EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the screening of foreign investments in the Union and repealing Regulation (EU) 2019/452

REGULATION (EU) 2026/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of …

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 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[3],

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1 OJ C, C/2024/6027, 23.10.2024, ELI: http://data.europa.eu/eli/C/2024/6027/oj.
2 OJ C, C/2025/290, 24.1.2025, ELI: http://data.europa.eu/eli/C/2025/290/oj.
3 Position of the European Parliament of 19 May 2026 (not yet published in the Official Journal) and decision of the Council of …

Whereas:

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

(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 the 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 Co-operation and Development (OECD) and in trade and investment agreements concluded with third countries, it is possible for the Union or the 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[4], a framework has been set up for the screening by Member States of foreign direct investments in the Union. In particular, that Regulation 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 Member State in which the foreign direct investment is taking place to give due consideration to the comments provided 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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[4] 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 79 I, 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, the Commission and the High Representative of the Union for Foreign Affairs and Security Policy adopted a joint communication entitled ‘European economic security strategy’, and, on 3 December 2025, they adopted a joint communication entitled ‘Strengthening EU economic security’. Those communications identify Foreign Direct Investment (FDI) screening as a tool to protect the Union against economic security risks. The 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 foreign investments that are not covered by Regulation (EU) 2019/452 could create risks for security or public order. Those risks concern, in particular, certain foreign investments carried out in Member States that do not yet have a screening mechanism in force, foreign investments carried out in Member States that do have a screening mechanism in force but the scope of which does not include certain sensitive foreign investments, and foreign investments that are made by foreign investors through a subsidiary established in the Union ('intra-Union investments') and that potentially present the same risks to security or public order as foreign investments made directly from third countries.

(8) When a significant majority of Member States, but not all, had a legislative instrument in force that provided for a mechanism to screen foreign direct investments, the absence of a screening mechanism in certain Member States allowed 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 a foreign investment is likely to negatively affect security or public order. There are also differences in screening procedures. This Regulation is aimed at reducing divergences on key elements of the screening mechanisms implemented at national level. In certain Member States, the foreign investment can be implemented before having received clearance with respect to the effect on security or public order. However, others require that the foreign 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 ensuring 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 can 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 an undertaking established under the laws of one Member State also affects the security or 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-Union investments, thereby creating a level-playing field, increasing certainty for foreign investors, and preventing the emergence of additional obstacles to the internal market.

(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 foreign investments targeting entities operating in a specific set of sensitive areas are screened. That obligation should ensure that certain sensitive foreign investments are screened in all Member States. Moreover, this 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 of whether a request is deemed complete. Where necessary, an in-depth investigation should be carried out. In addition, the timelines for notification through the cooperation mechanism should be harmonised, and the steps for the procedure under the cooperation mechanism, particularly with respect to the provision of comments by Member States and the issuance of Commission opinions, should be better aligned. Such harmonisation and alignment would allow situations where the timelines of national procedures are not aligned, and which could therefore delay a transaction, to be addressed. There should be a certain level of harmonisation of the criteria which Member States and the Commission should consider when assessing whether a foreign investment is likely to negatively affect security or public order. That common set of criteria should include the security, integrity, resilience and functioning of critical entities, the availability of critical technologies or the continuity of supply of critical inputs. The common set of criteria would ensure a more uniform assessment of the likely negative effect of foreign investments on security or public order while preserving the possibility for Member States to take into account further criteria which can differ between Member States.

(10) The screening of foreign investments should be carried out in accordance with this Regulation. Such screening should take into account all information available and should 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. Such reasons of public policy or public security include 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.

(11) To enable the 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.

(12) It is necessary to make the Member State in which a foreign investment is planned to be or is completed ('host Member State') more accountable to the Commission and to those Member States that express duly justified concerns for security or public order.

(13) 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. That common framework should also be without prejudice to the protection of Member States' essential security interests in accordance with Article 346 TFEU.

(14) This Regulation should cover foreign investments that create or maintain lasting and direct links between foreign investors, including State bodies, and Union targets carrying out an economic activity in a Member State. This Regulation should apply where foreign investments are carried out directly by a foreign investor or are intra-Union investments. 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).

