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'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 2)
No. prev. doc.:	16056/25 + ADD 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on the screening of foreign investments in the Union and repealing Regulation (EU) 2019/452 of the European Parliament and of the Council - Confirmation of the final compromise text with a view to agreement

1. On 25 January 2024, the Commission submitted to the Council a proposal for a Regulation of the European Parliament and of the Council on the screening of foreign investments in the Union and repealing Regulation (EU) 2019/452 of the European Parliament and of the Council[1], which aims to further strengthen the protection of security and public order by proposing improved screening of foreign investment into the EU.

2. On 11 June 2025, the Permanent Representatives Committee adopted a Council negotiating mandate[2] for a Regulation of the European Parliament and of the Council on the screening of foreign investments in the Union and repealing Regulation (EU) 2019/452 of the European Parliament and of the Council.

[1] 5882/24 + ADD 1-3.
[2] 9517/25.

3. The Polish Presidency held the first trilogue with the European Parliament and the Commission on 17 June 2025 in Strasbourg and all parties expressed the desire to conclude the negotiations before the end of 2025. The Danish Presidency held the second trilogue on 23 September 2025 and agreed the outline solution for the common minimum scope and the accountability mechanism. The Danish Presidency reached agreement with the European Parliament on the compromise text during the third trilogue held on 11 December 2025.

4. On 3 February 2026, the Working Party on Trade Questions endorsed the compromise text agreed during the third trilogue with further technical amendments agreed with the European Parliament.

5. The European Parliament's Committee on International Trade (INTA) is expected to vote on the overall compromise in one of its upcoming meetings, paving the way for the adoption of the draft Regulation at first reading.

6. The Permanent Representatives Committee is therefore invited to:

- confirm agreement on the final compromise text as set out in the Annex to this note (changes compared to the Commission proposal are marked with ***bold italic*** and ▌ for deletions); and

- authorise the Presidency to send a letter to the Chair of the European Parliament's Committee on International Trade (INTA) confirming that, should the European Parliament adopt its position at first reading in accordance with Article 294(3) of the Treaty, in the terms of the final compromise text set out in the Annex to the letter (subject to its finalisation by the lawyers-linguists of both institutions), the Council will, in accordance with Article 294(4) of the Treaty, approve the European Parliament's position and the act will be adopted in that wording.

PUBLIC

ANNEX

2024/0017 (COD)

Proposal for a

REGULATION *(EU)* …/… OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of …

on the screening of foreign investments in the Union and repealing Regulation (EU) 2019/452 of the European Parliament and of the Council

PUBLIC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and ***207(2)*** thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) ***The Union welcomes foreign*** investments ***as they*** contribute to its growth by improving its competitiveness, creating jobs and economies of scale, and bringing in capital, technologies, innovation and expertise.

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1 OJ C , , p. .
2 OJ C , , p. .

(2) Article 3(5) of the Treaty on European Union (TEU) specifies that the Union, in its relations with the wider world, is to uphold and promote its values and interests and contribute to the protection of its citizens. ▌

(3) ***The Union and Member States have an open investment environment, which is enshrined in the Treaty on the Functioning of the European Union (TFEU) and embedded in the Union and its Member States' international commitments.*** However***, Article 21(2) TEU states that the Union's policies and actions aim to safeguard its values, fundamental interests, security, independence, and integrity. Those principles and objectives underpin the Union's common commercial policy, as set out in Article 207 TFEU including in relation to foreign investment. Within that context***, under international commitments made in the World Trade Organization (WTO), the Organisation for Economic Cooperation and Development (OECD) ***and in*** trade and investment agreements concluded with third countries, it is possible for the Union ***or its Member*** States to restrict foreign direct investments ▌ on the grounds of security or public order, subject to certain requirements.

(4) ***Pursuant to*** Regulation (EU) 2019/452 of the European Parliament and of the Council[3] a framework has been set up for ***the*** screening ▌ by Member States ***of foreign direct investments in the Union by third-country investors***. In particular, that Regulation has set out a cooperation mechanism enabling Member States and the Commission to exchange information on ***foreign direct investments*** and raise concerns about risks to security or public order. That cooperation mechanism required the ***host*** Member State ▌ to give due consideration to the comments issued by other Member States and the opinion issued by the Commission in its screening decision.

(5) The framework set up ***pursuant to*** Regulation (EU) 2019/452 has delivered on its objective to provide a formal mechanism for Member States and the Commission to exchange information on ***foreign direct investments*** and to raise awareness on cross- border risks to security or public order arising from certain ***foreign direct investments***.

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[3] Regulation (EU) 2019/452 of the European Parliament and of the Council of 19 March 2019 establishing a framework for the screening of foreign direct investments into the Union (OJ L 79I, 21.3.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/452/oj).

(6) However, a new legislative instrument is needed to strengthen the efficiency and effectiveness of ***the screening of foreign direct investments and to*** ensure a higher degree of harmonisation across the Union. ***Such improvements are necessary due to the evolving nature of investment flows. The integration of global economies, combined with war and geopolitical tensions, has led to the emergence of new risks that need to be addressed by the Union and the Member States. On 20 June 2023 and 3 December 2025, the Commission adopted Communications on the "European economic security strategy", and on "Strengthening EU economic security" which identify FDI screening as a tool to protect the Union against economic security risks. Those communications underscore the need to address risks associated with the resilience of supply chains, access to critical infrastructure, technology leakage, and the weaponisation of economic dependencies or economic coercion.***

(7) Certain investments ***that are*** not covered by Regulation (EU) 2019/452 could create risks for ▌ security and public order. ***Those concern,*** in particular, ▌ certain investments carried out in Member States that do not ***yet*** have a screening mechanism ***in force,*** investments carried out in Member States that ***do*** have a screening mechanism ***in force but the*** scope ***of which*** does not include certain sensitive investments***,*** and investments that are made by ***third-country*** investors through a subsidiary established in the Union ***(intra-Union investments)*** and that potentially present the same risks to security or public order as ▌ investments made ***directly*** from third countries.

PUBLIC

(8) A significant majority of Member States, but not all, have a legislative instrument in ***force*** that provides for a mechanism to screen ***foreign direct investments***. ***The absence of a screening mechanism in certain Member States allows problematic foreign investors wanting to invest in sensitive assets to invest in those Member States as a gateway into the internal market. Furthermore,*** in many Member States, national laws also extend ▌ screening ***to*** intra-Union investments. Among the Member States ▌ there are substantial differences as to the scope, thresholds and criteria used to assess whether an investment is likely to negatively affect security or public order. There are also differences in ▌ screening processes***. This Regulation is aimed at reducing divergences on key elements of the screening mechanisms implemented at national level***. In certain Member States, the investment can be implemented before having received clearance with respect to the impact on security and public order. However, others require that the investment is only finalised after authorisation under the screening mechanism. Such divergences create a problem for the smooth functioning of the internal market. For example, they create an uneven playing field and increase compliance costs for investors seeking to notify transactions in more than one Member State. ▌ Reducing ***divergence*** is crucial to ensure predictability for investors ***in respect of*** the applicable national regimes and their characteristics, thereby reducing ▌ associated compliance costs. This is all the more relevant considering the level of integration of ***the*** internal market, which may result in a single transaction impacting multiple Member States across the Union. It is for example possible that a transaction aimed ***at*** the acquisition of a target company in one Member State ***('Union target')*** also affects ***the*** security and public order ***of*** another Member State, due to the supply chain structure or other economic elements connecting the ***Union*** target with other companies based in ***other*** Member States. In order to address ***such problems related to the integration of the*** internal market ▌ and ***in order to*** ensure greater consistency and predictability, it is appropriate that the criteria and elements to be used for the assessment of foreign investments are established through Union action. ***Thus, this Regulation is aimed at increasing the convergence of national rules applicable to the screening of foreign investments, including intra-EU investments, thereby creating a level-playing field, increasing certainty for foreign investors, and preventing the emergence of additional obstacles to the internal market.***

PUBLIC

(9) ***In order*** to ensure a consistent approach to foreign investment screening across the Union, all Member States should be required to screen foreign investments on the grounds of security or public order. ***Furthermore***, the core elements of national screening mechanisms should be harmonised. That minimum harmonisation ***should include an obligation for Member States to ensure that*** investments ***targeting entities operating in a specific set of sensitive areas are*** screened***. This obligation should ensure that certain sensitive investments are screened in all Member States. Moreover, the Regulation should further harmonise and clarify the procedures under the cooperation mechanism*** and the interaction between the ***screening mechanisms*** and the ▌ cooperation mechanism. ***In particular, it is appropriate to ensure that all screening mechanisms include an initial review which should not last more than 45 calendar days from the date on which the filing is deemed complete by the screening authority. Therefore, for the purposes of this Regulation, a definition of 'filing' should be introduced that captures both the initial submission of documentation required as well as the assessment whether a request is deemed complete ▌. Where necessary, an in-depth review should be carried out. In*** addition, ***the timelines for notification to the cooperation mechanism should be harmonised, and the steps for the procedure under the cooperation mechanism, particularly with respect to the provision of comments from*** Member States ***and Commission opinions,*** should ***be better aligned. This would allow to address situations where the timelines of*** national ***procedures are not aligned and could delay a transaction. There should be a certain level of harmonisation on the criteria Member States and the Commission should consider when assessing whether a*** foreign ***investment is likely to negatively affect*** security or public order. ***This common set of criteria includes the security, integrity, resilience and functioning of critical entities, the availability of critical technologies or the continuity of supply of critical inputs. This would ensure a more uniform assessment of the impacts of foreign investments on security and public order while preserving the possibility for Member States to take into account further criteria which may differ between Member States.***

PUBLIC

(9a) This Regulation only provides for core elements of the screening mechanisms. Thus, Member States may adopt national provisions that are complementary to or are more specific than the provisions of this Regulation. For example, Member States should be able to specify thresholds of voting rights acquired by investors triggering the screening of foreign investments. Member States may extend the scope of their national screening mechanism to include foreign investments in sectors not covered by the common minimum scope. Where a Member State opts to extend the scope of its screening mechanism beyond the common minimum scope, such screening should comply with this Regulation, provided that such screening falls within the scope of this Regulation.

(10) Regulation (EU) 2019/452 only covers ***foreign direct investments made by third-country investors ('foreign investors') in*** the Union. However, it is ▌ necessary to extend the scope of the ***Union*** cooperation mechanism to investments made between Member States, ***that is through an undertaking established*** in one Member State ***that*** is controlled, directly or indirectly, by a foreign ***investor ('foreign investor's subsidiary in the Union'). These investments carry the same specific risks to security or public order as foreign direct investments carried out through a legal*** entity ***not established in the Union, because the controlling foreign investor has power and influence over the Union target even if exercised through that subsidiary. These specific risks could be caused by the jurisdiction to which the foreign investor is subject or by the influence from the government or non-state actors of a third country. Such risks are not caused by investments carried out by investors that are not controlled, directly or indirectly, by a third-country person or entity. It is therefore appropriate to cover under the cooperation mechanism investments made through a foreign investor's subsidiary*** in the Union ***but not investments made by other Union investors,*** in particular, ▌ to ensure that any investment creating a lasting link between the foreign investor and the Union target, whether ▌ carried out directly by a foreign investor or through an entity established in the Union and controlled by a foreign investor, is consistently ***covered and screened. This would increase*** the consistency and predictability of screening rules across Member States, which in turn ***would*** reduce compliance costs for foreign investors and ***remove the incentive to invest exclusively*** in Member States where such transactions ***were not screened***.

PUBLIC

(12) ***The*** screening ***of*** foreign investments should be carried out in accordance with this Regulation***. It should take*** into account all ▌ information available and ***adhere*** to the principle of proportionality***. It should respect the objective of preserving an open investment environment and the internal market***. Moreover, the screening of foreign investments ▌ should ▌ comply with ▌ Union law, and in particular with ***Articles 49 and 63 TFEU***. Any restrictions ***on*** the freedom of establishment ***or the*** free movement of capital ***that could result*** from screening ***mechanisms or screening decisions***, such as ***the imposition of*** mitigating measures ***or the prohibition or unwinding of a foreign investment,*** should be ***justified by reasons of public policy or public security, including*** genuine and sufficiently serious ***threats*** to a fundamental interest of society***. This includes risks to the functioning*** of the ***institutions and essential public services, to the supply of essential products or services*** or to the ***survival of the population, risks of a serious disturbance to foreign relations or to peaceful coexistence of nations, or risks to military interests***.

(13) To enable the ***Union*** cooperation mechanism ***established by*** this Regulation to function efficiently and effectively, it is necessary to define a ***common*** minimum ▌ scope ***of*** foreign investments that all Member States should ***screen***. ▌

(14) It is also necessary to make the ***host*** Member State ▌ more accountable to the Commission and to those Member States that express duly justified concerns for ***security or*** public order ▌

(15) The common framework set out in this Regulation should be without prejudice to the sole responsibility of ***each*** Member State to safeguard ***its*** national security as provided for in Article 4(2) TEU. It should also be without prejudice to the protection of ***Member States'*** essential security interests ***pursuant to*** Article 346 TFEU.

PUBLIC

(16) ***This Regulation should cover*** foreign investments that create or maintain lasting and direct links between ***third-country*** investors ▌ (including State bodies) and Union targets carrying out an economic activity in a Member State. This Regulation ▌ should apply where ▌ investments are ▌ carried out ***directly from a third-country investor*** or by a Union entity ***controlled by such an investor (intra-Union investment)***. However, ***it*** should not cover the acquisition of company securities intended purely for financial investment without any intention to influence the management ***or*** control of the ***company (‘***portfolio investments***’***). ▌

(16a) Lasting and direct links between the third-country investor and a Union target are created where the foreign investor acquires effective participation in the management or control of the Union target. This is certainly the case where the foreign investor acquires decisive influence over the Union target, meaning the capacity to solely or jointly determine the commercial policy of the target either de facto or de jure. However, effective participation in the management or control might also exist where the foreign investor, without having decisive influence over the Union target, can nonetheless materially impact its commercial policy, behaviour or decisions, for example through shareholding, voting rights, contracts, including leverage resulting from supplier relationships, and significant board representation.

PUBLIC

(16b) Restructuring operations within a corporate group should fall outside of the scope of this Regulation. Such operations should only be excluded from the scope of application to the extent that they are conducted solely for the purpose of the internal reorganisation, for example through merger or division, of a Union target or of the corporate group to which the Union target belongs, without resulting in any changes in the beneficial ownership of the Union target. In particular, internal restructurings should be excluded from the scope of application where: they do not result in the acquisition of ownership or control by a new foreign investor over the Union target or over a company that directly or indirectly owns or controls that Union target; they do not lead to an increase in the shares held by foreign investors; and they do not confer additional rights on foreign investors that may lead to a change in the effective participation of one or more foreign investors in the management or control of the Union target. However, internal restructurings which entail the introduction of a new legal entity established in a third country that is not already present in the upstream ownership chain of the Union target, may create security risks and should thus be included in the scope of this Regulation. For instance, such an entity could be subject to the legislation of a third country that imposes obligations on natural or legal persons to share information for intelligence purposes without due process or oversight mechanisms.

(16c) Acquisitions through resolution tools under the respective resolution frameworks (for banks, central counterparties or insurance or reinsurance undertakings) should be excluded from the scope of this Regulation. In such circumstances, time is of the essence and decisions are often made overnight. The screening procedures provided for in this Regulation could hinder the ability to provide a timely response. In order to avoid financial stability risks, resolution transactions should therefore be excluded. Resolution authorities should take into account, to the extent possible, the objectives pursued by this Regulation when performing resolution actions with the involvement of a foreign investor, in particular when strategic assets are involved.

PUBLIC

(16d) To ensure a proper assessment of whether a foreign investment is likely to negatively affect security or public order, it is important that the term 'beneficial owner' captures the true holders of influence, whether directly or indirectly, over a foreign investor or Union target. In the case of trusts, the legal ownership lies with the trust as such, but the economic benefit is for the natural person or persons on whose behalf the trust operates. For this reason, the definition of 'beneficial owner' should also capture those who ultimately benefit from the foreign investment, notably beneficiaries of a trust. However, it is necessary to take into account the fact that foreign investors can sometimes be a front for the person actually behind the foreign investment. Similarly, foreign investors can sometimes be coerced by other actors who are ultimately able to exert influence over the foreign investment. Thus, the definition of 'beneficial owner' should also include natural persons on whose behalf the foreign investment is made or on whose behalf the control over that foreign investment is exercised. In general, a single natural person is the beneficial owner of a foreign investor. However, it cannot be excluded that there could be more than one person, such as in the case of spouses or other family members. Likewise, it is necessary to take into account situations where it is not possible to identify the natural person, including in the case of publicly traded companies. In such situations, the legal person, entity or trust at the highest identifiable level in the upstream ownership or control chain of the foreign investor or Union target should be considered as the beneficial owner.

(17) Greenfield foreign investments occur where the foreign investor or a foreign investor's subsidiary in the Union sets up new facilities or a new undertaking ***for the generation of an economic activity*** in the Union. Greenfield foreign investments should fall within the scope of this Regulation***. However, this Regulation should not impose a prior authorisation requirement in respect of those*** investments***. Thus***, ▌ Member States ***should remain free to decide whether*** to include ***such*** investments in the scope of ▌ their screening mechanisms ▌ .

(18) ***In order*** to ensure consistent and predictable screening processes, it is appropriate to lay down the essential features of the screening mechanisms to be implemented by Member States. Those features should at least include the ***minimum*** scope of the transactions to be subject to ***a prior*** authorisation requirement***, the division of the screening procedure in an initial review and an in-depth review***, deadlines for the screening***, a public annual report,*** the possibility for ***parties subject to*** the screening decision to seek ***judicial*** recourse against such decisions***, and the ability of screening authorities to effectively address cases of non-compliance or circumvention***. Rules and procedures relating to screening mechanisms should be transparent and should not discriminate between third countries.

(18a) To enhance transparency and predictability in screening procedures, screening authorities should, where applicable and without undue delay, inform the person who made the filing of the completeness of that filing. This does not preclude the screening authority from requesting further information or posing additional questions after confirming the completeness of the filing. Furthermore, this is without prejudice to the possibility for screening authorities to inform the person who made the filing of other important procedural milestones.

PUBLIC

(19) The cooperation mechanism laid down in Regulation (EU) 2019/452 enables Member States to cooperate and help each other where a foreign direct investment in one Member State could affect the security or public order of other Member States or of projects or programmes of Union interest. This mechanism has proven very useful so far, hence it should be maintained and strengthened ***by*** this Regulation ***to ensure a more aligned approach to foreign investments across the Union***.

