be adapted in particular by reducing the maximum limits for toxic elements, by including maximum limits for impurities of safety concern and by modifying the definition of polyglycerol polyricinoleate (E 476).
- (27) It is therefore appropriate to authorise polyglycerol polyricinoleate (E 476) in food category 03 'Edible ices' at a maximum level of 4 000 mg/kg, increase the authorised maximum level in food category 12.6 'Sauces' to 8 000 mg/kg for emulsified sauces with a fat content of 20 % or more and amend its specifications in light of the Authority's scientific opinion. The definition of the food additive should be amended in order to restrict the use of glycerol for the production of the food additive to glycerol compliant with the specifications for the food additive (E 422). The current maximum limits for toxic elements should be reduced and maximum limits for the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) and glycidyl fatty acid esters (expressed as glycidol) should be established in accordance with the scientific opinion of the Authority and taking into account the level which is currently achievable by the application of good manufacturing practices.
- (28) Considering that the Authority did not identify an immediate health concern linked to the presence of toxic elements, 3-monochloropropanediol (3-MCPD), 3-MCPD fatty acid esters and glycidyl fatty acid esters, it is appropriate to allow during a transitional period the use of the food additive polyglycerol polyricinoleate (E 476) lawfully placed on the market before the date of entry into force of this Regulation.
- (29) For the same reasons, it is appropriate that foods containing the food additive polyglycerol polyricinoleate (E 476) that has been lawfully placed on the market before the date of entry into force of this Regulation may continue to be placed on the market during a transitional period and to remain on the market until their date of minimum durability or 'use-by-date'.
- (30) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (31) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

The food additive glycerol (E 422) that has been lawfully placed on the market before 20 July 2023 and that does not comply with the maximum limits for arsenic, lead, mercury, cadmium or acrolein applicable from 20 July 2023 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until 20 January 2024.

Foods containing the food additive glycerol (E 422) that has been lawfully placed on the market before 20 July 2023 and that does not comply with the maximum limits for arsenic, lead, mercury, cadmium or acrolein applicable from 20 July 2023 may continue to be placed on the market until 20 January 2024 and may continue to be marketed until their date of minimum durability or 'use-by date'.

⁽⁹⁾ EFSA Journal 2022;20(5):7294.

The food additive polyglycerol esters of fatty acids (E 475) that has been lawfully placed on the market before 20 July 2023 and that does not comply with the maximum limits for arsenic, lead, mercury, cadmium, the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD), erucic acid or glycidyl fatty acids esters (expressed as glycidol) applicable from 20 July 2023 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until 20 January 2024.

Foods containing the food additive polyglycerol esters of fatty acids (E 475) that has been lawfully placed on the market before 20 July 2023 and that does not comply with the maximum limits arsenic, lead, mercury, cadmium, the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD), erucic acid or for glycidyl fatty acids esters (expressed as glycidol) applicable from 20 July 2023 may continue to be placed on the market until 20 January 2024 and may continue to be marketed until their date of minimum durability or 'use-by date'.

The food additive polyglycerol esters of fatty acids (E 475) that has been lawfully placed on the market after 20 July 2023 and up to 20 January 2024 and that does not comply with the maximum limits for glycidyl fatty acids esters (expressed as glycidol) applicable from 20 January 2024 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

Foods containing the food additive polyglycerol esters of fatty acids (E 475) that has been lawfully placed on the market after 20 July 2023 and up to 20 January 2024 and that does not comply with the maximum limits for glycidyl fatty acids esters (expressed as glycidol) applicable from 20 January 2024 may continue to be placed on the market and may continue to be marketed until their date of minimum durability or 'use by date'.

The food additive polyglycerol polyricinoleate (E 476) that has been lawfully placed on the market before 20 July 2023 and that does not comply with the maximum limits for arsenic, lead, mercury, cadmium, the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) or glycidyl fatty acids esters (expressed as glycidol) applicable from 20 July 2023 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until 20 January 2024.

Foods containing the food additive polyglycerol polyricinoleate (E 476) that has been lawfully placed on the market before 20 July 2023 and that does not comply with the maximum limits for arsenic, lead, mercury, cadmium, the sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD) or glycidyl fatty acids esters (expressed as glycidol) applicable from 20 July 2023 may continue to be placed on the market until 20 January 2024 and may continue to be marketed until their date of minimum durability or 'use-by date'.

Article 4

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, 29 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Part E of Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) in Category 03 (Edible ices), the following entry is inserted after the entry for E 473–474:

	E 476	Polyglycerol polyricinoleate	4 000		except sorbets'
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(2) in Category 12.6 (Sauces), the entry for E 476 (Polyglycerol polyricinoleate) is replaced by the following:

	E 476	Polyglycerol polyricinoleate	4 000		only emulsified sauces with a fat content of less than 20 %
	E 476	Polyglycerol polyricinoleate	8 000		only emulsified sauces with a fat content of 20 % or more'

ANNEX II

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) the entry for food additive E 422 Glycerol is replaced by the following:

E 422 GLYCEROL	
Synonyms	Glycerin; Glycerine
Definition	Glycerol is obtained only from vegetable oils and fats, either directly or from the crude glycerol obtained as a by-product of biodiesel production and undergoes purification processes that involve distillation, and other clean up steps to obtain refined glycerol.
Einecs	200-289-5
Chemical name	1,2,3-propanetriol; Glycerol; Trihydroxypropane
Chemical formula	C ₃ H ₈ O ₃
Molecular weight	92,10
Assay	Content not less than 98 % of glycerol on the anhydrous basis
Description	Clear, colourless hygroscopic syrupy liquid with not more than a slight characteristic odour, which is neither harsh nor disagreeable
Identification	
Specific gravity (25 °C/25 °C)	Not less than 1,257
Refractive index	[n] _D ²⁰ between 1,471 and 1,474
Purity	
Water content	Not more than 5 % (Karl Fischer method)
Sulphated ash	Not more than 0,01 % determined at 800 ± 25 °C
Butanetriols	Not more than 0,2 %
Acrolein	Not more than 3 mg/kg
Fatty acids and esters	Not more than 0,1 % calculated as butyric acid
Chlorinated compounds	Not more than 30 mg/kg (as chlorine)
3-Monochloropropane-1,2-diol (3- MCPD)	Not more than 0,1 mg/kg
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg'

(2) the entry for food additive E 475 Polyglycerol esters of fatty acids is replaced by the following:

E 475 POLYGLYCEROL ESTERS OF FATTY ACIDS

Synonyms	Polyglycerol fatty acid esters; Polyglycerin esters of fatty acid esters
Definition	Polyglycerol esters of fatty acids are produced by the esterification of polyglycerol with food fats and oils or with fatty acids occurring in foods fats and oils. The polyglycerol moiety is predominantly di-, tri- and tetraglycerol and contains not more than 10 % of polyglycerols equal to or higher than heptaglycerol. The polyglycerol is produced from glycerol complying with the specifications for E 422.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	Content of total fatty acid ester not less than 90 %
Description	Light yellow to amber, oily to very viscous liquids; light tan to medium brown, plastic or soft solids; and light tan to brown, hard, waxy solids
Identification	
Test for glycerol	Passes test
Test for polyglycerols	Passes test
Test for fatty acids	Passes test
Solubility	The esters range from very hydrophilic to very lipophilic, but as a class tend to be dispersible in water and soluble in organic solvents and oils
Purity	
Sulphated ash	Not more than 0,5 % (800 ± 25 °C)
Acids other than fatty acids	Less than 1 %
Free fatty acids	Not more than 6 % estimated as oleic acid
Total glycerol and polyglycerol	Not less than 18 % and not more than 60 %
Free glycerol and polyglycerol	Not more than 7 %
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,3 mg/kg
Mercury	Not more than 0,1 mg/kg

Cadmium	Not more than 0,1 mg/kg
Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters, expressed as 3-MCPD	Not more than 2,5 mg/kg
Glycidyl fatty acid esters, expressed as glycidol	Not more than 10 mg/kg. This applies from 20 July 2023 until 20 January 2024. Not more than 5 mg/kg. This applies from 20 January 2024.
Erucic acid	Not more than 2 %

Purity criteria apply to the additive free of sodium, potassium and calcium salts of fatty acids, however these substances may be present up to a maximum level of 6 % (expressed as sodium oleate).';

(3) the entry for food additive E 476 Polyglycerol polyricinoleate is replaced by the following:

E 476 POLYGLYCEROL POLYRICINOLEATE	
Synonyms	Glycerol esters of condensed castor oil fatty acids; Polyglycerol esters of polycondensed fatty acids from castor oil; Polyglycerol esters of interesterified ricinoleic acid; PGPR
Definition	Polyglycerol polyricinoleate is prepared by the esterification of polyglycerol with condensed castor oil fatty acids. Castor oil used for the production of polyglycerol polyricinoleate is free of ricin. The polyglycerol is produced from glycerol complying with the specifications for E 422.
Einecs	
Chemical name	
Chemical formula	
Molecular weight	
Assay	
Description	Clear, highly viscous liquid
Identification	
Solubility	Insoluble in water and in ethanol; soluble in ether, hydrocarbons and halogenated hydrocarbons
Test for glycerol	Passes test
Test for polyglycerols	Passes test
Test for ricinoleic acid	Passes test
Refractive index	$[n]_D^{65}$ between 1,4630 and 1,4665
Purity	
Polyglycerols	The polyglycerol moiety shall be composed of not less than 75 % of di-, tri- and tetraglycerols and shall contain not more than 10 % of polyglycerols equal to or higher than heptaglycerol
Hydroxyl value	Not less than 80 and not more than 100

Acid value	Not more than 6
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Sum of 3-monochloropropanediol (3-MCPD) and 3-MCPD fatty acid esters (expressed as 3-MCPD)	Not more than 2,5 mg/kg
Glycidyl fatty acid esters (expressed as glycidol)	Not more than 1 mg/kg'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1330**of 29 June 2023****imposing a definitive anti-dumping duty on imports of certain lightweight thermal paper originating in the Republic of Korea following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ⁽¹⁾ ('the basic Regulation'), and in particular Article 11(2) thereof,

Whereas:

1. PROCEDURE**1.1. Previous investigations and measures in force**

- (1) By Implementing Regulation (EU) 2017/763 ⁽²⁾, the European Commission ('the Commission') imposed anti-dumping duties on imports of certain lightweight thermal paper originating in the Republic of Korea ('the original measures'). The investigation that led to the imposition of the original measures will hereinafter be referred to as 'the original investigation'. The measures took the form of fixed duty rates at the level of EUR 104,46 per tonne net, for both the sole cooperating exporting group and for all other companies.
- (2) The judgments in cases T-383/17 ⁽³⁾ and C-260/20 P ⁽⁴⁾ entailed the annulment of the measures for the sole cooperating exporting group. By Implementing Regulation (EU) 2023/593 ⁽⁵⁾, the European Commission re-imposed the anti-dumping duties on imports of certain lightweight thermal paper originating in the Republic of Korea at the revised level of EUR 103,16 per tonne net, for both the sole cooperating exporting group and for all other companies.

1.2. Request for an expiry review

- (3) Following the publication of a notice of impending expiry ⁽⁶⁾ the Commission received a request for a review pursuant to Article 11(2) of the basic Regulation.
- (4) The request for review was submitted on 1 February 2022 by the European Thermal Paper Association ('the applicant') on behalf of the Union industry of certain lightweight thermal paper in the sense of Article 5(4) of the basic Regulation. The request for review was based on the grounds that the expiry of the measures would be likely to result in continuation or recurrence of dumping and continuation or recurrence of injury to the Union industry.

⁽¹⁾ OJ L 176, 30.6.2016, p. 21.

⁽²⁾ Commission Implementing Regulation (EU) 2017/763 of 2 May 2017 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain lightweight thermal paper originating in the Republic of Korea (OJ L 114, 3.5.2017, p. 3).

⁽³⁾ ECLI:EU:T:2020:139.

⁽⁴⁾ ECLI:EU:C:2022:370.

⁽⁵⁾ Commission Implementing Regulation (EU) 2023/593 of 16 March 2023 re-imposing a definitive anti-dumping duty on imports of certain lightweight thermal paper originating in the Republic of Korea as regards the Hansol Group and amending the residual duty (OJ L 79, 17.3.2023, p. 54).

⁽⁶⁾ OJ C 314, 6.8.2021, p. 9.

1.3. Initiation of an expiry review

- (5) Having determined, after consulting the Committee established by Article 15(1) of the basic Regulation, that sufficient evidence existed for the initiation of an expiry review, on 3 May 2022 the Commission initiated an expiry review with regard to imports into the Union of certain lightweight thermal paper originating in the Republic of Korea ('the country concerned') on the basis of Article 11(2) of the basic Regulation. It published a Notice of Initiation in the *Official Journal of the European Union* ⁽⁷⁾ ('the Notice of Initiation').

1.4. Review investigation period and period considered

- (6) The investigation of continuation or recurrence of dumping covered the period from 1 January 2021 to 31 December 2021 ('review investigation period'). The examination of trends relevant for the assessment of the likelihood of a continuation or recurrence of injury covered the period from 1 January 2018 to the end of the review investigation period ('the period considered').

1.5. Interested parties

- (7) In the Notice of Initiation, interested parties were invited to contact the Commission in order to participate in the investigation. In addition, the Commission specifically informed the applicant, the known producer in the Republic of Korea and the authorities of the Republic of Korea, known importers, users and traders, about the initiation of the expiry and invited them to participate.
- (8) Interested parties had an opportunity to comment on the initiation of the expiry review and to request a hearing with the Commission and/or the Hearing Officer in trade proceedings.

1.6. Comments on initiation

- (9) The Commission received comments on initiation from Hansol Paper Co. Ltd. ('Hansol Paper'). This party claimed that the data in the request do not show that the Union industry is suffering material injury.
- (10) The Commission recalled that Hansol Paper had carried out an examination of the request in accordance with Article 11(2) and other relevant paragraphs of Article 11 of the basic Regulation, coming to the conclusion that the requirements for initiation of an investigation were met, i.e., that the adequacy and accuracy of the evidence presented by the applicants were sufficient evidence tending to show likelihood of continuation or recurrence of injurious dumping.
- (11) In this respect, it also recalled that at the stage of the request it is not necessary that the Commission has before it the same evidence of likelihood of continuation or recurrence of dumping and injury of a quantity and quality that would be necessary for the extension of the measures. An anti-dumping investigation is a process where certainty on the existence of the elements necessary to adopt or prolong a measure or to terminate a proceeding is reached gradually as the investigation moves forward. Furthermore, it is not excluded that certain errors or inaccuracies may exist in the application. However, their existence does not necessarily have an impact on the overall conclusion that the request contains sufficient evidence of a likelihood of continuation or recurrence of injurious dumping, and that the file merits investigation.
- (12) Furthermore, the legal standard of evidence required for a request (sufficient evidence) makes it clear that the quantity and quality of information in the request is not the same as the one available at the end of an investigation. It is not excluded that changes will occur between the stage of the request and the conclusion of the investigation. However, such changes do not necessarily have an impact on the overall conclusion that the file merits an investigation since there is sufficient evidence of likelihood of continuation or recurrence of injurious dumping.

⁽⁷⁾ Notice of initiation of an expiry review of the anti-dumping measures applicable to imports of certain lightweight thermal paper originating in the Republic of Korea (OJ C 180, 3.5.2022, p. 4).

- (13) With regard to the claim that the data in the request would not show that the Union industry is suffering material injury, Hansol Paper submitted that the economic indicators provided in the request would show that imports from Korea are at non-injurious levels, Korea's market share is negligible and the Union industry is performing well in terms of sales volume, market share, investments and operating efficiency. According to Hansol Paper, the request acknowledged that sales prices of the Union producers have declined over the period considered but submitted that this is due to other market-wide factors that have nothing to do with imports from Korea.
- (14) The Commission clarified that in the request the applicant alleges the likelihood of continuation or recurrence of injury from the country concerned. The Commission indeed considered that, in the request, the applicant provided sufficient evidence demonstrating that, following an initial period of recovery, the Union industry was injured when the imports from the country concerned increased between 1 October 2020 until 30 September 2021. In this respect, it recalled that a finding of material injury requires an examination, inter alia, of the relevant factors as described in Article 5(2)(d) of the basic Regulation. Indeed, the wording of Article 5(2) of the basic Regulation states that the complaint shall contain the information on changes in the volume of the allegedly dumped imports, the effect of those imports on prices of the like product on the Union market and the consequent impact of the imports on the Union industry, as demonstrated by relevant (not necessarily all) factors and indices having a bearing on the state of the Union industry, such as those listed in Articles 3(3) and 3(5). This is applicable *mutatis mutandis* to the likelihood analysis in an expiry review. Equally, not all factors must show a deterioration in order for material injury (and hence, likelihood of continuation or recurrence thereof) to be established. Furthermore, the existence of other factors which may have an impact on the situation of the Union industry does not necessarily imply that the effect of dumped imports on this industry is not material (again, this is similarly applicable to the likelihood analysis). This is all the more true in the case of an expiry review where the focus lies on what would happen should measures be repealed. Moreover, in the case of expiry reviews, anti-dumping measures may have a certain positive effect even if injury continues overall. In any event, the Commission further noted that the request contained sufficient evidence on likelihood of recurrence of injury. In particular, it showed that the Korean market is characterised by significant production overcapacity. The Korean domestic market is unable to absorb this excess production. Therefore, the Union market, which is globally the largest thermal paper market is attractive to Korean exporters in terms of size. In addition, other export markets are difficult to access for several reasons ⁽⁸⁾. On this basis, the Commission was entitled to initiate the investigation.
- (15) As to Hansol Paper allegations regarding the positive development of some injury indicators in the request, e.g., market share and sales volume, the Commission noted that anti-dumping measures often have a positive effect on the state of the Union industry — a factor which was of course taken into account in the Commission's analysis.
- (16) Regarding the comment on Union interest, the Commission has no legal obligation to examine Union interest at the initiation stage.

1.7. Sampling

- (17) In the Notice of Initiation, the Commission stated that it might sample the interested parties in accordance with Article 17 of the basic Regulation.

1.7.1. Sampling of Union producers

- (18) In the Notice of Initiation, the Commission stated that it had provisionally selected a sample of Union producers. The Commission selected a sample of three Union producers. The criteria used for the selection of the sample were the largest representative volume of sales and production of the like product in the EU between 1 January 2021 and 31 December 2021. The sampled Union producers accounted for 86 % of the estimated total volume of production and sales in the Union. In accordance with Article 17(2) of the basic Regulation, the Commission invited interested parties to comment on the provisional sample. One comment was received from the Union association who supported the provisional sample. The sample was confirmed on 12 May 2022. The sample is representative of the Union industry.

⁽⁸⁾ Request section 10.3, pages 26-28.

1.7.2. *Sampling of importers*

- (19) To decide whether sampling was necessary and, if so, to select a sample, the Commission asked unrelated importers to provide the information specified in the Notice of Initiation. No unrelated importers submitted the requested information. Consequently, the Commission decided that sampling was not necessary.

1.8. **Replies to the questionnaire**

- (20) The Commission invited the three sampled Union producers and the main known exporting producer in Korea to fill in the relevant questionnaires made available online ⁽⁹⁾ on the day of the initiation.
- (21) Questionnaire replies were received from the three sampled Union producers, the main known exporting producer, Hansol Paper, and its related importers Hansol Europe B.V. and Hansol America Inc. Moreover, the applicant provided a questionnaire reply with macro-data.

1.9. **Verification**

- (22) The Commission sought and verified all the information deemed necessary for the determination of likelihood of continuation or recurrence of dumping and injury and of the Union interest. Verification visits pursuant to Article 16 of the basic Regulation were carried out at the premises of the following companies:

Union producers

- Koehler Paper SE, Oberkirch, Germany
- Mitsubishi HiTec Paper Europe GmbH, Bielefeld, Germany.
- Jujo Thermal Oy, Kauttua, Finland.

Exporting producer in the Republic of Korea

- Hansol Paper Co. Ltd, Seoul and Seochon-gun, Chungcheongnam-do, the Republic of Korea ('Hansol Paper')

Related importers

- Hansol Europe B.V., Hoofddorp, the Netherlands ('Hansol Europe')
- Hansol America Inc., Fort Lee, the United States of America ('Hansol America')

1.10. **Subsequent procedure**

- (23) On 27 April 2023, the Commission disclosed the essential facts and considerations on the basis of which it intended to maintain the anti-dumping duties in force. On 10 May 2023, the Commission sent an update of the undercutting calculation to Hansol Paper only. All parties were granted a period within which they could make comments on the disclosure. Comments were received from the applicants and Hansol Paper.
- (24) The comments made by interested parties were considered by the Commission and taken into account, where appropriate. No parties requested a hearing.

1.11. **Presentation of data**

- (25) Given the limited number of parties that submitted data, some of the figures presented below had to be in the form of ranges in order to avoid confidentiality breaches. The data from the sole cooperating exporting producer are also given in ranges as it is the only company that cooperated.

⁽⁹⁾ <https://tron.trade.ec.europa.eu/investigations/case-view?caseId=2596>

2. PRODUCT UNDER REVIEW, PRODUCT CONCERNED AND LIKE PRODUCT

2.1. Product under review

- (26) The product under review is the same as in the original investigation, namely certain lightweight thermal paper weighing 65 g/m² or less; in rolls of a width of 20 cm or more, a weight of the roll (including the paper) of 50 kg or more and a diameter of the roll (including the paper) of 40 cm or more ('jumbo rolls'); with or without a base coat on one or both sides; coated with a thermo-sensitive substance on one or both sides; and with or without a top coat ('the product under review'), currently falling under CN codes ex 4809 90 00, ex 4811 90 00, ex 4816 90 00 and ex 4823 90 85 (TARIC codes: 4809 90 00 10, 4811 90 00 10, 4816 90 00 10, 4823 90 85 20).
- (27) Lightweight thermal paper is a specialty paper. It has a thermal active coating which reacts to form an image when heat is applied by printers with thermal printheads. Lightweight thermal paper is used for point-of-sale applications such as the receipts issued by retail, but also for self-adhesive labels for e-commerce packaging, tickets and tags.
- (28) Lightweight thermal paper can be produced with several types of chemical developers. All types are concerned by the present investigation.

2.2. Product concerned

- (29) The product concerned by this investigation is the product under review originating in the Republic of Korea.

2.3. Like product

- (30) As established in the original investigation, this expiry review investigation confirmed that the following products have the same basic physical and technical characteristics as well as the same basic uses:
- the product concerned when exported to the Union;
 - the product under review produced and sold on the domestic market of the Republic of Korea; and
 - the product under review produced and sold in the Union by the Union industry.
- (31) These products are therefore considered to be like products within the meaning of Article 1(4) of the basic Regulation.

2.4. Claims regarding product scope

- (32) In a submission of 1 July 2022, the exporting producer requested a clarification whether new product types produced by Union industry would be included or excluded from the scope of the expiry review. These new product types do not use any chemical developer and the image is released based on physics instead of a chemical process. A note to the file dated 19 September 2022 clarified the scope of the investigation in the sense that only lightweight thermal paper with a chemical developer is covered by the proceeding.

3. DUMPING

3.1. Preliminary remarks

- (33) During the review investigation period, imports of lightweight thermal paper from the Republic of Korea continued, albeit at lower levels than in the investigation period of the original investigation (i.e. from 1 January 2015 to 31 December 2015). According to table 2 below, imports of lightweight thermal paper from the Republic of Korea accounted for 2,7 % of the Union market in the review investigation period compared to 13,6 % market share during the original investigation.
- (34) Hansol Paper cooperated with the investigation. It accounted for (close to) all imports of the product under review from the Republic of Korea. No other exporting producer came forward. The findings with regard to the continuation of dumping are based on the verified data of Hansol Paper.

3.2. Continuation of dumping during the review investigation period

3.2.1. Normal value

- (35) The Commission first examined whether the total volume of domestic sales of the cooperating exporting producer was representative, in accordance with Article 2(2) of the basic Regulation. The domestic sales are representative if the total domestic sales volume of the like product to independent customers on the domestic market per exporting producer represented at least 5 % of its total export sales volume of the product under review to the Union during the review investigation period. On this basis, the total sales by the exporting producer of the like product on the domestic market were representative.
- (36) The Commission subsequently identified the product types sold domestically that were identical or comparable with the product types sold for export to the Union for the exporting producer with representative domestic sales.
- (37) The Commission then examined whether the domestic sales by the exporting producer on its domestic market for each product type that is identical or comparable with a product type sold for export to the Union were representative, in accordance with Article 2(2) of the basic Regulation. The domestic sales of a product type are representative if the total volume of domestic sales of that product type to independent customers during the review investigation period represents at least 5 % of the total volume of export sales of the identical or comparable product type to the Union. The Commission established that, for some product types that were exported to the Union during the review investigation period, there were no domestic sales and were thus not representative.
- (38) The Commission next defined the proportion of profitable sales to independent customers on the domestic market for each product type during the review investigation period in order to decide whether to use actual domestic sales for the calculation of the normal value, in accordance with Article 2(4) of the basic Regulation.
- (39) The normal value is based on the actual domestic price per product type, irrespective of whether those sales are profitable or not, if:
- (a) the sales volume of the product type, sold at a net sales price equal to or above the calculated cost of production, represented more than 80 % of the total sales volume of this product type; and
 - (b) the weighted average sales price of that product type is equal to or higher than the unit cost of production.
- (40) In this case, the normal value is the weighted average of the prices of all domestic sales of that product type during the review investigation period.
- (41) The normal value is the actual domestic price per product type of only the profitable domestic sales of the product types during the review investigation period, if:
- (a) the volume of profitable sales of the product type represents 80 % or less of the total sales volume of this type; or
 - (b) the weighted average price of this product type is below the unit cost of production.
- (42) The analysis of domestic sales showed that, depending on the product type, between 32 % and 100 % of all domestic sales volume were profitable and that the weighted average sales price of each product type was higher than the cost of production. Accordingly, depending on the product type, the normal value was calculated as a weighted average of the price of all domestic sales during the review investigation period or as a weighted average of the profitable sales only.
- (43) Where a product type was not sold on the domestic market, and in the absence of a domestic sales price of such product type by any other exporting producer, the Commission constructed the normal value in accordance with Article 2(3) and (6) of the basic Regulation.

- (44) Normal value was constructed by adding the following to the average cost of production of the like product of the cooperating exporting producer during the review investigation period:
- (a) the weighted average selling, general and administrative ('SG&A') expenses incurred by the cooperating exporting producer on domestic sales of the like product, in the ordinary course of trade, during the review investigation period; and
 - (b) the weighted average profit realised by the cooperating exporting producer on domestic sales of the like product, in the ordinary course of trade, during the review investigation period.

3.2.2. *Export price*

- (45) Hansol Paper exported the product under review to the Union either directly to independent customers or through its related company Hansol Europe.
- (46) For sales of the exporting producer directly to independent customers in the Union, the export price was the price actually paid or payable for the product under review when sold for export to the Union, in accordance with Article 2(8) of the basic Regulation.
- (47) For sales of the exporting producer to the Union through Hansol Europe acting as an importer, the export price was established on the basis of the price at which the imported product was first resold to independent customers in the Union, in accordance with Article 2(9) of the basic Regulation. In this case, adjustments to the price were made for all costs incurred between importation and resale, including SG&A expenses, and for profits accruing.
- (48) With respect to the profit margin used, in line with established case-law of Union courts, ⁽¹⁰⁾ the Commission did not use the profit margin of the related company as it is considered unreliable. In the absence of any other information, it resorted to the profit margin of 4,5 % which had also been used in the original investigation. ⁽¹¹⁾

3.2.3. *Comparison*

- (49) The Commission compared, per product type, the normal value and the export price of the exporting producer on an ex-works basis.
- (50) Where justified by the need to ensure a fair comparison, the Commission adjusted the normal value and/or the export price for differences affecting prices and price comparability, in accordance with Article 2(10) of the basic Regulation. Adjustments for transport costs, handling and loading costs, bank charges, EU customs duties, year-end rebates, commissions and for a duty drawback were deducted from domestic and/or export sales prices, where they were reported and found to be justified. The Commission found the claims for adjustments relating to packing costs and credit costs unjustified.
- (51) The packing for export and for domestic sales was basically identical, therefore there was no reason to grant the adjustment claim.
- (52) Article 2(10)(g) of the basic Regulation provides that when credit is a factor taken into account in the determination of the prices charged, an adjustment may be justifiable. The Commission rejected the credit cost adjustment based on the reasoning which, due to its sensitive nature, was disclosed only to the exporting producer. The Commission concluded that the cost of credit granted was not a factor taken into account by the party in the determination of the prices charged.

⁽¹⁰⁾ See for example paragraph 68 of Judgment of the General Court (Second Chamber), 17 March 2015 in Case T-466/12, RFA International, LP v European Commission.

⁽¹¹⁾ For details, see recital (40) of Commission Implementing Regulation (EU) 2016/2005 of 16 November 2016 imposing a provisional anti-dumping duty on imports of certain lightweight thermal paper originating in the Republic of Korea (OJ L 310, 17.11.2016, p. 1)

3.2.4. Dumping margin

- (53) The Commission compared the weighted average normal value of each type of the like product with the weighted average export price of the corresponding type of the product under review, in accordance with Article 2(11) and (12) of the basic Regulation.
- (54) On this basis, the weighted average dumping margin expressed as a percentage of the CIF Union frontier price, duty unpaid, was 29 % for Hansol Paper. It was therefore concluded that dumping continued during the review investigation period.
- (55) Following final disclosure, Hansol Paper noted that most of the dumping derived from a label-grade thermal paper and pointed at the difference in terms of product mix between its sales into the Union in the original investigation and the review investigation. The Commission recalls that the normal value and the export price were compared per product type, as described in the sections above, and that, ultimately, only one single dumping margin had to be established for the sales of all the products covered by the measures in force. Therefore, the difference in the product mix between the original investigation and the review was taken into account when establishing the dumping margin.