(15) Lasting and direct links between the foreign 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 Union target either de facto or de jure. However, effective participation in the management or control of the Union target 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.

(16) Acquisitions through resolution tools under the resolution frameworks concerned (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 objective of this Regulation when performing resolution actions with the involvement of a foreign investor, in particular when strategic assets are involved.

(17) Restructuring operations within a corporate group should fall outside of the scope of application of this Regulation where such operations 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 could 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 represented in the upstream ownership chain of the Union target, could create security risks and should therefore be included within the scope of this Regulation. For instance, such an entity could be subject to the law of a third country that imposes obligations on natural or legal persons to share information for intelligence purposes without due process or oversight mechanisms.

(18) Regulation (EU) 2019/452 only covers foreign direct investments made directly by foreign investors in the Union. However, it is necessary to extend the scope of application of this Regulation to foreign investments made between Member States that are carried out through an undertaking that is established in a Member State and that is controlled, directly or indirectly, by a foreign investor ('foreign investor's subsidiary in the Union'). Those foreign 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 the foreign investor's subsidiary in the Union. Those 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 foreign investments carried out by investors that are not controlled, directly or indirectly, by a third-country person or entity. It is therefore appropriate to include in the scope of application of this Regulation foreign investments made through a foreign investor's subsidiary in the Union but not investments made by other Union investors, in particular to ensure that foreign investments 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, are consistently covered. 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 in Member States where such transactions are not screened.

(19) To ensure a proper assessment of whether a foreign investment is likely to negatively affect security or public order, it is important for the term ‘beneficial owner’ to capture 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, particularly 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 chain or chain of control of the foreign investor or Union target should be considered as the beneficial owner.

(20) This Regulation only provides for core elements of the screening mechanisms. Thus, Member States should be able to 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 should be able to 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, screening should comply with this Regulation, provided that it falls within the scope of this Regulation.

(21) In order to ensure consistent and predictable screening procedures, 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 into an initial review and an in-depth investigation, 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.

(22) 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. The provision of that information should not preclude the screening authority from requesting further information or posing additional questions after confirming the completeness of the filing and should be without prejudice to the possibility for screening authorities to inform the person who made the filing of other important procedural milestones.

(23) 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 that purpose, the screening authority and the Commission should make publicly available the contact details through which stakeholders are able to submit information concerning foreign investments in a confidential manner.

(24) 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 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 cooperation mechanism while preserving Member States' sole responsibility for national security.

(25) 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[5] or military goods and technologies listed in the Annex to Directive 2009/43/EC of the European Parliament and of the Council[6], 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 semiconductor or quantum technologies, or conduct research in or develop 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[7], namely exploration, extraction, processing, recycling, recovery or stockpiling. Foreign control over such activities can create risks of supply disruption, strategic dependency or undue leverage.

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5 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).

6 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).

7 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).

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 the stability, integrity and resilience of the Union financial system and taking into account the objectives of the savings and investments union.

(26) 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 that 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 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, where appropriate, take into account risk assessments carried out pursuant to Directive (EU) 2022/2557 of the European Parliament and of the Council[8]. 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.

[8] 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).

Moreover, 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, firstly, in the energy sector: energy storage facility as defined in Directive (EU) 2019/944 of the European Parliament and of the Council[9] and gas transmission system operators within the meaning of Directive (EU) 2024/1788 of the European Parliament and of the Council[10]; secondly, in the transport sector: airports as defined in Directive 2009/12/EC of the European Parliament and of the Council[11], including the core airports listed in Regulation (EU) 2024/1679 of the European Parliament and of the Council[12] and entities operating ancillary installations contained within the airports, when those installations are essential for the security and continuity of operations of such airports, managing bodies of ports as defined in Regulation (EU) 2017/352 of the European Parliament and of the Council[13], in relation to core ports listed in Regulation (EU) 2024/1679, providers of port services as defined in Regulation (EU) 2017/352, and other entities within the core ports when those other entities are essential for the security and continuity of operations of such core ports; and thirdly, in the digital infrastructure sector: providers of cloud computing services and providers of public electronic communications networks.

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9 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, p. 125, ELI: http://data.europa.eu/eli/dir/2019/944/oj).

10 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).