(20) ***To ensure a consistent and effective level of protection of security and public order throughout the Union, it is necessary to provide for minimum harmonisation of the scope of screening mechanisms. Member States should be required to screen foreign investments where the Union target is active in sectors or activities that are of particular relevance for security, defence, the integrity of democratic processes, the resilience of essential services or the safeguarding of vital societal functions. Establishing such a common minimum scope of application of screening mechanisms is necessary*** to ensure that foreign investments likely to negatively affect security or public order ***are*** identified ***irrespective of the*** Member States ***in which the*** Union targets ***are located, thereby strengthening the effectiveness of the Union cooperation mechanism while preserving*** Member ***States' sole responsibility for national*** security ▌ .

PUBLIC

(20a) The common minimum scope should include foreign investments in Union targets that develop, produce or commercialise dual-use items listed in Annex I to Regulation (EU) 2021/821 of the European Parliament and of the Council[4] or military goods and technologies listed in the Annex to Directive 2009/43/EC[5], given the inherent risks linked to the transfer of control over defence-related capabilities, technologies and know-how, which are vital for maintaining security. The common minimum scope should also cover foreign investments in Union targets that produce, conduct research in or develop semiconductors, quantum technologies or certain artificial intelligence technologies, in view of their strategic importance and their enabling role across a wide range of applications critical for security. Furthermore, Member States should screen foreign investments in Union targets exercising certain activities related to strategic raw materials listed in Section I of Annex I to Regulation (EU) 2024/1252 of the European Parliament and of the Council[6], namely exploration, extraction, processing, recycling, recovery or stockpiling. Foreign control over such activities can create risks of supply disruption, strategic dependency or undue leverage. Moreover, Member States should screen foreign investments in Union targets that own, develop or operate voter registration databases, voting systems and other relevant information systems. In addition, foreign investments in certain financial market infrastructure and systemically important financial entities — including central counterparties, central securities depositories, operators of regulated markets, operators of payment systems other than central banks, other systemically important institutions and global providers of specialised financial messaging services — should also be screened, given the central role of that infrastructure and those entities in

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4 Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (OJ L 206, 11.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/821/oj).

5 Directive 2009/43/EC of the European Parliament and of the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community (OJ L 146, 10.6.2009, p. 1, ELI: http://data.europa.eu/eli/dir/2009/43/oj).

6 Regulation (EU) 2024/1252 of the European Parliament and of the Council of 11 April 2024 establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1724 and (EU) 2019/1020 (OJ L, 2024/1252, 3.5.2024, ELI: http://data.europa.eu/eli/reg/2024/1252/oj).

the stability, integrity and resilience of the Union financial system and taking into account the objectives of the Savings and Investment Union.

(20b) The common minimum scope should also include foreign investments in Union targets that are active in the transport, energy or digital infrastructure sectors but only to the extent they are considered critical following a risk-based, targeted assessment carried out by the Member State where they are established. That assessment should take into account national security interests and vital societal functions, in light of the essential services provided by the Union target concerned. Member States should retain discretion to designate the entities concerned within those sectors and should, as appropriate, take into account assessments carried out pursuant to Directive (EU) 2022/2557 of the European Parliament and of the Council[7]. In order to ensure predictability for foreign investors, entities should be able to ascertain, if necessary after having contacted the competent screening authority, whether they are considered as critical for the purposes of this Regulation. Moreover, the Member States should regularly reassess which Union targets should be considered as critical for the purposes of this Regulation. Examples of entities to be assessed include: (a) in the energy sector: energy storage facility within the meaning of Directive (EU) 2019/944 of the European Parliament and of the Council[8], gas transmission system operators within the meaning of Directive (EU) 2024/1788 of the European Parliament and of the Council[9]; (b) in the transport sector: airports within the meaning of Directive 2009/12/EC of the European Parliament and of the Council[10],

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7 *Directive (EU) 2022/2557 of the European Parliament and of the Council of 14 December 2022 on the resilience of critical entities and repealing Council Directive 2008/114/EC (OJ L 333, 27.12.2022, p. 164, ELI: http://data.europa.eu/eli/dir/2022/2557/oj).*

8 *Directive (EU) 2019/944 of the European Parliament and of the Council of 5 June 2019 on common rules for the internal market for electricity and amending Directive 2012/27/EU (OJ L 158, 14.6.2019, ELI: http://data.europa.eu/eli/dir/2019/944/oj).*

9 *Directive (EU) 2024/1788 of the European Parliament and of the Council of 13 June 2024 on common rules for the internal markets for renewable gas, natural gas and hydrogen, amending Directive (EU) 2023/1791 and repealing Directive 2009/73/EC (OJ L, 2024/1788, 15.7.2024, ELI: http://data.europa.eu/eli/dir/2024/1788/oj).*

10 *Directive 2009/12/EC of the European Parliament and of the Council of 11 March 2009 on airport charges (OJ L 70, 14.3.2009, ELI: http://data.europa.eu/eli/dir/2009/12/oj).*

including the core airports listed in Regulation (EU) 2024/1679 of the European Parliament and of the Council[11] and entities operating ancillary installations contained within the airports, when these installations are essential for the security and continuity of operations of such airports, managing bodies within the meaning of Regulation (EU) 2017/352 of the European Parliament and of the Council[12] of core ports or providers of port services within the meaning of that Regulation and other entities within the core ports, when these are essential for the security and continuity of operations of such core ports; and (c) in the digital infrastructure sector: providers of cloud computing services, providers of public electronic communications networks.

(20c) To adequately protect security and public order and ensure the effectiveness of the Union cooperation mechanism, it is necessary that all Member States carry out ex ante screening of foreign investments falling within the common minimum scope. A prior authorisation requirement is essential, as many risks associated with foreign investments materialise at the moment the foreign investor obtains an effective participation in the management or control and cannot be effectively mitigated after the completion of the foreign investments. This is particularly true for the foreign investments falling within the common minimum scope, since such foreign investments are liable to provide irreversible access to sensitive information, critical technologies, essential infrastructure or strategic assets. Ex post intervention would, in such circumstances, be disproportionately burdensome and, in any event, ineffective to properly safeguard security and public order.

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11 Regulation (EU) 2024/1679 of the European Parliament and of the Council of 13 June 2024 on Union guidelines for the development of the trans-European transport network, amending Regulations (EU) 2021/1153 and (EU) No 913/2010 and repealing Regulation (EU) No 1315/2013 (OJ L, 2024/1679, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1679/oj).

12 Regulation (EU) 2017/352 of the European Parliament and of the Council of 15 February 2017 establishing a framework for the provision of port services and common rules on the financial transparency of ports (OJ L 57, 3.3.2017, (ELI: http://data.europa.eu/eli/reg/2017/352/oj).

(21) ***For the Union*** cooperation mechanism ***to focus*** only on those foreign investments where the characteristics of the foreign investor or the Union target make ***a negative*** effect on security or public order likely, it is appropriate to establish risk-based conditions for the notification of foreign investments undergoing screening in a Member State to the other Member States and the Commission. ***In particular, where a foreign investor or its subsidiary in the Union is directly or indirectly controlled by a third-country government, it is more likely that it may pursue that third-country's policy objectives. It is therefore appropriate that Member States notify foreign investments made by such foreign investors where they fall within the common minimum scope of screening mechanisms. Direct or indirect control by a third-country government could be exercised in several ways and could be determined on the basis of, inter alia, ownership structure, government funding, specific governance arrangements such as golden shares, or other features aimed at influencing management decisions. Equally, it is appropriate that Member States notify foreign investments falling within the common minimum scope where the foreign investor was involved in foreign investments that were prohibited or authorised subject mitigating measures which were significantly or repeatedly not complied with. Hence, mere procedural or formal cases of non- compliance would in general not be a reason for notification. Similarly, Member States should notify foreign investments where they decide to conduct an in-depth investigation and the Union target is linked to projects or programmes of Union interest or to other Member States. Moreover,*** where a foreign investment does not meet the conditions ***otherwise laid down for its notification to the cooperation mechanism***, the Member State where the foreign investment is undergoing screening ***should nevertheless*** notify ***that*** foreign investment to the other Member States and the Commission, ▌ where ***this*** Member ***State considers that the foreign investment could negatively affect security or public order in one or more*** Member States. ***This ensures that all foreign investments that could negatively affect security or public order are notified to the cooperation mechanism, whilst ensuring that the host Member States retains a margin of discretion in determining whether the conditions for notification are fulfilled. In such a case, the notifying Member State should explain the reasons for notifying that investment.***

PUBLIC

(22) To ***adequately identify*** the likely ***negative*** effect of a foreign ***investment*** on the security or public order of one or more Member States ▌, Member States should be able to provide comments ***and the Commission should be able to issue an opinion*** to a ***host*** Member State ▌ even if that Member State is not screening that foreign investment or if the foreign investment ***has been*** screened but not notified ***through the Union*** cooperation mechanism. Requests for information, replies and comments from Member States should ***simultaneously be transmitted*** to the Commission***.***

▌

(24) ***Where the likely negative effect on*** security or public order ▌ emanates from a foreign investment into a Union target that ***is part of or participates in one of the projects or programmes of Union interest***, which are critical for the Union as a whole, the Commission should be allowed to issue an opinion. ▌ A Commission opinion identifying the likely ***negative effect*** on projects or programmes of Union interest on the grounds of security or public order should be notified to all Member States.

(25) ▌ It should be possible for the Commission to ***issue*** an opinion addressed to all Member States ***where*** it identifies several foreign investments that, taken together, are likely to ***negatively affect*** security or public order ▌. This could ***in particular*** be the case where several foreign investments present comparable characteristics***, for example,*** where the foreign investments are made by the same foreign investor, ***where several*** foreign investors ***present*** similar risks, or where several foreign investments concern the same target or the same infrastructure, ***such as*** trans-European infrastructure for transport, energy ***or*** communication. Member States and the Commission ***could*** discuss the ***Commission's*** analysis ***of the risks identified in its opinion*** and the possible ways to address ***those*** risks

▌.

PUBLIC

(25a) The Member States should not take a screening decision before the deadlines for comments and opinions have expired unless security or public order interests, such as avoiding bankruptcy of the Union target, require an earlier decision. Such exceptional circumstances should be notified to the other Member States and the Commission, which should issue their comments or opinion expeditiously.

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(28) ***To adequately address*** the likely ***negative*** effect of a foreign investment on the security or public order of one or more Member States***, a*** Member ***State that receives*** duly justified comments from other Member States or an opinion from the Commission should give such comments or opinion ***due*** consideration, including where it considers that its own security or public order is not affected. ***That*** Member State should***, where necessary,*** coordinate with the Commission and the Member States concerned ▌ and provide them with ***the operative part*** and the ***summary of the main reasons of its*** decision***. That summary*** should ***include the extent to which the host*** Member State ***gave the Member States' comments or the Commission opinion due consideration as well as,*** where ***applicable, the reasons for its disagreement with the Member States' comments or the Commission opinion***. ***The provision of that information ensures that Member States are accountable for how they gave due consideration to the concerns raised by other Member States or the Commission, whilst respecting the sensitive nature of screening decisions and confidential information contained therein.***

PUBLIC

(28a) It is important to take into account that foreign investments that were not notified to the cooperation mechanism might pose a risk for security or public order. Thus, Member States and the Commission should be able, no later than 15 months following the completion of a foreign investment, to issue duly justified comments or an opinion to the host Member State on a foreign investment which has not been notified to the cooperation mechanism. To avoid overburdening the cooperation mechanism, Member States and the Commission should, before issuing comments or an opinion, verify whether the host Member State has already started or completed the screening of the foreign investment and whether it intends to notify the foreign investment through the cooperation mechanism. The host Member State should give due consideration to the comments of the other Member States and to the opinion of the Commission and, on this basis, inform the Member States that have issued comments and the Commission if it does not intend to screen the foreign investment. This can for example be the case if the host Member State disagrees with the risks identified in the comments or the opinion. Similarly, the host Member State could indicate that it does not intend to screen the foreign investment because the latter does not fall within the scope of its screening mechanism or has already been screened, although these situations should ideally have been clarified before any comments or opinion were issued. Where the host Member State indicates that it does not intend to screen the foreign investment, a meeting should be organised at the request of either a Member State that issued comments or at the request of the Commission, where the latter issued an opinion. The Commission should be invited to the meeting even if it did not issue an opinion. The Member States having issued comments or the Commission might notably request such a meeting to further present or discuss the risks identified. Where, following the meeting and despite the additional explanations received from the Member States having issued comments or the Commission, the host Member State decides not to screen the foreign investment, it should inform the Member States that issued comments and the Commission thereof and provide them with a written explanation. This written explanation might have overlaps with previously indicated reasons stated, for example at the requested meeting.

PUBLIC

(29) To ensure the effective functioning of the ***Union*** cooperation mechanism, ▌ Member State notifying the foreign investment ***through*** the cooperation mechanism ***should be required to provide*** a minimum level of information in a standardised format. Where ▌ a foreign investment ***is*** not notified ***through*** the cooperation mechanism, the ***host*** Member State ▌ should be able to provide at least the same minimum level of information. The Commission and Member States ***should be able to request*** additional information from the ***host*** Member State ***. A*** request for additional information should be duly justified, limited to the information necessary for the Member States to ***issue*** comments or for the Commission to issue an opinion, proportionate to the purpose of the request and not unduly burdensome for the ***host*** Member State.

(30) To ensure that ▌ cooperation is based on complete and accurate information, ***the host Member State may request*** a foreign investor or ***any other natural or legal person either within the chain of control of the foreign investor or within the chain of control of the Union target to*** provide ***information To ensure the quality of information, Member States should, where they have reasonable doubts about the completeness and accuracy of the information, take reasonable steps to verify the*** information ***provided to them by natural or legal persons. For example,*** the Member State ***should identify obvious contradictions and obviously false, misleading, or missing information***. In exceptional circumstances, ***where***, despite its best efforts, a Member State is unable to obtain ▌ information requested by another Member State or the Commission, it should notify them without delay. In such ▌ case, ***the other*** Member ***States and*** the Commission ***may base their comment and opinion, respectively,*** on the information available to them.

PUBLIC

(31) ***The host Member State and the Commission may face potential obstacles in gathering relevant information from natural or legal persons in other Member States. Therefore, where a certain piece of information is strictly necessary for determination of whether the foreign investment is likely to negatively affect*** security ***or*** public order, ***the host Member State and the Commission may request another Member State to gather information from a natural or legal person residing or established in its territory. Furthermore, a host Member State may face a situation where it is necessary to ask several other*** Member States ***to assist in gathering the abovementioned information, which can constitute a significant burden, especially for Member States with more limited resources. To enhance the effectiveness of the information gathering assistance, a host Member State*** should ***be able to request the Commission to assist in this process and gather the information for it. At the same time, the Member State, in whose territory the natural or legal person from whom the information is sought resides or is established, should be able to, within a reasonable time limit, object to this process or offer to provide that information itself. The possibility for that Member State to object ensures that Member States retain control over the collection of information on their territory. Therefore, the Commission should sufficiently inform that Member State, including as regards what information is requested by the host Member State. A host Member State may choose to request another Member State to gather the necessary information or to request the assistance of the Commission, depending on what it deems more efficient or more appropriate in a given situation. As part of a request for information, the natural or legal person from whom information is sought may, even indirectly, receive confidential information, such as information about the planned foreign investment. Hence, it is necessary to specify that such a natural or legal person should not use any confidential information it received for any purpose other than to reply to the*** request for information ***and that it should not disclose it.***

PUBLIC

(32) ***The screening authority and*** the Commission ***should be able to take into consideration*** relevant information received from ***stakeholders, including*** economic operators, civil society organisations ***and*** social partners (such as trade unions)***, concerning*** a foreign investment***. Such information could lead to the initiation of a screening procedure by the host Member State. For this purpose, the screening authority and the Commission should make publicly available the contact details through which stakeholders could submit information concerning foreign investments in a confidential manner.***

(34) ***In order*** to ensure the efficiency and effectiveness of the cooperation mechanism, it is necessary to align deadlines and procedures ***where*** several foreign investments linked to the same broader transaction are screened in several Member States. In such multi-country transactions, the ***applicants*** should ***endeavour to make the separate filings*** in the Member States concerned ***on the same day.*** Those Member States should ***endeavour to*** notify ***those filings on the same day through*** the cooperation mechanism. To ensure an efficient handling of ***those*** multi-country transactions, the Member States concerned should coordinate ***throughout the screening procedure. In particular, they should discuss among themselves and with the Commission, if a Member State so requests,*** whether the foreign investments ▌ should be notified ***They*** should also ***discuss their screening decisions and endeavour to align the timing of their respective procedures, including the date of adoption of their screening decisions. Where*** the Member States concerned intend to authorise the foreign investment ***subject to mitigating measures***, they should ***discuss whether the intended screening decisions*** are compatible with one another and ▌ adequately ▌ address the ***identified risks.***

PUBLIC

(34a) To safeguard the confidentiality and integrity of communications, the Commission should establish and maintain a secure and encrypted system that complies with the highest standards of data protection and security and includes monitoring and auditing capabilities to ensure compliance with security standards. All substantive communications between Member States, as well as between Member States and the Commission under this Regulation, should be transmitted through that system, unless the nature of the information to be transmitted requires the use of other means, such as physical documents. Substantive communication between the Member States and the Commission should include in particular, notifications to the cooperation mechanism, information about the intention to issue a comment or an opinion, requests for information from the host Member State, answers to those requests, comments and opinions, and substantial new information following the notification of the foreign investment. The establishment and use of the secure and encrypted system should not affect the overall communication between screening authorities and the Commission, which should remain possible by all appropriate means.

(34b) To ensure the effectiveness of the cooperation mechanism, the Commission should set up a secure database with information on the foreign investments notified to the cooperation mechanism and the outcome of the assessments under screening mechanisms since 12 October 2020. Member States should, after the completion of the national procedure, upload to the secure database certain information about the foreign investment, and they could also provide additional information, including where applicable, relevant business intelligence procured and verified from commercial vendors, such as providers of risk analysis or sanctions and compliance screening services. Such information should be shared through the cooperation mechanism only to the extent permitted by the contractual arrangements governing its use and disclosure. Furthermore, Member States should also be able to upload to the database relevant information on cases where mitigating measures were significantly or repeatedly not complied with, since such information could be relevant for determining whether other foreign investments should be notified to the cooperation mechanism or are likely to negatively affect security or public order.

PUBLIC

(34c) To ensure the secure and efficient submission and processing of filings related to foreign investment screening, and to alleviate the administrative burden on both natural or legal persons making a filing and screening authorities, the Commission should, at the request of at least nine Member States, establish an online EU portal. That portal should provide a unified mechanism for natural or legal persons making a filing to electronically file transactions with screening authorities. The Commission should design the system to be user-friendly and ensure that it complies with applicable data protection requirements and security standards. The online EU portal should, if established, only apply in respect of foreign investments in Member States which have so requested. If a Member State requests to opt out of that portal, the portal should no longer apply to that the foreign investments in that Member State, without affecting the continued use of the portal by the other relevant Member States.