3.3. Likelihood of continuation of dumping should measures be repealed

- (56) Further to the finding of the existence of dumping during the review investigation period, the Commission investigated, in accordance with Article 11(2) of the basic Regulation, the likelihood of continuation of dumping, should the measures be repealed. The following elements were analysed: the production capacity and spare capacity in the Republic of Korea and the attractiveness of the Union market versus other markets.

3.3.1. Production capacity and spare capacity in the Republic of Korea

- (57) According to market intelligence, Hansol Paper was by far the largest producer of the product under review in the Republic of Korea. Its production capacity varied depending on the source. The 2019 *Hansol Paper Sustainability Report* established it at 355 000 tonnes per year for the division including lightweight thermal paper ⁽¹²⁾. In the course of the investigation, while admitting that that figure was the designed capacity of thermal coating, Hansol Paper submitted production capacity figures in the range of 250 000 – 300 000 tonnes per year. During the on-spot verification, the company claimed that the figure quoted in the 2019 Report was inaccurate. The company considered that the capacity figures in the *Thermal Paper 2019-2024 World Market Study* of Laves Chemie Consulting were more accurate. That study estimated Hansol Paper's thermal paper production capacity at 260 000 tonnes per year ⁽¹³⁾.
- (58) According to the above-mentioned study by Laves Chemie Consulting, until recently there would have been three other thermal paper producers in the Republic of Korea with a total production capacity of 45 000 tonnes ⁽¹⁴⁾. However, it remains unclear to what extent this capacity might be activated for lightweight thermal paper if the market circumstances would give reason for that. According to Union producers, the only additional Korean producer still manufacturing thermal paper would be Donghwa Ind co. Ltd, with a production capacity of 15 000 tonnes per year ⁽¹⁵⁾.

⁽¹²⁾ Request, para. 99 to 101 (pages 23-24).

⁽¹³⁾ Laves Chemie Consulting: Thermal Paper 2019-2024 World Market Study, Annex 6 to the request (t22.002094).

⁽¹⁴⁾ Laves Chemie Consulting: Thermal Paper 2019-2024 World Market Study, Annex 6 to the request, page 19.

⁽¹⁵⁾ Open version of questionnaire replies in t22.003621 (Koehler), t22.003615 (Jujo) and t22.003616 (Mitsubishi).

- (59) In light of the above, whereas the Commission was unable to quantify the spare capacity in Korea overall, it could establish that production capacity is significant, being some 10 times bigger than domestic consumption in Korea and representing almost twice the Union consumption. Furthermore, Hansol Paper has repeatedly announced its intention to expand its thermal paper business, as shown in its financial report for the first half of 2021 ⁽¹⁶⁾ and subsequent financial reports (also in 2022 ⁽¹⁷⁾). Such an expansion would represent an addition to the Korean thermal paper production capacity in the review investigation period, which was already significantly higher than lightweight thermal paper consumption in the Union (see Table 1).
- (60) Following final disclosure, Hansol Paper stated that the Commission's findings on capacity in Korea were unsubstantiated and incorrect namely because: (i) Hansol Paper was the only producer of the product under review in Korea, (ii) the Commission had misinterpreted Hansol Paper's expansion announcements and (iii) the Commission had exaggerated when establishing that Hansol Paper's production capacity is significantly flexible.
- (61) The Commission disagreed. As to Hansol Paper allegedly being the only producer of the product under review in Korea, the Commission noted that this was contradicted by other information on the file including statements made by Hansol Paper itself in the course of the expiry review investigation ⁽¹⁸⁾. Whereas the Commission has consistently held that Hansol Paper was the sole cooperating exporting producer in this review investigation, the Commission had not concluded that Hansol Paper was the only producer of lightweight thermal paper in the Republic of Korea. To the contrary, as explained in recital (58) above, evidence on the file suggested that at least one other producer of the lightweight thermal paper in the Republic of Korea, namely Donghwa Ind co. Ltd, could be producing the product under review. The Commission noted that Donghwa Ind's website ⁽¹⁹⁾ included references to thermal paper production in general and pictures of products such as point-of-sale receipts typically made of lightweight thermal paper. The Commission also noted that, in view of the evidence to the contrary, Hansol Paper failed to submit evidence to substantiate its claim of being the only producer of lightweight thermal paper in the Republic of Korea. The claim was therefore rejected.
- (62) The Commission disagreed that, as stated by Hansol, the spare capacity in Korea was nil. For instance, Hansol Paper provided such low capacity figures that its reported capacity utilisation would have exceeded 100 % in some years of the period considered.
- (63) As far as the alleged misinterpretation of Hansol Paper's expansion announcements and the issue of the flexible production capacity, the Commission disagreed. Hansol Paper itself had repeatedly publicly announced in its financial reports its intention to expand its thermal paper business ⁽²⁰⁾. The fact that the investment plans available at the time of the verification visit did not include investments aimed at increasing capacity does not preclude Hansol Paper from following through on its announcements at a later stage. In any case, the means for Hansol Paper to expand its thermal paper business are manifold, including switching capacities. As noted by the party itself in the 2022 *Hansol Paper Sustainability Report* ⁽²¹⁾, undeniably, Hansol Paper has flexible production facilities. Even if the quantification of the flexibility is not clearly available, the fact that it appeared in the report suggests that the flexibility is not minor and, thus, worth a public announcement. The product mix in Hansol Paper's 2023 production plan does not prevent the party from switching a non-negligible amount of capacities to the product under review when needed.

⁽¹⁶⁾ For an excerpt, see, *inter alia*, page 24 of the request.

⁽¹⁷⁾ For Hansol Paper's financial report covering the first three quarters of 2022, see <https://dart.fss.or.kr/dsaf001/main.do?rcpNo=20221111000618> (in Korean).

⁽¹⁸⁾ On 10 May 2022 (t22.002756) Hansol Paper referred to itself as "the main exporting producer of LWTP in Korea".

⁽¹⁹⁾ Company website: <http://www.donghwaind.co.kr>

⁽²⁰⁾ See footnotes 16 and 17 above.

⁽²¹⁾ The 2022 Hansol Paper Sustainability report is available at <https://www.hansolpaper.co.kr/m/eng/management/data>. Page 10 of the report reads: "Janghang Mill ... has a flexible facility system that can swing special material paper such as high-quality printing paper, thermal paper and label paper according to market conditions.... Shintanjin Mill... has a flexible facility system to produce printing paper and thermal paper....".

3.3.2. Attractiveness of the Union market versus other markets

- (64) The domestic market of the Republic of Korea is small, with an annual consumption ranging 20 000 - 37 200 tonnes ⁽²²⁾. Hansol Paper's annual production alone is 4 to 9 times bigger than the consumption of the product under review in its domestic market. The investigation established that, volume-wise, the domestic consumption is shrinking as the lightweight thermal paper domestic sales of Hansol Paper, the country's dominant producer, dropped by 29 % during the period considered ⁽²³⁾. Therefore, the Korean lightweight thermal paper industry is export-oriented. As to the profitability of Hansol Paper's domestic sales, see section 3.2.1 above.
- (65) On the basis of the verified data of Hansol Paper, the Commission established that the volume of Korean exports to destinations other than the Union grew during the period under review ⁽²⁴⁾. It also established that Korean exports, in particular to the US, were significant ⁽²⁵⁾. However, the sales prices of Korean exports to destinations other than the Union dropped over the period under review. This is clearly visible on the US market ⁽²⁶⁾. Moreover, the US authorities imposed anti-dumping measures on imports of thermal paper originating, *inter alia*, in the Republic of Korea on 27 September 2021 ⁽²⁷⁾. For those reasons, in terms of prices, the US market has become less attractive to Korean exports.
- (66) The Union market is the largest market for lightweight thermal paper in the world, accounting for some 25 % of global consumption, and it has a high growth potential in absolute terms ⁽²⁸⁾. The investigation established that the Union market is attractive in terms of prices as compared to other markets. After the imposition of the anti-dumping measures in 2017, imports from the Republic of Korea dropped significantly and they amounted to 1 000 - 2 500 tonnes only in 2020. However, since then, and despite the anti-dumping duties in force, Korean sales to the Union increased again ⁽²⁹⁾ and they amounted to 4 500 - 6 000 tonnes in the review investigation period, representing a market share of 2,7 %.
- (67) Following final disclosure, Hansol Paper requested the Commission to calculate a dumping margin for Hansol Paper's sales to third country markets on the grounds that such calculation was a consistent practice in expiry reviews carried out by the Commission and that the Commission had not assessed whether Hansol Paper's export prices to non-EU markets indicated dumping. The Commission clarified that, the purpose of an expiry review is to establish whether the expiry of measures would be likely to lead to a continuation or recurrence of dumping and injury. Given the finding of significant dumping during the review investigation period for sales to the Union and the subsequent conclusion on likelihood of continuation of dumping, the Commission was not required to perform any further dumping determination in the present investigation. As to Hansol Paper's export prices to non-EU markets, they were analysed in recital (65) above. They are further analysed in the recitals below.

⁽²²⁾ Laves Chemie Consulting: Thermal Paper 2019-2024 World Market Study, Annex 6 to the request, table "Balance of Supply and Demand in Metric Tonnes", page 22, established that thermal paper consumption in Korea amounted to 60 000 tonnes in 2019. The open version of the questionnaire replies in t22.003621 (Koehler), t22.003615 (Jujo) and t22.003616 (Mitsubishi) estimated lightweight thermal paper yearly consumption in Korea at 37 200 tonnes.

⁽²³⁾ Hansol Paper's questionnaire reply (t22.003569), table C.2 (sales quantity).

⁽²⁴⁾ *Ibid.*

⁽²⁵⁾ Request, Annex 6, page 21 ("Korea exports 78% of production to North and Central & South America, and also to other Asian countries. ...").

⁽²⁶⁾ Hansol Paper's questionnaire reply (t22.003569), tables K.3 of the file "R768 Tables K-L-M (HAI) - OPEN.pdf", in light of which, over the period under review, the turnover of the product under review of Hansol America fell by 13 % whereas sales volume increased by 2 %. It is to be noted that, in light of the U.S. Census Bureau, the prices of Korean thermal paper fell from 2 223 USD/tonne in 2018 to 1 645 USD/tonne in 2020 (see "import statistics" in the following website of the International Trade Administration of the US: <https://www.trade.gov/faq/final-determinations-antidumping-duty-investigations-thermal-paper-germany-japan-south-korea>).

⁽²⁷⁾ See the official website of the International Trade Administration of the US, namely <https://www.trade.gov/faq/final-determinations-antidumping-duty-investigations-thermal-paper-germany-japan-south-korea>.

⁽²⁸⁾ Request, Annex 6, tables "Consumption by Grade and Geographic Area 2020", "Consumption by Geographic Area in Metric Tonnes 2022-2024" and "Consumption by Grade and Geographic Area 2024".

⁽²⁹⁾ Hansol Paper's questionnaire reply (t22.003569), tables K.3 of the file "R768 Tables K-L-M (HEB) - OPEN.pdf".

- (68) Following final disclosure, Hansol Paper alleged that the Commission should have found that the Union lightweight thermal paper market was no longer attractive in light of information already submitted by Hansol paper (and, allegedly, not sufficiently addressed by the Commission) and, in particular, the claims that Hansol Paper would no longer concentrate on the Union market, the importance of the US market for Hansol Paper, the level of US anti-dumping measures on thermal paper and that the Commission did not describe in this Regulation Hansol Paper's activities in other third markets.
- (69) The Commission disagreed with the alleged unattractiveness of the Union market for Korean exports. The facts that during the review investigation period the Union market was not Hansol Paper's main market volume-wise and that Hansol Paper had significant sales to the US do not undermine the attractiveness of the Union market. Also, the Commission maintained that the mere existence of anti-dumping measures in the US makes the US market less attractive than before any measures were imposed, even if the level of the measures is not prohibitive. As to Hansol Paper's sales on other markets, the Commission was not able to disclose its sales volumes and prices on other markets per country in this Regulation to the extent that such information had been considered as sensitive by the party (i.e. the only source of the data in question). The Commission took nevertheless stock of Hansol Paper's sales and price strategy on other markets, as shared with the party via the verification reports. In this respect, the Commission found that, worldwide, there is thermal paper production in a handful of countries, as shown in the *Thermal Paper 2019-2024 World Market Study* of Laves Chemie. Therefore, producers of the product under review face competition from local producers only in a few areas of the world. South and Central America, Africa, Australasia and most Asian countries were thus net importers of thermal paper ⁽³⁰⁾, mainly from Korea. Even if, in principle, markets without (significant) domestic production would seem more attractive at first sight, the Commission found that, in broad terms, Hansol Paper's sale prices of the product under review to non-EU export markets, including the US, decreased over the period considered by a similar degree as prices to the Union. A comparison of Hansol Paper's sale prices to all non-EU export markets and Hansol Paper's sale prices to the Union revealed that, during the period considered, EU prices were overall consistently higher than Hansol Paper's sale prices to the rest of the world. The Commission therefore confirmed that the Union market, the largest market for lightweight thermal paper in the world and a market with a high growth potential in absolute terms, was volume- and price-wise an attractive market for Korean exports, regardless of the changes in Hansol Paper's sales network since the original investigation.

3.3.3. Conclusion on the likelihood of continuation of dumping

- (70) In view of its findings on the continuation of dumping during the review investigation period as established in recital (54), the existence of non-negligible flexible production capacity in the Republic of Korea, the yet again growing Korean interest in the large Union market with attractive prices and the recently imposed anti-dumping measures on its currently main export market ⁽³¹⁾, a further increase of dumped imports of the product concerned can be expected if the measures are repealed. Therefore, the Commission concluded that there is a strong likelihood that the expiry of the anti-dumping measures on imports of the product concerned would result in the continuation of dumping.

4. INJURY

4.1. Definition of the Union industry and Union production

- (71) The like product was manufactured by five producers in the Union during the period considered. They constitute the 'Union industry' within the meaning of Article 4(1) of the basic Regulation.

⁽³⁰⁾ Request, Annex 6, page 21 ("Korea exports 78% of production mainly to North and Central & South America, and also to other Asian countries. (...) Central & South America exports are insignificant. Imports (*into Central & South America*) are 50% of consumption mainly from Europe, North America, China, and Korea. ROW countries in this context comprise Asia (except China, Japan, Korea), Africa, and Australasia. Exports (*by ROW countries*) are insignificant but ROW countries import 80% of consumption mainly from Korea, China and Europe...").

⁽³¹⁾ In light of the U.S. Census Bureau, thermal paper imports from Korea amounted to 54 337 tonnes in 2020 (see "import statistics" in the following website of the International Trade Administration of the US: <https://www.trade.gov/faq/final-determinations-antidumping-duty-investigations-thermal-paper-germany-japan-south-korea>).

- (72) The total Union production during the review investigation period was established at around 360 727 tonnes. The Commission established the figure on the basis of all the available information concerning the Union industry, such as the questionnaire reply submitted by the applicant, cross checked against the individual questionnaire replies of the sampled Union producers. As indicated in recital (18), three Union producers were selected in the sample representing 86 % of the total Union production of the like product.

4.2. Union consumption

- (73) The Commission established the Union consumption on the basis of: (a) the applicant's data concerning Union industry's sales of the like product, partially cross-checked with the sales volumes reported by sampled Union producers ⁽³²⁾; and (b) imports of the product under review from all third countries as reported in the Eurostat and analysis of the export data of the co-operating exporting producer.
- (74) Union consumption developed as follows:

Table 1

Union consumption (tonnes)

	2018	2019	2020	RIP
Total Union consumption	179 500 –184 000	170 000 –174 500	165 500 –170 000	177 000 –181 500
Index	100	94	92	98

Source: Eurostat, Questionnaire replies and Request.

- (75) Union consumption decreased by 8 % from 2018 to 2020. Union consumption was affected in 2020 due to the global COVID pandemic, however, Union consumption rebounded during the review investigation period and there is an overall decrease of 2 % over the period considered.

4.3. Imports from the country concerned

4.3.1. Volume and market share of the imports from the country concerned

- (76) The Commission established the volume of imports on the basis of the questionnaire reply submitted by the co-operating exporting producer and Eurostat statistics. The market share of the imports was established on the basis of Union consumption.
- (77) Imports from the country concerned developed as follows:

Table 2

Import volume (tonnes) and market share

	2018	2019	2020	RIP
Volume of imports from the country (tonnes)	2 500 –4 000	1 500 – 3 000	1 000 – 2 500	4 500 – 6 000
Index	100	64	48	165
Market share	1,6 %	1,1 %	0,9 %	2,7 %
Index	100	68	53	167

Source: Dumping questionnaire and Eurostat.

⁽³²⁾ Source: questionnaire reply submitted by the applicant and verified individual questionnaire replies of the sampled Union producers.

- (78) The volume of imports from the country concerned decreased from 2018 to 2020. However, the volume increased significantly during the review investigation period and are 65 % up from the 2018 figure. Market share increased during the period considered rising from 1,6 % in 2018 to 2,7 % in the RIP.
- (79) In order to establish the import volumes and values in the period considered, the Commission analysed the export data reported by Hansol Paper, the co-operating exporting producer in the country concerned, in the light of the import statistics recorded in Eurostat. The Commission found discrepancies between Hansol Paper's reported exports to Denmark, Estonia, Finland and Lithuania and imports in those Member States recorded in Eurostat. Based on the information submitted by the company, the Commission concluded that the product under review exported by Hansol Paper to Denmark, Estonia, Finland and partially also to Lithuania, did not enter the customs territory of the Union. Those sales likely remained in transit and/or were destined for countries outside of the Union. Therefore, with regard to imports to the four above-mentioned Member States, the Commission relied on statistics recorded in Eurostat.

4.3.2. *Prices of the imports from the country concerned and price undercutting*

- (80) The Commission established the prices of imports on the basis of the questionnaire reply submitted by the exporting producer and Eurostat statistics.
- (81) The average price of imports from the country concerned developed as follows:

Table 3

Import prices (EUR/tonne)

	2018	2019	2020	RIP
Average price of imports from Republic of Korea	1 800 – 2 000	1 550 – 1 750	1 450 – 1 650	1 450 – 1 650
<i>Index</i>	100	91	82	81

Source: Dumping questionnaire and Eurostat.

- (82) The average price of imports from the country concerned decreased by 19 % over the period considered.
- (83) The Commission determined the price undercutting during the review investigation period by comparing:
- the weighted average sales prices per product type of the sampled Union producers charged to unrelated customers on the Union market, adjusted to an ex-works level; and
 - the corresponding weighted average prices per product type of the imports from the cooperating producer to the first independent customer on the Union market, established on a Cost, insurance, freight (CIF) basis, with appropriate adjustments for post-importation costs.
- (84) The price comparison was made on a type-by-type basis for transactions at the same level of trade, duly adjusted where necessary and after deduction of rebates and discounts. The result of the comparison was expressed as a percentage of the theoretical turnover (exporting producer's exported quantities valued at the Union industry's sales price) per model of each exporting producer where an identical PCN for the Union industry was found.
- (85) It showed a weighted average undercutting margin of 13,7 % by the imports from the country concerned on the Union market. Around 83 % of the import volumes were found to be undercutting.

- (86) Following final disclosure, Hansol Paper claimed that the majority of the undercutting concerned a label-grade thermal paper that does not relate to the products covered by the original investigation. The Commission calculated the undercutting margin on product type comparison as in the original investigation. Therefore, this claim was dismissed.

4.4. Imports from third countries other than the Republic of Korea

- (87) The imports of certain lightweight thermal paper from third countries other than the Republic of Korea were mainly from China and the USA.
- (88) The volume of imports as well as the market share and price trends for imports of certain lightweight thermal paper from other third countries developed as follows:

Table 4

Imports from third countries

Country		2018	2019	2020	RIP
PRC	Volume (tonnes)	6 000-7 500	4 500-6 000	3 500-5 000	3 500-5 000
	<i>Index</i>	100	80	62	48
	Market share	3,5 %	3,0 %	2,4 %	1,7 %
	<i>Index</i>	100	85	67	49
	Average price (EUR/tonne)	1 500-1 650	1 600-1 750	1 500-1 650	1 500-1 650
	<i>Index</i>	100	104	96	96
USA	Volume (tonnes)	2 850-3 000	2 350-2 500	2 850-3 000	3 000-3 150
	<i>Index</i>	100	84	100	105
	Market share	1,6 %	1,4 %	1,7 %	1,7 %
	<i>Index</i>	100	89	109	107
	Average Price (EUR/tonne)	2 400-2 550	2 950-3 100	2 950-3 100	2 800-2 950
	<i>Index</i>	100	122	120	115
Total of all third countries except the country concerned	Volume (tonnes)	10 00-00-11 500	9 500-11 000	9 000-10 500	9 000-10 500
	<i>Index</i>	100	93	87	90
	Market share	5,8 %	5,7 %	5,5 %	5,3 %
	<i>Index</i>	100	98	95	91
	Average price (EUR/tonne)	1 950 – 2 150	2 250-2 450	2 250-2 450	2 450 – 2 650
	<i>Index</i>	100	115	118	126

Source: Eurostat.

- (89) Imports from China decreased by more than 50 % during the period considered, while imports from the USA increased by 5 %. The market share of other third countries decreased steadily from 5,8 % in 2018 to 5,3 % in the RIP.

4.5. Economic situation of the Union industry

4.5.1. General remarks

- (90) In accordance with Article 3(5) of the basic Regulation, the examination of the impact of the dumped imports on the Union industry included an evaluation of all economic indicators having a bearing on the state of the Union industry during the period considered.
- (91) For the injury determination, the Commission distinguished between macroeconomic and microeconomic injury indicators. The Commission evaluated the macroeconomic indicators on the basis of data contained in the questionnaire reply of the applicant, duly cross-checked with the information in the request and Eurostat statistics. The data related to all Union producers. The Commission evaluated the microeconomic indicators on the basis of data contained in the questionnaire replies submitted by the sampled Union producers. Both sets of data were found to be representative of the economic situation of the Union industry.
- (92) The macroeconomic indicators are: production, production capacity, capacity utilisation, sales volume, market share, growth, employment, productivity, magnitude of the dumping margin, and recovery from past dumping.
- (93) The microeconomic indicators are: average unit prices, unit cost, labour costs, inventories, profitability, cash flow, investments, return on investments, and ability to raise capital.

4.5.2. Macroeconomic indicators

4.5.2.1. Production, production capacity and capacity utilisation

- (94) The total Union production, production capacity and capacity utilisation developed over the period considered as follows:

Table 5

Production, production capacity and capacity utilisation

	2018	2019	2020	RIP
Production volume (tonnes)	399 607	392 619	348 216	360 727
<i>Index</i>	100	98	87	90
Production capacity (tonnes)	563 021	581 338	640 533	633 474
<i>Index</i>	100	103	114	113
Capacity utilisation	71 %	68 %	54 %	57 %
<i>Index</i>	100	95	77	80

Source: Injury questionnaire and Request.

- (95) Over the period considered, the Union industry's production volume decreased by 10 %. There was a 13 % decrease in the production volume in 2020 in relation to 2018, due to the impact of the COVID-19 pandemic.
- (96) The production capacity increased during the period considered and remained relatively stable during 2020 and the RIP.

- (97) The capacity utilisation rate decreased by 23 % between 2018 and 2020. There was a slight increase in the utilisation rate by 3 percentage points between 2020 and the RIP.

4.5.2.2. Sales volume and market share

- (98) The Union industry's sales volume and market share developed over the period considered as follows:

Table 6

Sales volume and market share

	2018	2019	2020	RIP
Sales volume on the Union market (tonnes)	168 151	159 905	156 357	164 118
<i>Index</i>	100	95	93	98
Market share	92,6 %	93,2 %	93,7 %	92,0 %
<i>Index</i>	100	101	101	99

Source: Injury questionnaire, Request and Eurostat.

- (99) The Union industry sales volume on the Union market decreased by 2 % during the period considered. Again, there was a significant drop in sales in 2020, linked to the COVID crisis. There was an increase in sales in the RIP which is similar to the trend for consumption shown in Table 1.
- (100) The Union industry's market share remained relatively stable during the period considered, at 92 % in the RIP.

4.5.2.3. Growth

- (101) During the period considered, Union consumption decreased by 2 %. At the same time, there was a similar decrease in industry sales on the EU market. The market share of the Union industry decreased only slightly, from 92,6 % to 92 %.

4.5.2.4. Employment and productivity

- (102) Employment and productivity developed over the period considered as follows:

Table 7

Employment and productivity

	2018	2019	2020	RIP
Number of employees	1 080	1 057	951	870
<i>Index</i>	100	98	88	81
Productivity (tonnes/employee)	370	371	366	415
<i>Index</i>	100	100	99	112

Source: Injury questionnaire and Request.

- (103) During the period considered, there has been a significant drop in the number of employees employed by the Union industry, decreasing by 19 percentage points overall.

- (104) The productivity of the Union industry's workforce was stable during the period of 2018 to 2020 and has increased by 13% since 2020.

4.5.2.5. Magnitude of the dumping margin and recovery from past dumping

- (105) During the review investigation period, the individual dumping margin found for the cooperating exporting producer was still substantial (see recital (54) above).
- (106) However, despite the fact there was still dumping for the country concerned, the analysis of the injury indicators shows that the measures in place had a positive impact on the Union industry.

4.5.3. Microeconomic indicators

4.5.3.1. Prices and factors affecting prices

- (107) The weighted average unit sales prices of the sampled Union producers to unrelated customers in the Union developed over the period considered as follows:

Table 8

Sales prices and cost of production in the Union (EUR/tonne)

	2018	2019	2020	RIP
Average unit sales price in the Union on the total market	1 721	1 729	1 525	1 518
<i>Index</i>	100	100	89	88
Unit cost of production	1 557	1 504	1 377	1 453
<i>Index</i>	100	97	88	93

Source: Injury questionnaire.

- (108) During the period considered, the average sales price of the Union industry decreased by 12 %. The cost of production decreased between 2018 and the RIP by 7%. It first decreased by 12 % between 2018 and 2020, but then it increased by 5,5 % between 2020 and the RIP. This was due to an increase in the cost of raw materials, notably the cost of wood pulp, and the energy costs.

4.5.3.2. Labour costs

- (109) The average labour costs of the sampled Union producers developed over the period considered as follows:

Table 9

Average labour costs per employee

	2018	2019	2020	RIP
Average labour costs per employee (EUR)	61 576	68 809	74 604	75 027
<i>Index</i>	100	112	121	122

Source: Injury questionnaire.

- (110) During the period considered, labour costs increased by 22 %. At the same time there was a decrease in employee numbers. This increase in labour costs was far above that of the overall increase in costs for the Union industry due to inflation.

4.5.3.3. Inventories

- (111) Stock levels of the sampled Union producers developed over the period considered as follows:

Table 10

Inventories

	2018	2019	2020	RIP
Closing stocks (tonnes)	17 878	18 452	15 810	16 082
<i>Index</i>	100	103	88	90
Closing stocks as a percentage of production	5,3 %	5,5 %	5,2 %	5,0 %
<i>Index</i>	100	105	100	96

Source: Injury questionnaire.

- (112) The closing stocks as a percentage of production show a stable footing across the period considered. The production of the product under review is usually done to order and therefore closing stocks tend to be stable. However, the level of closing stock decreased by 10 % during the period considered, which coincides with a decrease in production over the same period.

4.5.3.4. Profitability, cash flow, investments, return on investments and ability to raise capital

- (113) Profitability, cash flow, investments and return on investments of the sampled Union producers developed over the period considered as follows:

Table 11

Profitability, cash flow, investments and return on investments

	2018	2019	2020	RIP
Profitability of sales in the Union to unrelated customers (% of sales turnover)	11,3 %	14,8 %	12,2 %	6,6 %
<i>Index</i>	100	131	108	59
Cash flow (EUR)	87 661 559	87 198 733	67 116 931	41 474 900
<i>Index</i>	100	99	77	47
Investments (EUR)	34 123 041	58 784 540	61 376 912	6 839 111
<i>Index</i>	100	172	180	20
Return on investments	104 %	50 %	25 %	24 %
<i>Index</i>	100	49	24	24

Source: Injury questionnaire.

- (114) The Commission established the profitability of the sampled Union producers by expressing the pre-tax net profit of the sales of the like product to unrelated customers in the Union as a percentage of the turnover of those sales.
- (115) Profitability was positive throughout the period considered. However, following an increase in the costs of production, profitability dropped during the RIP, falling to 6,6 %, well below the target profit of 11,5 % established in the original investigation. This drop in profitability is due in part to the increase in costs between 2020 and the RIP, documented in recital (108), and coincides with the significant surge in imports from the country concerned in the same period.
- (116) The net cash flow is the ability of the Union producers to self-finance their activities. The trend in net cash flow developed downward during the period considered dropping by 53 %. This is similar to the situation that occurred in the original investigation.
- (117) Union industry continued investment during the period 2018 to 2020. However, this investment decreased dramatically during the RIP.
- (118) The return on investments is the profit in percentage of the net book value of investments. It developed in a downward trend during the period considered dropping by 76 %. This drop in the return on investments is in line with the drop in profitability.
- (119) The ability to raise capital by Union industry has been affected by the diminishing profitability, as can be seen from the significant drop in investment during the RIP.