11 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, p. 11, ELI: http://data.europa.eu/eli/dir/2009/12/oj).

12 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).

13 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, p. 1, ELI: http://data.europa.eu/eli/reg/2017/352/oj).

(27) To adequately protect security and public order and ensure the effectiveness of the cooperation mechanism, it is necessary for all Member States to 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 that the foreign investor obtains an effective participation in the management or control and cannot be effectively mitigated after the completion of the foreign investments. That is particularly true for the foreign investments falling within the common minimum scope, since such foreign investments could lead to provision of 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 in properly safeguarding security and public order.

(28) Greenfield investments occur where a foreign investor or a foreign investor's subsidiary in the Union sets up new facilities or a new undertaking for the performance of an economic activity in the Union. Greenfield 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.

(29) 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 is likely to affect the security or public order of other Member States or projects or programmes of Union interest. That cooperation 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.

(30) For the cooperation mechanism to focus only on those foreign investments where the characteristics of the foreign investor or the Union target are likely to have a negative effect on security or public order, 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 could pursue that third country's policy objectives. It is therefore appropriate for Member States to 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 for Member States to notify foreign investments falling within the common minimum scope where the foreign investor was involved in foreign investments that were prohibited or authorised subject to mitigating measures which were significantly or repeatedly not complied with. Hence, mere procedural or formal cases of non-compliance would, as a general rule, 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 through 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 that Member State considers that the foreign investment could negatively affect security or public order in at least one other Member State. This ensures that all foreign investments that could negatively affect security or public order are notified through the cooperation mechanism, whilst ensuring that the host Member State 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 foreign investment.

(31) In order to ensure the efficiency and effectiveness of the cooperation mechanism, it is necessary to align deadlines and procedures where two or more foreign investments linked to the same broader transaction are screened in two or more 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.

(32) 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 cooperation mechanism. Member States should simultaneously transmit their requests for information, replies and comments to the Commission.

(33) 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 able 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.

(34) The Commission should be able to issue an opinion addressed to all Member States where it identifies two or more foreign investments that, taken together, are likely to negatively affect security or public order. That could in particular be the case where two or more foreign investments present comparable characteristics, for example, where the foreign investments are made by the same foreign investor, where two or more foreign investors present similar risks, or where two or more 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 should discuss the Commission's analysis of the risks identified in its opinion and the possible ways to address those risks.

(35) The Member States should not adopt 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 provide their comments or issue its opinion expeditiously.

(36) 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 for 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 give 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.

(37) It is important to take into account that foreign investments that were not notified through the cooperation mechanism might pose a risk to security or public order. Therefore, Member States and the Commission should be able, no later than 15 months from the completion of a foreign investment, to provide duly justified comments or issue an opinion, respectively, to the host Member State on a foreign investment which has not been notified through the cooperation mechanism. To avoid overburdening the cooperation mechanism, Member States and the Commission should, before providing comments or issuing an opinion, respectively, 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 provided 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 foreign investment does not fall within the scope of its screening mechanism or has already been screened, although those situations should ideally have been clarified before any comments were provided or any opinion was 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 provided comments or at the request of the Commission, where the Commission issued an opinion. The Commission should be invited to the meeting even if it did not issue an opinion. The Member States having provided comments or the Commission might, in particular, 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 provided comments or the Commission, the host Member State decides not to screen the foreign investment, it should inform the Member States that provided comments and the Commission thereof and provide them with a written explanation. That written explanation might have overlaps with previously indicated reasons stated, for example at the requested meeting.

(38) 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 suitably placed in their respective administrative structures. Those contact points should have the qualified staff and powers needed to carry out their work under the cooperation mechanism and ensure the proper handling of confidential information.

(39) To ensure the effective functioning of the 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 provide 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.

(40) To ensure that cooperation is based on complete and accurate information, the host Member State should be able to 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, the host 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 that foreign investor or other natural or legal person. For example, the host Member State should identify obvious contradictions and obviously false, misleading or missing information. In exceptional circumstances, where, despite its best efforts, the host Member State is unable to obtain information requested by another Member State or the Commission, it should notify them without delay. In such a case, the other Member States and the Commission should be able to base their comments and their opinion, respectively, on the information available to them.