(34e) In order to enhance the ability of Member States and the Commission to identify, assess and mitigate potential risks to security or public order stemming from foreign investments, it is important that they have high quality business intelligence capability at their disposal. This capability should allow for the collection and analysis of relevant information and thus facilitate coordinated risk assessments. Within the Commission, in the framework of the crisis-preparedness architecture established under the Internal Market Emergency and Resilience Act (IMERA, Regulation (EU) 2024/2747 of the European Parliament and the Council) the Commission will develop elements for such a capability . It could complement the cooperation mechanism under this Regulation insofar as the information gathered, processed or analysed under IMERA concerns potential risks to security or public order.

(35) To ensure a consistent approach to the screening of ***foreign*** investments across the Union, it is essential that ***some of*** the standards and criteria used to assess likely risks to security and public order are ▌ set at Union level in this Regulation. ***These criteria*** should ▌ take into account ***risks pertaining to the*** investment ***and risks pertaining to the*** investor ▌ . ▌

PUBLIC

(35a) Foreign investments are more likely to pose risks to security or public order where they are liable to produce effects on certain sectors, assets or activities that are crucial to security or vital societal functions. It is therefore appropriate for Member States and the Commission to focus on these potential effects when determining whether an investment could negatively affect security or public order. In particular, they should assess the impact of an investment on the security, integrity, resilience and functioning of a critical entity within the meaning of Article 2(1) of Directive (EU) 2022/2557 , in view of the core functions performed by such entities and the consequences that their disruption would entail. The same applies to foreign investments that could affect the availability of critical technologies, or the protection and availability of intellectual property or other intangible assets such as trade secrets, databases, algorithms, processes, since the leakage or inaccessibility of such technologies or assets could undermine security. It is equally important that Member States and the Commission assess the extent to which a foreign investment could affect food security, public health, including the provision and availability of critical medicines, or the continued supply of critical inputs as well as the security of military facilities and other sensitive public facilities, given the essential role these sectors and assets play in safeguarding societal resilience and the continuity of vital services. Member States and the Commission should also consider the potential effects of foreign investments on sensitive information, including personal data, in particular where large-scale data sets are concerned, due to the risk of misuse or strategic exploitation of such data. Moreover, particular attention should be given to foreign investments that may affect projects or programmes of Union interest, where disruptions or undue influence could have cross-border implications for the Union as a whole. Finally, in order to protect from potential foreign interference, Member States and the Commission should consider the potential effects of foreign investments on the freedom and pluralism of the media, including online and social media platforms or their ancillary features, or other digital and interactive environments for education or recreation purposes. For clarity purposes, the list of projects or programmes of Union interest should be listed in an annex. Those should include the trans-European networks for transport, energy or communication, as well as programmes providing funding for research and development for activities that are relevant for the security or public order. The list of technology areas of importance for security and public order and the list of critical medicines should be set out in separate annexes.

PUBLIC

(35b) Similarly, Member States and the Commission should also take into account the context and circumstances of the foreign investment. This should include, in particular, whether the foreign investor, a natural person or entity controlling the foreign investor, the beneficial owner of the foreign investor, any of the subsidiaries of the foreign investor, or any other party owned or controlled by, or acting on behalf or at the direction of the foreign investor is likely to pursue a third country's policy objectives or to facilitate the development of a third country's military capabilities, as well as whether it could use the foreign investment to support the commission of serious violations of human rights or international humanitarian law. Such serious violations are liable to cause a serious disturbance to foreign relations or to peaceful coexistence of nations, thereby affecting the security of Member States. Furthermore, circumstances such as previous rejections of authorisation requests or non-compliance with mitigating measures, the prior involvement in activities negatively affecting security or public order, illegal or criminal activities, including the circumvention of Union restrictive measures adopted pursuant to Article 29 TEU and Article 215 TFEU, the establishment in a jurisdiction identified as a third country with significant strategic deficiencies in its national AML/CFT regime, a legal requirement to share information for intelligence purposes or an opaque ownership structure may constitute risk factors and should therefore also be assessed. In addition, Member States and the Commission should also examine whether the foreign investor could be a conduit for a third-country government or a non-state actor to acquire and exert influence on the Union target indirectly. Such influence could go beyond influence conveyed through corporate structures or other means of corporate law and could be conveyed by natural persons like the investor's shareholders, directors or board members in any manner of ways. This extends to informal means including leveraging personal relationships, applying personal or political pressure, and employing threats and other manipulative or deceptive practices.

PUBLIC

(36) Where the ***host*** Member State ▌ considers that a foreign investment is likely to negatively affect security or public order ▌ , it is appropriate to require that ***that*** Member State ▌ take appropriate measures to mitigate ***that risk***, where ***adequate*** measures are available, ▌ taking into ***due*** consideration ***any*** comments issued by other Member States and ***an*** opinion issued by the Commission ▌ . Foreign investments should ***only*** be prohibited ***or unwound*** on an exceptional basis, ▌ where mitigating measures or measures available under Union or national law other than ***those within*** the screening mechanism are not sufficient to mitigate the ***negative*** effect on security or public order.

(37) To support the implementation of the cooperation mechanism and to foster the exchange of good practices among Member States, the expert group on the screening of foreign investments ***referred to in*** Regulation (EU) 2019/452 should be maintained ***and its tasks updated in accordance with this Regulation***.

(37a) In order to enhance transparency for foreign investors, the Commission should maintain a publicly available list of all screening mechanisms. Furthermore, in so far this is not already laid down in national law, Member States should publish and regularly update detailed guidance on the scope of their screening mechanisms, the thresholds and triggers for notification obligations, and the applicable timelines and procedural rules.

(38) Member States should notify ***to the Commission*** their screening mechanisms and any amendment ***thereto***. They should ***publish an annual*** report ▌ on the application of their screening mechanisms**,** relevant legislative developments and the activities of the screening authority, including aggregate ***and anonymised*** data on the transactions screened ▌ .

PUBLIC

(39) ***To ensure the efficiency of the cooperation mechanism, the contact points put in place by Member States and the Commission for the application of this Regulation should be placed in the respective administrations. Those contact points should have the qualified staff and powers needed to carry out their work under the cooperation mechanism and ensure a proper handling of confidential information.***

(40) Member States and the Commission should be encouraged to cooperate with the responsible authorities of like-minded third countries on issues related to the screening of foreign investments ***on grounds of*** security or public order. Such administrative cooperation should aim ***at strengthening*** the effectiveness of the framework for screening foreign investments by Member States and the cooperation between ***the*** Member States and the Commission pursuant to this Regulation. ***That cooperation may involve the exchange of information and best practices, as well as technical and capacity-building support. In the context of that cooperation, the Commission should encourage the establishment of investment screening mechanisms by third countries, particularly those that are candidates for accession to the Union and countries in the Union's neighbourhood. It should also monitor the developments with regards to screening mechanisms in third countries.*** The Commission should be kept informed of ▌ contacts ***with third countries*** to the extent that they relate to systemic issues related to investment screening. ▌

PUBLIC

(41) Member States and the Commission ***should*** ensure the confidentiality of the information they provide or receive in application of this Regulation, in accordance with national and Union law. ***Information received as a result of the application of this Regulation shall be used only for the purpose for which it was requested, which includes the use of such information in the judicial review of screening decisions.*** Where the unauthorised disclosure of information ***might*** cause ▌ prejudice to the interests of the ▌ Union, or of one or more of the Member States, the originator of the information should classify the information in accordance with national and Union law. When responding to requests ***for*** access to documents handled in application of this Regulation, Member States and the Commission shall coordinate and provide at least the level of protection of the protected interests available under Article 4 of Regulation (EC) ***No 1049/2001 of the European Parliament and of the Council***[1], with a view to protect the purpose of investigations. The Commission should take all necessary measures to ensure the protection of confidential information in compliance with, in particular, Commission ***Decisions*** (EU, Euratom) 2015/443[2] ***and*** (EU, Euratom) 2015/444[3]***. Furthermore***, Member States and the Commission should take all necessary measures to ensure compliance with the Agreement between the Member States of the European Union, meeting within the Council, regarding the protection of classified information exchanged in the interests of the Union[4]. This includes, in particular, the obligation not to downgrade or declassify classified information without the prior written consent of the originator. Any non-classified sensitive information or information which is provided on a confidential basis should be handled as such by the authorities. ***The screening authority should give the entity providing the information the opportunity to indicate which information it considers to be confidential. This can for example be done by means of the form to be submitted to request a prior authorisation of the foreign investment.***

PUBLIC

(42) Any processing of personal data pursuant to this Regulation should comply with the applicable rules on the protection of personal data. Processing of personal data by the contact points and other entities within Member States should be carried out in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council[13]. Processing of personal data by the Commission should be carried out in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council[14].***Personal data might be contained in documents and other sources of information which are processed for the purpose of investment screening. This data might include names of natural persons who are investors or target companies, names and contact data of natural persons who are involved in the management of the investor or target company, names and positions of persons involved in operating contact points. Each competent national authority of a Member State and the Commission should be individually responsible for the processing of personal data when using the cooperation mechanism.***

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[13] 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, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

[14] 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, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

(42a) The European Data Protection Supervisor was consulted pursuant to Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on 15 March 2024. The Commission and Member States should be considered joint controllers, within the meaning of Regulation (EU) 2018/1725 and Regulation (EU) 2016/679, for the processing of personal data. On 28 April 2022, the Commission and the Member States' representatives or authorities participating in the cooperation mechanism under Regulation (EU) 2019/452 signed a Joint Controllership Agreement, which is compatible with this Regulation. Therefore, the Commission and the Member States' representatives or authorities participating in the mechanism should maintain that Joint Controllership Arrangement, which should continue to apply also in respect of this Regulation, and references in the Joint Controllership Arrangement to provisions of Regulation (EU) 2019/452 should, for that purpose, be read as references to the corresponding provisions of this Regulation. While taking into account the Opinion 13/2024 of the European Data Protection Supervisor, it was considered that defining common retention periods would not be appropriate, since this Regulation is providing only for the minimum requirements of the screening mechanisms and since some of the Member States only started developing their screening mechanisms.

(43) The Commission should draw up an annual report on the implementation of this Regulation and submit it to the European Parliament and to the Council. ***In the interest of*** transparency, ***that*** report should ***also*** be made public. The report should be based on, among other things, reports submitted by all Member States to the Commission on a confidential basis with due respect to the need to ensure the protection of the confidentiality of certain information, in particular where the publication of data could affect the security or public order of the Union or jeopardise ***the anonymity of specific transactions***. ***The report should include information on trends and figures of foreign investment into the Union, updates on relevant legislative developments in the Member States, as well as information on international cooperation efforts.***

PUBLIC

(44) The Commission should evaluate the functioning and effectiveness of this Regulation ***3*** years after the date of application of this Regulation and every 5 years ***thereafter*** and present a report to the European Parliament and to the Council. That report should ***analyse the evolution of foreign investments into the Union and assess the contribution of this Regulation to the economic security of the Union. It should also assess whether a modification of the common minimum scope of screening mechanisms is warranted, including as regards foreign investments into Union targets that manufacture or hold a marketing authorisation for critical medicines. In addition, that report should evaluate the risks linked to foreign investments in media services and how best to address them. It should also*** include an assessment of whether ▌ this Regulation should be amended. Where the report ***contains a proposal to amend*** this Regulation, ***the Commission could decide to append*** a legislative proposal ***thereto***.

(45) The implementation of this Regulation by the Union and the Member States should comply with the relevant requirements for imposing restrictive measures on the grounds of security and public order laid down in the ▌ Agreements ***of the World Trade Organisation***, including, in particular, Article XIV(a) and Article XIV bis of the General Agreement on Trade in Services[15]***. This Regulation*** should also comply with the ▌ Treaties and be consistent with commitments made under other trade and investment agreements to which the Union or Member States are parties ***as well as*** trade and investment arrangements to which the Union or Member States are adherents.

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[15] Council Decision of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ L 336, 23.12.1994, p. 1).

(46) ***Where*** a foreign investment constitutes a concentration falling within the scope of Council Regulation (EC) No 139/2004[16], the application of this Regulation should be without prejudice to the application of Article 21(4) of Regulation (EC) No 139/2004. This Regulation and Article 21(4) of Regulation (EC) No 139/2004 should be applied ***in a coherent manner***. To the extent that the respective scope of application of ***both*** Regulations overlap, the grounds for screening set out in Article 12 of this Regulation and the notion of legitimate interests within the meaning of Article 21(4), third subparagraph, of Regulation (EC) No 139/2004 should be interpreted coherently, without prejudice to the assessment of the compatibility of the national measures aimed at protecting those interests with the general principles and other provisions of Union law.

(47) This Regulation should not affect Union rules on the prudential assessment of acquisitions of qualifying holdings in the financial sector, laid down by Directives 2009/138/EC[17], 2013/36/EU[18] and 2014/65/EU[19] of the European Parliament and of the Council, which is a distinct procedure with a specific objective.

(48) The application of this Regulation should be consistent with**,** and without prejudice to**,** other notification and authorisation procedures set out in Union law. The Commission should be allowed to use the information notified by the Member States ***within the framework of*** the cooperation mechanism to exercise its role of overseeing the application of Union law in accordance with Article 17 TEU.

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16 Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (OJ L 24, 29.1.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/139/oj).

17 Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335, 17.12.2009, p. 1, ELI: http://data.europa.eu/eli/dir/2009/138/oj).

18 Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338, ELI: http://data.europa.eu/eli/dir/2013/36/oj).

19 Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (OJ L 173, 12.6.2014, p. 349, ELI: http://data.europa.eu/eli/dir/2014/65/oj).

(49) In order to take into account ***the adoption or amendment of Union legal acts establishing*** projects or programmes***,*** to adapt the list of technology ***areas*** of ▌ importance for the security or public order interests of the Union ***and to take into account the adoption of legal acts providing for the establishment of the Union List of Critical Medicinal Products***, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amendments to the ***relevant provision of*** this Regulation ***and the Annexes thereto***. The list of projects and programmes of Union interest set out in ***the respective*** Annex ▌ should cover projects or programmes ***established by Union law that*** provide for the development, maintenance or acquisition of critical infrastructure, critical technologies or critical inputs which are ***of particular importance*** for security or public order. The list of technology ***areas*** of ▌ importance for ▌ security or public order ▌ set out in ***the respective*** Annex ▌ should include areas where a foreign investment may affect security or public order in more than one Member State ▌ through ***a*** Union target, which does not participate in or receive funds from a project or programme of Union interest***. As regards critical medicines, it is important that, when the Commission has established the Union List of Critical Medicinal Products by means of an implementing act adopted pursuant to the Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, the reference to the critical medicines to be taken into account by Member States and the Commission when determining whether a foreign investment is likely to negatively affect security or public order should be updated and replaced with a reference to the Union List of Critical Medicinal Products and subsequent amendments thereto and that the relevant annex be deleted***. It is of particular importance that the Commission carries 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[20]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament

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[20] OJ L 123, 12.5.2016, p. 1***, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.***

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.

(50) In order to ensure uniform conditions for the implementation of this Regulation, in particular as regards the form to be used to provide ▌ information about foreign investments***, the arrangements for the functioning of the online EU portal and the secure and encrypted system, the technical guidance to Member States concerning the database on the outcome of assessments under national screening mechanisms, and the form to be used by Member States for their annual reporting to the Commission***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[21].

(51) Regulation (EU) 2019/452 should be repealed. In order to allow ***for*** sufficient time for Member States and entities to prepare for ***its*** implementation, this Regulation should ***start applying eighteen*** months after ***its*** entry into force***. To ensure legal certainty and a smooth cooperation*** between ***Member States*** and the ***Commission in the screening of foreign investments***, ***and taking into account the legitimate expectations of foreign investors, it is appropriate that*** Regulation (EU) 2019/452 should continue to apply ***to foreign direct investments which are undergoing screening on***, ***or are completed by, the date of application of this Regulation. This includes the possibility for Member States and the Commission to provide comments or an opinion pursuant to Article 7(8) of Regulation (EU) 2019/452. This Regulation should not apply to foreign direct investments to which Regulation (EU) 2019/452 continues to apply. It should also not apply to other foreign investments which are undergoing screening on the date of application of this Regulation, such as intra-Union investments which may already be subject to screening pursuant to national law. It is equally appropriate to clarify that this Regulation does not apply to those foreign investments completed by the date of application of this Regulation,***

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[21] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

HAVE ADOPTED THIS REGULATION:

PUBLIC

CHAPTER 1
GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation establishes a Union framework for the screening, by Member States, of foreign investments in their territory, on the grounds of security or public order.

2. This Regulation establishes a cooperation mechanism to enable Member States and the Commission to exchange ***relevant*** information on foreign investments, assess their potential impact on security or public order, and identify potential concerns ***to which due consideration*** shall be ***given*** by the ***host*** Member State**.**

4. This Regulation is without prejudice to each Member State having sole responsibility for its national security, as provided for in Article 4(2) TEU, and to the right of each Member State to protect its essential security interests ***pursuant to*** Article 346 TFEU.

▌

5a. This Regulation does not apply to

(i) Foreign investments made in the application of a resolution tool or of write-down and conversion powers within the meaning of Article 2(66) of Directive 2014/59/EU or Article 2(56) of Directive (EU) 2025/1 or Article 3 (44) of Regulation (EU) 806/2014;

(ii) internal restructurings, unless a new legal entity established in a third country not already present in the upstream ownership chain of the Union target is introduced in that chain.

Article 2

Definitions

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

(1) 'foreign investment' means ▌ an investment ***of any kind, carried out either by a foreign investor itself or through a foreign investor's subsidiary in*** the Union***, aiming to establish or to maintain lasting and direct links between the*** foreign ***investor and a Union target***, ***to*** which ***the foreign investor makes capital available in order to carry out an economic activity in a Member State, enabling*** effective participation in the management or control of ***that*** Union target;

(3a) 'greenfield investment' means a foreign investment carried out through the establishment of new facilities or of an undertaking for the performance of an economic activity in the Union;

(***3b) 'resolution tool' means a resolution tool within the meaning of Article 2(19) and Article 37 (9) of Directive 2014/59/EU of the European Parliament and of the Council[22], Article 3(9) of Regulation (EU) 806/2014 of the European Parliament and of the Council[23], Article 2(4) of Regulation (EU) 2021/23 of the European Parliament and of the***

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22 Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190, ELI: http://data.europa.eu/eli/dir/2014/59/oj).

23 Regulation (EU) No 806/2014 of the European Parliament and of the Council of 15 July 2014 establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation (EU) No 1093/2010 (OJ L 225, 30.7.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/806/oj).