4.6. Conclusion on injury

- (120) During the period considered, the market share of the Union industry remained high and stable, at 92% or above. Sales volumes on the Union market decreased slightly, paralleling a similar decrease in consumption.
- (121) In terms of financial indicators, the Union industry profitability has been positive throughout the period considered, and over or around the target profit of 11,5% established in the original investigation for most of the period considered. Notably, the Union industry made profits over of 11,3 %, 14,8 % and 12,2 % in years 2018, 2019, and 2020 respectively. However, costs increased by 5,5 % from 2020 to the review investigation period, while prices remained stable, which drove profitability down to 6,6 %. This also coincided with an increase of dumped imports, from 0,9 % market share in 2020 to 2,7 % market share in the review investigation period.
- (122) The indicators examined demonstrate that the anti-dumping measures had achieved their intended result of removing the injury suffered by the Union producers. Indeed, the imposition of the original measures in 2017 has allowed the Union industry to recover, and keep, high market shares in the Union and make profits throughout the period considered. However, the Union industry's profitability dropped below the target profit in the review investigation period, due to the price pressure from the dumped imports that prevented the Union industry from increasing their prices in line with the increase in their cost of production.
- (123) On the basis of the above, the situation of the Union industry verified during the review investigation period was injurious. Irrespective of whether that injury would already qualify as material within the meaning of Article 3(5) of the basic Regulation, the Commission decided to analyse the likelihood of recurrence of injury.
- (124) Following disclosure, Hansol Paper claimed that the situation of the Union industry was not injurious during the review investigation period.
- (125) As stated in recital (83), the Commission established an undercutting margin of 13,7 %. The Commission also noted in recital (114) that there was a dramatic decrease in investment for the Union industry over the period considered, dropping by 80 %. During the review investigation period the Union industry's profitability was well below that of the target profit of 11,5 % established in the original investigation. All of these issues show an injurious situation of the Union industry during the review investigation period. This claim was therefore rejected.

5. LIKELIHOOD OF RECURRENCE OF INJURY

- (126) The Commission further assessed, in accordance with Article 11(2) of the basic Regulation, whether there would be a likelihood of recurrence of injury originally caused by the dumped imports from the Republic of Korea, if the measures against were allowed to lapse.
- (127) In this respect the following elements were analysed by the Commission: the production capacity and spare capacity in the country concerned, the attractiveness of the Union market and the impact of the potential import volume and import prices on the Union industry's situation should the measures be allowed to lapse.
- (128) As described in recitals (57) to (59), the exporting producer in the country concerned has the capability to increase its allocation of production capacity to benefit the production of lightweight thermal paper. Indeed, Hansol Paper's sustainability report noted the possibility for swing capacities that allow to produce different paper types depending on the market situation. Furthermore, as noted in recital (59), production capacity in Korea is significant, being some 10 times bigger than domestic consumption in the country and nearly twice Union consumption.
- (129) Secondly, as described in recital (66), the Union market is the largest market for lightweight thermal paper in the world, accounting for some 25 % of global consumption. Furthermore, as described in recital (65), the US authorities have recently imposed anti-dumping measures on the product concerned, making this major market less attractive to Korean exports. In addition, these exports, in certain periods of the period considered, were sold at higher prices on the Union market in comparison to the US market. This makes the Union market attractive both in terms of price and accessibility and there is a strong likelihood that the expiry of the anti-dumping measures would result in a significant increase of dumped imports.
- (130) Thirdly, as shown in tables 2 and 3, during the period considered, the import volumes from the country concerned have increased, while the import prices have decreased. These import prices are lower than those of the Union industry. Indeed, as described in recitals (83) to (85), the undercutting analysis carried out by the Commission has shown an undercutting margin without duties of 13,7 % in the RIP. This shows that, if measures are allowed to lapse, Korean exporters would have an incentive to export to the Union at injurious price levels. This would cause price pressure on the Union industry that would then lose sales volumes and/or be obliged to decrease their price levels, with the consequent impact on profitability.
- (131) On this basis, it is concluded that the absence of measures would in all likelihood result in a significant increase of dumped imports from the Republic of Korea and material injury would be likely to recur.

6. UNION INTEREST

- (132) In accordance with Article 21 of the basic Regulation, the Commission examined whether maintaining the existing anti-dumping measures would be against the interest of the Union as whole. The determination of the Union interest was based on an appreciation of all the various interests involved, including those of the Union industry, importers and users.
- (133) All interested parties were given the opportunity to make their views known pursuant to Article 21(2) of the basic Regulation.
- (134) On this basis, the Commission examined whether, despite the conclusions on the likelihood of continuation of dumping and the likelihood of recurrence of injury, compelling reasons existed which would lead to the conclusion that it was not in the Union interest to maintain the existing measures.

6.1. Interest of the Union industry

- (135) The Union industry consists of five producers located in three Member States (Germany, Spain and Finland). All five producers were in favour of the expiry review.

(136) As concluded in recital (123), the situation of the Union industry during the review investigation period was injurious. Moreover, as concluded in recital (130) the Union industry would not be able to cope with a removal of the measures, as it would likely result in a strong increase of dumped imports. Allowing the measures to lapse would therefore put the industry's long term financial viability in jeopardy.

(137) The Commission concluded that the continuation of the measures, therefore, is in the interest of the Union industry.

6.2. Interest of unrelated importers and users

(138) All known unrelated importers and users were informed about the initiation of the review. However, the Commission received no cooperation from unrelated importers and users.

(139) Therefore, there were no indications that the maintenance of the measures would have a negative impact on the users and/or importers outweighing the positive impact of the measures.

6.3. Conclusion on Union interest

(140) On the basis of the above, the Commission concluded that there were no compelling reasons of the Union interest against the maintenance of the existing measures on imports of certain lightweight thermal paper originating in the Republic of Korea.

7. ANTI-DUMPING MEASURES

(141) On the basis of the conclusions reached by the Commission on the likelihood of continuation of dumping, likelihood of recurrence of injury and Union interest, the anti-dumping measures on certain lightweight thermal paper from the Republic of Korea should be maintained.

(142) All interested parties were informed of the essential facts and considerations on the basis of which it was intended to recommend that the existing measures be maintained. All parties were also granted a period to make representations subsequent to this disclosure and to request a hearing with the Commission and/or the Hearing Officer in trade proceedings. The submissions and comments were duly taken into consideration.

(143) In view of Article 109 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽³³⁾ when an amount is to be reimbursed following a judgment of the Court of Justice of the European Union, the interest to be paid should be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the Official Journal of the European Union on the first calendar day of each month.

(144) The measures provided for in this regulation are in accordance with the opinion of the Committee established by Article 15(1) Regulation (EU) 2016/1036,

HAS ADOPTED THIS REGULATION:

Article 1

1. A definitive anti-dumping duty is imposed on imports of certain lightweight thermal paper weighing 65 g/m² or less; in rolls of a width of 20 cm or more, a weight of the roll (including the paper) of 50 kg or more and a diameter of the roll (including the paper) of 40 cm or more ('jumbo rolls'); with or without a base coat on one or both sides; coated with a thermo-sensitive substance on one or both sides; and with or without a top coat, currently falling under CN codes ex 4809 90 00, ex 4811 90 00, ex 4816 90 00 and ex 4823 90 85 (TARIC codes: 4809 90 00 10, 4811 90 00 10, 4816 90 00 10, 4823 90 85 20), originating in the Republic of Korea.

⁽³³⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

2. The rate of the definitive anti-dumping duty applicable to the product described in paragraph 1 shall be a fixed amount of EUR 103,16 per tonne net.
3. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

Article 2

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

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

Done at Brussels, 29 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1331**of 29 June 2023****amending Implementing Regulation (EU) 2019/159 imposing a definitive safeguard measure on imports of certain steel products**

THE EUROPEAN COMMISSION,

Having regard to Regulation (EU) 2015/478 of the European Parliament and of the Council of 11 March 2015 on common rules for imports ⁽¹⁾ and in particular Article 20 thereof,

Having regard to Regulation (EU) 2015/755 of the European Parliament and of the Council of 29 April 2015 on common rules for imports from certain third countries ⁽²⁾, and in particular Article 16 thereof,

Whereas:

1. BACKGROUND

- (1) By Commission Implementing Regulation (EU) 2019/159 ⁽³⁾ the Union applies a safeguard measure on imports of certain steel products. The measure takes the form of a tariff-rate quota (TRQ), with imports allowed free-of-duty within a quota based on historical trade flows. The free-of-duty quota is applicable to imports into the Union territory. A safeguard duty of 25 % applies to imports made beyond the applicable quota.
- (2) Regulation (EU) 2023/1321 ⁽⁴⁾ amended Regulation (EU) 2020/2170 of the European Parliament and of the Council ⁽⁵⁾ on the application of Union tariff rate quotas and other import quotas.
- (3) As a result of this amendment, steel categories 7 (Non Alloy and Other Alloy Quarto Plates ⁽⁶⁾) and 17 (Angles, Shapes and Sections of Iron or Non Alloy Steel ⁽⁷⁾) in the safeguard measure, listed in Annex 1 to Regulation (EU) 2020/2170, originating in the United Kingdom and brought into Northern Ireland by direct transport from other parts of the United Kingdom shall be eligible for treatment pursuant to the relevant Union tariff rate quotas if those goods are released for free circulation in the territory of Northern Ireland.

2. PROCEDURE

- (4) On 30 March 2023 the Commission published a Notice in the *Official Journal of the European Union* explaining that, following the amendment of Regulation (EU) 2020/2170 it was necessary that the Commission amended the EU safeguard Regulation by creating a new TRQ limited to transfers into Northern Ireland of the product categories included in the Annex to Regulation (EU) 2023/1321 originating in the United Kingdom and consigned directly from other parts of the United Kingdom. In this way, transfers of products falling within these product categories originating in the United Kingdom and consigned directly from other parts of the United Kingdom could enter Northern Ireland free-of-duty until the allocated quota is exhausted. Out of such quota, a 25 % safeguard duty would apply. Interested parties were given the possibility to comment on the content of the Notice.

⁽¹⁾ Regulation (EU) 2015/478 of the European Parliament and of the Council of 11 March 2015 on common rules for imports (OJ L 83, 27.3.2015, p. 16) ('the EU safeguard Regulation').

⁽²⁾ Regulation (EU) 2015/755 of the European Parliament and of the Council of 29 April 2015 on common rules for imports from certain third countries (OJ L 123, 19.5.2015, p. 33).

⁽³⁾ Commission Implementing Regulation (EU) 2019/159 of 31 January 2019 imposing a definitive safeguard measure against imports of certain steel products (OJ L 31, 1.2.2019, p. 27).

⁽⁴⁾ Regulation (EU) 2023/1321 of the European Parliament and of the Council of 14 June 2023 amending Regulation (EU) 2020/2170 as regards the application of Union tariff rate quotas and other import quotas to certain steel products transferred to Northern Ireland (see page 1 of this Official Journal).

⁽⁵⁾ Regulation (EU) 2020/2170 of the European Parliament and of the Council of 16 December 2020 on the application of Union tariff rate quotas and other import quotas (OJ L 432, 21.12.2020, p. 1).

⁽⁶⁾ CN codes (for information only): 7208 51 20, 7208 51 91, 7208 51 98, 7208 52 91, 7208 90 20, 7208 90 80, 7210 90 30, 7225 40 12, 7225 40 40, 7225 40 60, 7225 99 00.

⁽⁷⁾ CN codes (for information only): 7216 31 10, 7216 31 90, 7216 32 11, 7216 32 19, 7216 32 91, 7216 32 99, 7216 33 10, 7216 33 90.

- (5) To calculate the adequate volume of TRQs that would ensure, as foreseen in Regulation (EU) 2023/1321, the economic viability of these direct transfers to Northern Ireland from other parts of the United Kingdom, in view of the specific circumstances in Northern Ireland, the Commission analysed the available statistics ⁽⁸⁾ to calculate the volume of transfers to Northern Ireland from other parts of the United Kingdom.
- (6) The TRQs created by this Regulation are to be used exclusively by United Kingdom originating goods, as listed in the Annex to Regulation (EU) 2023/1321, and which are brought into Northern Ireland by direct transport from other parts of the United Kingdom and released for free circulation in the territory of Northern Ireland. Therefore, these new TRQs do not affect the allocation or volumes of existing TRQs for third countries into the Union territory.

Comments from interested parties

- (7) The Notice of Initiation gave the possibility to interested parties to submit comments within a stipulated deadline. The Commission did not receive any comments from any interested party.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Safeguards established under Article 3(3) of Regulation (EU) 2015/478 and Article 22(3) of Regulation (EU) 2015/755 respectively,

HAS ADOPTED THIS REGULATION:

⁽⁸⁾ Data available from the electronic system set up on the basis of Articles 55 and 56 of Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

Article 1

In Table 'IV.1 — Volumes of tariff–rate quotas' of Annex IV to Regulation (EU) 2019/159, parts 7 and 17 are amended and shall read as follows:

Product Number	Product category	CN Codes	Allocation by country (Where Applicable)	Year 5				Year 6				Additional duty rate	Order numbers
				From 1.7.2022 to 30.9.2022	From 1.10.2022 to 31.12.2022	From 1.1.2023 to 31.3.2023	From 1.4.2023 to 30.6.2023	From 1.7.2023 to 30.9.2023	From 1.10.2023 to 31.12.2023	From 1.1.2024 to 31.3.2024	From 1.4.2024 to 30.6.2024		
				Volume of tariff quota (net tonnes)				Volume of tariff quota (net tonnes)					
‘7	Non Alloy and Other Alloy Quarto Plates	7208 51 20, 7208 51 91, 7208 51 98, 7208 52 91, 7208 90 20, 7208 90 80, 7210 90 30, 7225 40 12, 7225 40 40, 7225 40 60, 7225 99 00	Ukraine	270 017,57	270 017,57	264 147,62	267 082,59	280 051,01	280 051,01	277 006,97	277 006,97	25 %	09.8836
		Other countries	554 571,27	554 571,27	542 515,37	548 543,32	575 178,29	575 178,29	568 926,35	568 926,35	25 %	(9)	
		United Kingdom (to Northern Ireland from other parts of the United Kingdom)	-	-	-	-	5 231,58	5 231,58	5 174,72	5 174,72	25 %	09.8498'	
‘17	Angles, Shapes and Sections of Iron or Non Alloy Steel	7216 31 10, 7216 31 90, 7216 32 11, 7216 32 19, 7216 32 91, 7216 32 99, 7216 33 10, 7216 33 90	Ukraine	30 113,25	30 113,25	29 458,61	29 785,93	31 232,21	31 232,21	30 892,73	30 892,73	25 %	09.8891
		Other countries	64 947,85	64 947,85	63 535,94	64 241,90	67 361,21	67 361,21	66 629,03	66 629,03	25 %	(18)	
		United Kingdom (to Northern Ireland from other parts of the United Kingdom)	-	-	-	-	14 061,23	14 061,23	13 908,39	13 908,39	25 %	09.8499'	

Article 2

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 as of 1 July 2023.

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

Done at Brussels, 29 June 2023.

For the Commission

The President

Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1332

of 29 June 2023

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 114044 as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and weaned piglets (holder of the authorisation: Roal Oy), and repealing Regulation (EC) No 902/2009

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such an authorisation.
- (2) An enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 114044 was authorised for 10 years as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding by Commission Regulation (EC) No 902/2009 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 114044 as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and weaned piglets in the additive category 'zootechnical additives' and functional group 'digestibility enhancers'. The preparation is available in solid and liquid formulations. The application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 4 October 2019 ⁽³⁾ and 27 January 2021 ⁽⁴⁾ that the preparation remains safe for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and weaned piglets, consumers and the environment. It found that the preparation is non-irritant to skin, and that the tested liquid form is neither irritant to the eyes nor a dermal sensitiser. It further stated that the additive should be considered a potential respiratory sensitiser in all forms. The Authority does not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be renewed as specified in the Annex to this Regulation. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (6) As a consequence of the renewal of the authorisation of the preparation as a feed additive, Regulation (EC) No 902/2009 should be repealed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Regulation (EC) No 902/2009 of 28 September 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy) (OJ L 256, 29.9.2009, p. 23).⁽³⁾ EFSA Journal 2019;17(11):5880.⁽⁴⁾ EFSA Journal 2021;19(3):6458.

- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the preparation, it is appropriate to provide a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 114044 and premixtures containing it, which are produced and labelled before 20 January 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the preparation referred to in paragraph 1, which are produced and labelled before 20 July 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted, where they are intended for food-producing animals.

Article 3

Repeal of Regulation (EC) No 902/2009

Regulation (EC) No 902/2009 repealed.

Article 4

Entry into force

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, 29 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feed with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers.

4a8i	Roal Oy	Endo-1,4-beta-xylanase (EC 3.2.1.8)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> CBS 114044 having a minimum activity of: solid form: 160 000 BXU ⁽¹⁾/g liquid form: 160 000 BXU/g <i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> CBS 114044 <i>Analytical method ⁽²⁾</i> Characterisation of the active substance in the additive and the premixture: reducing sugar assay for endo-1,4- beta-xylanase by colorimetric reaction of dinitrosalicylic acid reagent on reducing sugar yield at pH 5,3 and 50 °C; Characterisation of the active substance in the compound feed: colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate.	Chickens for fattening and chickens reared for laying	-	8 000 BXU	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, skin and eye protection for solid forms, and breathing protection for liquid forms.	20 July 2033
				Turkeys for fattening and turkeys reared for breeding		16 000 BXU			
				Piglets (weaned)		24 000 BXU			

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- ⁽¹⁾ 1 BXU is the amount of enzyme which liberates 1 nmol reducing sugars as xylose from birch xylan per second at pH 5,3 and 50 °C.
- ⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>
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COMMISSION IMPLEMENTING REGULATION (EU) 2023/1333

of 29 June 2023

concerning the authorisation of a preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 as a feed additive for chickens for fattening and weaned piglets (holder of authorisation: DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.), amending Regulation (EC) No 1811/2005 and repealing Regulation (EC) No 1259/2004

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 (previously taxonomically identified as *Aspergillus aculeatus*) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 1259/2004 ⁽³⁾ and for piglets (weaned) by Commission Regulation (EC) No 1811/2005 ⁽⁴⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of the preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 as a feed additive for chickens for fattening and weaned piglets. The applicant requested the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 November 2022 ⁽⁵⁾ that, under the proposed conditions of use, the preparation does not have adverse effects on animal health, consumer safety or the environment. As regards safety for the users when handling the preparation, owing to the lack of data with the final formulations, the Authority could not conclude on the potential of the additive to be irritant to skin and eyes or on its potential as a dermal sensitiser, but considered that the additive is a respiratory sensitiser due to the proteinaceous nature of the active substance. The Authority concluded that the additive is efficacious as a zootechnical additive in chickens for fattening and weaned piglets at the minimum recommended level of 10 FBG/kg feed. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ Commission Regulation (EC) No 1259/2004 of 8 July 2004 concerning the permanent authorisation of certain additives already authorised in feedingstuffs (OJ L 239, 9.7.2004, p. 8).⁽⁴⁾ Commission Regulation (EC) No 1811/2005 of 4 November 2005 concerning the provisional and permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 291, 5.11.2005, p. 12).⁽⁵⁾ EFSA Journal 2023;21(1):7703.

- (5) The assessment of the additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation concerned, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) As a consequence of the authorisation of the preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus fijiensis* CBS 589.94 as a feed additive, Regulation (EC) No 1811/2005 should be amended and Regulation (EC) No 1259/2004 should be repealed.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment of Regulation (EC) No 1811/2005

Article 1 and Annex I to Regulation (EC) No 1811/2005 are deleted.

Article 3

Repeal of Regulation (EC) No 1259/2004

Regulation (EC) No 1259/2004 is repealed.

Article 4

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 20 January 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 20 July 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

Entry into force

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, 29 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a1603	DSM Nutritional Products Ltd., represented by DSM Nutritional Products Sp. z o.o.	Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)	Additive composition Preparation of endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by <i>Aspergillus fijiensis</i> CBS 589.94 with a minimum activity of: Coated form: 50 FBG ⁽¹⁾ /g. Liquid form: 120 FBG/mL Characterisation of the active substance Endo-1,3(4)-beta-glucanase produced by <i>Aspergillus fijiensis</i> CBS 589.94 Analytical method ⁽²⁾ For the quantification of 1,3(4)-beta-glucanase activity in the feed additive: colorimetric method measuring coloured compound produced by the dinitro salicylic acid (DNSA) based on the enzymatic hydrolysis of beta-glucan at pH 5,0 and 50 °C. For the quantification of 1,3(4)-beta-glucanase activity in premixtures and compound feed: colorimetric method measuring water soluble dyed fragments based on the enzymatic hydrolysis of cross-linked azo-barley-glucan at pH 4,5 and 50 °C.	Chickens for fattening Weaned piglets	-	10 FBG	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	20 July 2033

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- (¹) One glucanase unit (FBG) corresponds to the amount of enzyme which under standard conditions (pH 5,0 and 30 °C) liberates glucose or other reducing carbohydrates at a rate corresponding to 1 µmol glucose per minute.
- (²) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en
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COMMISSION IMPLEMENTING REGULATION (EU) 2023/1334**of 29 June 2023****concerning the renewal of the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species and repealing Regulation (EU) No 349/2010****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) The preparation of copper chelate of hydroxy analogue of methionine was authorised for a period of 10 years as a feed additive for all animal species by Commission Regulation (EU) No 349/2010 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species, requesting the additive to be classified in the additive category 'nutritional additives' and in the functional group 'compounds of trace elements'. The application included a proposal for amending the conditions of the current authorisation, consisting of the removal of the mineral oil from the additive, which is therefore to be considered as a substance and no longer a preparation. In addition, the minimum content of copper in the additive has been slightly modified. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021 ⁽³⁾ that the applicant has provided evidence that the additive, in its new composition, remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is considered as a skin and eye irritant and a skin sensitiser, while the risk of respiratory sensitisation is considered low. The Authority stated that the proposed modification of the conditions of the original authorisation does not have an impact on the efficacy of the additive. Finally, it did not consider that there is a need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 349/2010 of 23 April 2010 concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species (OJ L 104, 24.4.2010, p. 31).

⁽³⁾ EFSA Journal 2021;19(5):6618.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

- (6) The assessment of copper chelate of hydroxy analogue of methionine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive, Regulation (EU) No 349/2010 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of copper chelate of hydroxy analogue of methionine, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation, with regard to the composition of the additive, which now consists of a substance, and the derived modification of the identification number of the additive.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the authorisation

The authorisation of the substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal

Regulation (EU) No 349/2010 is repealed.

Article 3

Transitional measures

1. The additive specified in the Annex and premixtures containing that additive, which are produced and labelled before 20 January 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the additive specified in the Annex, which are produced and labelled before 20 July 2024 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the additive specified in the Annex, which are produced and labelled before 20 July 2025 in accordance with the rules applicable before 20 July 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 4

Entry into force

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, 29 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Content of the element (Cu) in mg/kg of complete feed with a moisture content of 12 %			

Category of nutritional additives. Functional group: compounds of trace elements

3b410i	Copper chelate of hydroxy analogue of methionine	<i>Additive composition</i> Copper chelate of hydroxy analogue of methionine containing a minimum of 16 % copper and a minimum of 78 % (2-hydroxy-4-methylthio) butanoic acid Maximum content of nickel: 20 ppm. Solid form	All animal species	-	-	Bovines: — Bovines before the start of rumination: 15 (total); — Other bovines: 30 (total). Ovines: 15 (total). Caprines: 35 (total) Piglets: — Suckling and weaned up to 4 weeks after weaning: 150 (total); — From 5-th week after weaning up to 8 weeks after weaning: 100 (total). Crustaceans: 50 (total). Other animals: 25 (total).	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment. 3. The following words shall be included in the labelling: — for feed for sheep if the level of copper in the feed exceeds 10 mg/kg: 'The level of copper in this feed may cause poisoning in certain breeds of sheep.' — of feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: 'The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.'	20 July 2033
		<i>Characterisation of the active substances</i> Chemical formula: copper bis (-2-hydroxy-4-methylthio)butanoate: $\text{Cu}(\text{CH}_3\text{S}(\text{CH}_2)_2\text{-CH}(\text{OH})\text{-COO})_2$ CAS: 292140-30-8						
		<i>Analytical methods ⁽¹⁾</i> For the quantification of the hydroxy analogue of methionine content in the feed additive: titrimetry, potentiometric titration after oxidation reduction reaction. For the quantification of total copper in the feed additive: — Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or						

		— Atomic absorption spectrometry, AAS (ISO 6869) For the quantification of total copper in premixtures: — Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — Atomic absorption spectrometry, AAS (ISO 6869) or — Inductively coupled plasma mass spectrometry, ICP-MS (EN 17053). For the quantification of total copper in compound feed: — Inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — Atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or — Inductively coupled plasma mass spectrometry, ICP-MS (EN 17053).						
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(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

DECISIONS

COUNCIL DECISION (EU) 2023/1335

of 27 June 2023

appointing the European Prosecutors of the European Public Prosecutor's Office

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') ⁽¹⁾, and in particular Article 16 thereof,

Having regard to Council Implementing Decision (EU) 2018/1696 of 13 July 2018 on the operating rules of the selection panel provided for in Article 14(3) of Regulation (EU) 2017/1939 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') ⁽²⁾,

Having regard to Council Decision (EU) 2023/133 of 17 January 2023 appointing the members of the selection panel provided for in Article 14(3) of Regulation (EU) 2017/1939 ⁽³⁾,

Having regard to the reasoned opinions and the ranking of the candidates drawn up by the selection panel,

Whereas:

- (1) The EPPO was established by Regulation (EU) 2017/1939.
- (2) The European Prosecutors are to supervise investigations and prosecutions in accordance with Article 12 of Regulation (EU) 2017/1939.
- (3) The mandates of eight European Prosecutors appointed for a non-renewable period of three years by Council Implementing Decision (EU) 2020/1117 ⁽⁴⁾ expire on 28 July 2023. To ensure the continuity of functioning of the EPPO College, which consists of the European Chief Prosecutor and one European Prosecutor per participating Member State, it is necessary for the Council to appoint eight European Prosecutors for those positions becoming vacant from 29 July 2023.
- (4) Implementing Decision (EU) 2018/1696 lays down the operating rules of the selection panel provided for in Article 14(3) of Regulation (EU) 2017/1939 (the 'operating rules of the selection panel').
- (5) Pursuant to Article 16(1) of Regulation (EU) 2017/1939, each participating Member State is to nominate three candidates for the position of European Prosecutor from among candidates who are active members of the public prosecution service or judiciary of the relevant Member State, whose independence is beyond doubt and who possess the qualifications required for appointment to high prosecutorial or judicial office in their respective Member States, and who have relevant practical experience of national legal systems, of financial investigations and of international judicial cooperation in criminal matters.

⁽¹⁾ OJ L 283, 31.10.2017, p. 1.

⁽²⁾ OJ L 282, 12.11.2018, p. 8.

⁽³⁾ OJ L 17, 19.1.2023, p. 90.

⁽⁴⁾ Council Implementing Decision (EU) 2020/1117 of 27 July 2020 appointing the European Prosecutors of the European Public Prosecutor's Office (OJ L 244, 29.7.2020, p. 18).

- (6) Greece, Italy, Cyprus, Lithuania and Austria have nominated the candidates for the positions becoming vacant from 29 July 2023.
- (7) The selection panel drew up the reasoned opinions and the ranking for each of the candidates nominated by those Member States who fulfilled the conditions set out in Article 16(1) of Regulation (EU) 2017/1939 and submitted them to the Council, which received them on 2 May 2023.
- (8) Pursuant to the fourth paragraph of Rule VII.2 of the operating rules of the selection panel, the selection panel ranked the candidates according to their qualifications and experience. The ranking indicates the selection panel's order of preference and is not binding on the Council.
- (9) In accordance with Article 16(2) of Regulation (EU) 2017/1939, after having received the reasoned opinions of the selection panel, the Council is to select and appoint one of the candidates to be the European Prosecutor of the participating Member State in question.
- (10) In accordance with Article 16(3) of Regulation (EU) 2017/1939, the Council, acting by simple majority, is to select and appoint the European Prosecutors for a non-renewable term of 6 years.
- (11) The Council assessed the respective merits of the candidates taking into account the reasoned opinions submitted by the selection panel.
- (12) With regard to the reasoned opinion concerning the candidates nominated by Cyprus, the grounds put forward by the selection panel sufficiently establish that given the exceptional circumstances in that Member State, it is objectively impossible for that Member State to find further eligible candidates within a reasonable time, in spite of the fact that that Member State has deployed all necessary efforts to do so. Therefore, the conditions set out in the third paragraph of Rule VII.2. of the operating rules of the selection panel are met. In the light of the above-mentioned exceptional circumstances, the Council considered that the reasoned opinion submitted with regard to candidates nominated by Cyprus offered it sufficient choice of suitable candidates and, since any further delay in the appointment of the European Prosecutors would have serious adverse consequences on the effectiveness of European Union law, decided to proceed on that basis.
- (13) On the basis of an assessment of the respective merits of the candidates, the Council followed the non-binding order of preference indicated by the selection panel for the candidates nominated by Greece, Cyprus, Lithuania and Austria.
- (14) As regards the candidates nominated by Italy, on the basis of an assessment of the respective merits of those candidates, which was carried out in the relevant preparatory bodies of the Council, and taking into account the reasoned opinion submitted by the selection panel, complementary information and relevant documents submitted by Italy, the Council did not follow the non-binding order of preference of the selection panel,

HAS ADOPTED THIS DECISION:

Article 1

The following persons are hereby appointed European Prosecutors of the EPPO for a non-renewable period of six years from 29 July 2023:

Mr Nikolaos PASCHALIS ⁽⁵⁾,

Mr Andrea VENEGONI ⁽⁶⁾,

⁽⁵⁾ Nominated by Greece.