(41) The host Member State and the Commission could face 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 should be able to request another Member State to gather information from a natural or legal person residing or established in its territory. Furthermore, a host Member State could face a situation where it is necessary to ask two or more other Member States to assist in gathering that 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 timeframe, 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 should be able to 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 could, 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.

(42) Member States and the Commission should ensure the confidentiality of the information they provide or receive in the application of this Regulation, in accordance with Union and national law. Information received as a result of the application of this Regulation should be used only for the purpose for which it was provided, 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 Union and national law. When responding to requests for access to documents handled in the application of this Regulation, Member States and the Commission are to 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[14], with a view to protecting 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[15] and (EU, Euratom) 2015/444[16].

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14 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: http://data.europa.eu/eli/reg/2001/1049/oj).

15 Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41, ELI: http://data.europa.eu/eli/dec/2015/443/oj).

16 Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53, ELI: http://data.europa.eu/eli/dec/2015/444/oj).

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 European Union[17]. That 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.

[17] OJ C 202, 8.7.2011, p. 13.

(43) 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 through the cooperation mechanism, information about the intention to provide a comment or issue 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.

(44) 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 (the 'online EU portal'). The online EU 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 be used in respect of foreign investments in Member States which have so requested. If a Member State requests to opt out of that online EU portal, the online EU portal should no longer be used in respect of foreign investments in that Member State, without affecting the continued use of the online EU portal by the other relevant Member States.

(45) To ensure the effectiveness of the cooperation mechanism, the Commission should set up a secure database with information on the foreign investments notified through 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. It is appropriate for such information to 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 secure 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 through the cooperation mechanism or are likely to negatively affect security or public order.

(46) 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. That capability should allow for the collection and analysis of relevant information and thus facilitate coordinated risk assessments. In the framework of the crisis-preparedness architecture established under Regulation (EU) 2024/2747 of the European Parliament and the Council[18], the Commission will develop elements for such a capability. It could complement the cooperation mechanism under this Regulation to the extent that the information gathered, processed or analysed under Regulation (EU) 2024/2747 concerns potential risks to security or public order.

(47) To ensure a consistent approach to the screening of foreign investments across the Union, it is essential for some of the standards and criteria used to assess likely risks to security or public order to be set at Union level. Those standards and criteria should take into account risks pertaining to the foreign investment and risks pertaining to the foreign investor.

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[18] Regulation (EU) 2024/2747 of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, 2024/2747, 8.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2747/oj).

(48) 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 likely negative effect of an investment on the security, integrity, resilience and functioning of a critical entity as defined in 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 or processes, since the leakage or inaccessibility of such technologies or assets could undermine security. It is equally important for Member States and the Commission to 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 could 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 the purposes of clarity, the list of projects or programmes of Union interest should be set out 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. A list of technology areas that are relevant for risk assessments under this Regulation and a list of critical medicines should be set out in separate annexes.

(49) 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 requests for authorisation or non-compliance with mitigating measures, prior involvement in activities negatively affecting security or public order, illegal or criminal activities, including circumvention of Union restrictive measures adopted pursuant to Article 29 TEU and Article 215 TFEU, establishment in a third country identified as having significant strategic deficiencies in its national regime on anti-money laundering and on countering the financing of terrorism, a legal requirement to share information for intelligence purposes or an opaque ownership structure can constitute risk factors and should therefore also be assessed. In addition, Member States and the Commission should 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 such as the investor's shareholders or board directors in any manner of ways. That extends to informal means including leveraging personal relationships, applying personal or political pressure, and employing threats and other manipulative or deceptive practices.

(50) 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 Member State to take appropriate measures to mitigate that risk, where adequate measures are available, taking into due consideration any comments provided 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.

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

(52) 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. It should be possible for that cooperation to 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 countries that are candidates for accession to the Union and countries in the Union's neighbourhood. The Commission 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.

(53) In order to enhance transparency for foreign investors, the Commission should maintain a publicly available list of all screening mechanisms. Furthermore, to the extent that that is not already laid down in national law, Member States should 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.

(54) Member States should notify to the Commission their screening mechanisms and any amendment thereto. The Member States 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.