Council[24], or Article 2(14) and Article 26 (7) of Directive (EU) 2025/1 of the European Parliament and of the Council[25];

(3c) ***'internal restructuring' means a reorganisation of a corporate group to which a Union target belongs , which does not result in a change of the beneficial owner of the Union target.***

(4) 'request for authorisation' means ***a*** filing ▌ under a screening mechanism ▌ of a request to authorise ***a*** foreign investment subject to ***a prior*** authorisation requirement;

(6) 'foreign investor' means:

(a) a natural person ***who does not hold the nationality of a Member State***; or

(b) an undertaking or entity established or otherwise organised under the laws of a third country;

(6a) ***'beneficial owner' means: i) one or more natural persons, - who, directly or indirectly, own or control a foreign investor or Union target, - who ultimately benefit from the foreign investment, or - on whose behalf the foreign investment is made or on whose behalf the control over that foreign investment is exercised; ii) where no natural persons are identified, a legal person, entity or trust which, - directly or indirectly owns or controls a foreign investor or Union target, or - ultimately benefits from the foreign investment;***

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24 ***Regulation (EU) 2021/23 of the European Parliament and of the Council of 16 December 2020 on a framework for the recovery and resolution of central counterparties and amending Regulations (EU) No 1095/2010, (EU) No 648/2012, (EU) No 600/2014, (EU) No 806/2014 and (EU) 2015/2365 and Directives 2002/47/EC, 2004/25/EC, 2007/36/EC, 2014/59/EU and (EU) 2017/1132 (OJ L 22, 22.1.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/23/oj).***

25 ***Directive (EU) 2025/1 of the European Parliament and of the Council of 27 November 2024 establishing a framework for the recovery and resolution of insurance and reinsurance undertakings and amending Directives 2002/47/EC, 2004/25/EC, 2007/36/EC, 2014/59/EU and (EU) 2017/1132 and Regulations (EU) No 1094/2010, (EU) No 648/2012, (EU) No 806/2014 and (EU) 2017/1129 (OJ L, 2025/1, 8.1.2025, ELI: http://data.europa.eu/eli/dir/2025/1/oj).***

(7) 'foreign investor's subsidiary in the Union' means an ▌ undertaking established under the laws of a Member State***, which is*** directly or indirectly controlled by a foreign investor;

(7a) 'opaque ownership structure' means an arrangement in which the ownership or control of an entity is unclear, concealed or difficult to ascertain due to, inter alia, the use of complex legal structures, multiple layers of ownership, nominee shareholders, or other mechanisms that obscure the identity of the beneficial owner;

(8) 'Union target' means an undertaking established ***or to be established*** under the laws of a Member State;

(9a) 'filing' means the initial submission to the screening authority of all information or documentation required under the applicable screening mechanism, including, where applicable, a complete request for authorisation of a foreign investment.

(11) 'third country' means a jurisdiction, which is not a member of the Union;

(11a) 'host Member State' means the Member State in which a foreign investment is planned or completed.

(12) 'screening' means a procedure that allows a Member State to assess, investigate, authorise, authorise subject to mitigating measures, prohibit or unwind foreign investments on the grounds of security or public order;

(13) 'screening mechanism' means an instrument of general application, such as a law or regulation, and accompanying administrative requirements, implementing rules or guidelines, that set out the terms, conditions and procedures for the screening of foreign investments on the grounds of security or public order;

(14) 'screening decision' means a measure adopted by a screening authority in application of a screening mechanism resulting in the authorisation, authorisation subject to mitigating measures, prohibition or unwind of a foreign investment;

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(15) 'screening authority' or 'screening authorities' means the authority or authorities designated by a Member State to screen foreign investments;

(16) 'completion' means the point in time when the last condition precedent has been met in relation to an investment decision by the parties to a foreign investment transaction;

(17) 'cooperation mechanism' means the cooperation between Member States and the Commission on foreign investments pursuant to this Regulation;

(19) 'notifying Member State' means a Member State that has notified a ***foreign*** investment to the cooperation mechanism pursuant to Article 5;

(20) 'multi-country transaction' means a foreign investment subject to screening mechanisms in several Member States;

(21) 'multi-country notification' means a ***notification sent*** to the cooperation mechanism ***by the Member States concerned with regards to a multi-country transaction***;

(22) 'mitigating measure' means any condition to resolve the likely negative effect ***on*** security or public order arising from the foreign investment***;***

(23) 'Contact point' means the person or entity designated by a Member State to ***send and receive all communication through*** the cooperation mechanism, ***including notifications and exchanges of information*** related to foreign investments covered by this Regulation

(23a) 'stockpiling' means storing a quantity of a particular raw material for future use, including in anticipation of possible shortages.

PUBLIC

CHAPTER 2

NATIONAL SCREENING MECHANISMS

Article 3

Establishment of screening mechanisms

1. Member States shall establish a screening mechanism in accordance with this Regulation. ***Member States may, for that purpose, adopt national provisions that are complementary to or are more specific than the provisions of this Regulation, provided that such provisions do not undermine and are consistent with the objectives of this Regulation.***

2. Member States shall ensure that the screening mechanism ▌ applies ▌ to ***foreign*** investments ***covered by*** Article 4(4).

2a. Member States may decide that the screening mechanism applies also to foreign investments falling within the scope of this Regulation other than those referred to in Article 4(4). Where Member States decide to include such foreign investments in the scope of application of their screening mechanism, this Regulation shall apply to the screening of those foreign investments.

3. Each Member State shall notify to the Commission the measures adopted pursuant to paragraph 1 ***of this Article*** no later than [***18 months after the date of entry into force of this Regulation***]. Member States shall thereafter notify the Commission of any amendment to their screening mechanism within 30 days of the adoption of ***that*** amendment.

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Article 4

Minimum requirements

1. Rules and procedures related to screening mechanisms, and measures taken pursuant to such rules and procedures, shall comply with Union law, be transparent and shall not discriminate between third countries or between the Member States in which the foreign investor's subsidiary in the Union is established.

2. Member States shall ensure that their screening mechanisms comply with the following requirements:

   (a) ***for foreign investments that fall within the scope of their screening mechanism and that are subject to a filing requirement,*** adequate procedures ***and resources*** shall be provided for the screening authority to***:***

      (i) carry out an initial review of the investment within 45 calendar days following the filing to decide whether an in-depth investigation is necessary to determine if the foreign investment is likely to negatively affect security or public order; and

      (ii) based on the results of its initial review, where necessary, carry out an in-depth investigation to determine whether that foreign investment is likely to negatively affect security or public order

   (b) the screening authority shall monitor and ensure compliance with the screening mechanism and screening decisions***,*** in particular ***by identifying, preventing and addressing their*** circumvention***. It shall be provided with sufficient resources to carry out these tasks.***

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(c) the screening authority shall be empowered to ***screen and adopt a*** screening ***decision on*** foreign investments ***falling within the scope of the respective Member State's screening mechanism on*** its own initiative for at least 15 months ***and up to a maximum of 5 years, following*** the completion of a foreign investment that is not subject to ***a prior*** authorisation requirement where the screening authority has grounds to consider that ***such*** foreign investment may affect security or public order;

(d) the screening authority shall be empowered***, for at least 24 months following the completion of a*** foreign ***investment, to screen and adopt a screening decision on that investment provided that it is*** subject to a prior authorisation requirement ***and was*** not filed or ***was*** filed after ***its*** completion ▌ ;

(e) confidential information ▌ made available to the Member State carrying out the screening shall be protected***. The screening authority shall give the entity providing the information the opportunity to indicate which information it considers to be confidential.***

(f) ***the parties subject to the*** screening decision shall have the ***right*** to seek ***effective*** judicial recourse against that screening decision;

(g) an annual report shall be made public, and shall include information on relevant legislative developments in the Member State and aggregate and anonymised data on the investments screened, including the outcome of screening decisions, nationalities, or country of establishment as the case may be, of parties to the investments notified to the screening authority, and the economic sectors in which those transactions took place***, with the exception of data for which full anonymisation is not possible***;

(h) foreign investments subject to ***a prior*** authorisation requirement as referred to in paragraph 4 shall be filed by the applicant requesting ***an*** authorisation with the screening authority and shall be screened before the foreign investment is completed;

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(ga) The screening authority shall, where applicable and without undue delay, inform the person who made the filing of the completeness of that filing;

(ha) the screening authority shall be empowered to impose effective, proportionate and dissuasive penalties on foreign investors that fail to comply with the requirements of the screening mechanism, including failure to file the investment where required or failure to comply with mitigating measures.

(hb) the screening authority and the Commission shall make publicly available the contact details through which stakeholders may submit information concerning foreign investments in a confidential manner.

(j) adequate procedures shall be provided for the notification of ***foreign*** investments to the cooperation mechanism pursuant to Article 5.

3. Before ***adopting*** a decision to authorise a foreign investment subject to mitigating measures or to prohibit ***or to unwind*** a foreign investment, ***the screening authority*** shall ***give the parties*** subject to the ***intended screening decision*** the opportunity to make their views known ***effectively***.

4. Member States shall ensure that their screening mechanisms impose ***a prior*** authorisation requirement for foreign investments where the Union target established in their territory:

(a) ***develops, produces or commercialises items*** listed in Annex I ***to Regulation (EU) 2021/821*** of the European Parliament and ▌ the Council ***(common list of dual-use items subject to export controls);***

(b) ***develops, produces or commercialises goods or technology*** listed in ***the*** Annex ***to Directive 2009/43/EC of the European Parliament and the Council;***

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(ba) produces, conducts research in or develops semiconductors or quantum technologies, or conducts research in or develops artificial intelligence technology described in Annex I;

(bc) is active in the transport, energy or digital infrastructure sectors and is considered critical pursuant to a risk-based targeted assessment performed by the Member State where that Union target is established. This assessment shall take into account national security and vital societal functions in light of the essential services such Union target provides;

(bd) exercises, as regards any strategic raw materials listed in Section I of Annex I to Regulation (EU) 2024/1252 (Critical Raw Materials Act), activities of exploration, extraction, processing, recycling or recovery as defined in Article 2 of that Regulation, or of stockpiling.

(be) constitutes one of the following entities:

(i) central counterparties[26];

(ii) central securities depositories[27];

(iii) operators of regulated markets[28];

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26 Means central counterparties as defined in Article 2(1) of Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories.

27 Means central securities depositories as defined in Article 2(1)(1) of Regulation (EU) No 909/2014 of the European Parliament and of the Council of 23 July 2014 on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012.

28 Means market operators of regulated markets as defined in Article 4(1)(18) and Article 4(1)(21) of Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU.

(iv) operators of payment systems, excluding central banks[29];

(v) other systemically important institutions[30];

(vi) global providers of specialised financial messaging services;

(bf) owns, develops or operates voter registration databases, voting systems and other information systems specifically designed to manage electoral operations such as the counting, auditing, and displaying of election results, and post-election reporting to certify and validate results.

5. Paragraph 4 shall not apply to greenfield investments.

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29 Means operators of payment systems as defined in Article 2(a) of Directive 98/26/EC of the European Parliament and of the Council of 19 May 1998 on settlement finality in payment and securities settlement systems, and designated as such pursuant to article 10(1) of Directive 98/26/EC, with the exclusion of payment systems operated by central banks.

30 Means other systemically important institutions as defined in Article 131(3) of Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC Text with EEA relevance.

CHAPTER 3

THE UNION COOPERATION MECHANISM ON FOREIGN INVESTMENTS LIKELY TO NEGATIVELY AFFECT SECURITY OR PUBLIC ORDER

PUBLIC

SECTION I

NOTIFICATION OF FOREIGN INVESTMENTS

Article 5

Notification of foreign investments

1. Member States shall notify the Commission and the other Member States through the cooperation mechanism of any foreign investment in a Union target established in their territory that ***meets the conditions set out in Article 4(4) as well as any of the following conditions***:

   (i) the foreign investor or the foreign investor's subsidiary in the Union is directly or indirectly controlled by the government, including state bodies, regional or local authorities or armed forces, of a third country, including ***in the form of*** ownership structure, significant funding, special rights or state-appointed directors or managers;

   (ii) the foreign investor, a natural person or ***an*** entity controlling the foreign investor, the beneficial owner of the foreign investor, any of the subsidiaries of the foreign investor, or any other party owned or controlled by, or acting on behalf or at the direction of, such a foreign investor is subject to Union restrictive measures pursuant to Article ***29 TEU and Article*** 215 TFEU;

(iii) the foreign investor***, a natural person or an entity controlling the foreign investor, the beneficial owner of the foreign investor***, or any of ***the foreign investor's*** subsidiaries was involved in a foreign investment ***which was*** previously screened by a Member State and was not authorised or ***was*** authorised ***subject to mitigating measures, which were significantly or repeatedly not complied*** with ▌ ; to determine this, the notifying Member State shall rely on information available to ***it***, including the information contained in the secure database ***referred to in*** Article ***18*** and information provided by the foreign investor on ***that*** matter.

2. Member States shall notify the Commission and the other Member States of any foreign investment in a Union target ▌ in their territory where they initiate an in-depth investigation ***in the framework of*** their screening procedures ▌ , where ***one of the following conditions is met:***

a) the Union target is active in a project or programme of Union interest listed in Annex IV;

b) the Union target has one or more subsidiaries in at least one other Member States, or is part of a group that has one or more subsidiaries in at least one other Member State.

2a. Member States shall notify the Commission and the other Member States of any foreign investment in their territory where, in exceptional cases, they intend to impose a mitigating measure or to prohibit or unwind the transaction without an in-depth investigation. The conditions set out in paragraph 2, points (a) and (b), shall also apply to this paragraph.

2b. Foreign investments notified pursuant to paragraph 1 shall not be notified pursuant to paragraphs 2 or 2a.

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3. ***A host Member State shall notify the Commission and the other*** Member States ***of*** any foreign investment that ***falls within the scope of its screening mechanism but does not fall under paragraph 1, 2 or 2a, if it*** considers that ***the*** foreign investment could ***negatively affect*** security or public order ***in at least one other Member State, especially*** where the Union target has significant operations in other Member States, or belongs to a corporate group that ***consists of*** several ***entities*** in different Member States which ***fall under Article 4(4), points (a) to (h). Any such notification shall be duly justified***.

Article 6

Content and procedures for notification of foreign investments

1. Member States shall ensure that a notification pursuant to Article 5 contains the information ***set out*** in Article ***15(1)*** and is sent to the Commission and other Member States ▌ :

   (a) within 15 calendar days of ***the filing*** for foreign investments meeting ▌ the conditions set out in Article 5(1) ▌ ;

   (b) within ***45*** calendar days of ***the filing*** for foreign investments meeting the conditions set out in Article 5(2)***;***

   (c) without undue delay after making the decision to notify a case in accordance with Article 5 (3):

   (d) without undue delay where Article 5(2a) applies.

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Article 7

Specific rules applicable to multi-country transactions

Without prejudice to Article 6, the following procedures shall apply to multi-country transactions:

(a) ***The person making the filing shall endeavour to do so in all Member States concerned on the same day, and each filing shall make reference to the other filings.***

(b) ***Where a Member State receives a filing that meets the conditions set out in point a, it shall discuss with the other Member States concerned, inter alia, whether the conditions of Article 5 are met. At the request of a Member State, the Commission may participate in such coordination.***

(c) ***If the filing concerns a foreign investment that meets the conditions set out in Article 5 (1), (2) or (3), the respective Member States shall endeavour to send their notifications to the cooperation mechanism on the same day.***

(d) ***The Member States concerned shall coordinate closely throughout the procedure. In particular, they shall endeavour to align the timing of their respective screening procedures, including as regards the adoption of their respective screening decisions, and, where appropriate, shall discuss whether their respective screening decisions are compatible with each other and adequately address the identified risks to security or public order.***

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SECTION II

COMMENTS BY MEMBER STATES AND OPINIONS BY THE COMMISSION

*Article **8***

Comments ▌ and opinions ▌ on notified foreign investments

1. Any Member State may issue duly ***justified*** comments to the notifying Member State ▌ if it:

   (a) considers that ***the notified*** foreign investment is likely to negatively affect its security or public order; or

   (b) has information relevant for the screening of that foreign investment.

2. The Commission ***shall, where appropriate,*** issue a duly ***justified*** opinion addressed to the notifying Member State ▌ if ***it***:

   (a) ▌ considers that ***the notified*** foreign investment is likely to negatively affect the security or public order of more than one Member State;

   (b) ▌ considers that ***the notified*** foreign investment is likely to negatively affect ***a project or programme*** of Union interest ***as listed in Annex IV*** on grounds of security or public order; ***or***

   (c) ***has additional*** information ***relevant for*** that foreign investment. ▌

   The Commission may issue an opinion regardless of whether Member States have issued comments.

2a. Where the notifying Member State duly considers that the notified foreign investment is likely to affect its security or public order, it may request the Commission to issue an opinion or other Member States to provide comments.

2b. Where appropriate, the opinion of the Commission may propose mitigating measures.

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3. The Commission ***shall, where appropriate,*** issue a duly ***justified*** opinion addressed to all Member States if it considers that several foreign investments***, whether completed or not,*** ▌ taken together ▌ and having regard to their characteristics could ***negatively*** affect ▌ security or public order ▌ . After ***the*** Commission ***has*** issued ***its opinion***, the Commission ***shall, where*** appropriate, discuss with Member States how to address the identified risks.

▌

Article 9

Intention to issue comments or an opinion

1. Before a Member State issues ***comments*** or the Commission issues an opinion pursuant to Article ***8***, the following procedure shall apply:

   (a) Member States shall inform the notifying Member State ***about*** their ***intention*** to issue comments no later than 15 calendar days following the receipt of ***a*** notification pursuant to Article 5;

   (b) the Commission shall inform the notifying Member State ***about its intention*** to issue an opinion no later than 20 calendar days following the receipt of ***a*** notification pursuant to Article 5.

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Article 10

Additional information

1. When ***informing about*** their ***intention*** to issue comments or an opinion, Member States and the Commission may request ▌ information from the notifying Member State ***in addition to the information referred in Article 15(1)***.

2. ***Member States and the Commission may request additional information, where such information is necessary for responding to a request for an opinion or a comment made by the notifying Member State pursuant to Article 8(2a).***

3. Any request for additional information shall be***:***

(a) duly justified;

(b) limited to the information necessary for the Member States to provide comments pursuant to Article 8 (1) or in response to a request pursuant to Article 8(2a) or for the Commission to issue an opinion pursuant to Article 8(2), Article 8(3), or in response to a request pursuant to Article 8(2a);

(c) proportionate to the purpose of the request; and

(d) not unduly burdensome for the notifying Member State.