⁽⁶⁾ Nominated by Italy.

Ms Anne PANTAZI LAMPROU ⁽⁷⁾,
Mr Gedgaudas NORKŪNAS ⁽⁸⁾,
Ms Ursula SCHMUDERMAYER ⁽⁹⁾.

Article 2

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

Done at Luxembourg, 27 June 2023.

For the Council
The President
J. ROSWALL

⁽⁷⁾ Nominated by Cyprus.

⁽⁸⁾ Nominated by Lithuania.

⁽⁹⁾ Nominated by Austria.

COMMISSION IMPLEMENTING DECISION (EU) 2023/1336**of 16 June 2023****on corrective measures to be taken by Belgium and Luxembourg regarding certain performance targets for the third reference period in accordance with Regulation (EC) No 549/2004 of the European Parliament and of the Council***(notified under document C(2023)3852)***Only the Dutch and French texts are authentic****(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 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky ⁽¹⁾ (the framework Regulation), and in particular Article 11(3) point (c), third paragraph, thereof,Having regard to Commission Implementing Regulation (EU) 2019/317 of 11 February 2019 laying down a performance and charging scheme in the single European sky ⁽²⁾, and in particular Article 15(5) thereof,

Whereas:

GENERAL CONSIDERATIONS

- (1) Pursuant to Article 10 of Implementing Regulation (EU) 2019/317, Member States are to draw up, either at national level or at the level of functional airspace blocks ('FABs'), binding performance targets for each reference period of the performance scheme for air navigation services and network functions. Those performance targets have to be consistent with the Union-wide performance targets adopted by the Commission for the reference period concerned.
- (2) In response to the impact of the COVID-19 pandemic on the provision of air navigation services, Commission Implementing Regulation (EU) 2020/1627 ⁽³⁾ set out exceptional derogation measures from Implementing Regulation (EU) 2019/317 for the third reference period ('RP3'). On those bases, Commission Implementing Decision (EU) 2021/891 ⁽⁴⁾ set out revised Union-wide performance targets for the third reference period ('RP3').
- (3) Belgium, Germany, France, Luxembourg, and the Netherlands adopted jointly at the level of Functional Airspace Block Europe Central ('FABEC') a draft performance plan for RP3 ('the draft performance plan') which was submitted to the Commission in October 2021. Following an assessment, the Commission concluded in Implementing Decision (EU) 2022/728 ⁽⁵⁾ that the cost-efficiency performance targets for the Belgium-Luxembourg *en route* charging zone ('Belgium-Luxembourg charging zone') contained in that draft performance plan were

⁽¹⁾ OJ L 96, 31.3.2004, p. 1.

⁽²⁾ OJ L 56, 25.2.2019, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2020/1627 of 3 November 2020 on exceptional measures for the third reference period (2020-2024) of the single European sky performance and charging scheme due to COVID-19 pandemic (OJ L 366, 4.11.2020, p. 7).

⁽⁴⁾ Commission Implementing Decision (EU) 2021/891 of 2 June 2021 setting revised Union-wide performance targets for the air traffic management network for the third reference period (2020-2024) and repealing Implementing Decision (EU) 2019/903 (OJ L 195, 3.6.2021, p. 3).

⁽⁵⁾ Commission Implementing Decision (EU) 2022/728 of 13 April 2022 on the inconsistency of certain performance targets contained in the draft national and functional airspace block performance plans submitted by Belgium, Germany, Greece, France, Cyprus, Latvia, Luxembourg, Malta, the Netherlands, Romania, and Sweden pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period and setting out recommendations for the revision of those targets (OJ L 135, 12.5.2022, p. 4).

inconsistent with the Union-wide performance targets and set out recommendations for the revision of those local performance targets. Switzerland is also member of FABEC and was part of the draft FABEC performance plan. As a Third Country subject to the performance and charging scheme pursuant to the Air Transport Agreement between the EU and Switzerland, Switzerland was notified separately, through Commission Implementing Decision (EU) 2022/780 ⁽⁶⁾ of 13 April 2022, of the inconsistency of the local cost-efficiency performance targets of Belgium and Luxembourg contained in the draft FABEC performance plan.

- (4) On 13 July 2022, Belgium, Germany, France, Luxembourg and the Netherlands submitted a revised draft FABEC performance plan ('the revised draft performance plan') for RP3 to the Commission.
- (5) On 24 October 2022, the Commission in its Decision (EU) 2022/2255 ⁽⁷⁾ initiated the detailed examination referred to in Article 15(3) of Implementing Regulation (EU) 2019/317 ('the detailed examination') with regard to the revised cost-efficiency performance targets proposed for the Belgium-Luxembourg charging zone, included in the revised draft performance plan.
- (6) France, Germany and the Netherlands informed the Commission, on 28 October 2022, 3 November 2022 and 4 November 2022 respectively, that they had withdrawn from the revised draft performance plan established jointly at the level of FABEC. Simultaneously, those Member States submitted to the Commission individual, revised draft national performance plans for RP3.
- (7) Following a new assessment, the Commission found that the respective revised national performance targets were consistent with the Union-wide performance targets and notified France, Germany and the Netherlands thereof through Commission Decisions (EU) 2023/176 ⁽⁸⁾, (EU) 2023/177 ⁽⁹⁾ and (EU) 2023/179 ⁽¹⁰⁾ respectively. Switzerland also informed the Commission of its withdrawal from the revised draft performance plan and simultaneously submitted a revised draft national performance plan on 4 November 2022. The Commission found that the performance targets contained in the revised draft national performance plan of Switzerland are consistent with the Union-wide performance targets and notified Switzerland thereof by Commission Decision (EU) 2022/178 of 14 December 2022.
- (8) Belgium and Luxembourg have not notified any separate national performance plans. As a result, the revised draft performance plan previously established at FAB level, and subject to the Commission's detailed examination initiated by its Decision (EU) 2022/2255, continues to constitute the basis for the assessment of the performance targets of Belgium and Luxembourg.

⁽⁶⁾ Commission Implementing Decision (EU) 2022/780 of 13 April 2022 on the inconsistency of certain performance targets contained in the draft functional airspace block performance plan submitted by Switzerland pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period and setting out recommendations for the revision of those targets (OJ L 139, 18.5.2022, p. 218).

⁽⁷⁾ Commission Decision (EU) 2022/2255 of 24 October 2022 on the initiation of the detailed examination of certain performance targets contained in the revised draft performance plan for the third reference period submitted at functional airspace block level by Belgium, Germany, France, Luxembourg, and the Netherlands pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council (OJ L 297, 17.11.2022, p. 71).

⁽⁸⁾ Commission Decision (EU) 2023/176 of 14 December 2022 on the consistency of the performance targets contained in the revised draft performance plan submitted by France pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period (OJ L 25, 27.1.2023, p. 70).

⁽⁹⁾ Commission Decision (EU) 2023/177 of 14 December 2022 on the consistency of the performance targets contained in the revised draft performance plan submitted by Germany pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period (OJ L 25, 27.1.2023, p. 79).

⁽¹⁰⁾ Commission Decision (EU) 2023/179 of 14 December 2022 on the consistency of the performance targets contained in the revised draft performance plan submitted by the Netherlands pursuant to Regulation (EC) No 549/2004 of the European Parliament and of the Council with the Union-wide performance targets for the third reference period (OJ L 25, 27.1.2023, p. 95).

- (9) Therefore, this Decision should be addressed to Belgium and Luxembourg only because France, Germany and the Netherlands have withdrawn from the revised draft performance plan submitted by FABEC and submitted separate national performance plans. Those plans were found consistent with the Union-wide performance targets (see Commission's decisions referred to in recital (7)).
- (10) On 27 October 2022, the Commission services sent a first request for information to Belgium regarding the elements covered by the detailed examination. The letter of the Commission services to Belgium of 27 October 2022 was also sent simultaneously to Luxembourg, for information only. In response to that request, the Belgian authorities forwarded to the Commission services, on 6 November 2022 and 9 November 2022, information received from air navigation service providers ('ANSPs').
- (11) On 9 November 2022, the Commission services held a meeting with the Belgian authorities.
- (12) On 11 November 2022, the Commission services sent a second request for information to Belgium and received additional documents from the Belgian authorities on 28 November 2022. The letter of the Commission services to Belgium of 11 November 2022 was also sent simultaneously to Luxembourg, for information only.
- (13) On 29 November 2022, the Commission services requested additional information from Belgium. The Belgian authorities replied to that request on 8 December 2022 and also complemented the data and information which they had submitted on 28 November 2022. The letter of the Commission services to Belgium of 29 November 2022 was also sent simultaneously to Luxembourg, for information only.
- (14) On 8 December 2022 and 15 December 2022, the Commission services met with the Belgian authorities.
- (15) On 20 December 2022, the Commission services sent a final information request to Belgium. The Belgian authorities provided additional information in response to that request on 12 January 2023. The letter of the Commission services to Belgium of 20 December 2022 was also sent simultaneously to Luxembourg, for information only.
- (16) On 3 February 2023, the Commission services invited Luxembourg to submit any relevant complementary observations or comments to the materials provided by Belgium in response to the information requests referred to in recitals (10), (12), (13) and (15). The authorities of Luxembourg did not submit any information in response to the request of the Commission services.
- (17) On 2 March 2023, the Commission services met with the authorities of Belgium and Luxembourg.

ASSESSMENT OF THE REVISED PERFORMANCE TARGETS DURING THE DETAILED EXAMINATION

Scope of the detailed examination

- (18) The Performance Review Body ('PRB'), assisting the Commission in the implementation of the performance scheme pursuant to Article 11(2) of Regulation (EC) No 549/2004, submitted reports to the Commission on the assessment of the revised draft performance plan and on the detailed examination of the revised cost-efficiency performance targets proposed for the Belgium-Luxembourg charging zone.

- (19) The Commission notes that the safety, capacity and environment performance targets set in the revised draft performance plan remained unchanged. The Commission did not raise any findings on those performance targets in its Implementing Decision (EU) 2022/758 and in its Decision (EU) 2022/2255. Therefore, no further observations are set out in this Decision on the assessment of the safety, capacity and environment performance targets.
- (20) The detailed examination enabled the Commission to further analyze the cost-efficiency performance targets proposed by Belgium and Luxembourg (as presented in the table below), given the doubts set out in Decision (EU) 2022/2255 as to their consistency with the Union-wide performance targets.

<i>En route</i> charging zone of Belgium-Luxembourg	2014 baseline value	2019 baseline value	2020-2021	2022	2023	2024
Revised <i>en route</i> cost-efficiency targets on the determined unit cost , expressed in real terms in 2017 prices ('EUR 2017')	81,78 EUR	83,26 EUR	189,52 EUR	104,47 EUR	94,18 EUR	89,87 EUR

- (21) The detailed examination covered the elements set out in the Annex to Decision (EU) 2022/2255 and focused on services relating to the airspace of Belgium. For that reason, the Commission's services requests for information (see recitals (10) to (15)) were addressed to the Belgian authorities, whilst the relevant national authorities of Luxembourg received those requests for information only.

Assessment of the revised performance targets on the basis of the assessment criteria set out in points 1.4 (a), (b) and (c) of Annex IV to Implementing Regulation 2019/317

- (22) The Commission has assessed the consistency of the revised cost-efficiency performance targets presented in recital (18) with the Union-wide performance targets in accordance with the assessment criteria contained in points 1.4(a), (b) and (c) of Annex IV to Implementing Regulation 2019/317 taking into account the findings of the detailed examination which are set out in recitals (26) to (67) below.
- (23) Concerning the criteria laid down in points 1.4(a) and 1.4(b) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission observes that the cost-efficiency performance targets for the Belgium-Luxembourg charging zone underperform both the Union-wide DUC trend over RP3 and the long-term Union-wide DUC trend over RP2 and RP3 combined. Indeed, the DUC trend for RP3 of +1,9 % of Belgium and Luxembourg fails to meet the Union-wide trend of +1,0 % over the same period, whereas their long-term DUC trend of +1,1 % is significantly above the level of the corresponding Union-wide trend, namely -1,3 %.
- (24) Concerning the criterion laid down in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission found that the baseline value for the DUC of EUR 83,26 of Belgium and Luxembourg in EUR2017 is 13,2 % higher than the average baseline value of 73,53 EUR 2017 of the relevant comparator group.
- (25) As part of the detailed examination, the Commission has further substantiated its assessment of the Belgium-Luxembourg cost-efficiency performance targets on the basis of the assessment criteria set out in points 1.4(a), (b) and (c) of Annex IV to Implementing Regulation 2019/317 by analysing the following elements:
- the determined costs for the charging zone, broken down per air navigation service provider ('ANSP');
 - the complexity of the provision of air navigation services in the charging zone;

- the cross-border service provision arrangements with neighbouring countries, and their operational and financial impact; and
- the cost allocation between en route and terminal services.

Findings on the determined costs for the charging zone, broken down per ANSP

- (26) The Commission observes that the revised draft performance plan results in a determined unit cost ('DUC') of EUR 89,87 (in EUR 2017) for year 2024 for the Belgium-Luxembourg charging zone, as presented in recital (18). This is the highest level of DUC for 2024 of all the *en route* charging zones comprised in the scope of the performance and charging scheme.
- (27) Three ANSPs, namely skeyes, the Maastricht Upper Area Control Centre ('MUAC') and the Air Navigation Administration of Luxembourg ('ANA Luxembourg'), are serving the charging zone under examination. In addition, determined costs are incurred in respect of the national supervisory authorities ('NSAs') of Belgium and Luxembourg respectively.
- (28) The table below presents how the cost base of the charging zone is divided per entity and how the respective costs of those entities have evolved over time.

En route charging zone of Belgium-Luxembourg	2014 baseline value (EUR 2017)	2019 baseline value (EUR 2017)	2024 determined costs (EUR 2017)	Variation ⁽¹⁾ per year between 2014 and 2024	Variation ⁽¹²⁾ per year between 2019 and 2024
skeyes	114 M EUR	131 M EUR	135 M EUR	+ 1,8 %	+ 0,7 %
MUAC	54 M EUR	61 M EUR	75 M EUR	+ 3,7 %	+ 5,5 %
ANA Luxembourg	6 M EUR	6 M EUR	6 M EUR	+ 0,7 %	-0,9 %
NSAs of Belgium and Luxembourg ⁽¹³⁾	13 M EUR	13 M EUR	12 M EUR	-0,5 %	-1,9 %
Total	187 M EUR	211 M EUR	228 M EUR	+ 2,2 %	+ 2,0 %

- (29) In respect of the determined costs for 2024, the Commission notes that 59 % of the determined costs of the charging zone are incurred by skeyes, whilst MUAC accounts for 33 % of the cost base. The combined share of ANA Luxembourg and of the NSAs of Belgium and Luxembourg represents 8 % of the determined costs.
- (30) The Commission acknowledges that the revised draft performance plan decreases the total determined costs for the charging zone by 19,3 million EUR (in EUR 2017) for year 2024 in comparison with the draft performance plan. The Commission observes that skeyes largely contributes to that decrease with a cost reduction of 16 million EUR (in EUR 2017). According to Belgium, skeyes achieved that cost decrease through:
- productivity improvements (-5,5 million EUR in EUR 2017);
 - the revision of its investment plan and other operational expenses (-4,2 million EUR in EUR 2017); and
 - an exceptional cost reduction funded through the surplus resulting from the difference between the determined costs set in the draft performance plan for year 2021 and the actual costs recorded for that year (-6,5 million EUR in EUR 2017).

⁽¹¹⁾ Compound annual growth rate (CAGR).

⁽¹²⁾ Compound annual growth rate (CAGR).

⁽¹³⁾ The costs incurred by Belgium and Luxembourg in respect of the Eurocontrol International Convention relating to cooperation for the safety of air navigation of 13 December 1960 (as last amended) are included in the NSA costs.

- (31) On the other hand, the Commission notes that the MUAC costs allocated to the charging zone remained almost unchanged in the revised draft performance plan, as only a minor cost reduction amounting to 0,3 million EUR (in EUR 2017) was applied.
- (32) Based on the evaluation made by the PRB, the Commission notes that both skeyes and MUAC have substantially increased their costs in real terms over RP2 and that those costs continued to increase during RP3, mostly driven by higher staff costs and other operating costs. In 2024, the skeyes staff costs are planned to be higher by 6,9 % from their 2019 level, amounting to a difference of 6,5 million EUR (in EUR 2017). For MUAC, the increase of staff costs incurred in the charging zone, in comparison with the situation in 2019, is even more significant, as those costs are planned to be 30 % higher in 2024 than in 2019, which constitutes an increase of 15,0 million EUR (in EUR 2017).
- (33) The determined costs set in respect of ANA Luxembourg and of the NSAs of Belgium and Luxembourg do not give rise to any concerns.

Specific observations regarding skeyes

- (34) In respect of skeyes, which has the largest proportion of determined costs in the charging zone, the Commission has received additional benchmarking analysis from the PRB. That analysis shows that the relative cost-efficiency performance of skeyes has deteriorated in comparison with LVNL⁽¹⁴⁾, which has a very similar operational environment and which is included in the same comparator group for the purpose of assessing performance targets in the key performance area of cost-efficiency⁽¹⁵⁾. At the end of RP2, the unit cost of skeyes for 2019 was 2,2 % higher than the unit cost of LVNL.⁽¹⁶⁾ By the end of RP3, in 2024, after adjusting the unit cost of skeyes for the one-off cost reduction of 6,5 million EUR (in EUR 2017) referred to in recital (30), the unit cost of skeyes is expected to be higher by 9,4 % than the unit cost of LVNL.
- (35) On the basis of the PRB evaluation, this difference in the cost-efficiency between skeyes and LVNL is caused mainly by the staff costs. Based on the revised draft performance plan, skeyes plans to spend in 2024 23 % more on staff costs per *en route* service unit than LVNL. Expressed in monetary terms and adjusted to the annual cost base of skeyes, that gap would represent a surcharge to airspace users of 18,7 million EUR (in EUR 2017) for that year.
- (36) Furthermore, the Commission observes that the cost-efficiency of skeyes is significantly impacted by costs deriving from an early retirement scheme called 'DISPO functional availability regime' ('DISPO scheme' or 'DISPO') which, in accordance with Belgian law⁽¹⁷⁾, allows air traffic controllers ('ATCOs') working at skeyes to withdraw from duty five years before their legal retirement date. During those five years, they receive an allowance equaling between 75 % and 85 % of their last salary. According to the information provided in the revised draft performance plan, ATCOs are currently placed in DISPO at the age of 56 and this age limit is to be raised to 57 from 2025 onwards.
- (37) The Commission notes that the costs of the DISPO scheme are fully borne by skeyes, which passes on those costs to airspace users through its *en route* and terminal cost bases. Based on the historical cost data and the detailed future cost estimates for RP3 provided by Belgium, the *en route* costs resulting from DISPO amount to a total of 29 million EUR (in EUR 2017) over RP3 and have nearly doubled compared to RP2. In respect of year 2024, the *en route* determined costs resulting from the DISPO scheme are reported by Belgium to amount to 8,7 million EUR (in EUR 2017).
- (38) The Commission recognizes that the growing cost of DISPO over time is caused by the higher number of ATCOs benefiting from that scheme. Indeed, whereas Belgium reported for skeyes as a whole a total of 43 FTEs under DISPO in 2022, that number is expected to reach 71 FTEs in 2024. A gradual, steady increase in the number of FTEs under DISPO is expected by Belgium, even after RP3, at least until 2030.

⁽¹⁴⁾ 'Air Traffic Control the Netherlands' (LVNL).

⁽¹⁵⁾ As set out in Article 6 of Commission Implementing Decision (EU) 2021/891.

⁽¹⁶⁾ The unit costs of skeyes and LVNL both exclude the service units attributable to MUAC within their respective charging zones. The unit costs for skeyes and LVNL cover all the *en route* air navigation services, including meteorological services (MET) which in the Netherlands are provided by a MET provider separate from LVNL.

⁽¹⁷⁾ Royal Decree of 23 April 2017.

- (39) The Commission notes that during their placement under the DISPO scheme the ATCOs concerned remain at the disposal of skeyes and may be recalled to service by skeyes at any time, with full remuneration, in order to perform tasks other than those of an operational ATCO. However, information provided by Belgium indicates that only a very limited number of ATCOs placed under DISPO have actually been recalled by skeyes. Since 2015, 17 ATCOs have been recalled, some of them several times for different functions. Having regard to the estimates provided by the PRB, those recalled ATCOs provided a contribution of approximately 4 FTEs in 2022 to activities related to *en route* service provision. Those 4 FTEs represent only one tenth of the total pool of FTEs which could have been available under DISPO. This indicates that skeyes makes a very limited use of the staff available under DISPO.
- (40) Belgium has not proposed any mitigation measures in the revised draft performance plan to limit this growing financial impact of the DISPO scheme on the RP3 cost base.

Specific observations regarding MUAC

- (41) The Commission has further examined how the Member States belonging to the MUAC Agreement ⁽¹⁸⁾, namely Belgium, Germany, Luxembourg and the Netherlands ('the MUAC States') allocate the total determined costs incurred by MUAC to their respective charging zones.
- (42) In this respect, the Commission notes that the determined costs of MUAC are distributed between the MUAC States on the basis of one single criterion, namely the number of qualified ATCOs in service or planned to be in service in the three sector groups ⁽¹⁹⁾ of MUAC on the 1st of January of each year. The Commission further notes that 92 % of the costs of the Brussels sector group ('Brussels sector') are allocated to the Belgium-Luxembourg charging zone. The two other MUAC sector groups, namely 'the DECO sector group' and the 'Hannover sector group', are located outside of the geographical scope of the Belgium-Luxembourg charging zone and hence do not generate costs allocated to that charging zone.
- (43) The Commission understands that the cost allocation methodology has been set out in the MUAC Agreement and is underpinned by the assumption that the number of ATCOs in each sector reflects the workload for providing the services and hence the costs of the services and the complexity of each sector.
- (44) However, the Commission notes that over the last few years Belgium has expressed its concerns as to the effects of this cost allocation methodology on its charging zone. In particular, Belgium contends that its contribution to the total costs of MUAC, calculated on the basis of the number of ATCOs allocated to the Brussels sector, is disproportionately high when taking into account the fact that the Brussels sector generates a comparatively lower number of service units and related revenue than the other two MUAC sectors. Belgium further points out that the higher complexity of its airspace, which leads to additional workload for ATCOs, explains the higher cost per service unit of the MUAC Brussels sector as compared to the other two MUAC sectors.
- (45) Based on the PRB evaluation, the Commission notes that the share of the total MUAC costs allocated to Belgium and Luxembourg has indeed increased over time, as the number of ATCOs assigned to the Brussels sector has increased. Consequently, whilst Belgium and Luxembourg contributed to 32 % of MUAC costs in 2014, that share has risen to 34 % in RP3. The effect of that change on the cost base of the Belgium-Luxembourg charging zone is further exacerbated by the overall increase of total MUAC costs. The Commission notes that the MUAC determined costs for the Belgium-Luxembourg charging zone are set 39 % higher in real terms for 2024 than in 2014 ⁽²⁰⁾, whilst the service units for the charging zone in 2024 are forecasted to be only 11 % above their level of 2014.

⁽¹⁸⁾ Agreement relating to the Provision and Operation of Air Traffic Services and Facilities by Eurocontrol at the Maastricht Area Control Centre, signed on 25 November 1986.

⁽¹⁹⁾ MUAC operations are split in three sector groups, namely the 'Brussels sector group', the 'DECO sector group' group and the 'Hannover sector group'.

⁽²⁰⁾ Calculated on the basis of the baseline value for 2014.

- (46) The Commission takes note of the statement made by Belgium during the detailed examination indicating that the methodology for the funding of the costs of MUAC established in 1986 “*is based on a cost recovery system*” and “*does not follow the economic regulation imposed by the performance scheme*”. According to the related observations raised by the PRB, MUAC benefits, *de facto*, from a so-called full cost recovery system. Thus, despite being an air navigation service provider falling within the scope of application of the performance and charging scheme in accordance with Article 1(2) of Implementing Regulation (EU) 2019/317, MUAC does not bear the financial risks or apply the financial incentives deriving from the traffic risk sharing mechanism set out in Article 27 of Implementing Regulation (EU) 2019/317, the cost risk sharing mechanism set out in Article 28 of that Implementing Regulation 2019/317 and the incentives for the achievement of capacity targets set out in Article 11(3) of that Implementing Regulation.
- (47) The Commission notes that the information obtained for the first time during the detailed examination on the implementation of the performance and charging scheme in respect of MUAC raises concerns in terms of compliance with the relevant legal requirements. This conclusion is without prejudice to any infringement proceedings, which the Commission may undertake in respect of that matter.

Costs related to the postponed or cancelled RP2 investments

- (48) The Commission notes that, during RP2, both skeyes and MUAC postponed or cancelled several planned investments in fixed assets, which were part of the RP2 performance plan. Airspace users were partially charged for those investments as part of the cost base for the Belgium-Luxembourg charging zone despite the fact that those investments were not completed and thus did not provide the expected operational benefits. According to the calculations made by the PRB, that generated, in nominal terms and for RP2 as a whole, a gain of 7,8 million EUR in respect of skeyes and a gain of 2,1 million EUR in respect of MUAC. Belgium indicates that it does not plan to reimburse to airspace users any amounts charged in RP2 for the planned and not completed investments in fixed assets as it considers that there is no legal requirement to do so in respect of RP2.
- (49) In case some of those RP2 investments are finalised at a later stage, in accordance with Article 22(7) of Implementing Regulation (EU) 2019/317, the NSAs of Belgium and Luxembourg should ensure that any related amounts, which have already been recovered in RP2, are not charged for a second time to airspace users in RP3 or in subsequent reference periods.

Findings on the complexity of the provision of air navigation services in the charging zone, and its evolution over time

- (50) Belgium and Luxembourg argue that airspace complexity is a key factor behind the deviation of their proposed cost-efficiency performance targets from the Union-wide DUC trends. Belgium and Luxembourg explain in particular that the complexity of the Belgium-Luxembourg airspace increases the relative workload of ATCOs and thus weights negatively on ATCO productivity and on the *en route* cost base.
- (51) Having regard to the findings made by the PRB, the Commission acknowledges that the airspace in the charging zone of Belgium and Luxembourg is highly complex due to the high number of flights and the mixture of flight trajectories. Skeyes and MUAC are hence facing complex operating conditions.
- (52) However, the Commission notes that Belgium and Luxembourg have not provided any evidence demonstrating that the operations in RP3 became more complex than in RP2, or that in the remaining months of RP3 the complexity would further increase.
- (53) Based on the available information, which has been further analysed by the PRB, complexity remained relatively stable over RP2 in respect of both skeyes and MUAC. As regards 2020 and 2021, no meaningful conclusions can be drawn on the complexity of operations because of the exceptionally low traffic levels, which resulted from the COVID-19 pandemic. As regards the rest of RP3, there is no evidence to assume that complexity would differ significantly from the situation observed during RP2.

- (54) Given that the relatively high complexity of operations in Belgium and Luxembourg charging zone has been constant over time under normal traffic conditions, as explained in recitals (52) and (53), the Commission considers that such complexity cannot be invoked as a justification for the cost increases in RP3. Hence, the findings in recital (23) with regard to the assessment criteria set out in points 1.4(a) and (b) of Annex IV to Implementing Regulation (EU) 2019/317 are maintained.
- (55) Furthermore, the Commission recalls that the complexity of operations has already been taken into account while defining the comparator groups of ANSPs, which are used for the purpose of the assessment criterion set out in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317. Currently set comparator groups are comprised of ANSPs with similar operational and economic conditions and the comparator group of Belgium and Luxembourg comprises Austria, Switzerland and the Netherlands, which all face a relatively complex operational environment. Hence, the finding in recital (24) with regard to the assessment criterion set out in point 1.4(c) of Annex IV is maintained.