(55) 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 annual report should be based on, inter alia, 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 annual report should include information on trends and figures relating to foreign investment into the Union, updates on relevant legislative developments in the Member States, as well as information on international cooperation efforts.

(56) 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[19]. 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[20]. Personal data might be contained in documents and other sources of information which are processed for the purpose of investment screening. Those data might include names of natural persons who are investors in target companies, names and contact data of natural persons who are involved in the management of the investor or target company, or 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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[19] 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).

[20] 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).

(57) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 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 Opinion 13/2024 of the European Data Protection Supervisor, it was considered that defining common retention periods would not be appropriate, since this Regulation lays down only the minimum requirements of the screening mechanisms and since some of the Member States only started developing their screening mechanisms.

(58) The Commission should evaluate the functioning and effectiveness of this Regulation by four years and six months from the date of entry into force of this Regulation and every five years thereafter and should 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 should be able to append a legislative proposal thereto.

(59) 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 or public order laid down in the Agreements of the World Trade Organization[21], including, in particular, Article XIV(a) and Article XIV bis of the General Agreement on Trade in Services[22]. The implementation of this Regulation should also 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.

(60) Where a foreign investment constitutes a concentration falling within the scope of Council Regulation (EC) No 139/2004[23], 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 scopes of application of both Regulations overlap, the grounds for screening set out in this Regulation and the notion of legitimate interests within the meaning of Article 21(4) 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.

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21 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, ELI: http://data.europa.eu/eli/dec/1994/800/oj).

22 OJ L 336, 23.12.1994, p. 191, ELI: http://data.europa.eu/eli/agree_internation/1994/800(15)/oj.

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

(61) 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[24], 2013/36/EU[25] and 2014/65/EU[26] of the European Parliament and of the Council, which is a distinct procedure with a specific objective.

(62) 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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[24] 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).

[25] 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).

[26] 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).

(63) 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 that are relevant for risk assessments 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 provisions of this Regulation and the Annexes thereto. The list of projects and programmes of Union interest set out in the relevant Annex to this Regulation 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 that are relevant for risk assessments set out in the relevant Annex to this Regulation should include areas where a foreign investment could 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 a 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 Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (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 should 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[27]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

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

(64) 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 secure and encrypted system and the online EU portal, the technical guidance to Member States concerning the secure 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[28].

(65) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring that foreign investments into the Union do not have a negative effect on security or public order to lay down rules on a Union framework for the screening, by Member States, of foreign investments in their territory, on the grounds of security or public order and on a cooperation mechanism to enable Member States and the Commission to exchange relevant information on foreign investments, assess their potential effect on security or public order, and identify potential concerns. This Regulation does not go beyond what is necessary in order to achieve the objective pursued, in accordance with Article 5(4) TEU.

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[28] 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).

(66) 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 to apply 18 months from its date of entry into force. To ensure legal certainty and 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 for Regulation (EU) 2019/452 to 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 to provide comments or for the Commission to issue 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 are already subject to screening pursuant to national law. It is equally appropriate to clarify that this Regulation does not apply to foreign investments which are completed by the date of application of this Regulation,

HAVE ADOPTED THIS REGULATION:

Chapter 1
General provisions

Article 1

Subject matter and scope

1. The objective of this Regulation is to ensure that foreign investments into the Union do not have a negative effect on security or public order.

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

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

4. This Regulation is without prejudice to the sole responsibility of each Member State for its national security, as referred to in Article 4(2) TEU, or to the right of each Member State to protect its essential security interests in accordance with Article 346 TFEU.

5. This Regulation does not apply to:

(a) foreign investments made pursuant to the application of a resolution tool or of write-down and conversion powers as defined in Article 2(1), points (19) and (66), respectively, of Directive 2014/59/EU of the European Parliament and of the Council[29], of additional tools within the meaning of Article 37(9) of that Directive, of a resolution tool or of write-down and conversion powers as defined in Article 3(1), points (9) and (44), respectively, of Regulation (EU) No 806/2014 of the European Parliament and of the Council[30], of a resolution tool as defined in Article 2, point (4), of Regulation (EU) 2021/23 of the European Parliament and of the Council[31] and in Article 2, point (14), of Directive (EU) 2025/1 of the European Parliament and of the Council[32], of write-down or conversion powers as defined in Article 2, point (56), of that Directive, or of additional tools within the meaning of Article 26(7) of that Directive;

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29 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).