4. ***Where a Member State requests additional information from the notifying Member State, it shall send such requests to the Commission simultaneously.***

5. The notifying Member State shall provide the ▌ additional information***,*** requested by the Commission or other Member States pursuant to paragraph ***1 or 2*** without undue delay ▌. Where the notifying Member State provides additional information to a Member State, ***that*** additional information shall be sent to the Commission simultaneously.

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6. Where the notifying Member State receives several requests for additional information about the same ***notified*** investment, it shall ***endeavour to*** provide all the ***requested*** additional information ▌ simultaneously.

7. Where several notifying Member States receive requests for additional information about a ▌ multi-country notification, ***they*** shall ***endeavour to provide all requested*** information ***simultaneously***.

Article 11

Issuance of comments and opinions

1. The Member State issuing comments shall simultaneously send those comments to the Commission and inform all other Member States that comments have been issued.

2. The Commission shall:

a. send the opinions referred to in Article 8(2) points (a) and (c), to all Member States that issued comments and notify the other Member States that an opinion was issued;

b. send the opinions referred to in Article 8(2) point (b), and in Article 8(3) to all Member States.

3. The following deadlines shall apply to the issuing of comments by Member States and opinions by the Commission ▌ :

(a) where a Member State ***makes known its intention*** to issue comments on a notified foreign investment without requesting additional information from the notifying Member State, the respective comments shall be addressed to the notifying Member State ***within a reasonable period of time, and in any case*** no later than ***20*** calendar days following receipt of the ▌ notification of the foreign investment ;

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(b) where the Commission ***makes known its intention*** to issue an opinion on a notified foreign investment without requesting additional information from the notifying Member State, the respective opinion shall be addressed to the notifying Member State ***within a reasonable period of time, and in any case*** no later than ***30*** calendar days following receipt of the ▌ notification of the foreign investment ;

(c) where a Member State ***makes known its intention*** to issue comments on a notified foreign investment and requests additional information from the notifying Member State, the respective comments shall be addressed to the notifying Member State ***within a reasonable period of time, and in any case*** no later than ***15*** calendar days following receipt of the additional information;

(d) where the Commission ***makes known its intention*** to issue an opinion and requests additional information from the notifying Member State, the respective opinion shall be issued to the notifying Member State ***within a reasonable period of time, and in any case*** no later than ***25*** calendar days following receipt of the additional information.

4. The notifying Member State shall ***communicate to*** the Commission and the other Member States any substantial new information or circumstances relevant for the assessment of a foreign investment already notified pursuant to Article 5. If ***that*** information is made available before the ***respective deadline*** set out in ***paragraphs 3*** , the notifying Member State ***may, on a reasoned request by another Member State or the Commission, extend the relevant deadlines by up to 20 calendar days. The deadlines may be extended only once. The notifying Member State shall inform the other Member States***, the Commission and the ***foreign investor that made ▌ the filing that*** the deadline ***has been extended***.

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5. The notifying Member State shall take ***its*** screening decision only after the ***respective deadline set out in paragraph 3 of this Article*** points (a)-(d) ***has*** expired.

6. Where, due to exceptional circumstances, the notifying Member State considers that its security or public order requires ***adopting*** a screening decision before the ***expiry of respective*** deadlines ***set out*** in paragraph 3 ▌, it shall notify the other Member States and the Commission of its intention and duly justify the need for immediate action. The other Member States and the Commission shall ***issue*** comments or ▌ an opinion expeditiously. This procedure shall not be invoked to serve purely ▌ commercial interests of the applicant requesting the authorisation.

7. When issuing comments or an opinion pursuant to this Article, the Member States ***or*** the Commission, as the case may be, shall consider whether such comments or opinion should be classified information and what level of classification should apply thereto, in accordance with Union ***law*** and the ***applicable*** national law on classified information.

Article 12

Considerations of comments and opinions

1. Where a ***notifying*** Member State ▌ receives a comment from another Member State pursuant to ***Article 8(1)*** or an opinion from the Commission pursuant to ***Article 8(2) or Article 8(3)***, it shall give ***due*** consideration to such a comment or ***an*** opinion.

2. Following the receipt of ***comments or an opinion, and at the request of a Member State having issued comments or of the Commission, where the latter issued an opinion, the notifying*** Member State shall ***organise*** a meeting to discuss how ▌ best ***to*** address the risks identified.
The meeting referred to in the first subparagraph shall be organised with: a) the Member States ***that issued comments and the Commission, or b) the Commission, where no comments were issued.*** Where the ***comments or an opinion concern*** a multi-country transaction, ***the notifying Member State shall invite to the meeting referred to in the first subparagraph*** the other Member States who notified the foreign investment ▌.▌

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3. ***The screening decision shall be taken by the Member State undertaking the screen***ing.

4. Following the receipt of ***comments pursuant to Article 8(1) or*** an opinion pursuant to ***Article 8(2) or Article 8(3), the notifying*** Member State ***shall notify to the Member States concerned and to the Commission no later than 7 calendar days after the screening decision enters into force the operative part of its screening decision as well as a summary of the main reasons thereof in view of the issued comments or opinion, including:***

(a) ***the extent to which it gave the Member States' comments or the Commission opinion due consideration; and***

(b) ***where applicable, the reason for its disagreement with the Member States' comments or the Commission opinion.***

Article ***13***

Comments and opinions on non-notified foreign investments

1. ***Any*** Member State ***may issue duly justified comments addressed to a host*** Member State ***on a foreign investment*** which has not been notified to the cooperation mechanism***, where*** the Member State ***issuing the comments:***

(a) ***considers that that foreign investment is likely to negatively affect its security or public order, or***

(b) ***has information relevant to that foreign investment.***

The Member State issuing comments shall simultaneously send its comments to the Commission and inform all other Member States that comments have been issued.

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2. ***The Commission may issue a duly justified opinion addressed to a host*** Member ***State on a*** foreign investment ***which*** has not been notified to the cooperation mechanism ***where the Commission:***

(a) considers that the foreign investment is likely to negatively affect security or public order in more than one Member State, or

(b) considers that the foreign investment is likely to negatively affect projects or programmes of Union interest as listed in Annex IV on grounds of security or public order, or

(c) has information relevant to that foreign investment.

2a. The Commission shall: (a) send opinions meeting the conditions set out in points (a) and (c) of paragraph 2 to all Member States that provided comments and notify the other Member States that an opinion was issued; (b) send opinions meeting the conditions set out in point (b) of paragraph 2 to all Member States.

3. ***Member States, before issuing comments, and*** the Commission ***before issuing an opinion, shall check whether the host Member State has already started or completed screening the*** foreign investment ***and whether it intends*** to notify the foreign investment ***through*** the cooperation mechanism ***pursuant to Article 5***.

4. ***Before issuing comments or an opinion in relation to a foreign investment pursuant to paragraph 1, point (a) and paragraph 2, point (a) or (b), the Member States or*** the Commission shall ***send a request for information*** to the ***host Member State***.

5. ▌Any request for information pursuant to ▌paragraph ***4*** shall be***:***

(a) duly justified;

(b) limited to the information necessary for a Member State to issue comments or for the Commission to issue an opinion;

(c) proportionate to the purpose of the request, and

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(d) not unduly burdensome for the host Member State.

(e) Where the request for information is submitted by a Member State, that Member State shall send the request to the Commission simultaneously.

6. The ***host*** Member State ▌ shall provide the ▌ information requested by the other Member States or the Commission pursuant to paragraph ***4*** without undue delay ▌ . Where the ***host*** Member State provides ▌ information to ***another*** Member State, ***the host Member State shall simultaneously send that*** information ▌ to the Commission ▌

7. ***Comments issued pursuant to*** paragraph 1***, point (a) and opinions issued pursuant to paragraph 2, point (a) or (b) shall be sent*** to the ***host*** Member State ***within a reasonable period of time, and in any case no later than 20 calendar days*** following ***the receipt of the information pursuant to paragraph 6.***

Where a Member State has issued comments pursuant to paragraph 1, point (a), the Commission's deadline, as set out in the first subparagraph, for issuing its opinion shall be extended by an additional 10 calendar days.

7a. The host Member State shall give due consideration to the comments of the other Member States and to the opinion of the Commission. If the host Member State, on the basis of the comments of the other Member States and the opinion of the Commission, does not intend to screen the foreign investment, it shall inform the Member States that have issued comments and the Commission thereof.

7b. If, following the information as referred to in paragraph 7a, a Member State that issued comments so requests, the host Member State shall organise a meeting with the Member States that issued comments and with the Commission or, if the Commission so requests, a meeting with the Commission alone where only the Commission issued an opinion.

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6e. Where, following any such meeting, the host Member State decides not to screen the foreign investment, it shall inform Member States that issued comments and the Commission thereof and provide them with a written explanation on: (a) the reasons for not screening the foreign investment, including where applicable the reasons for its disagreement with the comments or opinion issued; and (b) where applicable, any alternative measures it intends to take in order to address the risks identified in the comments or the opinion.

7d. Without prejudice to Article 5(1), (2) and (2a), where the host Member State decides to screen the foreign investment, it shall notify the foreign investment in accordance with Article 5(3).

9. Member States may issue comments pursuant to paragraph 1 and the Commission may issue an opinion pursuant to paragraph 2 no later than 15 months following the completion of a foreign investment.

PUBLIC

SECTION V

REQUIREMENTS TO ENSURE AN EFFECTIVE COOPERATION

Article 14

General requirements

1. Member States ***and the Commission*** shall provide the necessary resources ***and*** legal and administrative means ***to efficiently and effectively meet the objectives of this Regulation including as regards*** their ▌ participation in the cooperation mechanism.

2. Each Member State and the Commission shall designate a contact point for the purposes of the cooperation mechanism.

3. Member States shall ensure that the deadlines and procedures set out in their screening mechanisms allow them to provide ▌ answers to requests for additional information by the Commission or other Member States.

4. Member States shall ensure that their screening mechanisms give sufficient time and means to assess and give ***due*** consideration to other Member States' comments and Commission opinions before a screening decision is taken. This includes having ***at their disposal, in any relevant instrument, including its screening mechanism, the*** necessary legal means and powers to consider concerns expressed or likely impacts identified by another Member State or the Commission ▌ . ▌

5. ▌ Screening authorities shall be empowered to investigate, assess, decide on and monitor foreign investments ***that fall within the scope of their screening mechanisms and are*** brought to their attention pursuant to Article ***13(1) or (2)***.

PUBLIC

6. ***Member States shall ensure that they have the necessary legal means and powers to effectively address within their territory the consequences of non-compliance with the mitigating measures provided for in their screening decision.*** Where mitigating measures in a screening decision require compliance by undertakings established in other Member States, the Member ***State*** that adopted a screening decision ***and other relevant Member States*** shall ***endeavor to*** cooperate with ***each*** other ***in*** the monitoring and enforcement of ***the*** screening decision***, in accordance with their national laws***.

7. ***Where, following the adoption of a screening decision on a foreign investment that was subject to the Union cooperation mechanism, a host Member State imposes penalties in accordance with Article 4(2), point (ha), it shall, where appropriate, notify the Commission and the Member States that provided comments on the transaction within a reasonable timeframe.***

*Article **15***

Information requirements

1. Member States shall ensure that information provided in the notification referred to in Article 5 and ***provided in response to a*** request of information ***pursuant to 13(6)*** include:

   (a) the name***, if possible written in both the Latin alphabet and in the original characters where applicable, and the address, website address and activities*** of the ***foreign*** investor, ***and, where applicable, the name, if possible written in both the Latin alphabet and in the original characters where applicable, and the address and website address of the beneficial*** owner of the ***foreign*** investor ▌, the ownership structure of the ***foreign*** investor and, where applicable, of the corporate group ***of*** which the ***foreign*** investor ***forms part.***

PUBLIC

(b) a comprehensive description of the ▌ foreign investment, ***its approximate value, its*** funding ***and*** source, on the basis of the best information available to the Member State***, and the date by which the foreign investment is planned to be completed or has been completed***;

(c) name and address of the Union target, its activities and alternative providers, the ***beneficial owner of the Union target, the*** ownership structure of the Union target ***before and after the foreign investment,*** and, where applicable, of the corporate group ***of*** which the Union target ***forms*** part***, before and after the foreign investment;***

(d) ***where*** applicable, information about the other legal entities of the same corporate group as the Union target that are located in other Member States ***and about relevant business operations that the Union target conducts in other Member States***;

(e) ***where applicable, details about the participation*** of the ***Union target in projects or programmes of Union interest as listed in Annex IV.***

(ea) whether the Union target, within the preceding five years, has been awarded at least one Union grant of EUR 750 000 or more;

(eb) where applicable, which of the conditions set out in Article 5 are fulfilled;

▌

2. ***By ... [18 months from the date of entry into force of this Regulation],*** the Commission shall ***establish***, by means of ***an*** implementing act ▌ , the form to be used to provide the ▌ information ***referred to in*** paragraph 1 ***of this Article, and update that form thereafter as necessary***. ***Those implementing acts shall be adopted in accordance with the procedure referred to in Article 29(2).***

▌

PUBLIC

4. ▌ The ***host*** Member State ▌ may request the ***foreign investor*** or any other ***natural or legal person either within the chain of control of the foreign investor or within the chain of control of the Union target*** to provide the information referred to in ***paragraph 1 of this Article, Article 10(1) and (2), and*** Article ***13(4)***. ▌ The requested information ***shall be provided*** to the ***host*** Member State ▌ within 15 calendar days ***following*** the request. ***By way of derogation, that Member State may extend the deadline by a period it deems appropriate in light of the complexity or quantity of the requested information.***

▌

6. A Member State shall notify the Commission and the other Member States concerned if, in exceptional circumstances, it is unable, despite its best efforts, to provide the information referred to in ***paragraph 1 of this article and indicate those circumstances***.

7. If no or incomplete information is provided, the ***comments*** issued by Member States, or the opinion issued by the Commission may be based on the information available to them.

8. Where the information referred to in paragraphs 1***and 4*** originates from ***a natural or legal person***, the Member State receiving the information ▌ shall***, where it has reasonable grounds to doubt*** the completeness ***and accuracy of that*** information***,*** take reasonable steps to ensure that the information is ***complete and*** accurate before providing it to the Commission and other Member States.

PUBLIC

Article 16

1. ***The host Member State and the Commission may request another Member State to gather information from a natural or legal person residing or established in its territory, provided that the natural or legal person is likely to possess the information in question. The Member State receiving the request for information shall endeavour, without delay, to gather that information and provide it to both the host Member State and the Commission.***

2. ***The host Member State may request the Commission to gather information from a natural person residing in another Member State's territory or a legal person established in another Member State's territory, provided that the natural or legal person is likely to possess the information in question. Provided that the Member State in whose territory the natural or legal person resides or is established has been informed by the Commission and does not, within a reasonable time limit, object or offer to provide that information itself, the Commission shall endeavour, without delay, to gather that information and provide it to both the host Member State and the other Member State.***

3. ***The information requested pursuant to paragraph 1 or 2 shall be relevant and strictly necessary for assessing a foreign investment pursuant to Article 19 and the request for information gathering assistance pursuant to paragraph 1 or 2 shall be duly justified.***

4. ***Where the Commission requests information from a natural or legal person pursuant to paragraph 2, the request by the Commission shall:***

   (a) state its legal basis and purpose,

   (b) state which national authority was informed by the Commission,

   (c) specify the requested information, and

   (d) set an appropriate time-limit for providing that information.

PUBLIC

5. Where, as a result of the application of this article, a natural or legal person receives confidential information from a Member State or the Commission, that person shall not use that information for any other purpose than to reply to the request for information and shall not disclose it.

6. Article 15(6) and (8) shall apply mutatis mutandis.

PUBLIC

I

*Article **17***

Confidentiality of information exchanges in the cooperation mechanism

1. Information received ***as a result of the application of this Regulation*** shall be used only for the purpose for which it was requested, unless ***the originator of the information explicitly agrees to another use.***

2. Member States and the Commission shall ensure the confidentiality of the information they provide or receive in application of this Regulation, in accordance with national and Union law. When dealing with requests for access to documents provided or received in application of this Regulation, Member States and the Commission shall refrain from disclosing any information that would undermine the purpose of the investigations conducted pursuant to this Regulation.

3. Member States and the Commission shall ensure that classified information provided or exchanged under this Regulation is not downgraded or declassified without the prior written consent of the originator.

Article 18

Secure and encrypted system, database and online EU portal

1. *By [12 months from the date of entry into force of this Regulation], the Commission shall establish and subsequently maintain a secure and encrypted system to facilitate the exchange of information between the contact points. All substantive communications between Member States, as well as between Member States and the Commission under this Regulation, shall be transmitted through that secure and encrypted system, unless the nature of the information requires different means, such as physical documents.*

2. *As part of the secure and encrypted system, and at the request of at least nine Member States, the Commission shall establish an online EU portal for the electronic filing of foreign investments with screening authorities and for communications between natural or legal persons making a filing and those authorities. That portal shall be operational no later than twelve months after the request referred to in the first sentence.*

3. *The online EU portal as referred to in paragraph 2 of this Article shall apply in respect to any foreign investment in a Member State that requested its establishment pursuant to paragraph 2 of this Article. It shall also apply in respect of foreign investments in a Member State which, after the establishment of that portal, so requests. The online EU portal shall no longer apply in a given Member State where it so requests. The Commission shall publish and keep updated a list of Member States using the online EU portal.*

4. *Filings of foreign investments in the Member States referred to in paragraph 3 of this Article shall only be submitted through an online form available on the online EU portal as referred to in paragraph 2 of this Article. That form shall include the information required under Article 15(1).*

PUBLIC

5. By no later than 12 months from the request referred to in paragraph 2 of this Article, the Commission shall set out, by means of an implementing act, ▌ the arrangements for the functioning of the online EU portal described in this Article and update those arrangements thereafter as necessary. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 29(2).

6. By [12 months from the date of entry into force of this Regulation], the Commission shall set up a secure database available to all Member States with information on the foreign investments notified to the cooperation mechanism and the outcome of the assessments of those foreign investments under screening mechanisms.

7. After completion of the national procedure, Member States shall upload to the database the following information:

(a) name, address or registered office and, where applicable, national registration number of the foreign investor and, where applicable, of the foreign investor's subsidiary in the Union;

(b) name, registered office and national registration number of the Union target;

(c) name, registered office and national registration number of companies affiliated with the Union target;

(d) outcome of the national procedure according to the following categories:

(i) not subject to national screening mechanism (non-eligible);

(ii) authorisation ,

(iii) authorisation subject to mitigating measures;

(iv) prohibition,

(v) withdrawal of a filing,

(vi) other;

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(e) the Member States that have issued comments and whether the Commission issued an opinion.

Points (a) to (c) only apply where this information has not been previously provided pursuant to Article 15 (1) or where it has changed since the notification.

7a. Member States may upload to the database relevant information on cases where mitigating measures were significantly or repeatedly not complied with.