Findings on the cross-border service provision arrangements with neighbouring countries and their operational and financial impact

- (56) In the revised draft performance plan, Belgium and Luxembourg explain that the Brussels sector of MUAC includes the provision of cross-border services in the airspace of France and Germany. Belgium and Luxembourg further specify that the *en route* service units for the flights controlled by MUAC in those cross-border areas are recorded in the charging zones of those Member States, whilst the costs for those provided services are charged to the users flying in the Belgium-Luxembourg charging zone. Belgium and Luxembourg point out that this situation leads to an increased determined unit cost in their charging zone.
- (57) During the detailed examination, the Commission has analysed the cross-border service provision arrangements related to the Belgium-Luxembourg charging zone. The Commission found that MUAC provides services in three cross-border areas located in France and Germany, which are of significance in terms of workload and for which MUAC receives no financial compensation from the Member States having delegated the service provision. The same observation can be made with regard to two cross-border areas located in the airspace of the Netherlands in which the provision of services is delegated to skeyes.
- (58) Based on further analysis conducted by the PRB, the Commission estimates that the services provided by MUAC and skeyes in the cross-border areas referred to in recital (57) represented a total cost of approximately 12,2 million EUR (in EUR 2017) in 2019, of which the share of MUAC amounts to 6,8 million EUR (in EUR 2017) and the share of skeyes to 5,4 million EUR (in EUR 2017).
- (59) The Commission notes, however, that Belgium has not reported any changes in the provision of services by skeyes and MUAC in cross-border areas during RP2 or RP3. Those activities have not expanded in terms of scope and have not generated additional workload for the ANSPs during RP2 and RP3. Hence, as the associated costs have remained proportionally stable as a share of the total cost base of the Belgium-Luxembourg charging zone, the services provided by skeyes and MUAC in cross-border areas do not have a notable impact on the calculation of the cost-efficiency trends. Hence, the findings in recital (23) with regard to the assessment criteria set out in points 1.4(a) and (b) of Annex IV are maintained.
- (60) Finally, whilst the examined cross-border service provision arrangements bring notable benefits by reducing the complexity of operations and enhancing the efficiency of services, the 'user pays' principle set out in Article 15 of Regulation (EU) No 550/2004 entails that "airspace users should pay for the costs they generate at, or as close possible to, the point of use" ⁽²¹⁾. Accordingly, Article 21(2) of Implementing Regulation (EU) 2019/317 requires for charging zones to be "consistent with the provision of air navigation services" and stipulates that they "may include services provided by an air navigation service provider established in another Member State in relation to cross-border airspace". Article 22(1) of that Implementing Regulation further specifies that the cost base for a charging zone "shall consist of the determined costs related to the provision of air navigation services in the charging zone concerned".

⁽²¹⁾ Recital 22 of Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the single European sky (OJ L 96, 31.3.2004, p. 10).

- (61) In the light of what has been said in recital (60), the Commission considers that the financing arrangements in place for the provision of air navigation services in the cross-border areas referred to in recital (57), are not in line with the legal requirements underpinning the performance and charging scheme. This conclusion is without prejudice to any infringement proceedings, which the Commission may undertake in respect of this matter.
- (62) Given that the financing of services provided in cross-border areas is not compliant with the legal provisions referred to in recital (60), it cannot be used to justify any adjustment of the baseline value for 2019 for the purpose of the assessment criterion set out in point 1.4(c) of Annex IV to Implementing Regulation (EU) 2019/317. Furthermore, having regard to the findings made by the PRB, even if the baseline value for 2019 of the Belgium-Luxembourg charging zone had been adjusted for services provided in cross-border areas, it would still have resulted in a difference of +5,9 % for the Belgium-Luxembourg charging zone compared to the average baseline value of the comparator group. Hence, the finding in recital (24) with regard to the assessment criterion set out in point 1.4(c) of Annex IV is maintained.

Findings on the cost allocation between en route and terminal services

- (63) Belgium introduced in RP3 a revised cost allocation methodology for the apportioning of determined costs between *en route* and terminal services for RP3. The applied changes concern the allocation of the costs of approach control services ('approach costs') incurred by skeyes and the allocation of the costs incurred by the Belgian NSA. The Commission notes that Belgium has decided to allocate its approach costs almost entirely to *en route* services, which leads to the transfer of additional determined costs to the Belgium-Luxembourg charging zone in RP3.
- (64) The Commission observes that Belgium and Luxembourg adjusted the baseline values for 2014 and 2019 in the revised draft performance plan in order to take account of the changes in cost allocation between *en route* and terminal services. Therefore, those changes do not directly impact the assessment of the cost-efficiency performance targets in accordance with the criteria set out in Annex IV to Implementing Regulation (EU) 2019/317.
- (65) However, having regard to the evaluation made by the PRB, the Commission notes that Belgium increased the 2019 baseline value for the *en route* charging zone by 14,3 million EUR (in EUR 2017) whilst at the same time it reduced the baseline value for its terminal charging zone, which includes Brussels airport (EBBR), by 4,4 million EUR (in EUR 2017). The Commission is aware that skeyes also incurs costs in relation to approach services provided at regional airports, which are outside of the scope of the performance plan in RP3. However, the Commission considers that Belgium has failed to adequately explain and justify the large discrepancy between the adjustments applied to the *en route* and terminal baseline values, as the reallocated approach costs relating to regional airports outside of the scope of the performance plan appear disproportionate.
- (66) Furthermore, the Commission finds that, by including its approach costs almost entirely in the *en route* cost base, Belgium has not allocated those costs in a proportional way between *en route* services and terminal services on the basis of a transparent methodology. The Commission considers that such an allocation of approach costs fails to comply with the requirements laid down in Article 15(2), point (e), of Regulation (EC) No 550/2004 and in Article 22(5) of Implementing Regulation (EU) 2019/317.
- (67) Therefore, in light of the observations in recitals (63) to (66), this Decision is without prejudice to any infringement proceedings, which the Commission may undertake in respect of the changes in the cost allocation methodology applied in RP3 by Belgium.

Conclusion on the assessment on the basis of the assessment criteria set out in points 1.4(a), (b) and (c) of Annex IV to Implementing Regulation 2019/317

- (68) In light of the foregoing observations, the Commission concludes that the cost-efficiency performance targets for the Belgium-Luxembourg charging zone do not fulfil any of the assessment criteria laid down in points 1.4(a), (b) and (c) of Annex IV to Implementing Regulation (EU) 2019/317.

Assessment of the measures invoked by Belgium and Luxembourg to justify the observed deviations from the Union-wide cost-efficiency trends

- (69) Furthermore, pursuant to point 1.4(d) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission has to examine whether the deviations from the criteria set out in points 1.4(a), 1.4(b) and 1.4(c) of that Annex are necessary and proportionate in order to allow the achievement of the performance targets in the key performance area of capacity or to implement restructuring measures within the meaning of Article 2(18) of Implementing Regulation (EU) 2019/317. In particular, the Commission verified whether the observed deviations from the Union-wide DUC trend and from the long-term Union-wide DUC trend are exclusively due to additional determined costs for capacity-related measures.
- (70) Having regard to the calculations made by the PRB, the Commission notes that the estimated difference between the RP3 determined *en route* costs of the Belgium-Luxembourg charging zone for year 2024 and the determined costs that would be required to meet the RP3 Union-wide DUC trend is approximately EUR 8,2 M in EUR2017, whilst a corresponding difference of approximately EUR 43,7 M in EUR2017 is observed in respect of the long-term Union-wide DUC trend.
- (71) The Commission notes that the revised draft performance plan contains seven measures for the achievement of capacity targets ('capacity-related measures'), which are regarded by Belgium and Luxembourg as necessary for the achievement of capacity targets and which according to Belgium and Luxembourg would justify the deviations of their cost-efficiency performance targets from the Union-wide cost-efficiency performance targets.
- (72) Following the findings set out in Decision (EU) 2022/2255 in respect of those capacity-related measures, the Commission has further analysed those measures.

Measure 1

- (73) The first capacity-related measure ('Measure 1') comprises the recruitment and training of ATCOs by skeyes in order to maintain adequate ATCO staffing levels in RP3 and in the fourth reference period ('RP4'). Belgium and Luxembourg explain that Measure 1 is essential in order to address the ageing of the ATCO workforce and the consequent high number of retirements expected during RP3 and RP4. Those retirements derive in particular from the application of the DISPO scheme referred to in recital (36).
- (74) Belgium further emphasised, during the detailed examination, that the number of ATCOs in operations at skeyes would decrease by 15 % by the end of RP3 without the training and recruitment activities foreseen under Measure 1. According to Belgium, that would lead to a significant reduction of capacity.
- (75) In light of the information provided by Belgium, the Commission agrees that the training and recruitment of ATCOs by skeyes is necessary in order to maintain and enhance ATCO staffing levels and to ensure that the number of ATCOs is adequate in light of forecasted future traffic evolution. However, the Commission also notes that the need for such extensive training of new ATCOs results to a large extent from the early retirements deriving from the DISPO scheme.
- (76) The total costs of Measure 1 increased in the revised draft performance plan and amount to approximately 27 million EUR (in EUR 2017) over RP3. In comparison with the draft performance plan, the costs of Measure 1 are higher, in nominal terms, by 22,4 % for 2022, by 49,0 % for 2023 and by 36,8 % for 2024.
- (77) Belgium argues that the increased costs of Measure 1 are justified by the impact of higher inflation and by a more accurate estimation of the actual costs of new recruitments, because of a faster traffic recovery and a higher than expected failure rate of ATCO students in the training cycles already completed during RP3. Specifically, Belgium explains that skeyes has updated its business plan before the submission of the revised draft performance plan and now plans to recruit additional ATCOs at its maximum training capacity during the years 2022 to 2024.

- (78) The Commission notes that, in parallel, under the revised draft performance plan the number of ATCOs planned to be in operations in 2024 is 6 % lower than in the draft performance plan. The Commission assumes that this situation results from the higher than anticipated failure rate of the ATCO students in training at skeyes, mentioned in recital (77).
- (79) The Commission observes that the cost increases concerning Measure 1, referred to in recital (76), are significantly higher than the changes in the inflation index reflected in the revised draft performance plan. The Commission notes that the costs initially presented in the draft performance plan with regard to Measure 1 were limited to the training of controllers for the purpose of the *en route* services provided by skeyes in the scope of the Belgium-Luxembourg charging zone. However, based on the information received from Belgium during the detailed examination, the increased costs of Measure 1 included in the revised draft performance plan also cover the training of controllers by skeyes for terminal air navigation services. Costs relating to the terminal charging zone should not be included in Measure 1.
- (80) Hence, the Commission considers that Belgium has not adequately explained, despite being requested to do so, how the planned ATCO training activities and the planned intake of ATCO students of skeyes in respect of *en route* services were adapted between the draft performance plan and the revised draft performance plan. In addition, Belgium did not substantiate, in respect of *en route* services, the estimated costs incurred by skeyes per ATCO student and did not provide explanations for the high variability of those costs from one year to another. In light of those considerations, it was not possible for the Commission to quantify how the planned increase in the number of ATCO students at skeyes, mentioned in recital (77), contributes to the change in the costs of Measure 1 observed in recital (76) with regard to *en route* services.
- (81) Even assuming that skeyes would indeed have higher training costs incurred in respect of *en route* services and due to an increased number of ATCO students from 2022 to 2024, the Commission considers that those higher training costs are at least to a significant extent mitigated by the reduced staff costs deriving from the lower number of planned ATCOs in operations over the same time period, as observed in recital (78).
- (82) The Commission notes that the costs incurred for Measure 1 *de facto* result to a significant extent from the DISPO scheme which Belgium itself has chosen to adopt and apply in respect of the ATCOs working at skeyes. It is clear that the DISPO scheme leads, during RP3, to a high number of early retirements of ATCOs, whose simultaneous replacement by new ATCOs constitutes a considerable operational and financial burden for skeyes. However, having regard to the evaluation made by the PRB and the imperative need for skeyes to ensure the safe and continuous provision of the required capacity in RP3, the Commission considers, on balance, that Measure 1 is necessary to achieve the local capacity performance targets. However, the Commission considers that Belgium has failed to justify that the significant increase of the costs presented in the revised draft performance plan for Measure 1, as compared to the draft performance plan, is justified and proportionate, except as regards the effect of the higher inflation forecast on those costs. Therefore, as regards the additional costs deemed necessary and proportionate for the achievement of capacity targets, the Commission concludes that the costs to be taken into account in respect of Measure 1 are those presented in the draft performance plan, as converted in real terms.

Measure 2

- (83) The second capacity-related measure ('Measure 2') consists of the replacement by skeyes of its air traffic management ('ATM') system with a single, integrated and harmonized airspace management system to be developed with MUAC and the Belgian Defence as part of the 'Shared Air Traffic Services System 3' project ('SAS 3 project'). That new ATM system of skeyes is however only planned to enter into operation after the end of RP3, possibly not before 2030, and thus only preparatory activities are planned for RP3.
- (84) Measure 2 also includes the mid-life upgrade of the current ATM system of skeyes, which should become operational during a transitional phase before the roll-out of the new ATM system deriving from the SAS 3 project. Belgium has clarified, during the detailed examination, that the mid-life upgrade includes both a technical upgrade and a functional upgrade, which is expected to enable additional capacity in RP4.

- (85) The total costs of Measure 2 were lowered in the revised draft performance plan and amount to approximately 7,4 million EUR (in EUR 2017) over RP3. In comparison with the draft performance plan, the costs of Measure 2 are lower, in nominal terms, by 1,9 % for 2022, by 9,5 % for 2023 and by 11,9 % for 2024. Belgium has clarified that those changes reflect better the actual value of the contract signed by skeyes in December 2021 for the midlife upgrade of its current ATM system.
- (86) Belgium has clarified during the detailed examination that no depreciation costs will be incurred in RP3 with regard to the new ATM system stemming from the SAS 3 project. However, it is apparent from the information provided by Belgium that a cost of capital on a 'new ATM system' is planned to be charged already in RP3, despite the fact that the deployment of that system would only take place several years after the end of RP3.
- (87) The Commission considers that the planned upgrade and the subsequent replacement of the current ATM system of skeyes are as such justified from an operational standpoint and can be deemed necessary for the purpose of achieving the capacity targets.
- (88) However, the Commission notes that there are serious doubts about the timely implementation of Measure 2. Indeed, during the detailed examination, the Commission was informed by third parties that skeyes was considering to withdraw from the SAS 3 project, which underpins the planned development of the new ATM system. The Belgian authorities did not contest this information, but emphasised that discussions were still ongoing between the involved parties on the future of the project. In light of those observations, the Commission considers that Belgium has not provided adequate assurance on the implementation of the SAS 3 project or on any alternative solutions to be put in place in the event that the project does not materialize.
- (89) Furthermore, the Commission notes that the costs of Measure 2 comprise a large share of other operating costs, in particular project costs related to the preparation of the midlife upgrade of the existing ATM system and in relation to the new system. The Commission considers that such operating costs are related to the normal operation of an ANSP and, contrary to the ATM systems themselves and their components, cannot be considered directly incurred for the achievement of the capacity targets.
- (90) Therefore, as regards the additional costs deemed necessary and proportionate for the achievement of capacity targets, the Commission concludes that the costs to be taken into account in respect of Measure 2 should be limited to the depreciation costs and the cost of capital incurred for the mid-life upgrade of the ATM system of skeyes.

Measure 3

- (91) The third capacity-related measure ('Measure 3') relates to the amendment of the General Conditions of Employment applicable to ATCOs working at MUAC ('the GCE package'), following a collective agreement concluded in 2019 before the outbreak of the COVID-19 pandemic. Measure 3 consists of an increase in the remuneration of ATCOs working at MUAC by 10,75 %, in exchange for a more flexible work organization.
- (92) Based on the information contained in the revised draft performance plan, the flexibility provisions introduced as part of Measure 3 include an increase in the annual working time for newly recruited ATCO staff, new rules on the organization of shifts, the possibility to contract additional working days from ATCOs, more flexible annual working time and leave planning, as well as the possibility to agree with already employed ATCOs a possible extension of the retirement age to 60 years.
- (93) The Commission notes that the purpose of Measure 3 is, in essence, to increase the availability of ATCOs and the flexibility of rostering in order to accommodate traffic demand. Belgium emphasised that Measure 3 was expected, in the pre-COVID traffic conditions, to reduce air traffic flow management delays and thus avoid the resulting costs for airspace users. Belgium further clarified that Measure 3 was initially estimated to allow MUAC to set up additional shifts for ATCOs, with a gain of 1 050 additional shifts in 2019 and of 3 150 additional shifts in 2024.
- (94) In its analysis provided to the Commission, the PRB concluded that Measure 3 indeed enables MUAC to offer additional capacity to airspace users during calendar years 2023 and 2024, and thus contributes to the achievement of capacity targets in RP3 in circumstances where traffic volumes are comparable to their pre-pandemic level.

- (95) The total costs of Measure 3 increased in the revised draft performance plan and amount to approximately 13,2 million EUR (in EUR 2017) over RP3. In comparison with the draft performance plan, the costs of Measure 3 are higher, in nominal terms, by 7,4 % for 2022, by 9,0 % for 2023 and by 9,2 % for 2024. According to the information provided by Belgium during the detailed examination, those cost increases are due to the higher than expected inflation, which leads to the indexation of the salaries of ATCOs working at MUAC.
- (96) Belgium indicates that, at the time of its approval, the costs of Measure 3 were estimated to be equivalent to hiring additional ATCOs in order to address the ATCO staff shortages experienced by MUAC. That claim has however not been supported by any figures or evidence on the overall impact of Measure 3 on the RP3 cost base. The Commission has thus not been able to verify that the cost of Measure 3 in RP3 would be equivalent to the cost that MUAC would have incurred for hiring additional ATCOs in order to deliver the same capacity benefits.
- (97) The Commission notes that the PRB found that the costs presented by Belgium and Luxembourg under Measure 3 are justified and commensurate with the resulting benefits for airspace users, including the avoidance of ATFM delays and of the resulting adverse operational and financial impacts for airspace users including passengers and the environment.
- (98) In particular, the PRB points out that there is evidence that the GCE package comprised under Measure 3 enabled MUAC to deliver significantly improved capacity performance in its first year of implementation, namely 2019, which avoided an estimated 30 million EUR of indirect costs from ATM delays for airspace users. The PRB further notes that, in 2020 and 2021, the heavy downturn in traffic due to the COVID-19 pandemic created exceptional circumstances in which the additional flexibility provisions set up under Measure 3 were not necessary. However, the PRB considers that MUAC has adequately mitigated the impact of Measure 3 in respect of 2020 and 2021, given that the revised draft performance plan specifies that “some of the surplus shifts from 2020 and the first quarter of 2021” were deferred in order to be used in the rest of RP3 at no additional cost. The PRB concludes that Measure 3 is overall justified for capacity reasons in RP3, as it is conducive to an improved availability of resources and a maximization of the capacity made available at times of high traffic demand.
- (99) Therefore, the Commission concludes that Measure 3 is necessary for the achievement of capacity targets and its costs are proportionate in light of their beneficial operational impact on capacity provision.

Measure 4

- (100) The fourth capacity-related measure ('Measure 4') consists of an enhanced post-operations analysis process to be put in place by MUAC with the support of relevant tools and 'business intelligence facilities'. Belgium and Luxembourg indicate that the purpose of Measure 4, referred to in the revised performance plan as the 'PABI project', is to enable the further optimization of the planning of the daily operations of MUAC.
- (101) Based on the information contained in the revised draft performance plan, Measure 4 should contribute to accommodating future traffic demand and avoiding unnecessary operational restrictions for airspace users (referred to as 'over-regulation'), which lead to ATFM delays. The Commission notes that Measure 4 was indicated by Belgium to become operational in 2022, although that information was not expressly confirmed by Belgium during the detailed examination.
- (102) Having regard to the evaluation made by the PRB, the Commission agrees that the operational analytics capabilities presented under Measure 4 contribute to making the best use of available resources with a view to maximizing the capacity made available to airspace users, especially at times of high traffic demand.
- (103) The total costs of Measure 4 amount to approximately 0,9 million EUR (in EUR 2017) over RP3 and remain unchanged from the draft performance plan submitted in 2021. The Commission notes that the PRB has reviewed the costs of Measure 4 and considers them as justified.

- (104) Therefore, the Commission concludes that Measure 4 is necessary for supporting the continuous achievement of capacity targets and considers that the costs of Measure 4 are proportionate in light of the structural, operational gains which they are estimated to deliver.

Measure 5

- (105) The fifth capacity-related measure ('Measure 5') concerns the *ab initio* training of new ATCOs for the MUAC Brussels sector. According to the revised draft performance, the ATCO training activities comprised under Measure 5 have been outsourced to an external training organization based in France.
- (106) Belgium explains that the continued ATCO recruitment and *ab initio* training by MUAC is necessary in order to avoid capacity constraints in RP3 and in future reference periods. In light of the information provided by Belgium, the Commission agrees that the training of new ATCOs by MUAC is necessary in order to maintain and enhance ATCO staffing levels and to ensure that the number of ATCOs is adequate in light of the forecasted future traffic evolution.
- (107) The total costs of Measure 5 amount to approximately 14,2 million EUR (in EUR 2017) over RP3. During the detailed examination, Belgium provided a breakdown of the costs of Measure 5 under three categories, namely staff costs of the ATCO students, costs for simulator pilots, and costs charged by the training organization. The Commission notes that the PRB has reviewed the costs of Measure 5 and considers them to be justified.
- (108) Therefore, the Commission concludes that Measure 5 is necessary for the achievement of capacity targets and that its costs are proportionate in light of their operational impact on capacity provision.

Measure 6

- (109) The sixth capacity-related measure ('Measure 6') comprises the employment of additional ATCOs for the MUAC Brussels sector in order to accommodate traffic demand in RP3 and in the subsequent years.
- (110) According to the information contained in the revised draft performance plan, the number of those ATCOs is planned to rise substantially from 106 to 119 ATCOs over RP3. Belgium indicates that the additional ATCO staff will enable increased sector opening times and increased operational flexibility. In light of the information provided by Belgium, the Commission agrees that the recruitment of additional ATCOs by MUAC is necessary in order to support the achievement of capacity targets.
- (111) The total costs of Measure 6 amount to approximately 4,4 million EUR (in EUR 2017) over RP3. Those costs relate to the remuneration of the additional ATCOs who enter into service during RP3. The Commission notes that the PRB has reviewed the costs of Measure 6 and considers them to be justified.
- (112) Therefore, the Commission considers that Measure 6 is necessary for the achievement of capacity targets and that its costs are proportionate in light of their operational impact on capacity provision.

Measure 7

- (113) The seventh capacity-related measure ('Measure 7') covers the development of a new manpower planning system by MUAC for the purpose of supporting the implementation of new operational requirements. Measure 7 includes the development of a new framework for manpower planning, a modernised rostering tool and other manpower planning tools required to implement new operational requirements.
- (114) Having regard to the evaluation made by the PRB, the Commission agrees that the efficiency gains enabled by the new manpower planning system will contribute to improved operational performance and to a more efficient delivery of services.

- (115) The total costs of Measure 7 amount to approximately 0,8 million EUR (in EUR 2017) over RP3. The Commission notes that the PRB has reviewed the costs of Measure 7 and considers them to be justified.
- (116) Therefore, the Commission considers that Measure 7 is necessary for the achievement of capacity targets and its costs are proportionate in light of their operational impact on the capacity provision.

Combined impact of the capacity-related measures presented by Belgium and Luxembourg

- (117) The Commission has further analysed the seven capacity-related measures presented by Belgium and Luxembourg in respect of their overall impact and in order to evaluate whether the simultaneous implementation of all of those measures is necessary for the achievement of the local capacity performance targets.
- (118) In this respect, the Commission takes note of the PRB findings according to which those seven capacity-related measures, considered together, are appropriate and justified in view of their overall expected operational outcome and the resulting combined impact on capacity provision. According to the PRB analysis, the combined implementation of those measures enables skyes and MUAC to effectively manage the forecasted traffic levels at times of peak traffic demand, whilst strengthening the flexibility and resilience of service provision in the event of unforeseen or volatile circumstances. The PRB further confirms that the implementation of those capacity-related measures taken together does not lead to over-capacity in respect of the air navigation services provided in the airspace of Belgium and Luxembourg in the remaining months of RP3 ⁽²²⁾. Finally, the PRB points out that measures presented in the revised draft performance plan in relation to the training and employment of additional air traffic controllers are complementary with the organisational and technical measures enabling enhanced capacity provision.

Conclusions on the measures invoked by Belgium and Luxembourg to justify the observed deviations from the Union-wide cost-efficiency trends

- (119) In respect of the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317, the Commission concludes on the basis of the findings set out in recitals (71) to (118) that the costs presented by Belgium and Luxembourg for Measures 1 and 2 are partially necessary and proportionate for the achievement of capacity performance targets, whilst in respect of Measures 3 to 7 the presented costs are fully necessary and proportionate for the achievement of those targets.
- (120) The table below shows the resulting contribution of the capacity-related measures to the gaps with Union-wide DUC trends observed in recital (70) with regard to the relevant year, namely 2024.

Capacity-related measures presented by Belgium and Luxembourg	Contribution to the gap with Union-wide DUC trends for the Belgium-Luxembourg charging zone, expressed in EUR 2017, taking into account the costs deemed by the Commission to be necessary and proportionate for the achievement of capacity targets
Measure 1	7,7M EUR ⁽²³⁾
Measure 2	0,3M EUR ⁽²⁴⁾
Measure 3	4,4M EUR
Measure 4	0,3M EUR
Measure 5	4,7M EUR

⁽²²⁾ Based on the traffic assumptions contained in the Eurocontrol STATFOR October 2021 base traffic forecast.

⁽²³⁾ Amount reflecting the share of the costs of Measure 1 which was found by the Commission to be necessary and proportionate for the achievement of the local capacity performance targets, in accordance with the findings set out in recital (82).

⁽²⁴⁾ Amount reflecting the share of the costs of Measure 2 which was found by the Commission to be necessary and proportionate for the achievement of the local capacity performance targets, in accordance with the findings set out in recital (90).

Measure 6	1,5M EUR
Measure 7	0,3M EUR
Total	19,2M EUR

- (121) As presented in the table set out in recital (120), the capacity-related measures justify an excess of 19,2 million EUR (in EUR 2017) against the Union-wide DUC trends. That excess is larger than the estimated deviation from the RP3 Union-wide DUC trend, amounting to 8,2 million EUR (in EUR 2017), but is smaller than the estimated deviation of 43,7 million EUR (in EUR 2017) from the long-term Union-wide DUC trend. Hence, Belgium and Luxembourg still have a remaining unjustified gap of 24,5 million EUR (in EUR 2017) against the long-term Union-wide DUC trend.
- (122) Therefore, the Commission concludes that the criterion set out in point 1.4(d)(i) of Annex IV to Implementing Regulation (EU) 2019/317 is not fulfilled in respect of Belgium and Luxembourg.
- (123) Furthermore, the Commission notes that Belgium and Luxembourg have not presented in the revised draft performance plan any restructuring measures which would justify a deviation from the Union-wide DUC trend or from the Union-wide long-term DUC trend pursuant to the criterion set out in point 1.4(d)(ii) of Annex IV to Implementing Regulation (EU) 2019/317.

Conclusion on the assessment of the revised performance targets

- (124) In the light of the assessment set out in recitals (22) to (123), the Commission concludes that the cost-efficiency performance targets for the Belgium-Luxembourg charging zone are inconsistent with the Union-wide performance targets.

FINDINGS FROM THE REVIEW OF THE REVISED PERFORMANCE TARGETS CONDUCTED IN ACCORDANCE WITH POINT 2 OF ANNEX IV TO IMPLEMENTING REGULATION (EU) 2019/317

Revised terminal cost-efficiency performance targets – point 2.1(c) of Annex IV to Implementing Regulation (EU) 2019/317

- (125) In Implementing Decision (EU) 2022/728, the Commission raised concerns on the terminal cost-efficiency performance targets proposed by Belgium in the draft performance plan. Those cost-efficiency targets apply only in respect of terminal air navigation services provided at Brussels airport. The Commission considered in that Implementing Decision that Belgium should have further justified those targets or revised them downwards.
- (126) The Commission notes that the revised draft performance plan contains improved terminal cost-efficiency performance targets for Belgium in respect of calendar years 2022 to 2024, including a reduction of the determined costs in real terms for those calendar years. The Commission observes that the terminal DUC trend of +4,5 % over RP3 remains nonetheless higher than the *en route* DUC trend of +1,9 % over RP3 and higher than the actual terminal DUC trend of +0,5 % observed over RP2. Furthermore, the Commission observes that the DUC for terminal air navigation services at Brussels airport remains higher, by an estimated significant margin of 55 %, than the median terminal DUC of its relevant comparator group of airports.

- (127) In the light of assessment set out in recitals (125) and (126), the Commission concludes that the revised terminal cost-efficiency performance targets proposed by Belgium continue to give rise to concerns. The Commission therefore reiterates its view, as set out in Implementing Decision (EU) 2022/728, that Belgium should provide adequate justifications for those targets or revise them downwards.

Incentive schemes for the achievement of capacity performance targets – point 2.1(f) of Annex IV to Implementing Regulation (EU) 2019/317

- (128) In Implementing Decision (EU) 2022/728, the Commission concluded that Belgium and Luxembourg were to revise their incentive schemes for achieving *en route* and terminal capacity targets in such a way that the maximum financial disadvantage stemming from those incentive schemes is set at a level having a material impact on the revenue at risk. The Commission notes that Belgium and Luxembourg have not made any changes to those incentive schemes in the revised draft performance plan.
- (129) Therefore, the Commission concludes that the incentive schemes set out by Belgium and Luxembourg in the revised draft performance plan continue to give rise to concerns. The Commission therefore reiterates its view that Belgium and Luxembourg should revise their incentive schemes for achieving *en route* and terminal capacity targets so that the maximum financial disadvantages stemming from those incentive schemes are set at a level having a material impact on the revenue at risk, as required by Article 11(3), point (a) of Implementing Regulation (EU) 2019/317. In the Commission's view the revised incentive scheme should lead to a maximum financial disadvantage equal to or higher than 1 % of determined costs.

CONCLUSIONS

- (130) In light of the above, Belgium and Luxembourg should take corrective measures within the meaning of Article 11(3), point (c), third paragraph, of Regulation (EU) No 549/2004. Those corrective measures should enable Belgium and Luxembourg to achieve consistency with the Union-wide cost-efficiency performance targets for RP3 which corresponds, on the basis of the Commission's assessment set out in this Decision, to a reduction of the determined costs for the *en route* charging zone of Belgium and Luxembourg by 24,5 million EUR, expressed in real terms in 2017 prices.
- (131) The Commission notes that Belgium intends to carry out a compliance review of the performance of skewes and MUAC, in which it has invited Commission services to take part as observers. The Commission understands that the compliance review will support the preparation by Belgium of a draft final performance plan, which should take into account the corrective measures. Should this compliance review produce new evidence, the Commission intends to take account of that new evidence.
- (132) Certain corrective measures to be taken by Belgium and Luxembourg in accordance with this Decision might not, due to their nature, produce their full effects in RP3. However, Belgium and Luxembourg should still start implementing them in RP3, on the basis of binding commitments to be set out as part of their draft final performance plans, even if those measures generate cost-efficiency improvements in the next reference period.
- (133) The corrective measures should be put in place as part of draft final performance plans to be submitted to the Commission within three months from the date of adoption of this Decision, in accordance with Article 15(6) of Implementing Regulation (EU) 2019/317. Those draft final performance plans should be adopted individually, at national level, by Belgium and Luxembourg, given that performance target setting activities at FABEC level have been discontinued as a result of the withdrawal of France, Germany and the Netherlands from the revised draft FABEC performance plan, as explained in recital (6).
- (134) In the light of the findings set out in this Decision, Belgium and Luxembourg should, in particular, appropriately address the following issues:
- (a) Incorrect application of the respective legal provisions governing traffic risk sharing, cost risk sharing and incentive schemes in respect of MUAC, referred to in recitals (46) and (47);

- (b) Requested verification by the NSAs that the costs charged in RP2 for the cancelled and delayed investments in fixed assets are not double-charged to airspace users in the event that those investments materialize at later stage, as referred to in recitals (48) and (49);
 - (c) Incorrect financing arrangements for the costs incurred for services provided in cross-border areas, referred to in recitals (56) to (62);
 - (d) Incorrect allocation of the approach costs between *en route* and terminal air navigation services in respect of skeyes, referred to in recitals (63) to (67);
 - (e) Lack of adequate justifications for excessive terminal cost-efficiency targets of Belgium, referred to in recitals (125), (126) and (127);
 - (f) Incorrect level of the maximum financial disadvantages in the incentive schemes of Belgium and Luxembourg supporting the achievement of *en route* and terminal capacity targets, referred to in recitals (128) and (129).
- (135) The Single Sky Committee did not deliver an opinion. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

- (1) Belgium and Luxembourg shall define and communicate to the Commission corrective measures designed to achieve the consistency of national cost-efficiency performance targets with the Union-wide cost-efficiency performance targets for the third reference period within three months from the date of the adoption of this Decision.
- (2) Belgium and Luxembourg shall start applying those corrective measures in respect of skeyes and the Maastricht Upper Area Control Centre ('MUAC') in RP3. Those measures shall result in the reduction of the determined costs for the Belgium-Luxembourg *en route* charging zone by an amount leading to the consistency of the national cost-efficiency performance targets with the Union-wide cost-efficiency performance targets. That amount will be more precisely determined by Belgium and Luxembourg on the basis of the results of the compliance review referred to in recital (131) of this Decision and reviewed by the Commission as a part of its assessment under Article 15(7) of Commission Implementing Regulation (EU) 2019/317, taking account of the evidence resulting from that compliance review. The corrective measures shall lead to the reduction of the operating costs of both skeyes and MUAC.
- (3) In defining the corrective measures, Belgium and Luxembourg may also take account of the proposed additional measures set out in the Annex.
- (4) Belgium and Luxembourg shall include information in their respective performance plans demonstrating that skeyes and MUAC will effectively implement the corrective measures.

Article 2

This Decision is addressed to the Kingdom of Belgium and the Grand Duchy of Luxembourg.

Done at Brussels, 16 June 2023.

For the Commission
Adina-Ioana VĂLEAN
Member of the Commission

ANNEX

PROPOSED ADDITIONAL MEASURES

Belgium and Luxembourg may take the following measures in order to remedy the inconsistency of the cost-efficiency performance targets for the Belgium-Luxembourg charging zone with the Union-wide cost-efficiency performance targets:

- (1) amend the DISPO functional availability regime applied in Belgium, in view of reducing its impact on the cost base of the Belgium-Luxembourg charging zone;
 - (2) waive the return on equity of skeyes which is planned to be charged as part of the cost of capital;
 - (3) reimburse to airspace users, through an exceptional cost reduction, any surplus from year 2022 resulting from the traffic risk sharing mechanism or from the difference between the determined and actual costs.
-

COMMISSION IMPLEMENTING DECISION (EU) 2023/1337**of 22 June 2023****amending the Annex to Implementing Decision (EU) 2021/641 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States***(notified under document C(2023) 4335)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to 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') ⁽¹⁾, and in particular Article 259(1), point (c), thereof,

Whereas:

- (1) Highly pathogenic avian influenza (HPAI) is an infectious viral disease in birds and may have a severe impact on the profitability of poultry farming causing disturbance to trade within the Union and exports to third countries. HPAI viruses can infect migratory birds, which can then spread these viruses over long distances during their autumn and spring migrations. Therefore, the presence of HPAI viruses in wild birds poses a continuous threat for the direct and indirect introduction of these viruses into establishments where poultry or captive birds are kept. In the event of an outbreak of HPAI, there is a risk that the disease agent may spread to other establishments where poultry or captive birds are kept.
- (2) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases that are transmissible to animals or humans. HPAI falls within the definition of a listed disease in that Regulation, and it is subject to the disease prevention and control rules laid down therein. In addition, Commission Delegated Regulation (EU) 2020/687 ⁽²⁾ supplements Regulation (EU) 2016/429 as regards the rules for the prevention and control of certain listed diseases, including disease control measures for HPAI.
- (3) Commission Implementing Decision (EU) 2021/641 ⁽³⁾ was adopted within the framework of Regulation (EU) 2016/429 and it lays down emergency measures at Union level in relation to outbreaks of HPAI.
- (4) More particularly, Implementing Decision (EU) 2021/641 provides that the protection, surveillance and further restricted zones established by the Member States following outbreaks of HPAI, in accordance with Delegated Regulation (EU) 2020/687, are to comprise at least the areas listed as protection, surveillance and further restricted zones in the Annex to that Implementing Decision.
- (5) The Annex to Implementing Decision (EU) 2021/641 was recently amended by Commission Implementing Decision (EU) 2023/1175 ⁽⁴⁾ following outbreaks of HPAI in poultry or captive birds in France that needed to be reflected in that Annex.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

⁽³⁾ Commission Implementing Decision (EU) 2021/641 of 16 April 2021 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States (OJ L 134, 20.4.2021, p. 166).

⁽⁴⁾ Commission Implementing Decision (EU) 2023/1175 of 12 June 2023 amending the Annex to Implementing Decision (EU) 2021/641 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States (OJ L 155, 16.6.2023, p. 36).

- (6) Since the date of adoption of Implementing Decision (EU) 2023/1175, France has notified the Commission of an outbreak of HPAI in an establishment where captive birds were kept, located in Occitania administrative region.
- (7) The competent authority of France has taken the necessary disease control measures required in accordance with Delegated Regulation (EU) 2020/687, including the establishment of protection and surveillance zones around this outbreak.
- (8) The Commission has examined the disease control measures taken by France in collaboration with that Member State, and it is satisfied that the boundaries of the protection and surveillance zones in France established by the competent authority of that Member State are at a sufficient distance from the establishment where the outbreak of HPAI has been confirmed.
- (9) In order to prevent any unnecessary disturbance to trade within the Union and to avoid unjustified barriers to trade being imposed by third countries, it is necessary to rapidly describe at Union level, in collaboration with France, the protection and surveillance zones duly established by that Member State in accordance with Delegated Regulation (EU) 2020/687.
- (10) Therefore, the areas listed as protection and surveillance zones for France in the Annex to Implementing Decision (EU) 2021/641 should be amended.
- (11) Accordingly, the Annex to Implementing Decision (EU) 2021/641 should be amended to update regionalisation at Union level to take account of the protection and surveillance zones duly established by France in accordance with Delegated Regulation (EU) 2020/687, and the duration of the measures applicable therein.
- (12) Implementing Decision (EU) 2021/641 should therefore be amended accordingly.
- (13) Given the urgency of the epidemiological situation in the Union as regards the spread of HPAI, it is important that the amendments to be made to Implementing Decision (EU) 2021/641 by this Decision take effect as soon as possible.
- (14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/641 is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 22 June 2023.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

‘ANNEX

Part A

Protection zones in the concerned Member States* as referred to in Articles 1 and 2:

Member State: France

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687
<i>Department: Gers (32)</i>		
FR-HPAI(P)-2023-00065	AIGNAN	5.7.2023
FR-HPAI(P)-2023-00068	ARBLADE-LE-BAS	
FR-HPAI(P)-2023-00069	ARBLADE-LE-HAUT	
FR-HPAI(P)-2023-00070	AURENSAN	
FR-HPAI(P)-2023-00066	AVERON-BERGELLE	
FR-HPAI(P)-2023-00071	AYZIEU	
FR-HPAI(P)-2023-00072	BARCELONNE-DU-GERS	
FR-HPAI(P)-2023-00073	BASCOUS	
FR-HPAI(P)-2023-00074	BEAUMARCHES	
FR-HPAI(P)-2023-00075	BELMONT	
FR-HPAI(P)-2023-00076	BERNEDE	
FR-HPAI(P)-2023-00077	BETOUS	
FR-HPAI(P)-2023-00078	BOURROUILLAN	
FR-HPAI(P)-2023-00079	BOUZON-GELLENAVE	
FR-HPAI(P)-2023-00080	CAHUZAC-SUR-ADOUR	
FR-HPAI(P)-2023-00081	CAMPAGNE-D'ARMAGNAC	
FR-HPAI(P)-2023-00085	CASTELNAU-D'ANGLES	
FR-HPAI(P)-2023-00088	CASTELNAVET	
FR-HPAI(P)-2023-00090	CASTILLON-DEBATS	
FR-HPAI(P)-2023-00092	CAUMONT	
FR-HPAI(P)-2023-00093	CAUPENNE-D'ARMAGNAC	
FR-HPAI(P)-2023-00094	CAZAUBON	
FR-HPAI(P)-2023-00095	CORNEILLAN	
FR-HPAI(P)-2023-00096	COULOUME-MONDEBAT	
FR-HPAI(P)-2023-00100	COURTIES	
FR-HPAI(P)-2023-00101	CRAVENCERES	
FR-HPAI(P)-2023-00102	DEMU	
FR-HPAI(P)-2023-00103	EAUZE	
FR-HPAI(P)-2023-00104	ESCLASSAN-LABASTIDE	
FR-HPAI(P)-2023-00105	ESPAS	
FR-HPAI(P)-2023-00106	ESTANG	
FR-HPAI(P)-2023-00107	FUSTEROUAU	
FR-HPAI(P)-2023-00108	GEE-RIVIERE	
FR-HPAI(P)-2023-00109	IZOTGES	
FR-HPAI(P)-2023-00110	JUILLAC	
FR-HPAI(P)-2023-00111	LABARTHE	
FR-HPAI(P)-2023-00112	LABARTHETE	
FR-HPAI(P)-2023-00113	LADEVEZE-RIVIERE	
FR-HPAI(P)-2023-00114	LAGARDE-HACHAN	
FR-HPAI(P)-2023-00115	LANNE-SOUBIRAN	
FR-HPAI(P)-2023-00116	LANNUX	
FR-HPAI(P)-2023-00122	LAREE	
FR-HPAI(P)-2023-00123	LASSERADE	
FR-HPAI(P)-2023-00124	LAUJUZAN	
FR-HPAI(P)-2023-00127	LE HOUGA	

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687
FR-HPAI(P)-2023-00128 FR-HPAI(P)-2023-00130 FR-HPAI(P)-2023-00132 FR-HPAI(P)-2023-00133 FR-HPAI(P)-2023-00134 FR-HPAI(P)-2023-00139 FR-HPAI(P)-2023-00141 FR-HPAI(P)-2023-00140 FR-HPAI(P)-2023-00144 FR-HPAI(P)-2023-00145 FR-HPAI(P)-2023-00146 FR-HPAI(P)-2023-00149 FR-HPAI(NON-P)-2023-00376	LELIN-LAPUJOLLE LIAS-D'ARMAGNAC LOUBEDAT LOURTIES-MONBRUN LOUSSOUS-DEBAT LUPIAC LUPPE-VIOLLES MAGNAN MANCIET MARGOUET-MEYMES MARGUESTAU MASSEUBE MAULEON-D'ARMAGNAC MAULICHERES MAUPAS MONCLAR MONLEZUN-D'ARMAGNAC MONTAUT MONTESQUIOU MORMES NOGARO PANJAS PERCHEDE PEYRUSSE-GRANDE PEYRUSSE-VIEILLE POUY-LOUBRIN POUYDRAGUIN PRENERON REANS RIGUEPEU RISCLE SABAZAN SAINT-ARAILLES SAINT-ARROMAN SAINT-AUNIX-LENGROS SAINT-ELIX-THEUX SAINT-GERME SAINT-GRIEDE SAINT-MARTIN-D'ARMAGNAC SAINT-MICHEL SAINT-MONT SAINT-OST SAINT-PIERRE-D'AUBEZIES SAINTE-AURENCE-CAZAUX SAINTE-CHRISTIE-D'ARMAGNAC SALLES-D'ARMAGNAC SARRAGACHIES SAUVIAC SEAILLES SEGOS SION SORBETS TARSAC TASQUE TERMES-D'ARMAGNAC TOUJOUSE TOURDUN URGOSSE	

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687
	VERGOIGNAN VERLUS VIC-FEZENSAC VIELLA VIOZAN "AUJAN-MOURNEDE ZP à l'ouest de route entre « Le Rentier » et « Le Sage » ZS à l'est de cette même route"	
<i>Department: Landes (40)</i>		
FR-HPAI(P)-2023-00067 FR-HPAI(P)-2023-00082 FR-HPAI(P)-2023-00083 FR-HPAI(P)-2023-00084 FR-HPAI(P)-2023-00089 FR-HPAI(P)-2023-00091 FR-HPAI(P)-2023-00097 FR-HPAI(P)-2023-00098 FR-HPAI(P)-2023-00099 FR-HPAI(P)-2023-00117 FR-HPAI(P)-2023-00118 FR-HPAI(P)-2023-00119 FR-HPAI(P)-2023-00120 FR-HPAI(P)-2023-00121 FR-HPAI(P)-2023-00125 FR-HPAI(P)-2023-00126 FR-HPAI(P)-2023-00129 FR-HPAI(P)-2023-00131 FR-HPAI(P)-2023-00136 FR-HPAI(P)-2023-00137 FR-HPAI(P)-2023-00138 FR-HPAI(P)-2023-00142 FR-HPAI(P)-2023-00143 FR-HPAI(P)-2023-00148	Aire-sur-l'Adour Arboucave Artassenx Bahus-Soubiran Bascons Bats Benquet Bordères-et-Lamensans Bourdalat Bretagne-de-Marsan Buanes Castandet Castelnau-Tursan Cazères-sur-l'Adour Classun Clèdes Duhort-Bachen Eugénie-les-Bains Fargues Geaune Grenade-sur-l'Adour Hontanx Labastide-d'Armagnac Lacajunte Lagrange Larrivière-Saint-Savin Latrille Lussagnet Mauries Maurrin Mauvezin-d'Armagnac Miramont-Sensacq Montgaillard Montsoué Payros-Cazautets Pécorade Philondenx Pimbo Puyol-Cazalet Renung Saint-Agnet Saint-Gein Saint-Loubouer Saint-Maurice-sur-Adour Saint-Sever (Est D933.S) Samadet Sarron	22.6.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 39 of Delegated Regulation (EU) 2020/687
	Sorbets Urgons Vielle-Tursan Le Vignau	
<i>Department: Hautes-Pyrénées (65)</i>		
FR-HPAI(P)-2023-00147	ARIES-ESPENAN BETBEZE DEVEZE LALANNE MONLEON-MAGNOAC POUY SARIAC-MAGNOAC THERMES-MAGNOAC VILLEMUR	22.6.2023

Part B

Surveillance zones in the concerned Member States* as referred to in Articles 1 and 3:

Member State: Germany

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
BAYERN		
DE-HPAI (P)-2023-00026	Landkreis Regensburg Betroffen sind folgende Gemeinden bzw. Teile der Gemeinden: Gemeinde Bernhardswald, Ortsteile Adlmannstein, Bernhardswald, Darmannsdorf, Dingstetten, Elendbaumgarten, Erlbach, Gerstenhof, Hackenberg, Hauzendorf, Hinterappendorf, Högelstein, Kreuth, Kürn, Lehen, Lohhof, Oberharm, Oberhohenroith, Oberlipplgüt, Ödenhof, Pettenreuth, Pillmannsberg, Plitting, Rothenhofstatt, Schneckenreuth, Seibersdorf, Thalhof, Thonseigen, Unterbraunstuben, Unterlipplgüt, Weg, Wolfersdorf Gemeinde Holzheim, Ortsteile Trischlberg, Traidenloh, Haslach, Ödenholz, Bubach Gemeinde Lappersdorf, Ortsteile Baiern, Benhof, Einhausen, Geiersberg, Hainsacker, Kaulhausen, Lorenzen, Pielmühle, Schwaighausen, Unterkaulhausen Markt Regensburg, Ortsteile Asing, Birkenzant, Breitwies, Brennthäl, Buchenlohe, Danersdorf, Drackenstein, Edlhausen, Eitlbrunn, Ellmau, Ferneichlberg, Forstberg, Gfangen, Glapfenberg, Grafenwinn, Grub, Hirschling, Irlbründl, Kerm, Kirchberg, Kleeberg, Kürnberg, Lindach, Mettenbach, Neuried, Oberhaslach, Oberhub, Preßgrund, Regensburg, Reiterberg, Richterskeller, Schönleiten, Steinsberg	29.6.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	Gemeinde Wenzelbach, Ortsteile Abbachhof, Birkenhof, Birkenhof, Brunnhöfl, Fußenberg, Gonnersdorf, Grafenhofen, Grünthal, Irlbach, Jägerberg, Lehen, Probstberg, Roith, Schnaitterhof, Thanhausen, Zeitlhof, Ziegenhof Gemeinde Zeilarn, Ortsteile Laub, Neuhof, Ödenthal, Pentlhof, Regendorf, Zeilarn	
	Landkreis Regensburg Markt Regensburg, Ortsteile Wöhrhof, Diesenbach, Karlstein, Kleinramspau, Steinsberg, Fidelhof, Fronau, Hagenau, Schneitweg, Medersbach, Regensburg, Stadel, Ramspau, Münchsried, Kleeberg	21.6.2023 - 29.6.2023
	Landkreis Schwandorf Stadt Nittenau Ortsteile: Berglarn, Dürrmaul, Geiseck, Gunt, Hadriwa, Hammerhäng, Harthöfl, Hengersbach, Hinterberg, Hof A. Regen, Hofer Mühle, Kaaghof, Ödgarten (bei Stefling), Roneck, Rumelsölden, Schönberg (bei Sankt Martin), Steinhof (bei Sankt Martin), Untermainsbach, Vorderkohlstetten, Weinting, Wetzlgüt, Wetzlhof, Dobl, Eckartsreuth, Elendhof bei Pettenreuth, Eschlbach bei Grafenwinn, Höflarn, Knollenhof, Sankt Martin, Schwarzenberg, Steinmühl, Straßhof, Überfuhr am Regen, Weißenhof, Stefling, Hinterkohlstetten Stadt Burglengenfeld Ortsteile: Augustenhof, Burglengenfeld, Greinhof, Karlsberg, Wölland. Stadt Maxhütte-Haidhof Ortsteil: Almenhöhe, Berghof, Binkenhof, Birkenhöhe, Birkenzell, Blattenhof, Brunnheim, Deglhof, Eichelberg, Engelbrunn, Harberhof, Haugshöhe, Ibenthann, Katzheim, Kreilnberg, Lehenhaus, Lintermühle, Meßnerskreith, Neukappl, Pfaltermühle, Pirkensee, Rappenbügl, Roßbach, Stadlhof, Steinhof, Strieglhof, Verrau, Winkerling, Ziegelhütte, Rohrhof, Almenhof, Fürstthof, Haidhof, Kappl, Leonberg, Ponholz, Roding, Schwarzhof, Roßbergeröd, Maxhütte Stadt Teublitz Ortsteile: Kuntsdorf, Saltendorf, Teublitz	29.6.2023
	Landkreis Schwandorf 3 km Radius um den Ausbruchsbetrieb (Koordinaten UTM 32: 32728906/5447575). Betroffen sind: Stadt Maxhütte-Haidhof Ortsteile: Waldgebiete	21.6.2023 - 29.6.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	Stadt Regensburg Betroffen ist die Stadt Regensburg mit den Ortsteilen Haslbach, Ödenthal sowie Teile von Sallern-Gallingkofen und Wutzelhofen. Beginnend bei Schnittstelle B16 Richtung Cham mit östlichem Regenufer- Dem südl. Rand der B16 folgend bis zur Unterführung „Am Mühlberg“- Der Straße „Am Mühlberg“ Richtung Süden folgend bis zur Kreuzung mit „Chamer Str.“- Chamer Str. folgend Richtung Osten bis auf Höhe Grundstück „Wutzlhofen 4“- Abklickend der Straße „Wutzelhofen“ in süd-östl. Richtung folgend bis Bahndamm- Dem Bahndamm in süd-Richtung folgend bis auf Höhe nördl.Kante Sportplatz „BSC Regensburg“- Dem am nördl. Sportplatzrand verlaufenden Feldweg folgend bis zum östl. Waldrand des „Schwarzholz“- Dem Weg weiter Richtung Norden folgend bis zur Stadtgrenze- Von hier der Stadtgrenze entgegen des Uhrzeigersinnes folgend bis zur Schnittstelle B16 und Regen.	29.6.2023

Member State: France

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
<i>Département: Gers (32)</i>		
FR-HPAI(P)-2023-00065 FR-HPAI(P)-2023-00068 FR-HPAI(P)-2023-00069 FR-HPAI(P)-2023-00070 FR-HPAI(P)-2023-00066 FR-HPAI(P)-2023-00071 FR-HPAI(P)-2023-00072 FR-HPAI(P)-2023-00073 FR-HPAI(P)-2023-00074 FR-HPAI(P)-2023-00075 FR-HPAI(P)-2023-00076 FR-HPAI(P)-2023-00077 FR-HPAI(P)-2023-00078 FR-HPAI(P)-2023-00079 FR-HPAI(P)-2023-00080 FR-HPAI(P)-2023-00081 FR-HPAI(P)-2023-00085 FR-HPAI(P)-2023-00088 FR-HPAI(P)-2023-00090 FR-HPAI(P)-2023-00092 FR-HPAI(P)-2023-00093 FR-HPAI(P)-2023-00094 FR-HPAI(P)-2023-00095 FR-HPAI(P)-2023-00096 FR-HPAI(P)-2023-00100 FR-HPAI(P)-2023-00101 FR-HPAI(P)-2023-00102 FR-HPAI(P)-2023-00103 FR-HPAI(P)-2023-00104	"AUJAN-MOURNEDE ZP à l'ouest de route entre « Le Rentier » et « Le Sage » ZS à l'est de cette même route" "SAINT-BLANCARD ZS à l'Ouest des routes D 139 et D576 ZRS à l'Est" ARMENTIEUX ARMOUS-ET-CAU ARROUEDE AUSSOS BARRUGNAN BARRAN BARS BASSOUES BAZIAN BAZUGUES BELLEGARDE BELLOC-SAINT-CLAMENS BERDOUES BETCAVE-AGUIN BEZOLLES BEZUES-BAJON BIRAN BRETAGNE-D'ARMAGNAC CABAS-LOUMASSES CAILLAVET CALLIAN CANNET CASTELNAU D'AUZAN LABARRÈRE	21.7.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
FR-HPAI(P)-2023-00105 FR-HPAI(P)-2023-00106 FR-HPAI(P)-2023-00107 FR-HPAI(P)-2023-00108 FR-HPAI(P)-2023-00109 FR-HPAI(P)-2023-00110 FR-HPAI(P)-2023-00111 FR-HPAI(P)-2023-00112 FR-HPAI(P)-2023-00113 FR-HPAI(P)-2023-00114 FR-HPAI(P)-2023-00115 FR-HPAI(P)-2023-00116 FR-HPAI(P)-2023-00122 FR-HPAI(P)-2023-00123 FR-HPAI(P)-2023-00124 FR-HPAI(P)-2023-00127 FR-HPAI(P)-2023-00128 FR-HPAI(P)-2023-00130 FR-HPAI(P)-2023-00132 FR-HPAI(P)-2023-00133 FR-HPAI(P)-2023-00134 FR-HPAI(P)-2023-00139 FR-HPAI(P)-2023-00141 FR-HPAI(P)-2023-00140 FR-HPAI(P)-2023-00144 FR-HPAI(P)-2023-00145 FR-HPAI(P)-2023-00146 FR-HPAI(P)-2023-00149 FR-HPAI(NON-P)-2023-00376	CASTEX-D'ARMAGNAC CAZAUX-D'ANGLES CAZENEUVE CHELAN CLERMONT-POUYGUILLES COURRENSAN CUELAS DUFFORT DURBAN ESTIPOUY GALIAX GAZAX-ET-BACCARISSE GONDRIN GOUX IDRAC-RESPAILLES JU-BELLOC JUSTIAN L'ISLE-DE-NOE LABEJAN LADEVEZE-VILLE LAGRAULET-DU-GERS LALANNE-ARQUE LAMAGUERE LANNEMAIGNAN LANNEPAX LAVERAET LE BROUILH-MONBERT LOUBERSAN LOUSLITGES MANAS-BASTANOUS MANENT-MONTANE MARAMBAT MARCIAC MASCARAS MAUMUSSON-LAGUIAN MEILHAN MIRANDE MIRANNES MONCASSIN MONCLAR-SUR-LOSSE MONCORNEIL-GRAZAN MONFERRAN-PLAVES MONGUILHEM MONLAUR-BERNET MONLEZUN MONT-D'ASTARAC MONT-DE-MARRAST MONTIES MOUCHES MOUREDE NOULENS ORNEZAN PANASSAC PLAISANCE PONSAMPERE PONSAN-SOUBIRAN POUYLEBON PRECHAC-SUR-ADOUR	

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	PROJAN RAMOUZENS RICOURT ROQUEBRUNE ROQUES ROZES SADEILLAN SAINT-CHRISTAUD SAINT-JEAN-POUTGE SAINT-JUSTIN SAINT-MARTIN SAINT-MEDARD SAINT-PAUL-DE-BAISE SAINTE-DODE SAMARAN SARRAGUZAN SCIEURAC-ET-FLOURES SEISSAN SERE TACHOIRES TIESTE-URAGNOUX TUDELLE	
	AIGNAN ARBLADE-LE-BAS ARBLADE-LE-HAUT AURENSAN AVERON-BERGELLE AYZIEU BARCELONNE-DU-GERS BASCOUS BEAUMARCHES BELMONT BERNEDE BETOUS BOURROUILLAN BOUZON-GELLENAVE CAHUZAC-SUR-ADOUR CAMPAGNE-D'ARMAGNAC CASTELNAU-D'ANGLES CASTELNAVET CASTILLON-DEBATS CAUMONT CAUPENNE-D'ARMAGNAC CAZAUBON CORNEILLAN COULOUME-MONDEBAT COURTIES CRAVENCERES DEMU EAUZE ESCLASSAN-LABASTIDE ESPAS ESTANG FUSTEROUAU GEE-RIVIERE IZOTGES JUILLAC	6.7.2023 – 21.7.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	LABARTHE LABARTHETE LADEVEZE-RIVIERE LAGARDE-HACHAN LANNE-SOUBIRAN LANNUX LAREE LASSERADE LAUJUZZAN LE HOUGA LELIN-LAPUJOLLE LIAS-D'ARMAGNAC LOUBEDAT LOURTIES-MONBRUN LOUSSOUS-DEBAT LUPIAC LUPPE-VIOLLES MAGNAN MANCIET MARGOUET-MEYMES MARGUESTAU MASSEUBE MAULEON-D'ARMAGNAC MAULICHERES MAUPAS MONCLAR MONLEZUN-D'ARMAGNAC MONTAUT MONTESQUIOU MORMES NOGARO PANJAS PERCHEDE PEYRUSSE-GRANDE PEYRUSSE-VIEILLE POUY-LOUBRIN POUYDRAGUIN PRENERON REANS RIGUEPEU RISCLE SABAZAN SAINT-ARAILLES SAINT-ARROMAN SAINT-AUNIX-LENGROS SAINT-ELIX-THEUX SAINT-GERME SAINT-GRIEDE SAINT-MARTIN-D'ARMAGNAC SAINT-MICHEL SAINT-MONT SAINT-OST SAINT-PIERRE-D'AUBEZIES SAINTE-AURENCE-CAZAUX SAINTE-CHRISTIE-D'ARMAGNAC SALLES-D'ARMAGNAC SARRAGACHIES SAUVIAC	