8. By … [15 months from the date of entry into force of this Regulation] the Commission shall provide, by means of an implementing act, technical guidance to Member States concerning the implementation of paragraphs 7 and 10 of this Article, and update this technical guidance thereafter as necessary. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 29(2).

9. By [12 months from the date of entry into force of this Regulation,] the Commission shall upload to the database the information it has at its disposal since 12 October 2020 based on the notifications sent by Member States that screened foreign investments pursuant to Regulation (EU) 2019/452.

10. By …[OJ: please insert the date of application of this Regulation] Member States shall upload to that database the information at their disposal about the outcome of their screening mechanisms under the Regulation (EU) 2019/452. The Member States and the Commission may also provide additional information or explanations, including, where applicable, relevant business intelligence they have procured and verified from commercial vendors.

11. By… [12 months from the date of entry into force of this Regulation], the Commission shall set out, by means of an implementing act , the arrangements for the functioning of the secure and encrypted system referred to in paragraph 1 and the database referred to in paragraph 6, and update those arrangements thereafter as necessary. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 29(2).

PUBLIC

CHAPTER 4

FOREIGN INVESTMENTS LIKELY TO NEGATIVELY AFFECT SECURITY OR PUBLIC ORDER

PUBLIC

*Article **19***

Determination of likely negative impact on security and public order

1. ***When determining*** whether a foreign investment is likely to negatively affect security or public order***, for the purposes of taking a screening decision, or issuing comments or an opinion, the Member States and the Commission shall in particular consider its potential effects on:***

   (a) the availability, including outside the Union as a result of the foreign investment, of critical technologies, in particular those listed in Annex III, and the protection and availability of intellectual property or other intangible assets;

   (b) a project or programme of Union interest listed in Annex [IV];

   (c) the security, integrity, resilience and functioning of a critical entity or critical infrastructure within the meaning of Article 2 of Directive (EU) 2022/2557, including the land and property necessary for the operation of such infrastructure, as well as those of entities falling within the scope of Directive (EU) 2022/2555, taking into account the relevant Union-level coordinated security risk assessments carried out in accordance with Article 22 of Directive 2022/2555;

   (d) the continuity of supply of critical inputs, including services;

(e) the protection of sensitive information, including personal data as defined in Article 4, point (1), of Regulation (EU) 2016/679[31], in particular with regard to the ability of the foreign investor to access, control, and otherwise process such information;

(f) the freedom and pluralism of the media, including online and social media platforms that can be used for large scale disinformation or criminal activities;

(g) the protection of electoral processes;

(h) the protection of public health, including the provision and availability of the critical medicines listed in Annex II;

(i) the protection of food security, including farming when the Union target possesses or operates more than 10,000 hectares of farmland.

(j) the security of military facilities and other sensitive public facilities in the immediate geographical proximity of the Union target;

4. When determining whether ***a foreign*** investment is likely to negatively affect security or public order, ***for the purposes of taking a screening decision or issuing comments or an opinion,*** the Member States ***and*** the Commission shall also take into account information related to the foreign investor, including:

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[31] 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. 1–88, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

(-a) whether the foreign investor, a natural person or entity controlling the foreign investor, the beneficial owner of the foreign investor, any of the subsidiaries of the foreign investor, or any other party owned or controlled by, or acting on behalf or at the direction of the foreign investor is likely to: (i) pursue a third country's policy objectives, including by using the investment to coerce a Member State or the Union to prevent or obtain the cessation, modification or adoption of a particular act; (ii) facilitate the development of a third country's military capabilities; or (iii) use the foreign investment to support internal repression in a third country or the commission of serious violations of human rights or international humanitarian law, in particular when the Union target develops or produces items included in Annex I of Regulation (EU) 2021/821 or items included in Annex I of the Directive 2009/43/EC;

(a) whether the foreign investor, a natural person or entity controlling the foreign investor, the beneficial owner of the foreign investor, any of the subsidiaries of the foreign investor, or any other party owned or controlled by, or acting on behalf or at the direction of the foreign investor ***made*** a foreign investment ***that was*** previously screened by a Member State ***yet*** not authorised or was only authorised ***subject to mitigating measures which were significantly or repeatedly not complied with.*** To determine this, Member States and the Commission shall rely on information available to them, including the information contained in the secure database set up pursuant to Article ***18 (6) and information provided by the foreign investor on that matter***;

(b) where applicable, the reasons for subjecting the foreign investor, a natural person or entity controlling the foreign investor, the beneficial owner of the foreign investor, any of the subsidiaries of the foreign investor, or any other party owned or controlled by▌ or acting on behalf or at the direction of the foreign investor to restrictive measures ***adopted*** pursuant to Article ***29 TEU and Article*** 215 TFEU;

(c) whether the foreign investor***, a natural person or entity controlling the foreign investor, the beneficial owner of the foreign investor,*** or any of ***the*** subsidiaries ***of the foreign investor, or any other party owned or controlled by or acting on behalf or at the direction of the foreign investor*** has already been involved in activities negatively affecting the security or public order in a Member State;

(d) whether the foreign investor***, a natural person or entity controlling the foreign investor, the beneficial owner of the foreign investor,*** or any of ***the*** subsidiaries ***of the foreign investor, or any other party owned or controlled by or acting on behalf or at the direction of the foreign investor*** has engaged in illegal or criminal activities, including the circumvention of Union restrictive measures pursuant to Article ***29 TEU and Article*** 215 TFEU;

(ea) whether the foreign investor is established in a jurisdiction identified as a third country with significant strategic deficiencies in its national AML/CFT regime in accordance with Article 29 of Regulation (EU) 2024/1624 ;

(eb) whether the foreign investor is subject to the legislation of a third country that imposes obligations on natural or legal persons to share information for intelligence purposes without due process or oversight mechanisms.

(ec) whether the foreign investor has an opaque ownership structure.

4a. The Commission shall make available a risk evaluation form that may be used by Member States to assess the elements referred to in paragraphs 1 and 2.

4b. The Commission may carry out risk assessments relating to specific sectors, critical technologies, foreign investors or Union undertakings. Those risk assessments shall be made available in the secure database set up pursuant to Article 18(6) and may be taken into account by Member States when determining whether a foreign investment is likely to negatively affect security or public order.

PUBLIC

*Article **20***

Screening decisions on foreign investments likely to negatively affect security or public order

▌

1. Where, taking into account the criteria laid down in Article ***19 as well as any additional information or element it may consider relevant to the foreign investment*** and, where applicable, in the light of comments ***issued*** by other Member States ▌, or an opinion ***issued*** by the Commission ▌, the ***host*** Member State ▌ concludes that the foreign investment is likely to negatively affect security or public order in one or more Member States, ▌ it shall issue a screening decision to:

   (a) authorise the foreign investment subject to mitigating measures, or

   (b) prohibit ***or unwind*** the foreign investment

   The screening decision shall comply with the principle of proportionality***, rely on a risk-based analysis*** and take into consideration all circumstances of the foreign investment.

2. ▌ The ***host*** Member State ***shall consider whether*** other measures pursuant to Union or national law are available and appropriate to address the foreign investment's ***impact*** on security ***or*** public order ▌.

3. The host Member State shall only issue a screening decision to prohibit or unwind the foreign investment where the impact on security or public order could not be adequately addressed through other means.

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4. The mitigating measures referred to in paragraph 1, point (a), shall be sufficient to address the foreign investment's effect on security and public order. Those measures may include:

(a) changes to the proposed governance structure of the Union target;

(b) modifications to the voting rights conferred on the foreign investor; conditions on access to sensitive technologies or information;

(c) commitments to ensure a specific supply and/or supply to a specific client;

(f) measures to ensure the continuation of business activities;

(g) requirements to source critical components from secure and reliable suppliers;

(h) implementation of cybersecurity protocols to protect against potential threats;

(i) an obligation to store and process specific data within the Union.

PUBLIC

CHAPTER 5

FINAL *AND TRANSITIONAL* PROVISIONS

PUBLIC

Article 21

Group of experts on the screening of foreign investments into the Union

1. The group of experts on the screening of foreign investments into the Union, which provides advice and expertise to the Commission, shall continue to engage in discussions regarding foreign investment screening. It shall share best practices, lessons learnt, and exchange views on emerging trends and issues of common concern related to foreign investments. The Commission shall also seek the advice of that group on systemic matters concerning the implementation of this Regulation. The group of experts shall also assess and compare different databases and sources of market and business information.

2. The discussions in that group shall be kept confidential.

*Article **22***

International cooperation

Member States and the Commission may cooperate with the responsible authorities of third countries ***and engage bilaterally and multilaterally*** on issues relating to the screening of investments on grounds of security and public order.

Article 23

Public transparency requirements

1. ***The Commission shall make publicly available a list of Member States' screening mechanisms no later than 3 months after the deadline referred to in Article 3(3), first sentence. That list shall contain the contact details referred to in Article 4(2) point (hb), and, where available, relevant links to information on the screening mechanisms, including the guidance referred to in paragraph 2 of this article. The Commission shall keep that list up to date.***

2. ***In so far as this is not laid down in national law, Member States shall publish and regularly update detailed guidance on the scope of their screening mechanism, the thresholds and triggers for notification obligations, and the applicable timelines and procedural rules.***

*Article **24***

Annual reporting at Union level

1. By 31 March of each year beginning in ***… [the calendar year following that during which this Regulation starts to apply***], Member States shall report to the Commission, on a confidential basis, on their activities under their screening mechanism and ▌ the cooperation mechanism for the preceding calendar year. ***That*** report shall contain information on:

   (a) the number of foreign investments screened ▌ ;

   (b) the number of foreign investments ***authorised or authorised subject to mitigating measures*** ;

   (c) the number of foreign investments prohibited, ▌ withdrawn ***or unwound***;

   (d) the number of foreign investments notified to the cooperation mechanism, ▌

(e) the number of comments issued by the respective Member State;

(e) information on the origin of the foreign investors ***and its beneficial owner*** and the sector of activity of the targets of the foreign investments screened, authorised***, authorised subject to mitigating measures, foreign investments*** prohibited ***or unwound, respectively***;

(f) an aggregate presentation of ***the*** risks and vulnerabilities identified in the foreign investments that led to a screening decision;

(fa) the number of comments issued pursuant to Article 13(1) and the number of screening procedures initiated following the receipt of comments by other Member States pursuant to Article 13(1) or opinions by the Commission pursuant to Article 13(2).

1a. The Commission shall set out, by means of implementing acts, the form to be used for reporting the information referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 29(2). The first of those implementing acts shall be adopted by ... [1 January of the calendar year following that of the date on which this Regulation starts to apply],

2. ***Based*** on the information received in accordance with paragraph 1, ***the Commission's implementation practice,*** and its assessment of trends and developments, the Commission shall provide an annual report on implementation of this Regulation ***in the preceding year*** to the European Parliament and to the Council ***by 31 October of each year beginning in ... [the calendar year following that during which this Regulation starts to apply]***. That report shall be made public ***with a level of detail that guarantees the anonymity of specific transactions***.

2a. The Commission's annual report shall include an overview of the information referred to in paragraph 1, an assessment of the trends and figures on foreign investments into the Union, relevant legislative developments across Member States, international cooperation efforts.

PUBLIC

*Article **25***

Processing of personal data

1. Any processing of personal data pursuant to this Regulation shall be carried out in accordance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 and ***in so far as it is*** necessary for the screening of foreign investments by Member States and for ensuring the effectiveness of the cooperation ***mechanism***.

2. ***The national screening authorities of the Member States and the Commission shall be considered joint data controllers in accordance with Regulation (EU) 2016/679 of the European Parliament and the Council and Regulation (EU) 2018/1725 of the European Parliament and of the Council for the processing of operational*** personal data ***under*** this Regulation ▌ .

3. Personal data related to foreign investments pursuant to this Regulation shall be retained only for the time necessary to achieve the purposes for which they were collected.

PUBLIC

*Article **26***

Evaluation

1. The Commission shall evaluate the functioning and effectiveness of this Regulation ***three*** years after the date of application of this Regulation and every 5 years thereafter and present a report to the European Parliament and to the Council. Member States shall be involved in this ***evaluation process*** and, if necessary, provide the Commission with additional information for the preparation of that report. ***That report shall include an analysis of the evolution of foreign investments into the Union as well as an assessment of the contribution of this Regulation to the economic security of the Union. It shall include an assessment of whether Article 4(4) should be amended, including as regards foreign investments into Union targets that manufacture or hold a marketing authorisation for critical medicines. The report shall also assess the compliance costs faced by businesses.***

2. Where the report from the Commission recommends amendments to this Regulation, it may be accompanied by a legislative proposal.

PUBLIC

*Article **27***

Delegated acts

1. The Commission is empowered to adopt delegated acts in accordance with Article ***28*** for the purposes of amending, where necessary, the list of projects or programmes of Union interest***,*** set out in Annex ***IV, in order*** to take account of the adoption ***or*** amendment of Union ***legal acts establishing*** projects or programmes ***that provide for the development, maintenance or acquisition of critical infrastructure, technologies, inputs or capabilities which are of particular importance*** to security or public order.

2. The Commission is empowered to adopt delegated acts in accordance with Article ***28*** for the purposes of amending, where necessary, the list ***of technology areas of*** importance for ▌ security or public order ▌ set out in Annex ***III*** to take account of changes in the circumstances relevant to the security or public order ▌ . In particular, these considerations shall include the following:

   (a) the resilience of supply chains of particular importance for the security or public order***;***

   (b) the resilience of infrastructures of particular importance for the security or public order***;***

   (ba) the results of relevant risk assessments undertaken by the Commission and Member States;

   (c) the advancement of technologies of particular importance for security or public order

   (ca) the risk of leakage or misuse of technologies of particular importance for security or public order;

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(d) the emergence of vulnerabilities in relation to access to or other forms of processing of sensitive information, including personal data to the extent they are likely to negatively affect the security or public order***;***

(e) the emergence of a geopolitical situation of particular importance for security or public order***; and***

f) whether the technology area has a dual-use potential.

3. The Commission is empowered to adopt delegated acts in accordance with Article 28 amending this Regulation in order to delete Annex II and at the same time to replace the reference to that Annex in Article 19(1) point (g) with a reference to the Union List of Critical Medicinal Products and the legal acts establishing it, when that list is established by the Commission pursuant to the Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.

PUBLIC

*Article **28***

Exercise of the delegation

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 27*** shall be conferred on the Commission for ***a*** period of ***five years from ...*** [***the*** date of entry into force of ***this Regulation]. The Commission shall draw up a report in respect of the delegation of power no 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 Council opposes such extension no later than three months before the end of each period.***

3. The delegation of power ***referred to in Article 27*** 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 ***27*** shall enter into force only if no objection has been expressed by the European Parliament or the Council within ***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 on the initiative of the European Parliament or of the Council.

PUBLIC

*Article **29***

Committee

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

*Article **30***

Repeal *of Regulation (EU) 2019/452 and transitional measures*

1. Regulation (EU) 2019/452 is repealed with effect from ***... [18*** months ***from the date of*** entry into force ***of this Regulation***]. ***Without prejudice to paragraphs 2 and 3 of this Article, references to the repealed Regulation shall be construed as references to this Regulation.***

2. ***Regulation (EU) 2019/452 shall continue to apply for foreign direct investments undergoing screening, as defined in Article 2, point (5), of Regulation (EU) 2019/452, on ... [18 months from the date of entry into force of this Regulation] and to foreign direct investments, as defined in Article 2, point (1), of that Regulation, completed by ... [18 months from the date of entry into force of this Regulation].***

3. ***This Regulation shall not apply to the foreign direct investments referred to paragraph 2 of this Article nor to foreign investments as defined in Article 2, point (1), of this Regulation, which are undergoing screening on ... [18 months from the date of entry into force of this Regulation] or are completed by ... [18 months from the date of entry into force of this Regulation].***

4. ***When producing the first report pursuant to Article 24(1) and (2), Member States and the Commission shall also include information on foreign investments not already covered by a previous report pursuant to Article 5 of Regulation (EU) 2019/452.***

PUBLIC

*Article **31***

Entry into force and application

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

It shall apply from ***... [18*** months ***from the date of*** entry into force ***of this Regulation***]

However, Article 3(3), Article 15(2), Article 18(1), (2), (3), (4), (5), (6), (8), (9), (10) and (11) and Articles 27, 28 and 29 shall apply from ... [the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

PUBLIC

Annex *I*

Technology areas relevant for the common minimum scope pursuant to Article 4(4)

2.

Semiconductors technologies***, meaning any technology or know-how related to***:

(i) the design of integrated circuits and other semiconductors, including microprocessors, cryogenic components, graphic processors, microcontrollers, logic chips, memory chips, radio frequency chips***, photonic chips, analog chips, quantum chips, optical semiconductors, power semiconductors, discretes, micro-electro-mechanical systems (MEMS), sensors and microsystems, as well as related semiconductor intellectual property core;***

(ii) electronic design automation (EDA) software used for the design of integrated circuits and other semiconductors, or for the design of advanced ***packaging;***

(iii) front-end fabrication of integrated circuits and other semiconductors;

(iv) the assembly, testing and packaging of integrated circuits and other semiconductors, including advanced printed circuit boards and advanced packaging technologies;

(v) semiconductor manufacturing equipment, both for the front-end and back- end fabrication of integrated circuits and other semiconductors, including etching, deposition, epitaxy, lithography, advanced packaging, testing or metrology tools

(vi) core components or software of semiconductor manufacturing equipment;

(vii) materials used in the fabrication of integrated circuits and other semiconductors, in particular specialty chemicals, rare gases, substrates or wafers.