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	SEAILLES SEGOS SION SORBETS TARSAC TASQUE TERMES-D'ARMAGNAC TOUJOUSE TOURDUN URGOSSE VERGOIGNAN VERLUS VIC-FEZENSAC VIELLA VIOZAN "AUJAN-MOURNEDE ZP à l'ouest de route entre « Le Rentier » et « Le Sage » ZS à l'est de cette même route"	
<i>Département: Landes (40)</i>		
FR-HPAI(P)-2023-00067 FR-HPAI(P)-2023-00082 FR-HPAI(P)-2023-00083 FR-HPAI(P)-2023-00084 FR-HPAI(P)-2023-00089 FR-HPAI(P)-2023-00091 FR-HPAI(P)-2023-00097 FR-HPAI(P)-2023-00098 FR-HPAI(P)-2023-00099 FR-HPAI(P)-2023-00117 FR-HPAI(P)-2023-00118 FR-HPAI(P)-2023-00119 FR-HPAI(P)-2023-00120 FR-HPAI(P)-2023-00121 FR-HPAI(P)-2023-00125 FR-HPAI(P)-2023-00126 FR-HPAI(P)-2023-00129 FR-HPAI(P)-2023-00131 FR-HPAI(P)-2023-00136 FR-HPAI(P)-2023-00137 FR-HPAI(P)-2023-00138 FR-HPAI(P)-2023-00142 FR-HPAI(P)-2023-00143 FR-HPAI(P)-2023-00148	Amou Arsague Arthez-d'Armagnac Aubagnan Audignon Aurice Banos Bas-Mauco Betbezer-d'Armagnac Beyries Bonnegarde Bougue Brassempouy Castaignos-Souslens Castel-Sarrazin Cauna Coudures Créon-d'Armagnac Dumes Escalans Estigarde Eyres-Moncube Le Frêche Gabarret Gaujacq Hagetmau Haut-Mauco Herré Horsarrieu Laglorieuse Lamothe Lauret Mant Marpaps Mazerolles Monget Monségur	8.7.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	Mont-de-Marsan Montégut Mouscardès Nassiet Ossages Parleboscq Perquie Pomarez Pujo-le-Plan Sainte-Colombe Saint-Cricq-Villeneuve Saint-Julien-d'Armagnac Saint-Justin Saint-Perdon Saint-Pierre-du-Mont Saint-Sever (Ouest D933.S) Sarraziet Serres-Gaston Tilh Villeneuve-de-Marsan	
	Aire-sur-l'Adour Arboucave Artassenx Bahus-Soubiran Bascons Bats Benquet Bordères-et-Lamensans Bourdalat Bretagne-de-Marsan Buanes Castandet Castelnau-Tursan Cazères-sur-l'Adour Classun Clèdes Duhort-Bachen Eugénie-les-Bains Fargues Geaune Grenade-sur-l'Adour Hontanx Labastide-d'Armagnac Lacajunte Lagrange Larrivière-Saint-Savin Latrille Lussagnet Mauries Maurrin Mauvezin-d'Armagnac Miramont-Sensacq Montgaillard Montsoué Payros-Cazautets Pécorade Philondenx	23.6.2023 – 8.7.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	Pimbo Puyol-Cazalet Renung Saint-Agnet Saint-Gein Saint-Loubouer Saint-Maurice-sur-Adour Saint-Sever (Est D933.S) Samadet Sarron Sorbets Urgons Vielle-Tursan Le Vignau	
<i>Department: Lot-et-Garonne (47)</i>		
FR-HPAI(P)-2023-00104	SAINTE MAURE DE PEYRIAC SAINT PE SAINT SIMON	21.6.2023
<i>Department: Pyrénées-Atlantiques (64)</i>		
FR-HPAI(P)-2023-00135	BAIGTS-DE-BEARN BALANSUN BERENX BIRON CASTETIS LAA-MONDRANS LACADEE LANNEPLAA MESPLEDE "ORTHEZ Au sud de la route de Dax (D947) et au sud de la route de Bonnut (D56)" PUYOO RAMOUS "SAINT-BOES A l'ouest de la route de Dax (D947)" SAINT-GIRONS-EN-BEARN SALLES-MONGISCARD SARPOURENX SAULT-DE-NAVAILLES	23.6.2023
	BONNUT "ORTHEZ Au nord de la route de Dax (D947) et au nord de la route de Bonnut (D56)" "SAINT-BOES A l'est de la route de Dax (D947)" SALLESPISE	15.6.2023 – 23.6.2023
<i>Department: Hautes-Pyrénées (65)</i>		
FR-HPAI(P)-2023-00141 FR-HPAI(P)-2023-00147	ARNE AURIEBAT BARTHE BAZORDAN BETPOUY CASTELNAU-MAGNOAC CASTELNAU-RIVIERE-BASSE	1.7.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	CASTERETS CAUBOUS CAUSSADE-RIVIERE CIZOS ESTIRAC FONTRAILLES GAUSSAN GUIZERIX HACHAN HERES LABATUT-RIVIERE LARAN LARROQUE LASSALES MADIRAN MAUBOURGUET MONLONG ORGAN PEYRET-SAINT-ANDRE PUNTOUS SABARROS SADOURNIN SAINT-LANNE SAUVETERRE TRIE-SUR-BAISE VIEUZOS	
	ARIES-ESPENAN BETBEZE DEVEZE LALANNE MONLEON-MAGNOAC POUY SARIAC-MAGNOAC THERMES-MAGNOAC VILLEMUR	23.6.2023 – 1.7.2023

Member State: Poland

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
PL-HPAI(P)-2023-00068	W województwie warmińsko – mazurskim: 1. W gminie Kętrzyn: Bałtrucie, Godzikowo, Jurki, Karolewo, Kruszewiec, Kwiedzina, Martiany, Nowa Różanka, Nowa Wieś Kętrzyńska, Nowa Wieś Mała, Pożarki, Salpik, Stara Różanka, Wajsznory, Wilamowo, Wopławki, Wymiarki, Bałowo na północ od linii poprowadzonej przez miejscowości Skop i Zalesie Kętrzyńskie, Czerniki na zachód od linii poprowadzonej po wschodnim brzegu jeziora Mój do miejscowości Pożarki, Mażany na północ od linii poprowadzonej przez miejscowości Czerniki i Dłużec,	25.6.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	Nakomiady na północ od linii poprowadzonej przez miejscowości Grabno i Knis, Osewo na południe od linii poprowadzonej przez miejscowości Kwiedziny i Kronowo, Poganowo na wschód od linii poprowadzonej przez miejscowości Sławkowo i Koczarki, Sławkowo na wschód od linii poprowadzonej przez miejscowości Marszewo i Koczarki, 2. W gminie Srokowo: Kąty, Siniec, Solanka, Chojnica na południe od linii poprowadzonej przez miejscowości Skierki i Młynowo, Silec na południe od linii poprowadzonej przez miejscowości Niedziałki i Tarławki, 3. W gminie Barciany: Staniszewo, Skierki na wschód od linii poprowadzonej przez miejscowości Bałtrucie i Niedziałki, Winda na południe od linii poprowadzonej przez miejscowości Skierki i Szczeciniak, 4. Miasto Kętrzyn w powiecie kętrzyńskim. 1. w gminie Giżycko: Bogacko, Guty, Antonowo na zachód od linii poprowadzonej przez miejscowości Guty i Kietlice, Kamionki na wschód od linii poprowadzonej przez miejscowości Pilwa i Kronowo, Sterławki Małe na północ od linii poprowadzonej przez miejscowości Knis i Kalinowo, Wrony na zachód od linii poprowadzonej przez miejscowości Guty i Sterławki Małe, 2. W gminie Ryn: Kronowo na południowy wschód od linii poprowadzonej przez miejscowości Doba i Martiany, Orło na północ od linii poprowadzonej przez miejscowości Koczarki i Sterławki Małe, Sterławki Wielkie na północ od linii poprowadzonej przez miejscowość Koczarki i skrzyżowania linii kolejowej Kętrzyn - Giżycko z drogą nr 59 w miejscowości Wilkasy, w powiecie giżyckim. 1. W gminie Węgorzewo: Łabapa, Radzieje, Róże, Dłużec na północny wschód od linii poprowadzonej przez miejscowości Pilwa i Kąty, Pilwa na północny wschód od linii poprowadzonej przez miejscowości Dłużec i Doba, Sztynort Mały na południowy zachód od linii poprowadzonej przez miejscowości Stawiska i Gajewo, Tarławki na południe od linii poprowadzonej przez miejscowości Silec i Kamionek Wielki w powiecie węgorzewskim.	
	W województwie warmińsko – mazurskim: 1. W gminie Kętrzyn: Parcz, Czerniki na wschód od linii poprowadzonej po wschodnim brzegu jeziora Mój do miejscowości Pożarki, Osewo na północ od linii poprowadzonej przez miejscowości Kwiedzina i Kronowo, Mażany na południe od linii poprowadzonej przez miejscowości Czerniki i Dłużec	17.6.2023 – 25.6.2023

ADIS reference number of the outbreak	Area comprising:	Date until applicable in accordance with Article 55 of Delegated Regulation (EU) 2020/687
	w powiecie kętrzyńskim. 1. W gminie Giżycko: Kamionki na zachód od linii poprowadzonej przez miejscowości Pilwa i Kronowo, 2. W gminie Ryn: Kronowo na północny zachód od linii poprowadzonej przez miejscowości Doba i Martiany w powiecie giżyckim. 1. W gminie Węgorzewo: Dłużec na południowy zachód od linii poprowadzonej przez miejscowości Pilwa i Kąty, Pilwa na południowy zachód od linii poprowadzonej przez miejscowości Dłużec i Doba w powiecie węgorzewskim.	

Part C

Further restricted zones in the concerned Member States* as referred to in Articles 1 and 3a:

Member State: France

Area comprising:	Date until measures are to remain applicable in accordance with Article 3a
<i>Les communes suivantes dans le département: Cher (18)</i>	
GENOUILLY GRACAY SAINT-OUTRILLE	21.6.2023
<i>Les communes suivantes dans le département: Gers (32)</i>	
ANTRAS AUCH AUTERIVE AUX-AUSSAT AYGUETINTE BEAUCAIRE BEAUMONT BECCAS BETPLAN BLOUSSON-SERIAN BONAS BOUCAGNERES BOULAU CASSAIGNE CASTELNAU-BARBARENS CASTERA-VERDUZAN CASTEX CASTIN CAZAUX-VILLECOMTAL	21.7.2023

Area comprising:	Date until measures are to remain applicable in accordance with Article 3a
DURAN ESTAMPES FAGET-ABBATIAL FOURCES GAUJAC GAUJAN HAGET HAULIES JEGUN LAAS LAGARDERE LAGUIAN-MAZOUS LAMAZERE LARROQUE-SAINT-SERNIN LARTIGUE LASSERAN LASSEUBE-PROPRE LAURAET MAIGNAUT-TAUZIA MALABAT MANSENCOME MARSEILLAN MIELAN MIRAMONT-D'ASTARAC MONBARDON MONGAUSY MONPARDIAC MONTEGUT-ARROS MONTREAL MOUCHAN ORBESSAN ORDAN-LARROQUE PALLANNE PAVIE PELLEFIGUE PESSAN SABAILLAN SAINT-ELIX SAINT-JEAN-LE-COMTAL SAINT-LARY SAINT-MAUR SAINT-PUY SANSAN SARAMON SARCOS SEMBOUES	

Area comprising:	Date until measures are to remain applicable in accordance with Article 3a
SEMEZIES-CACHAN SIMORRE TILLAC TOURNAN TRAVERSERES TRONCENS VALENCE-SUR-BAISE VILLECOMTAL-SUR-ARROS VILLEFRANCHE "SAINT-BLANCARD ZS à l'Ouest des routes D 139 et D576 ZRS à l'Est" SADEILLAN SAINT-ARAILLES SAINT-BLANCARD	

Les communes suivantes dans le département: Landes (40)

Argelos Baigts Bassercles Bastennes Baudignan Bergouey Bostens Campagne Campet-et-Lamolère Castelnau-Chalosse Castelner Caupenne Cazalis Clermont Doazit Donzacq Estibeaux Gaillères Garrey Gibret Gouts Habas Hauriet Labastide-Chalosse Labatut Lacquy Lacrabe Lahosse Larbey	8.7.2023
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Area comprising:	Date until measures are to remain applicable in accordance with Article 3a
Le Leuy Losse Lubbon Lucbardez et Bargues Maylis Meilhan Mimbaste Misson Momuy Montaut Montfort-en-Chalosse Morganx Mugron Nerbis Nousse Ozourt Peyre Poudenx Pouillon Pouydesseaux Poyartin Rimbez-et-Baudiets Roquefort Saint-Aubin Saint-Avit Saint-Cricq-Chalosse Saint-Cricq-du-Gave Sainte-Foy Saint-Gor Saint-Martin-d'Oney Sarbazan Serreslous-et-Arribans Sorde-l'Abbaye Sort-en-Chalosse Souprosse Toulouzette Uchacq-et-Parentis Vielle-Soubiran	
<i>Les communes suivantes dans le département: Lot-et-Garonne (47)</i>	
SAINTE MAURE DE PEYRIAC SAINT PE SAINT SIMON	21.6.2023

Area comprising:	Date until measures are to remain applicable in accordance with Article 3a
<i>Les communes suivantes dans le département: Pyrénées-Atlantiques(64)</i>	
ANDREIN ARGAGNON ARGET AUDAUX BARRAUTE-CAMU BELLOCQ BUGNEIN BURGARONNE CARRESSE-CASSABER CASTAGNEDE CASTEIDE-CANDAU CASTETBON CASTETNER HAGETAUBIN L'HOPITAL-D'ORION LAAS LABEYRIE LAGOR LAHONTAN LOUBIENG MASLACQ MONT NARP ORAAS ORION ORRIULE OSSENX OZENX-MONTESTRUCQ SAINT-MEDARD SALIES-DE-BEARN SAUVELADE SAUVETERRE-DE-BEARN	23.6.2023
<i>Les communes suivantes dans le département: Hautes-Pyrénées (65)</i>	
ANSOST ARNE ARTAGNAN AURIEBAT BARBACHEN BARTHE BAZORDAN BETPOUY BUZON CAIXON CASTELNAU-MAGNOAC	1.7.2023

Area comprising:	Date until measures are to remain applicable in accordance with Article 3a
CASTELNAU-RIVIERE-BASSE CASTERETS CAUBOUS CAUSSADE-RIVIERE CIZOS ESCAUNETS ESTIRAC FONTRAILLES GARDERES GAUSSAN GENSAC GUIZERIX HACHAN HAGEDET HERES LABATUT-RIVIERE LAFITOLE LAHITTE-TOUPIERE LARAN LARREULE LARROQUE LASCAZERES LASSALES LIAC LUQUET MADIRAN MAUBOURGUET MONFAUCON MONLONG NOUILHAN ORGAN OROIX PEYRET-SAINT-ANDRE PUNTOUS RABASTENS-DE-BIGORRE SABARROS SADOURNIN SAINT-LANNE SARRIAC-BIGORRE SAUVETERRE SEGALAS SERON SOMBRUN SOUBLECAUSE TRIE-SUR-BAISE VIC-EN-BIGORRE	

Area comprising:	Date until measures are to remain applicable in accordance with Article 3a
VIDOUZE VIEUZOS VILLEFRANQUE VILLENAVE-PRES-BEARN	

* In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to Member State include the United Kingdom in respect of Northern Ireland.'

COMMISSION DECISION (EU) 2023/1338**of 28 June 2023****on the safety requirements to be met by European standards for certain children's products and related products pursuant to Directive 2001/95/EC of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety ⁽¹⁾, and in particular Article 4(1), point (a), thereof,

Whereas:

- (1) Directive 2001/95/EC applies to all the products as defined in its Article 2(a) in so far as there are no specific provisions with the same objective in rules of Union law governing the safety of the products concerned.
- (2) Products that conform to national standards transposing European standards drawn up under Directive 2001/95/EC and the references of which have been published by the Commission in the *Official Journal of the European Union* benefit from a presumption of safety.
- (3) With the new Consumer Agenda 2020 ⁽²⁾, the Commission commits to strengthening the safety of children's products, given the particular vulnerability of this category of consumers, by adopting safety requirements to be met by European standards for those products. Of all the products notified as dangerous in 2020 and 2021 using the Union rapid alert system 'Safety Gate', formerly known as Rapid Exchange of Information System 'RAPEX', more than 20 % were products for children. Furthermore, with its communication on Chemicals Strategy for sustainability towards a toxic-free environment ⁽³⁾, the Commission notably aims to enhance the safety of children from hazardous chemicals in consumer products intended for them.
- (4) Commission has already adopted Decision 2010/9/EU ⁽⁴⁾ on the safety requirements to be met by European standards for bath rings, bathing aids and bath tubs and stands for infants and young children, Decision 2010/376/EU ⁽⁵⁾ on the safety requirements to be met by European standards for certain products in the sleep environment of children and Decision 2013/121/EU ⁽⁶⁾ on the safety requirements to be met by European standards for certain seats for children. However, in addition to those decisions, it is necessary to lay down requirements to be met by European standards for a wider group of children's products and related products.

⁽¹⁾ OJ L 11, 15.1.2002, p. 4.

⁽²⁾ Communication from the Commission to the European Parliament and the Council, New Consumer Agenda – Strengthening consumer resilience for sustainable recovery, COM(2020) 696 final of 13.11.2020.

⁽³⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, COM(2020) 667 final of 14.10.2020.

⁽⁴⁾ Commission Decision 2010/9/EU of 6 January 2010 on the safety requirements to be met by European standards for bath rings, bathing aids and bath tubs and stands for infants and young children pursuant to Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 3, 7.1.2010, p. 23).

⁽⁵⁾ Commission Decision 2010/376/EU of 2 July 2010 on the safety requirements to be met by European standards for certain products in the sleep environment of children pursuant to Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 170, 6.7.2010, p. 39).

⁽⁶⁾ Commission Decision 2013/121/EU of 7 March 2013 on the safety requirements to be met by European standards for certain seats for children pursuant to Directive 2001/95/EC of the European Parliament and of the Council on general product safety (OJ L 65, 8.3.2013, p. 23).

- (5) The rules on the safety of toys are laid down in Directive 2009/48/EC of the European Parliament and of the Council ⁽⁷⁾. However, Directive 2001/95/EC applies to the aspects and risks or categories of risks not covered by Directive 2009/48/EC. This Decision should therefore include requirements to be met by European standards for children's products and related products insofar as risks or categories of risks are not covered by Directive 2009/48/EC.
- (6) The safety requirements are necessary for the purposes of drawing up and updating European standards for certain children's products and related products. Those requirements need to ensure that products which conform to those standards satisfy the general safety requirement set out in Article 3 of Directive 2001/95/EC.
- (7) Those safety requirements should reflect the new scientific and technical knowledge and the market evolution. The use of a hazard-based approach allows a comprehensive assessment of risks to which children can be exposed while using products intended for them. In addition, this approach helps to acknowledge and address uncertainties of future new products. Furthermore, the hazard-based format makes the comparison of these requirements and the content of the standards easier facilitating the compliance of standards with the requirements. It is therefore necessary to use a hazard-based approach when establishing the safety requirements to be met by European standards for children's products and related products.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 15 of Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

Article 1

Scope

This Decision applies to the European standards referred to in Article 4(1) of Directive 2001/95/EC for the following products:

- (a) children's products intended to be worn by children;
- (b) children's products intended to facilitate or protect the seating function, sleeping function, bathing function, body care, relaxation, transportation and early learning;
- (c) children's products intended to facilitate the feeding, drinking or sucking of children;
- (d) children's products that offer one or several functions listed in points (a), (b) and (c) and one or several other functions;
- (e) products related to children's products, including the following products:
 - (i) products and accessories specifically designed for use with children's products referred to in points (a) to (d) or in combination with those products;
 - (ii) products to be used and mounted or installed by adults which are accessible to a child or offer a protective function to a child.

Article 2

Safety requirements

The safety requirements to be met by European standards referred to in Article 4(1), point (a), of Directive 2001/95/EC for certain children's products and related products referred to in Article 1 of this Decision, are set out in the Annex to this Decision.

⁽⁷⁾ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

*Article 3***Entry into force**

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

Done at Brussels, 28 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SAFETY REQUIREMENTS TO BE MET BY EUROPEAN STANDARDS FOR CERTAIN CHILDREN'S
PRODUCTS AND RELATED PRODUCTS REFERRED TO IN ARTICLE 1

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This Annex sets out safety requirements to be met by European standards for children's products and related products referred to in Article 1 of this Decision. Those requirements intend to ensure that products which conform to those standards satisfy the general safety requirement set out in Article 3(1) of Directive 2001/95/EC.

Children's products shall not jeopardise the safety or health of children and carers when they are used under reasonably foreseeable conditions, bearing in mind the behaviour, the abilities or vulnerability of children and carers.

Whenever possible, special needs of users with disabilities – both carers and children, shall be taken into account to ensure their safety.

Safety-by-design shall always be prioritised.

Appropriate information to draw the attention of parents and carers shall be placed on the children's products – and/or packaging – indicating the inherent hazards involved in using the products and the methods to avoid them. This shall include warnings (pictograms and/or text) and instructions for use and/or maintenance.

Children's products shall maintain their safety and their safety characteristics during their foreseeable lifetime. They shall be designed and manufactured in such a way that any hazards associated with continued use over the foreseeable timeframe are limited as much as possible.

Children's products intended to be used in the course of a service shall meet specific requirements to take into account they are more often used, for a longer timeframe and may be subject to higher constraints.

Standards drafted further to Commission standardisation requests based on these safety requirements must take into account the latest anthropometric data, medical research, known health advice that relates specifically to child safety (e.g. safe sleep practices), and state-of-the-art scientific and technical knowledge regarding children's safety and/or health.

Designers and manufacturers must remember that hazards with product for children are not limited to those mentioned in this document. Furthermore, other Union rules on the safety of products, such as those on chemical safety, must be complied with.

Additional hazards must be considered, that relate to the safe use and function of products (including those associated with artificial intelligence, cybersecurity, internet connectivity, security and privacy).

Any hazards related to remote communication, observation and control of the child by the carer must be considered.

Children develop physically, mentally, emotionally at different rates. Every standard developed to meet these safety requirements shall clearly specify in its scope the stage of development (such as age group, weight and height) and deliver the product safety requirements accordingly.

Where this approach is not followed, there shall be a justification placed in the informative annex to the standard.

Usability shall be considered in children's products standards – in particular the design of the children product should allow a single adult user to install, manipulate and use the product.

Articles designed to be used with children's products but which are subject to other standards, shall fulfil the requirements of both standards.

1. CHEMICAL HAZARDS

Children's products shall be designed and manufactured in such a way that there are no risks of adverse effects on human health for children or third parties (children and adults) due to exposure to the chemical substances or mixtures of which the children's products are composed or which they contain, when the children products are used as intended or in a reasonably foreseeable condition of use, bearing in mind the behaviour of children, the particular use of a product and the resulting exposure conditions.

Children's products – and their packaging – shall comply with all relevant Union legislation relating to certain categories of products or to restrictions for certain substances or mixtures.

Standards shall reflect latest chemical guidelines and relate specifically to knowledge regarding the safety and health of children (regarding mouthing, inhalation and absorption).

Whenever recycled materials are used, they shall fulfil these same requirements as native materials.

When laying down the requirements for the chemical safety of children's products such as by determining appropriate limit value for chemicals, all relevant guidelines, regulatory provisions and latest scientific findings for similar products shall be taken into consideration. The current state of the art on testing methods should be applied for the assessment.

Due to specific use conditions (e.g.: exposure duration, particular use of a product) thresholds should also be adapted to meet the foreseeable use of the product.

2. THERMAL HAZARDS

Children's products shall be designed and manufactured in such a way that thermal hazards are limited as much as possible. The behaviour of the child and available data on the surface temperatures related to the burns shall be taken into consideration. Any residual hazards shall be covered by suitable warnings. Thermal hazards include, but are not limited to:

- (a) Contact with hot or cold surfaces.
- (b) Ingestion of hot foods or liquids.
- (c) Scalding.
- (d) Overheating (hyperthermia).
- (e) Becoming cold (hypothermia).

3. FLAMMABILITY HAZARDS

Children's products shall be designed and manufactured in such a way that flammability hazards are limited as much as possible.

Flammability hazards include, but are not limited to:

- (a) Hazards due to flash effect.
- (b) Hazards due to flame propagation.
- (c) Hazards from the melting behaviour of materials.
- (d) Hazards from contact with flames.

Children's products shall be composed of materials that fulfil one or more of the following (not exhaustive) conditions:

- (a) They are not readily flammable and are self-extinguishing.
- (b) If they do ignite, they burn slowly and present a low rate of spread of the flame.
- (c) Irrespective of their chemical composition, they are designed so as to mechanically delay the combustion process.

Substances known as releasing very toxic fumes in case of combustion shall not be used in children's products. Combustible materials shall not constitute a risk of ignition for other materials used in the product.

Substances and materials that are recognised as posing a serious danger to the health shall not migrate or be released in concentrations that could cause danger to the users of the product.

Standards should state that chemical flame-retardant substances should only be used when no other options is possible. If chemical flame retardant substances are used, their toxicity and end-of-life disposal shall not endanger the health of users, carers and the environment.

4. ENTRAPMENT HAZARDS

Children's products shall be designed and manufactured in such a way that entrapment hazards of a child's body parts are limited as much as possible. Products must prevent the entrapment of a child's head, neck, torso, arms, hands, fingers, legs, feet and toes.

Requirements for preventing entrapment shall include entrapment hazards from, but are not limited to, rigid and not rigid:

- (a) Completely bound openings.
- (b) Partially bound openings.
- (c) V-shaped openings.
- (d) Irregular shaped openings.
- (e) Dynamic openings.
- (f) Fastenings.
- (g) Holes.
- (h) Gaps.
- (i) Pressure from surrounding material.

All products forming a confined space into which a child can enter and get trapped shall be designed and manufactured in such a way that hazards from enclosure are minimised.

Standards shall clearly state safe dimensions in relation to entrapment hazards. These measurements shall always reflect latest anthropometric data of the children likely to use and interact with the product and relate specifically to knowledge regarding the safety of children.

Entrapment hazard created by movement shall be limited as much as possible by design. Residual hazards shall be covered by warnings and instructions.

Hazards associated with movement include, but are not limited to:

- (a) Entrapment created by the weight of a tipping product.
- (b) Entrapment created by gaps and openings associated with foreseeable use of the product (including those created by a moving child).
- (c) Entrapment created by gaps and openings accessible by the child but adjacent to the product.
- (d) Entrapment when the child lays their neck/throat on a soft or hard edge.
- (e) Entrapment caused by the product, but related to children who are not the main user of the product.

5. HAZARDS FROM MOVING PARTS – INCLUDING SHEARING, CUTTING CRUSHING HAZARDS.

Children's products shall be designed and manufactured in such a way that hazards from moving parts are limited as much as possible. Products must prevent scissoring, shearing (when components move relatively one to another and have a scissoring action), crushing (when components move relatively one to another and have a compression action), severing or cutting of whole body, limbs, fingers and toes.

Requirements for preventing hazards from moving parts shall be included for the following hazards (where appropriate), but are not limited to:

- (a) Movement of the product itself.
- (b) Movement of the bodyweight of the child.
- (c) Application/release of an external force.

Designers and manufacturers must take into account that hazards may change according to the accessibility of the moving parts; flexibility of the material (including fabric); effect of forces and positions of force; means of operating the moving parts; shape/material of the parts; ability of the child; etc.

6. HAZARDS FROM CHILDREN'S PRODUCTS DESIGNED TO FOLD FOR STORAGE AND TRANSPORTATION

Children's products shall be designed and manufactured in such a way that hazards associated with products designed to fold for storage or transportation are limited as much as possible. Products must prevent crushing, cutting, entrapment and suffocation from unintentional folding.

Requirements for preventing hazards from children products designed to fold for storage or transportation shall be included for the following (where appropriate), but are not limited to:

- (a) Locking devices shall be used to avoid incomplete/accidental deployment.
- (b) Locking/locked position shall be obvious to the parent/carer.
- (c) Unintentional release of locking mechanisms shall not occur.
- (d) The usability of the product to allow operation by 1 adult.
- (e) It shall not be possible to use such products without the locking mechanism/s being activated.

7. HAZARDS FROM CHILDREN'S PRODUCTS DESIGNED TO BE DISMANTLED FOR STORAGE AND TRANSPORTATION

Children's products shall be designed and manufactured in such a way that hazards associated with dismantling of products for storage/transportation and then reassembling for use are limited as much as possible.

Requirements for preventing hazards related to dismantling and reassembling shall be included for the following (where appropriate), but are not limited to:

Instructions that are clearly worded and easily comprehensible and can be understood by the average, non-professional consumer shall be included.

- (a) Information shall be provided on how to dismantle and re-assemble the product ensuring its continued safety in use.
- (b) Pictograms and illustrations should be included for the safety relevant information.
- (c) Durable warnings should be marked on the children's products to highlight particularly important safety information.
- (d) Any special tools required for assembly and installation should be supplied with the product.
- (e) All assembly fittings shall be capable of being tightened properly.
- (f) Locking devices shall be used to avoid unintentional dismantling.
- (g) Locking/locked position shall be obvious to the parent/carer.
- (h) Self-tapping screws shall not be used unless for parts not intended to be disassembled.

8. HAZARDS RELATED TO ATTACHMENT MECHANISMS AND OPENING AND CLOSING SYSTEMS

Children's products shall be designed and manufactured in such a way that hazards associated with their attachment mechanisms and/or opening and closing systems are limited as much as possible. Products must prevent crushing, shearing, cutting, scissoring, entrapment, falling and suffocation due to unintentional release.

Requirements for preventing hazards related to attachment mechanisms and opening and closing systems shall be included for the following (where appropriate), but are not limited to:

- (a) If the product can be used in several positions, the selected position shall be maintained when the product is subjected to forces typical of the actions and movements of the child.
- (b) Opening and closing systems shall be designed and manufactured to avoid unintentional operation.

9. HAZARDS ASSOCIATED WITH WHEELED PRODUCTS

Children's products with wheels or castors (for transportation or other movement) shall be designed and manufactured in such a way that hazards associated with wheels or castors and unintentional movement are limited as much as possible.

Requirements for preventing hazards related to wheels/castors and unintentional movement shall be included for the following (where appropriate), but are not limited to:

- (a) All wheeled products shall be fitted with suitable locking device/s, which guarantee stability when required.
- (b) All locking devices shall be safe in use.
- (c) Wheeled children's products shall have a parking function enabling them to be immobilised in a stable manner, regardless of the surface.

10. ENTANGLEMENT HAZARDS

Children's products shall be designed and manufactured in such a way that entanglement hazards are limited as much as possible.

Requirements shall be included for the following hazards (where appropriate), but are not limited to:

- (a) Snagging hazards.
- (b) Snagging of textile products such as clothing components (fastenings, buttons, decorations, stitching or similar resulting in holes, gaps and openings or protruding parts in design).
- (c) Strangulation hazards due to cords, ribbons, ties, cables or loops.
- (d) Hazards due to monofilament threads.
- (e) Hazards due to handles.

Standards shall clearly state safe dimensions and testing requirements in relation to cords, ribbons, ties, cables, loops and other entanglement hazards. These measurements shall always reflect latest anthropometric data and relate specifically to knowledge regarding the safety of children. Storage bags for products shall also be safe.

11. CHOKING HAZARDS

Children's products shall be designed and manufactured in such a way that choking hazards are eliminated.

Requirements for preventing hazards related to choking shall be included for the following (where appropriate), but are not limited to:

- (a) No part that can be detached by the force that a child could apply shall be small enough to present a choking hazard.
- (b) No part shall break, tear or separate in use (e.g. when dropped) that is small enough to present a choking hazard.
- (c) Any component that can be removed without the use of a tool shall not present a choking hazard.
- (d) Any component that are so long that the gag reflex can be triggered if the child puts the product in the mouth, should not be allowed for children who are too young to sit up unaided due to choking hazard.
- (e) Stuffing materials that constitute choking hazards shall not become accessible when submitted to forces that a child could apply.
- (f) Products shall not constitute hazards due to inhalation for the size of the elements they contain or because those elements become sufficiently small or accessible when submitted to the forces that a child could apply.
- (g) Total size and shape of products shall be considered, and technical/mechanical solutions shall be applied where necessary (e.g. air holes in products where the choking hazard is present in normal and foreseeable use).

Standards shall clearly state safe dimensions and test requirements in relation to choking hazards. These measurements shall always reflect latest anthropometric data and relate specifically to knowledge regarding the safety of children.

12. SUFFOCATION HAZARDS

Children's products shall be designed and manufactured in such a way that suffocation hazards associated with products and their packaging are limited as much as possible. Such hazards occur when the nose and mouth are blocked simultaneously.

Requirements shall be included for the following hazards (where appropriate), but are not limited to:

- (a) Suffocation from thin/soft materials that can mould themselves to cover the child's face (including decals).
- (b) Suffocation from thin plastic bags that have an opening perimeter that is larger than the circumference of a child's head.
- (c) Suffocation from self-adhesive packaging (e.g. cling film).
- (d) Suffocation from shaped products that can be placed over the child's face and cause an airtight seal.
- (e) Suffocation from airways being covered by or sinking into soft, fluffy, ductile materials especially in children's sleeping environment (the youngest children).

Hazardous packaging materials shall be avoided where possible, but when necessary they shall be safe by design (i.e.: perforation or under minimum thickness). In addition, awareness should be given to consumers on the hazards of the packaging (i.e.: external suffocation hazard).

12.1. Hazards linked to breathing

Children's products shall be designed and manufactured in such a way that suffocation hazards associated with a lack of air permeability are limited as much as possible.

Requirements for preventing hazards related to air permeability shall be included for the following (where appropriate), but are not limited to:

- (a) The child's nose and mouth shall not be covered simultaneously.
- (b) Mattresses, bedding and other similar products shall not mould themselves to cover the child's face.
- (c) Additional mattresses or bedding shall not result in additional suffocation hazards.

13. INGESTION HAZARDS

Children's products shall be designed and manufactured in such a way that hazards associated with ingestion are limited as much as possible.

Requirements for preventing hazards related to ingestion shall be included for the following (where appropriate), but are not limited to:

- (a) Attached components shall stay attached, and not break into pieces if they come free.
- (b) Small objects and components shall be of such a size and construction that they do not pass through the child's mouth and throat to the stomach.
- (c) Magnets, batteries and other similar components are particularly hazardous, and it shall not be possible for the child to access nor ingest such parts.

14. INSERTION AND ASPIRATION HAZARDS

Children's products shall be designed and manufactured in such a way that insertion and aspiration hazards due to small parts that could be inserted in ears or nose are limited as much as possible.

15. HAZARDOUS POINTS, EDGES AND PROJECTIONS

Children's products shall be designed and manufactured in such a way that cutting and similar hazards associated with sharp points, edges or projections are limited as much as possible.

Requirements for preventing hazards related to sharp points, edges or projections shall be included for the following (where appropriate), but are not limited to:

- (a) Surfaces should be smooth – except where the surface is specifically designed otherwise to assist with the safe functioning of the children product.

- (b) Sharp edges, corners, wires and points shall be eliminated.
- (c) There shall be no protruding parts that result in injury.
- (d) Projecting parts of products shall not result in significant injury.
- (e) Material shall be free from splinters.
- (f) Metal surfaces and other metallic parts shall be resistant to corrosion and flaking.
- (g) Sheet glass shall not be used.
- (h) Glass wool and other similar minerals shall not present any risks of strangulation or asphyxiation.
- (i) Padding/filling materials shall not contain hard or sharp objects.

16. STRUCTURAL INTEGRITY HAZARDS

Children's products shall have adequate strength and structural integrity to last for their intended lifetime. They shall be designed and manufactured in such a way that hazards associated with continued use over a foreseeable timeframe are limited as much as possible.

Requirements for preventing hazards related to structural integrity shall be included for the following (where appropriate), but are not limited to:

- (a) Products should have adequate strength and durability lasting for the overall lifetime of the product.
- (b) Products and materials (including fabrics and stitching) shall be sufficient to withstand all foreseen uses and conditions, and not degrade or become hazardous through use over the time and in temperature changes, humidity and exposure to UV-light etc.
- (c) Products requiring assembly and/or installation shall, after having been assembled/fitted according to the manufacturer's instructions, have the same structural integrity as products assembled/fitted by the manufacturer and shall satisfy all the safety requirements that apply to these products.
- (d) Products that can be adjusted as the child grows shall not alter in strength as a result of mechanical stress.
- (e) Securing devices designed to attach the product securely to other object, products or devices shall maintain their effectiveness for the lifetime of the product.

17. HAZARDS ASSOCIATED WITH PROTECTIVE FUNCTIONS

Children's products providing a protective function shall safely restrict a child's access to hazards. Products that contain a child within a specific environment (e.g.: barriers), or that protect a child from hazards associated with the weather and/or insects, or limit a child's movement and/or restrict a child's access to hazards (e.g. corner protectors) shall safely provide the intended protective function.

Requirements for preventing hazards related to protective functions shall be included for the following (where appropriate), but are not limited to:

- (a) The protective function shall be suitable for the age and ability of the child, shall not introduce nor allow access to additional hazards and shall not have their function and effectiveness reduced during its use.
- (b) Barriers shall be designed so that a child cannot climb over them, pass under them, pass through them or remove them.
- (c) The heights of barriers shall always be safe and reflect both the development stage of the child and the latest anthropometric data.
- (d) Products providing a protective function to the child shall not cause entrapment hazards.
- (e) Any locking/latching mechanisms shall not be disabled nor displaced by the child nor inadvertently by the carer.

- (f) Anti-tipping products (for example products that prevent furniture, storage furniture, TV screens from falling on children) need to be designed with suitable attachments and materials that withstand forces that they are foreseen to be exposed to, including ageing, UV-light etc.
- (g) Anti-opening mechanisms (for example products that prevent doors – windows from being opened by children) need to be designed with suitable locking device and forces to prevent falling hazards.

18. HAZARDS ASSOCIATED WITH RESTRAINT SYSTEMS

Children's products offering a restraint system shall safely restrict a child's access to hazards and not result in additional hazards from the restraints themselves.

Requirements for preventing hazards related to restraint systems shall be included for the following (where appropriate), but are not limited to:

- (a) Restraint systems shall be securely attached and not cause hazards themselves.
- (b) Restraint systems shall be capable of adjustment to the size of the child.
- (c) Restraint systems shall be effective at all times and in all situations of use.
- (d) Restraint systems shall take into account all potential movements and forces that the child can apply.
- (e) Products shall be safe in use and provide the intended restraint function. The child shall be able to be removed easily in an emergency situation.

19. HAZARDS ASSOCIATED WITH STABILITY

Children's products shall be designed and manufactured in such a way that hazards associated with the stability of the product (including falling or tipping) are limited as much as possible.

Requirements for preventing hazards related to stability shall be included for the following (where appropriate), but are not limited to:

- (a) Products shall avoid any tipping hazards which could cause the child to fall (e.g. tip highchair by pushing feet against table).
- (b) Products shall remain stable and safe when motion (of the child or product) is involved.
- (c) Accessories to the product or parts designed to be removable shall not alter the products' safety and stability (e.g. addition of tray table to highchair).

20. FALLING HAZARDS

Children's products shall be designed and manufactured in such a way that hazards associated with falling are limited as much as possible.

Requirements for preventing hazards related to falling hazards shall be included for the following (where appropriate), but are not limited to:

- (a) Products with carrying handles shall be designed and manufactured so that the handles do not become detached from the article when the child is being carried.
- (b) Any handles shall be attached so that there are no hazards associated with the child falling out of the product.
- (c) Swinging products shall not introduce falling hazards.
- (d) Products shall be of sufficient height (back rest, arm rest, barrier function, etc.) and strength (including products constructed from fabric) to ensure that the child is safely retained.
- (e) Products with a restraining function to prevent falling shall be secure in use and not result in additional hazards from the restraints themselves.
- (f) Products where the child is in high position shall not pose falling hazard (e.g. high chairs and their foot-holes, safety gates etc.).

21. DROWNING HAZARDS

Children's products shall be designed and manufactured in such a way that hazards associated with drowning are limited as much as possible.

Requirements for preventing hazards related to drowning shall be included for the following (where appropriate), but are not limited to:

- (a) Any securing devices shall be safe in use and not cause additional hazards themselves.
- (b) The child shall be able to be removed easily in an emergency situation.
- (c) The child shall not be able to slip out unintentionally from a product like a floating seat.
- (d) Floating products shall maintain floatation; they shall not lose air pressure rapidly; in the case of leakage, they shall retain residual buoyancy.
- (e) Floating products shall maintain safe stability and not be susceptible to wind and water current forces if they are foreseen to be used in open water.
- (f) All appropriate warnings such as child must never be left unattended, drowning can occur in a short time and in very shallow water, shall be clearly stated.

22. ELECTRICAL HAZARDS

Children's products shall be designed and manufactured in such a way that hazards associated with the use of electrical products (including electric shock) are limited as much as possible.

Requirements for preventing hazards related to electrical hazards shall be included for the following (where appropriate), but are not limited to:

- (a) When stored energy (e.g. from a battery) is used, the current used and design of the children product shall not create any risk to the child.
- (b) Batteries and live parts shall not be accessible to a child.
- (c) Cords of electrical products shall not introduce additional hazards.

23. BIOMETRIC HAZARDS

Children's products shall be designed and manufactured in such a way that hazards associated with the use of biometric parameters are limited as much as possible.

Requirements for preventing hazards related to biometrical hazards shall be included for the following (where appropriate), but are not limited to:

- (a) When biometric parameters are used, the children product shall not create any risk to the child.
- (b) There should always be a mechanical back-up system so that a person whose characteristics have not been programmed into the device could operate it especially in an emergency or if the battery failed.

24. ACOUSTIC HAZARDS

Children's products shall be designed and manufactured in such a way that hazards associated with sounds are limited as much as possible.

Products designed to emit sound shall not emit loud peak noises and/or loud continuous noises that can present a risk of damage to a child's hearing.

25. RADIATION HAZARDS

Children's products shall be designed and manufactured in such a way that health hazards or risk of injury to eyes or skin related to artificial and natural radiation are limited as much as possible.

Requirements for preventing hazards related to radiation from artificial sources shall be included for the following (where appropriate), but are not limited to:

- (a) Any light emitted by the product shall be safe and not disrupt natural sleep rhythms.

- (b) High intensity light and concentrated light shall not be used.
- (c) Non-visible radiation hazards shall be limited as much as possible (including electric, magnetic, electromagnetic fields and other types of radiation).
- (d) Requirements for preventing hazards related to radiation from natural sources, for example sunburns, shall be included.

26. RADIOACTIVE HAZARDS

Children's products shall avoid the use of any material that could increase the radioactive hazards.

27. HYGIENE'S HAZARDS

Children's products shall be designed and manufactured in such a way that hazards associated with hygiene are limited as much as possible.

Requirements for preventing hazards related to hygiene hazards shall be included for the following (where appropriate), but are not limited to:

- (a) Products shall be designed in such a way as to avoid the risk of infection or contamination.
- (b) Products shall not pose microbiological hazards from insufficient hygiene from material of animal origin (e.g. feathers).
- (c) Products shall be capable of being cleaned and all safety requirements shall still be met afterwards.
- (d) Products made from recycled materials shall also meet these requirements.
- (e) Manufacturer shall provide thorough cleaning instructions.
- (f) Material should be free from biological and pest contamination.

28. HAZARDS ASSOCIATED WITH INFORMATION SUPPLIED WITH THE PRODUCT

Safety information shall be provided and especially to prevent hazards that cannot be avoided by design of the product itself. Information supplied either on or with the product shall be given in such a way that hazards are limited as much as possible.

Requirements for safety information shall be included for the following, but are not limited to:

- (a) Safety information shall be provided in a clear and conspicuous way, comprising purchase information, instructions for use, markings and warnings.
- (b) Clear and understandable pictograms and illustrations should be used when possible instead of or in addition to text for safety related information.
- (c) Information shall be in the language(s) of the country in which the product is placed on the market.
- (d) Markings on the product shall remain clearly visible and easily legible throughout the life of the product.
- (e) The consumer shall be able to clearly and easily see all purchase information at the point of sale (including online sales).
- (f) Instructions for safe, installation, assembly, use and maintenance shall be provided.
- (g) Limitations of safe use shall be clearly stated.
- (h) Minimum/maximum age/weight/height of use shall be stated (where relevant to ensure safe use of the product).
- (i) Where a product may be subject to ageing, information shall be provided on how to check that the product is still safe in use,
- (j) Information on when and how to dispose of/recycle the product shall be provided when this can represent a safety issue.

- (k) Instructions to check the product before use shall be given, along with guidance to cease use immediately if the product is damaged in any way.
 - (l) Labels on products or on their packaging and the instructions for use which accompany them shall draw the attention of carers to the inherent hazards, risks of harm or side effects involved in using the articles and to the ways of avoiding them.
 - (m) Markings and pictures on labels or packaging shall not mislead about any safety requirement in the standard.
 - (n) Marking allowing the identification of the product to ensure its traceability through the distribution chain shall comply with applicable EU legislation.
 - (o) Children's products designed to be attached to other products shall have warnings indicating the hazards and risks of attachment to unsuitable products.
 - (p) Children's products designed to be attached to other products shall have purchase information indicating the type and range of products for which the article is suitable.
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RECOMMENDATIONS

COUNCIL RECOMMENDATION (EU) 2023/1339

of 27 June 2023

on joining the global digital health certification network established by the World Health Organization and on temporary arrangements to facilitate international travel in view of the expiry of Regulation (EU) 2021/953 of the European Parliament and of the Council

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(6) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The EU Digital COVID Certificate introduced by Regulation (EU) 2021/953 of the European Parliament and of the Council ⁽¹⁾ has rapidly become a global standard for vaccination, test and recovery certificates and has 51 third countries and territories connected to the system in addition to all Union Member States. Through its external dimension, the EU Digital COVID Certificate has also proven to be the most widely used solution and tool to foster safe international travel and recovery at global level. Apart from its use in the area of travel, the use of the EU Digital COVID certificate fostered the continuity of cross-border vaccination.
- (2) The EU Digital COVID Certificate was paramount in safeguarding free movement and travel and its underlying technology could continue to serve as a tool, useful to be better prepared for possible future health crises, allowing citizens and businesses to mitigate the impact of communicable diseases and ensure an adequate level of preparedness for health crises. This is also in line with the special report of the European Court of Auditors 01/2023 entitled 'Tools facilitating travel within the EU during the COVID-19 pandemic – Relevant initiatives with impact ranging from success to limited use'.
- (3) Regulation (EU) 2021/953 is set to expire on 30 June 2023. As from 1 July 2023, the possible issuance and acceptance of COVID-19 vaccination, test and recovery certificates should therefore be made on the basis of and pursuant to the conditions laid down by the national laws of the Member States. Also, references made in this recommendation to the implementing acts adopted pursuant to Regulation (EU) 2021/953 are made solely for ease of reference and should not be understood as maintaining in force such implementing acts or the powers of the Commission to adopt and amend implementing acts pursuant to Regulation (EU) 2021/953. Any reference to the implementing acts previously adopted pursuant to Regulation (EU) 2021/953 should be understood as static references to the said acts, in their version applicable on 30 June 2023.
- (4) The World Health Organization (WHO) will establish a global digital health certification network. The global digital health certification network is a mechanism to support the verification of certificates that are issued by participants of the global digital health certification network. Such certificates would initially concern COVID-19 certificates, and

⁽¹⁾ Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 1).

could, at a later stage, also include the certification of other documents, such as routine immunisation records and the International Certificate of Vaccination or Prophylaxis, set out in Annex 6 of the International Health Regulations (2005), for the purposes of international travel and continuity of care.

- (5) The establishment of systems to mitigate the impact of global health crises on travel for citizens and businesses should be seen as a major pillar of the Union's agenda for global health crises preparedness. Participation in the WHO global digital health certification network would contribute to the global alignment of health certificate standards and the establishment of a system for the recognition of digital health certificates for international travel and continuity of care.
- (6) The global digital health certification network being developed by the WHO takes up the EU Digital COVID Certificate trust framework, principles and open technologies into its own structure. The Commission intends to cooperate closely with the WHO with a view to ensure that the global digital health certification network is coherent with the technical specifications previously laid down in Commission Implementing Decision (EU) 2021/1073 ⁽²⁾. Member States should be encouraged to connect to the WHO global digital health certification network as soon as possible and by 31 December 2023 at the latest. For a smooth transition from the EU Digital COVID Certificate system to the WHO global digital health certification network, Member States should be invited to issue new document signer certificates used for the issuance of the EU Digital COVID Certificates before the expiry of Regulation (EU) 2021/953 to ensure their maximum technical validity and register those in the interoperability gateway of the trust framework set up under that Regulation (the 'EU Gateway').
- (7) The Commission intends to ensure a smooth transition for Member States to join the WHO global digital health certification network, by maintaining the EU Gateway until 31 December 2023 in a manner that supports the objectives of this Recommendation. To that end, the Commission intends to finance the EU Gateway through the Digital Europe Programme established by Regulation (EU) 2021/694 of the European Parliament and of the Council ⁽³⁾. This should allow the Member States and third countries connected to the EU Gateway sufficient time to adopt the procedures necessary to onboard the WHO global digital health certification network.
- (8) All Union citizens and residents travelling outside the Union should have at their disposal means to prove their COVID-19 related status, whenever this is specifically requested for travelling outside the Union. Therefore, once connected to the WHO global digital health certification network, Member States should also be invited to issue, upon request, certificates compatible with the format laid down by the WHO global digital health certification network, based on the technical specifications previously laid down in Implementing Decision (EU) 2021/1073, for the purposes of facilitating international travel to third countries requiring such certificates, in particular in case of a public health emergency of international concern. In addition to facilitating international travel, such issuance could contribute to the global alignment of health certificate standards and the development of a system for the recognition of digital health certificates facilitating the continuity of care.
- (9) Member States should issue such certificates in a digital or paper-based format, or both. The prospective holders should be entitled to receive the certificates in the format of their choice. The information contained in the certificates should also be shown in human-readable form and be provided in at least the official language or languages of the issuing Member State and in English.
- (10) The uptake of the EU Digital COVID Certificate by the WHO global digital health certification network should enable third countries that still have in place COVID-19 related requirements as conditions for entry into their territories, and which are connected to the EU Gateway, to accept and verify both certificates issued before and certificates issued after 1 July 2023.

⁽²⁾ Commission Implementing Decision (EU) 2021/1073 of 28 June 2021 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 230, 30.6.2021, p. 32).

⁽³⁾ Regulation (EU) 2021/694 of the European Parliament and of the Council of 29 April 2021 establishing the Digital Europe Programme and repealing Decision (EU) 2015/2240 (OJ L 166, 11.5.2021, p. 1).

- (11) From the perspective of travellers to the Union, once connected to the WHO global digital health certification network, in order to ensure that public health concerns related to the COVID-19 pandemic can be adequately addressed, Member States are advised to keep the ability to accept and verify certificates issued by third countries under the WHO global digital health certification network that continue to fulfil the high standards which were laid down pursuant to Regulation (EU) 2021/953. Where Member States require proof of COVID-19 vaccination, test or recovery in order to waive restrictions to travel into the Union, they should accept COVID-19 certificates which are technically compliant with the WHO global digital health certification network.
- (12) In its Conclusions on vaccination as one of the most effective tools for preventing disease and improving public health of 9 December 2022, the Council called on the Commission to 'explore the added value of a digital version of vaccination certificates, taking into consideration the experiences with European digital infrastructures and other existing tools, such as the International Certificate of Vaccination or Prophylaxis'. Similar developments are planned by the WHO as it intends to further develop its global digital health certification network, in order to, for example, support the digitisation of the International Certificate of Vaccination and Prophylaxis, or vaccination certificates for routine immunisation. Therefore, Member States are invited to actively participate in the effort to further develop the network, as well as to issue, accept and verify other types of vaccination certificates or health data, as relevant.
- (13) During a transitional period until 31 December 2023, and in order to ensure a smooth transition to the WHO global digital health certification network, Member States that have not yet connected to the WHO global digital health certification network are encouraged to issue upon request, in particular in case of a declared public health emergency of international concern, in accordance with national law, COVID-19 vaccination, test and recovery certificates in the format compatible with the technical specifications previously laid down in Implementing Decision (EU) 2021/1073, provided that a legal basis for the issuance of such certificates is laid down in their national law. Also, during this transitional period, where Member States require proof of COVID-19 certificates in order to waive restrictions to travel into the Union, they are encouraged to accept proof of COVID-19 vaccination, recovery or testing previously covered by an implementing act adopted pursuant to Article 3(10) or Article 8(2) of Regulation (EU) 2021/953, in line with the approach set out in Council Recommendation (EU) 2022/2548 ^(*).
- (14) During the same period, Member States that have not yet connected to the WHO global digital health certification network are also encouraged to remain connected to the EU Gateway, insofar as such gateway is being maintained by the Commission. Those Member States who have already connected to the WHO global digital health certification network are advised to synchronise the information they upload to the WHO global digital health certification network with the EU Gateway.
- (15) Member States are encouraged to give effect to this Recommendation as of 1 July 2023, which is the day after the expiry of Regulation (EU) 2021/953, so that any possible disruption, especially concerning international travel to third countries still requiring COVID certificates, is avoided. Specifically as regards the issuance of a new document signer certificate, Member States can only issue such certificate while Regulation (EU) 2021/953 is still in force. They are therefore invited to give this certificate the maximum possible technical validity and to register it in the EU Gateway before the expiry of Regulation (EU) 2021/953 on 30 June 2023.
- (16) Regulation (EU) 2016/679 of the European Parliament and of the Council ^([§]) applies to the processing of personal data carried out when implementing this Recommendation. Member States should therefore ensure at all times that the relevant provisions of Union law concerning personal data are complied with and in particular that the principle of lawfulness laid down in Regulation (EU) 2016/679 is complied with,

^(*) Council Recommendation (EU) 2022/2548 of 13 December 2022 on a coordinated approach to travel to the Union during the COVID-19 pandemic and replacing Council Recommendation (EU) 2020/912 (OJ L 328, 22.12.2022, p. 146).

^([§]) 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).

HAS ADOPTED THIS RECOMMENDATION:

Connection to the WHO global digital health certification network

1. The Council welcomes the Commission's intention to closely cooperate with the WHO in the development of the global digital health certification network, enabling the WHO to take up the EU Digital COVID Certificate trust framework, principles and open technologies into its own structure, on the basis of the technical specifications previously laid down in Implementing Decision (EU) 2021/1073.
2. Member States are encouraged to connect to the global digital health certification network that is being set up by the WHO, provided that an appropriate legal basis is laid down in their national law, as soon as possible and by 31 December 2023 at the latest.
3. Each Member State wishing to join the WHO global digital health certification network is encouraged to issue a new document signer certificate with the maximum possible technical validity and register it in the EU Gateway before the expiry of Regulation (EU) 2021/953.
4. The Council welcomes the Commission's intention to facilitate a seamless transition from the EU Digital COVID Certificate system to the WHO global digital health certification network. It is however, left to the Member States to decide whether to connect to the global digital health certification network and whether they wish to do so with the existing technology or to pursue a connection at a later stage.

Issuance and acceptance of certificates under the WHO global digital health certification network

5. Once connected to the WHO global digital health certification network, Member States are encouraged to carry out, as appropriate, the tasks prescribed by the WHO in relation to the operation of the WHO global digital health certification network as efficiently as possible, provided that an appropriate legal basis is laid down in Union or national law, in compliance with Regulation (EU) 2016/679, in particular:
 - (a) issue, as appropriate, in particular in case of a declared public health emergency of international concern, COVID-19 certificates in the format compatible with the WHO global digital health certification network to be based on technical specifications previously laid down in Implementing Decision (EU) 2021/1073;
 - (b) issue the certificates referred to in indent (a) of this point in a digital or paper-based format, or both, and facilitate as appropriate the process for the prospective holders to receive the certificates in the format of their choice. It is recommended that the information contained in the certificates be also shown in human-readable form and be provided in, at least, the official language or languages of the issuing Member State and in English;
 - (c) where they require proof of COVID-19 vaccination, test or recovery in order to waive restrictions, accept COVID-19 certificates compliant with the WHO global digital health certification network.

Further evolution of the WHO global digital health certification network

6. Member States are encouraged to actively participate in the effort to further develop the WHO global digital health certification network, taking in account the developments regarding the update of the International Health Regulations, and examine the potential benefits, challenges and legal requirements of WHO digital certificates, including exploring – inter alia – the use of digital certificates for other diseases and the authentication of other health data.

Transitional period until 31 December 2023

7. The Council welcomes the Commission's intention to maintain the EU Gateway for the EU Digital COVID Certificate in a manner that supports the objectives of this Recommendation until 31 December 2023, in order to facilitate the measures to be taken to connect to the global digital health certification network that is being set up by the WHO, and

continue to make it available to third countries and territories which are already connected to the EU Gateway provided that the relevant certificates of those third countries and territories continue to be issued based on standards and technological systems that are interoperable with the trust framework of the EU Gateway and that allow for the verification of their authenticity, validity and integrity.

8. Until Member States are connected to the WHO global digital health certification network referred to in point 1, and during the period until 31 December 2023, they are encouraged to remain connected to the EU Gateway, insofar as such gateway is being maintained by the Commission and provided that an appropriate legal basis is laid down in their national law, in compliance with Regulation (EU) 2016/679, in order to:
 - (a) issue, as appropriate, in particular in case of a declared public health emergency of international concern, COVID-19 certificates in the format based on the technical specifications previously laid down in Implementing Decision (EU) 2021/1073;
 - (b) issue the certificates referred to in indent (a) of this point in a digital or paper-based format, or both, and facilitate as appropriate the process for the prospective holders to receive the certificates in the format of their choice. It is recommended that the information contained in the certificates be also shown in human-readable form and be provided in at least the official language or languages of the issuing Member State and in English;
 - (c) where they require proof of COVID-19 vaccination, test or recovery in order to waive restrictions, in particular in case of a declared public health emergency of international concern, accept proof of COVID-19 vaccination, recovery or testing previously covered by an implementing act adopted pursuant to Article 3(10) or Article 8(2) of Regulation (EU) 2021/953;
9. Member States connected to the WHO global digital health certification network are also encouraged to ensure, until 31 December 2023, the synchronisation of information they upload in the EU Gateway and in the WHO global digital health certification network.

Done at Luxembourg, 27 June 2023.

For the Council
The President
J. ROSWALL

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