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2. Artificial intelligence ***('AI')*** technologies***, meaning any technology or know-how specifically related to a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments ('AI system'), used for***

(i) general-purpose AI models as defined in Art. 3(63) of the [add full reference to the EU AI Act] or AI systems based on such models suitable for the development of space or defence application, or

(ii) general-purpose AI models with systemic risk as defined in Art. 51 of the [add full reference to the EU AI Act] or AI systems based on such models;

3. Quantum technologies***, meaning any technology or know-how related to***:

i. quantum computing***;***

ii. quantum communications***;***

iii. quantum sensing***.***

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Annex II

List of critical medicines

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ATC level 5	*ATC description The Anatomical Therapeutic Chemical code: a unique code assigned to a medicine according to the organ or system it works on and how it works. The classification system is maintained by the World Health Organization (WHO).*	*Route of administration*
	A - Alimentary tract and metabolism	
	A02B - Drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)	
A02BC05	*ESOMEPRAZOLE*	*intravenous use*
	A03B - Belladonna and derivatives, plain	
A03BA01	*ATROPINE*	*intramuscular, intravenous, subcutaneous use*
	A03F - Propulsives	
A03FA01	*METOCLOPRAMIDE*	*intramuscular, intravenous, subcutaneous use*
	A07A - Intestinal antiinfectives	
A07AA12	*FIDAXOMICIN*	*oral use*
	A07B - Intestinal adsorbents	
A07BA01	*MEDICINAL CHARCOAL*	*oral use*
	A10A - Insulins and analogues	
A10AB01	*INSULIN HUMAN (fast-acting)*	*intramuscular, intravenous, subcutaneous use*
A10AB05	*INSULIN ASPART*	*intravenous, subcutaneous use*
A10AC01	*INSULIN HUMAN (intermediate-acting)*	*intramuscular, intravenous, subcutaneous use*
A10AD01	*INSULIN HUMAN (intermediate - or long-acting combined with fast-acting)*	*intramuscular, intravenous, subcutaneous use*
A10AE06	*INSULIN DEGLUDEC*	*subcutaneous use*

	A12C - Other mineral supplements	
A12CC 02	***MAGNESIUM SULFATE***	***intravenous, intramuscular use***
	A16A - Other alimentary tract and metabolism products	
A16AB 02	***IMIGLUCERASE***	***intravenous use***
	B - Blood and blood forming organs	
	B01A - Antithrombotic agents	
B01AA 03	***WARFARIN***	***oral use***
B01AB 01	***HEPARIN***	***haemodialysis, intraarterial, intravenous, subcutaneous use***
B01AB 02	***ANTITHROMBIN III***	***intravenous use***
B01AC 04	***CLOPIDOGREL***	***oral use***
B01AC 16	***EPTIFIBATIDE***	***intravenous use***
B01A D02	***ALTEPLASE***	***intravenous use***
B01A D11	***TENECTEPLASE***	***intravenous use***
B01AE 07	***DABIGATRAN***	***oral use***
	B02A - Antifibrinolytics	
B02AA 02	***TRANEXAMIC ACID***	***oral, intravenous use***
	B02B - Vitamin K and other hemostatics	
B02BA 01	***PHYTOMENADIONE***	***intramuscular, intravenous, oral use***
B02BB 01	***HUMAN FIBRINOGEN***	***intravenous use***
B02B D01	***HUMAN PROTHROMBIN COMPLEX***	***intravenous use***
B02B D02	***HUMAN COAGULATION FACTOR VIII***	***intravenous use***
B02B D03	***FACTOR VIII INHIBITOR BYPASSING ACTIVITY***	***intravenous use***
B02B D04	***HUMAN COAGULATION FACTOR IX***	***intravenous use***
B02B D05	***HUMAN COAGULATION FACTOR VII***	***intravenous use***
B02B D07	***HUMAN COAGULATION FACTOR XIII***	***intravenous use***
B02B D08	***EPTACOG ALFA***	***intravenous use***

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	B03B - Vitamin B12 and folic acid	
B03BA 03	***HYDROXOCOBALAMIN***	***intravenous, intramuscular, subcutaneous, oral use***
	B05A - Blood and related products	
B05AA 01	***ALBUMIN***	***intravenous use***
B05AA 02	***PLASMA PROTEIN FRACTION***	***intravenous use***
	B05B - IV solutions	
B05BB 01	***POTASSIUM CHLORIDE***	***intravenous use***
B05BC 01	***MANNITOL***	***intravenous use***
	B05X - IV solution additives	
B05XA 01	***POTASSIUM CHLORIDE***	***intravenous use***
B05XA 05	***MAGNESIUM SULFATE***	***intravenous use***
	B06A - Other hematological agents	
B06AB 01	***HUMAN HEMIN***	***intravenous use***
B06AC 01	***COMPLEMENT C1 ESTERASE INHIBITOR***	***intravenous, subcutaneous use***
	C - Cardiovascular system	
	C01A - Cardiac glycosides	
C01AA 05	***DIGOXIN***	***oral, intravenous use***
	C01B - Antiarrhythmics, class I and III	
C01BB 01	***LIDOCAINE***	***parenteral use***
C01BB 02	***MEXILETINE***	***oral use***
C01BC 04	***FLECAINIDE***	***oral use***
C01B D01	***AMIODARONE***	***intravenous use***
	C01C - Cardiac stimulants excl cardiac glycosides	
C01CA 02	***ISOPRENALINE***	***intravenous use***
C01CA 03	***NOREPINEPHRINE***	***intravenous use***
C01CA 04	***DOPAMINE***	***intravenous use***
C01CA 07	***DOBUTAMINE***	***intravenous use***

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C01CA 24	*EPINEPHRINE*	*endotracheopulmonary, intracardiac, intraosseous, intramuscular, intravenous, subcutaneous use*
C01CA 26	*EPHEDRINE*	*intravenous, intramuscular, subcutaneous use*
C01CE 02	*MILRINONE*	*intravenous use*
	C01D - Vasodilators used in cardiac diseases	
C01D A02	*GLYCERYL TRINITRATE*	*intravenous, sublingual use*
	C01E - Other cardiac preparations	
C01EB 10	*ADENOSINE*	*intravenous use*
	C02A - Antiadrenergic agents, centrally acting	
C02AB 01	*METHYLDOPA (levorotatory)*	*oral use*
C02AB 02	*METHYLDOPA (racemic)*	*oral use*
C02AC 01	*CLONIDINE*	*intramuscular, intravenous, subcutaneous, oral use*
	C02D - Arteriolar smooth muscle, agents acting on	
C02D D01	*SODIUM NITROPRUSSIDE*	*intravenous use*
	C03C - High-ceiling diuretics	
C03CA 01	*FUROSEMIDE*	*intravenous, intramuscular use*
	C07A - Beta blocking agents	
C07AA 05	*PROPRANOLOL*	*oral use*
C07A G01	*LABETALOL*	*intravenous use*
	C08C - Selective calcium channel blockers with mainly vascular effects	
C08CA 06	*NIMODIPINE*	*intravenous, intracisternal use*
	C08D - Selective calcium channel blockers with direct cardiac effects	
C08D A01	*VERAPAMIL*	*intravenous use*
	G - Genito urinary system and sex hormones	
	G02A - Uterotonics	
G02A B01	*METHYLERGOMETRINE*	*intramuscular, intrauterine, intravenous, subcutaneous use*

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	G03X - Other sex hormones and modulators of the genital system	
G03X B01	***MIFEPRISTONE***	***oral use***
	H - Systemic hormonal preparations, excl sex hormones and insulins	
	H01B - Posterior pituitary lobe hormones	
H01B A01	***ARGIPRESSIN***	***intramuscular, intravenous, subcutaneous use***
H01B A02	***DESMOPRESSIN***	***intramuscular, intravenous, subcutaneous use***
H01B B02	***OXYTOCIN***	***intramuscular, intravenous use***
H01B B03	***CARBETOCIN***	***intramuscular, intravenous use***
	H02A - Corticosteroids for systemic use, plain	
H02A A02	***FLUDROCORTISONE***	***oral use***
H02A B04	***METHYLPREDNISOLONE***	***intraarticular, intrabursal, intradermal, intralesional, intramuscular, intravenous, periarticular, rectal use***
H02A B06	***PREDNISOLONE***	***oral use***
H02A B09	***HYDROCORTISONE***	***intraarticular, intramuscular, intravenous, oral use***
	H03B - Antithyroid preparations	
H03B A02	***PROPYLTHIOURACIL***	***oral use***
H03B B01	***CARBIMAZOLE***	***oral use***
H03B B02	***THIAMAZOLE***	***oral use***
	H04A - Glycogenolytic hormones	
H04A A01	***GLUCAGON***	***intramuscular, intravenous, nasal, subcutaneous use***
	J - Antiinfectives for systemic use	
	J01A - Tetracyclines	
J01AA 02	***DOXYCYCLINE***	***oral use***
	J01C - Beta-lactam antibacterials, penicillins	
J01CA 01	***AMPICILLIN***	***intramuscular, intravenous use***
J01CA 04	***AMOXICILLIN***	***oral, intravenous, intramuscular use***

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J01CE 01	***BENZYLPENICILLIN***	***intraarticular, intramuscular, intrapleural, intrathecal, intravenous use***
J01CE 02	***PHENOXYMETHYLPENICILLIN***	***oral use***
J01CE 08	***BENZATHINE BENZYLPENICILLIN***	***intramuscular use***
J01CF 02	***CLOXACILLIN***	***intravenous, intramuscular use***
J01CF 05	***FLUCLOXACILLIN***	***inhalation, intraarticular, intramuscular, intrapleural, intravenous, oral use***
J01CR 02	***AMOXICILLIN, CLAVULANIC ACID***	***oral, intravenous use***
J01CR 05	***PIPERACILLIN, TAZOBACTAM***	***intravenous use***
	J01D - Other beta-lactam antibacterials	
J01DC 02	***CEFUROXIME***	***oral use***
J01DD 01	***CEFOTAXIME***	***intramuscular, intravenous use***
J01DD 02	***CEFTAZIDIME***	***intramuscular, intravenous use***
J01DD 04	***CEFTRIAXONE***	***intramuscular, intravenous, subcutaneous use***
J01DD 08	***CEFIXIME***	***oral use***
J01DD 52	***CEFTAZIDIME, AVIBACTAM***	***intravenous use***
J01DF 01	***AZTREONAM***	***intramuscular, intravenous use***
J01DH 56	***CILASTATIN SODIUM, IMIPENEM, RELEBACTAM***	***intravenous use***
J01DI 54	***TAZOBACTAM, CEFTOLOZANE***	***intravenous use***
	J01E - Sulfonamides and trimethoprim	
J01EA 01	***TRIMETHOPRIM***	***oral use***
J01EE 01	***CO-TRIMOXAZOLE***	***oral, intravenous use***
	J01F - Macrolides, lincosamides and streptogramins	
J01FA 01	***ERYTHROMYCIN***	***intravenous use***
J01FA 09	***CLARITHROMYCIN***	***intravenous use***
J01FA 10	***AZITHROMYCIN***	***intravenous, oral use***

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J01FF 01	***CLINDAMYCIN***	***intramuscular, intravenous use***
	J01G - Aminoglycoside antibacterials	
J01GB 01	***TOBRAMYCIN***	***inhalation, intramuscular, intravenous use***
J01GB 03	***GENTAMICIN***	***intramuscular, intravenous, subconjunctival use***
J01GB 06	***AMIKACIN***	***intramuscular, intravenous use***
	J01M - Quinolone antibacterials	
J01M A02	***CIPROFLOXACIN***	***intravenous use***
J01M A12	***LEVOFLOXACIN***	***intravenous use***
	J01X - Other antibacterials	
J01XA 01	***VANCOMYCIN***	***intraperitoneal, intravenous, oral use***
J01XA 02	***TEICOPLANIN***	***intramuscular, intravenous use***
J01XB 01	***COLISTIN***	***inhalation, intrathecal, intravenous use***
J01XD 01	***METRONIDAZOLE***	***intravenous use***
J01XX 01	***FOSFOMYCIN***	***intravenous use***
	J02A - Antimycotics for systemic use	
J02AA 01	***AMPHOTERICIN B***	***intravenous use***
J02AC 01	***FLUCONAZOLE***	***intravenous use***
J02AC 04	***POSACONAZOLE***	***intravenous use***
J02AC 05	***ISAVUCONAZOLE***	***intravenous, oral use***
	J04A - Drugs for treatment of tuberculosis	
J04AB 02	***RIFAMPICIN***	***oral use***
J04AB 04	***RIFABUTIN***	***oral use***
J04AC 01	***ISONIAZID***	***oral use***
J04AK 01	***PYRAZINAMIDE***	***oral use***
J04AK 02	***ETHAMBUTOL***	***oral use***

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J04AK 05	*BEDAQUILINE*	*oral use*
J04A M02	*ISONIAZID, RIFAMPICIN*	*oral use*
	J04B - Drugs for treatment of lepra	
J04BA 02	*DAPSONE*	*oral use*
	J05A - Direct acting antivirals	
J05AB 01	*ACICLOVIR*	*intravenous use*
J05AB 06	*GANCICLOVIR*	*intravenous use*
J05AB 14	*VALGANCICLOVIR*	*oral use*
J05AD 01	*FOSCARNET*	*intravenous use*
J05AF 01	*ZIDOVUDINE*	*intravenous, oral use*
J05AF 05	*LAMIVUDINE*	*oral use*
J05AF 06	*ABACAVIR*	*oral use*
J05AF 09	*EMTRICITABINE*	*oral use*
J05AG 01	*NEVIRAPINE*	*oral use*
J05AR 02	*ABACAVIR, LAMIVUDINE*	*oral use*
	J06B - Immunoglobulins	
J06BA 01	*HUMAN NORMAL IMMUNOGLOBULIN*	*intravenous, subcutaneous use*
J06BA 02	*HUMAN NORMAL IMMUNOGLOBULIN*	*intravenous use*
J06BB 01	*HUMAN ANTI-D IMMUNOGLOBULIN*	*intramuscular, intravenous use*
J06BB 02	*HUMAN TETANUS IMMUNOGLOBULIN*	*intramuscular, subcutaneous use*
J06BB 04	*HUMAN HEPATITIS B IMMUNOGLOBULIN*	*intramuscular, intravenous, subcutaneous use*
J06BB 05	*HUMAN RABIES IMMUNOGLOBULIN*	*intramuscular use*
	J07A - Bacterial vaccines	
J07AE 01	*CHOLERA VACCINE (inactivated)*	*oral use*
J07AH 07	*MENINGOCOCCAL GROUP C VACCINE*	*intramuscular use*
J07AH 09	*MENINGOCOCCAL GROUP B VACCINE*	*intramuscular use*

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J07AJ 51	*DIPHTHERIA, TETANUS, PERTUSSIS VACCINE (inactivated, whole cell)*	*intramuscular, subcutaneous use*
J07AJ 52	*DIPHTHERIA, TETANUS, PERTUSSIS VACCINE (purified antigen)*	*intramuscular, subcutaneous use*
J07A M51	*DIPHTHERIA, TETANUS VACCINE*	*intramuscular, subcutaneous use*
J07AP 03	*TYPHOID VACCINE (polysaccharide)*	*intramuscular, subcutaneous use*
	J07B - Viral vaccines	
J07BA 02	*ENCEPHALITIS (Japanese, whole virus, inactivated)*	*intramuscular use*
J07BB 01	*INFLUENZA VACCINE (various forms, strains)*	*intramuscular use*
J07BB 02	*INFLUENZA VACCINE (various forms, strains)*	*intramuscular, subcutaneous use*
J07BC 01	*HEPATITIS B VACCINE*	*intramuscular, subcutaneous use*
J07BC 02	*HEPATITIS A VACCINE*	*intramuscular, subcutaneous use*
J07BC 20	*HEPATITIS A AND B VACCINE*	*intramuscular, subcutaneous use*
J07BD 52	*MEASLES, MUMPS, RUBELLA VACCINE*	*intramuscular, subcutaneous use*
J07BD 54	*MEASLES, MUMPS, RUBELLA, VARICELLA VACCINE*	*intramuscular, subcutaneous use*
J07BF 03	*POLIOMYELITIS VACCINE (trivalent)*	*intramuscular, subcutaneous use*
J07BG 01	*RABIES VACCINE*	*intradermal, intramuscular, subcutaneous use*
J07BH 02	*ROTAVIRUS PENTAVALENT VACCINE*	*oral use*
J07BK 01	*VARICELLA VACCINE (live)*	*intramuscular, subcutaneous use*
J07BL 01	*YELLOW FEVER VACCINE*	*intramuscular, subcutaneous use*
J07B M01	*PAPILLOMAVIRUS VACCINE*	*intramuscular use*
J07B M02	*PAPILLOMAVIRUS VACCINE*	*intramuscular use*
J07B M03	*HUMAN PAPILLOMAVIRUS VACCINE (9-valent)*	*intramuscular use*
	J07C - Bacterial and viral vaccines, combined	
J07CA 01	*DIPHTHERIA, TETANUS, POLIOMYELITIS VACCINE*	*intramuscular, subcutaneous use*

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J07CA 02	*DIPHTHERIA, TETANUS, PERTUSSIS, POLIOMYELITIS VACCINE*	*intramuscular, subcutaneous use*
J07CA 06	*DIPHTHERIA, TETANUS, PERTUSSIS VACCINE*	*intramuscular, subcutaneous use*
J07CA 12	*DIPHTHERIA, TETANUS, PERTUSSIS, POLIOMYELITIS, HEPATITIS B VACCINE*	*intramuscular use*
	L - Antineoplastic and immunomodulating agents	
	L01A - Antineoplastic agents	
L01AA 01	*CYCLOPHOSPHAMIDE*	*intramuscular, intravenous, oral use*
L01AA 02	*CHLORAMBUCIL*	*oral use*
L01AA 03	*MELPHALAN*	*intraarterial, intravenous, oral use*
L01AA 06	*IFOSFAMIDE*	*intraarterial, intravenous use*
L01AB 01	*BUSULFAN*	*intravenous, oral, subcutaneous use*
L01AB 02	*TREOSULFAN*	*intravenous use*
L01AC 01	*THIOTEPA*	*intramuscular, intrapericardial, intraperitoneal, intrapleural, intravascular, intravenous use*
L01AX 04	*DACARBAZINE*	*intravenous use*
	L01B - Antimetabolites	
L01BA 01	*METHOTREXATE*	*epidural, intraarterial, intraarticular, intrabursal, intracoronary, intradiscal, intramuscular, intrathecal, intravenous, oral, periarticular, perineural, rectal, retrobulbar, subconjunctival, subcutaneous, transdermal use*
L01BB 02	*MERCAPTOPURINE*	*oral use*
L01BB 03	*TIOGUANINE*	*oral use*
L01BB 05	*FLUDARABINE*	*epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, oral, perineural, retrobulbar use*
L01BC 01	*CYTARABINE*	*intramuscular, intrathecal, intravenous, subcutaneous use*
L01BC 02	*FLUOROURACIL*	*intraarterial, intraarticular, intramuscular, intraperitoneal, intrapleural, intravenous use*
L01BC 05	*GEMCITABINE*	*intravenous use*
	L01C - Plant alkaloids and other natural products	

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L01CA 01	***VINBLASTINE***	***epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use***
L01CA 02	***VINCRISTINE***	***epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use***
L01CB 01	***ETOPOSIDE***	***epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, oral, perineural, retrobulbar use***
L01CD 01	***PACLITAXEL***	***intravenous use***
L01CE 01	***TOPOTECAN***	***intravenous, oral use***
	L01D - Cytotoxic antibiotics and related substances	
L01DB 01	***DOXORUBICIN***	***intravenous, intravesical use***
L01DB 02	***DAUNORUBICIN***	***intravenous use***
L01DB 03	***EPIRUBICIN***	***epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, intravesical, perineural, retrobulbar use***
L01DB 06	***IDARUBICIN***	***intravenous use***
L01DB 07	***MITOXANTRONE***	***intrapleural, intravenous use***
L01DC 01	***BLEOMYCIN***	***intraarterial, intramuscular, intraperitoneal, intrapleural, intratumoral, intravenous, subcutaneous use***
L01DC 03	***MITOMYCIN***	***intravenous, intravesical use***
	L01E - Protein kinase inhibitors	
L01EA 03	***NILOTINIB***	***oral use***
L01EC 02	***DABRAFENIB***	***oral use***
L01EC 03	***ENCORAFENIB***	***oral use***
L01EE 01	***TRAMETINIB***	***oral use***
L01EL 01	***IBRUTINIB***	***oral use***
	L01F - Monoclonal antibodies and antibody drug conjugates	
L01FA 03	***OBINUTUZUMAB***	***intravenous use***
L01FB 01	***INOTUZUMAB OZOGAMICIN***	***intravenous use***

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L01FC 01	*DARATUMUMAB*	*intravenous, subcutaneous use*
L01FF 01	*NIVOLUMAB*	*intravenous, subcutaneous use*
L01FF 02	*PEMBROLIZUMAB*	*intravenous use*
L01FF 03	*DURVALUMAB*	*intravenous use*
L01FX 02	*GEMTUZUMAB OZOGAMICIN*	*intravenous use*
L01FX 05	*BRENTUXIMAB VEDOTIN*	*intravenous use*
L01FX 17	*SACITUZUMAB GOVITECAN*	*intravenous use*
	L01X - Other neoplastic agents	
L01XA 01	*CISPLATIN*	*epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use*
L01XA 02	*CARBOPLATIN*	*epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use*
L01XA 03	*OXALIPLATIN*	*epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use*
L01XB 01	*PROCARBAZINE*	*oral use*
L01XF 01	*TRETINOIN*	*oral use*
L01XJ 01	*VISMODEGIB*	*oral use*
L01XX 05	*HYDROXYCARBAMIDE*	*oral use*
L01XX 23	*MITOTANE*	*oral use*
L01XX 24	*PEGASPARGASE*	*intramuscular, intravenous use*
	L02B - Hormone antagonists and related agents	
L02BA 01	*TAMOXIFEN*	*oral use*
	L03A - Immunostimulants	
L03AB 11	*PEGINTERFERON ALFA-2A*	*subcutaneous use*
L03AX 03	*BCG VACCINE (various forms)*	*intravesical use*
L03AX 13	*GLATIRAMER*	*intraarticular, intravenous, periarticular, subcutaneous, transdermal use*
L03AX 16	*PLERIXAFOR*	*subcutaneous use*

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	L04A - Immunosuppressants	
L04AA 03	***ANTILYMPHOCYTE IMMUNOGLOBULIN (horse)***	***intravenous use***
L04AA 04	***ANTITHYMOCYTE IMMUNOGLOBULIN (rabbit)***	***intravenous use***
L04AC 02	***BASILIXIMAB***	***intravenous use***
L04AC 03	***ANAKINRA***	***subcutaneous use***
L04AD 01	***CICLOSPORIN***	***intravenous, oral use***
L04AD 02	***TACROLIMUS***	***intravenous, oral use***
L04A H01	***SIROLIMUS***	***oral use***
L04AX 02	***THALIDOMIDE***	***oral use***
L04AX 03	***METHOTREXATE***	***oral use***
	M - Musculo-skeletal system	
	M01C - Specific antirheumatic agents	
M01C C01	***PENICILLAMINE***	***oral use***
	M03A - Muscle relaxants, peripherally acting agents	
M03A B01	***SUXAMETHONIUM***	***intramuscular, intraosseous, intravenous use***
M03A C04	***ATRACURIUM***	***intravenous use***
M03A C09	***ROCURONIUM***	***intravenous use***
M03A C11	***CISATRACURIUM***	***intravenous use***
	M03C - Muscle relaxants, directly acting agents	
M03C A01	***DANTROLENE***	***intravenous use***
	N - Nervous system	
	N01A - Anesthetics, general	
N01A H01	***FENTANYL***	***epidural, intramuscular, intravenous use***
N01A H03	***SUFENTANIL***	***epidural, intravenous use***
N01A H06	***REMIFENTANIL***	***intramuscular, intravenous use***
N01A X03	***KETAMINE***	***intramuscular, intravenous use***

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N01A X10	***PROPOFOL***	***intravenous use***
N01A X14	***ESKETAMINE***	***intramuscular, intravenous use***
	N02A - Opioids	
N02A A01	***MORPHINE***	***epidural, intramuscular, intravenous, subcutaneous use***
	N02B - Other analgesics and antipyretics	
N02B E01	***PARACETAMOL***	***intravenous use***
	N03A - Antiepileptics	
N03A A02	***PHENOBARBITAL***	***intramuscular, intravenous, oral use***
N03A B02	***PHENYTOIN***	***intramuscular, intravenous, oral use***
N03A D01	***ETHOSUXIMIDE***	***oral use***
N03A E01	***CLONAZEPAM***	***oral use***
N03A F01	***CARBAMAZEPINE***	***oral use***
N03A G01	***VALPROIC ACID***	***intravenous, oral use***
N03A G04	***VIGABATRIN***	***oral use***
	N04A - Anticholinergic agents	
N04A A02	***BIPERIDEN***	***intramuscular, intravenous use***
	N05A - Antipsychotics	
N05A D01	***HALOPERIDOL***	***intraarticular, intramuscular, intravascular, intravenous, oral use***
N05A H03	***OLANZAPINE***	***intramuscular use***
N05A N01	***LITHIUM***	***oral use***
	N05B - Anxiolytics	
N05B A01	***DIAZEPAM***	***intramuscular, intravenous, rectal use***
N05B A06	***LORAZEPAM***	***intramuscular, intravenous use***
	N05C - Hypnotics and sedatives	
N05C D08	***MIDAZOLAM***	***intramuscular, intravenous, subcutaneous, rectal use***
N05C M18	***DEXMEDETOMIDINE***	***intravenous, subcutaneous use***
	N06A - Antidepressants	
N06A X27	***ESKETAMINE***	***nasal use***

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	N06B - Psychostimulants, agents used for ADHD and nootropics	
N06B C01	***CAFFEINE***	***intravenous, oral use***
	N07A - Parasympathomimetics	
N07A A01	***NEOSTIGMINE***	***intramuscular, intravenous, subcutaneous use***
	N07X - Other nervous system drugs	
N07X X02	***RILUZOLE***	***oral use***
	P - Antiparasitic products, insecticides and repellents	
	P01A - Agents against amoebiasis and other protozoal diseases	
P01AB 01	***METRONIDAZOLE***	***intravenous use***
	P01C - Agents against leishmaniasis and trypanosomiasis	
P01CX 01	***PENTAMIDINE***	***inhalation, intramuscular, intravenous use***
	P02C - Antinematodal agents	
P02CA 03	***ALBENDAZOLE***	***oral use***
	R - Respiratory system	
	R03A - Adrenergics, inhalants	
R03AC 02	***SALBUTAMOL***	***inhalation, nasal, oral use***
	R03B - Other drugs for obstructive airway diseases, inhalants	
R03BB 01	***IPRATROPIUM***	***inhalation, oral use***
	R03C - Adrenergics for systemic use	
R03CA 02	***EPHEDRINE***	***intramuscular, intravenous, subcutaneous use***
R03CC 02	***SALBUTAMOL***	***intramuscular, intravenous, subcutaneous use***
	R05C - Expectorants, excl combinations with cough suppressants	
R05CB 01	***ACETYLCYSTEINE***	***intravenous use***
R05CB 13	***DORNASE ALFA (DESOXYRIBONUCLEASE)***	***inhalation use***
	S - Sensory organs	
	S01E - Antiglaucoma preparations and miotics	

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S01EB 01	***PILOCARPINE***	***ocular use***
S01EB 09	***ACETYLCHOLINE***	***intraocular use***
S01EC 01	***ACETAZOLAMIDE***	***oral use***
	S01F - Mydriatics and cycloplegics	
S01FA 04	***CYCLOPENTOLATE***	***ocular use***
	S01L - Ocular vascular disorder agents	
S01LA 01	***VERTEPORFIN***	***intravenous use***
	S02A - Antiinfectives	
S02AA 15	***CIPROFLOXACIN***	***oral use***
	S03A - Antiinfectives	
S03AA 07	***CIPROFLOXACIN***	***oral use***
	V - Various	
	V03A - All other therapeutic products	
V03AB 06	***SODIUM THIOSULFATE***	***intravenous use***
V03AB 14	***PROTAMINE***	***intravenous use***
V03AB 15	***NALOXONE***	***intramuscular, intravenous, subcutaneous use***
V03AB 17	***METHYLTHIONINIUM***	***intravenous use***
V03AB 23	***ACETYLCYSTEINE***	***intravenous use***
V03AB 25	***FLUMAZENIL***	***intravenous use***
V03AB 33	***HYDROXOCOBALAMIN***	***intramuscular, intravenous, oral, subcutaneous use***
V03AB 34	***FOMEPIZOLE***	***intravenous use***
V03AB 35	***SUGAMMADEX***	***intravenous use***
V03AB 37	***IDARUCIZUMAB***	***intravenous use***
V03AC 01	***DEFEROXAMINE***	***intramuscular, intraperitoneal, intravenous, subcutaneous use***
V03AE 01	***POLYSTYRENE SULFONIC ACID***	***oral use***
V03AF 01	***MESNA***	***intravenous, oral use***

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V03AF 02	***DEXRAZOXANE***	***intravenous use***
V03AF 03	***FOLINIC ACID***	***intramuscular, intravenous use***
V03AF 07	***RASBURICASE***	***intravenous use***
	V04C - Other diagnostic agents	
V04CF 01	***TUBERCULIN***	***intradermal use***
	V09G - Cardiovascular system	
V09G A04	***ALBUMIN (Technetium, 99mTc)***	***intravenous use***
V09G B02	***ALBUMIN (Iodine, 125I)***	***intradermal, intratumoral, intravenous, subcutaneous use***
	V10X - Other therapeutic radiopharmaceuticals	
V10XX 03	***RADIUM (223RA) DICHLORIDE***	***intravenous use***

PUBLIC

Annex III

Technology areas relevant to risk assessments pursuant to Article 19

PUBLIC

d. Biotechnologies:

- techniques of genetic modification
- new genomic techniques
- gene-drive
- synthetic biology

e. Advanced connectivity, navigation and digital technologies:

- Secure digital communications and connectivity, such as RAN & Open RAN (Radio Access Network) and 6G
- Cyber security technologies incl. cyber-surveillance, ***encryption,*** security and intrusion ***prevention and detection*** systems, digital forensics
- Internet of Things and Virtual Reality
- Distributed ledger and digital identity technologies
- ***Advanced*** guidance, navigation and control technologies, including avionics and marine positioning

ea. Submarine fibre-optic cables

f. Advanced sensing technologies:

- Electro-optical, radar, chemical, biological, radiation and ***distributed*** sensing

- Magnetometers, magnetic gradiometers

- Underwater electric field sensors

- Gravity meters and gradiometers

g. Space ***and*** propulsion technologies:

- Dedicated space-focused technologies, ranging from component to system level

- Space surveillance and Earth observation technologies

- Space positioning, navigation and timing (PNT)

- Secure communications including Low Earth Orbit (LEO) connectivity

- Propulsion technologies, including hypersonics and components for military use

ga. aerospace technologies

h. Energy technologies:

- Nuclear fusion technologies, reactors and power generation, ***radiological*** conversion/enrichment/recycling technologies

- Hydrogen and new fuels

- Net-zero technologies, including photovoltaics

- Smart grids and energy storage, batteries

PUBLIC

i. Robotics and autonomous systems:

- Drones and vehicles (air, land, surface and underwater)
- Robots and robot-controlled precision systems
- Exoskeletons
- AI-enabled systems

j. Advanced materials, manufacturing and recycling technologies:

- Technologies for nanomaterials, smart materials, advanced ceramic materials, stealth materials, safe and sustainable by design materials
- Additive manufacturing, including in the field
- Digital controlled micro-precision manufacturing and small-scale laser machining/welding

PUBLIC

Annex *IV*

Projects or programmes of Union interest

PUBLIC

1. Preparatory Action on Preparing the new EU GOVSATCOM programme

   Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18July 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, and in particular Article 58(2) point (b) thereof (OJ L 193, 30.7.2018, p. 1, ELI: http://data.europa.eu/eli/reg/2018/1046/oj).

2. Space Programme

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

3. Union secure connectivity programme

   Regulation (EU) 2023/588 of the European Parliament and of the Council of 15 March 2023 establishing the Union Secure Connectivity Programme for the period 2023-2027 (OJ L 79, 17.3.2023, p.1, ELI: http://data.europa.eu/eli/reg/2023/588/oj).

4. Horizon 2020 including research and development programmes pursuant to Article 185 TFEU, and joint undertakings or any other structure set up pursuant to Article 187 TFEU

Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-20) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104, ELI: http://data.europa.eu/eli/reg/2013/1291/oj).

5. Horizon Europe, including research and development programmes pursuant to Article 185 TFEU, and joint undertakings or any other structure set up pursuant to Article 187 TFEU

Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/695/oj).

6. Euratom Research and Training Programme 2021-25

Council Regulation (Euratom) 2021/765 of 10 May 2021 establishing the Research and Training Programme of the European Atomic Energy Community for the period 2021-25 complementing Horizon Europe – the Framework Programme for Research and Innovation and repealing Regulation (Euratom) 2018/1563 (OJ L 167I, 12.5.2021, p. 81, ELI: http://data.europa.eu/eli/reg/2021/765/oj).

7. Trans-European Networks for Transport (TEN-T)

Regulation (EU) ***2024/1679*** of the European Parliament and of the Council of ***13 June 2024*** on Union guidelines for the development of the trans-European transport network***, amending Regulations (EU) 2021/1153 and (EU) No 913/2010*** and repealing ***Regulation (EU) No 1315/2013 (OJ L 1679, 28.6.2024***, ELI: http://data.europa.***eu/eli/reg/2024/1679/oj)***.

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8. Trans-European Networks for Energy (TEN-E)

Regulation (EU) No 347/2013 of the European Parliament and of the Council of 17 April 2013 on guidelines for trans-European energy infrastructure and repealing Decision No 1364/2006/EC and amending Regulations (EC) No 713/2009, (EC) No 714/2009 and EC) No 715/2009 (OJ L 115, 25.4.2013, p. 39, ELI: http://data.europa.eu/eli/reg/2013/347/oj).

9. Trans-European Networks for Telecommunications [1]

Regulation (EU) No 283/2014 of the European Parliament and of the Council of 11 March 2014 on guidelines for trans-European networks in the area of telecommunications infrastructure and repealing Decision No 1336/97/EC (OJ L 86, 21.3.2014, p. 14, ELI: http://data.europa.eu/eli/reg/2014/283/oj).

10. Connecting Europe Facility

Regulation (EU) 2021/1153 of the European Parliament and of the Council of 7 July 2021 establishing the Connecting Europe Facility and repealing Regulations (EU) No 1316/2013 and (EU) No 283/2014 (OJ L 249, 14.7.2021, p. 38, ELI: http://data.europa.eu/eli/reg/2021/1153/oj).

11. Digital Europe Programme

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, ELI: http://data.europa.eu/eli/reg/2021/694/oj).

[1] Regulation (EU) No 283/2014 is maintained in this Annex in view of Article 27(2) of Regulation (EU) 2021/1153 establishing the Connecting Europe Facility and repealing Regulations (EU) No 1316/2013 and (EU) No 283/2014

12. European Defence Industrial Development Programme

Regulation (EU) 2018/1092 of the European Parliament and of the Council of 18 July 2018 establishing the European Defence Industrial Development Programme aiming at supporting the competitiveness and innovation capacity of the Union's defence industry (OJ L 200, 7.8.2018, p. 30, ELI: http://data.europa.eu/eli/reg/2018/1092/oj).

13. Preparatory Action on Defence Research

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, and in particular Article 58(2) point (b) thereof (OJ L 193, 30.7.2018, p. 1, ELI: http://data.europa.eu/eli/reg/2018/1046/oj).

14. European Defence Fund

Regulation (EU) 2021/697 of the European Parliament and of the Council of 29 April 2021 establishing the European Defence Fund and repealing Regulation (EU) 2018/1092 (OJ L 170, 12.5.2021, p. 149, ELI: http://data.europa.eu/eli/reg/2021/697/oj).

15. Act in Support of Ammunition Production (ASAP)

Regulation (EU) 2023/1525 of the European Parliament and of the Council of 20 July 2023 on supporting ammunition production (ASAP) (OJ L 185, 24.7.2023, p.7, ELI: http://data.europa.eu/eli/reg/2023/1525/oj).

16. European Defence Industry Reinforcement through common Procurement Act (EDIRPA)

Regulation (EU) 2023/2418 of the European Parliament and of the Council of 18 October 2023 on establishing an instrument for the reinforcement of the European defence industry through common procurement (EDIRPA) (OJ L 2023/2418, 26.10.2023, ELI: http://data.europa.eu/eli/reg/2023/2418/oj).

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17. Permanent structured cooperation (PESCO)

Council Decision (CFSP) 2018/340 of 6 March 2018 establishing the list of projects to be developed under PESCO (OJ L 65, 8.3.2018, p. 24, ELI: http://data.europa.eu/eli/dec/2018/340/oj).

Council Decision (CFSP) 2023/995 of 22 May 2023 amending and updating Decision (CFSP) 2018/340 establishing the list of projects to be developed under PESCO (OJ L135, 23.5.2023, p. 123, ELI: http://data.europa.eu/eli/dec/2023/995/oj).

18. European Defence Industry Programme (EDIP)

[Reference to be added once the Regulation has been adopted.]

European Joint Undertaking for ITER

Council Decision 2007/198/Euratom of 27 March 2007 establishing the European Joint Undertaking for ITER and the Development of Fusion Energy and conferring advantages upon it (OJ L 90, 30.3.2007, p. 58, ELI: http://data.europa.eu/eli/dec/2007/198/oj).

19. EU4Health Programme

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-27, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/522/oj).

20. Important Projects of Common European Interest (IPCEI)

Projects that the Commission ***has considered, in a decision adopted pursuant to Article 108 TFEU, to constitute an*** important ***project*** of common European interest ***within the meaning of Article 107(3), point (b), TFEU***.

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22. Projects of common interest and projects of mutual interest

Commission Delegated Regulation (EU) 2024/1041 of 28 November 2023, amending Regulation (EU) 2022/869 of the European Parliament and of the Council as regards the Union list of projects of common interest and projects of mutual interest. (OJ L 107, 26.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg_del/2024/1041/oj).

PUBLIC