30 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).

31 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).

32 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).

(b) internal restructuring, unless a new legal entity, established in a third country that is not already represented 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;

(2) ‘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;

(3) ‘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 submission under a screening mechanism of a request to authorise a foreign investment subject to a prior authorisation requirement;

(5) ‘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;

(6) ‘beneficial owner’ means:

(a) one or more natural persons:

(i) who, directly or indirectly, own or control a foreign investor or Union target;

(ii) who ultimately benefit from the foreign investment; or

(iii) on whose behalf the foreign investment is made or on whose behalf the control over that foreign investment is exercised; or

(b) where no natural persons are identified, a legal person, entity or trust which:

(i) directly or indirectly owns or controls a foreign investor or Union target; or

(ii) ultimately benefits from the foreign investment;

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

(8) ‘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;

(9) ‘Union target’ means an undertaking established or intended to be established under the laws of a Member State;

(10) ‘filing’ means an initial submission to the screening authority of all information or documentation required under the screening mechanism, including, where applicable, a complete request for authorisation;

(11) ‘host Member State’ means the Member State in which a foreign investment is planned to be or is completed;

(12) ‘screening’ means a procedure through which a host Member State can investigate, assess, authorise, authorise subject to mitigating measures, prohibit or unwind foreign investments on the grounds of security or public order;

(13) ‘screening mechanism’ means a legal instrument of general application and accompanying administrative requirements, implementing rules or guidelines, that set out the terms, conditions and procedures for screening;

(14) ‘screening decision’ means a measure adopted by a screening authority pursuant to a screening mechanism which results in the authorisation, authorisation subject to mitigating measures, prohibition or unwinding of a foreign investment;

(15) ‘screening authority’ or ‘screening authorities’ means the authority or authorities designated by a Member State to carry out screening;

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

(17) ‘notifying Member State’ means a Member State that has notified a foreign investment through the cooperation mechanism pursuant to Article 5;

(18) ‘multi-country transaction’ means a foreign investment subject to screening mechanisms in two or more Member States;

(19) ‘multi-country notification’ means a notification sent through the cooperation mechanism by each of the Member States concerned with regard to a multi-country transaction;

(20) ‘mitigating measure’ means any condition imposed by a Member State in order to resolve the likely negative effect on security or public order arising from a foreign investment;

(21) ‘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;

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

Chapter 2
National screening mechanisms

Article 3

Establishment of screening mechanisms

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

2. Each Member State shall notify to the Commission the measures adopted pursuant to paragraph 1 by … [18 months from the date of entry into force of this Regulation].

Member States shall thereafter notify the Commission of any amendment to the screening mechanism within 30 days of the adoption of that amendment.

Article 4

Minimum requirements

1. Rules and procedures related to screening shall be transparent and shall not discriminate between third countries or between the Member States.

2. For foreign investments that fall within the scope of their screening mechanism and that are subject to a filing requirement, Member States shall ensure that adequate procedures and resources are provided for the screening authority to:

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

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

3. Member States shall ensure that their screening authorities monitor and ensure compliance with their screening mechanism and screening decisions, in particular by identifying, preventing and addressing their circumvention, and are provided with sufficient resources to carry out those tasks.

4. Member States shall ensure that their screening authorities are empowered to screen and adopt a screening decision on foreign investments falling within the scope of the respective Member State's screening mechanism and not subject to a prior authorisation requirement on their own initiative for at least 15 months and up to a maximum of five years, after the completion of that foreign investment where the screening authority has grounds to consider that such foreign investment may affect security or public order.

5. Member States shall ensure that their screening authorities are empowered, for at least 24 months after the completion of a foreign investment, to screen and adopt a screening decision on that foreign investment provided that it is subject to a prior authorisation requirement and was not filed or was filed after its completion.

6. Confidential information made available to a host Member State for the purposes of screening shall be protected. Member States shall ensure that their screening authorities provide entities making information available with the opportunity to indicate the information they consider to be confidential.

7. Member States shall ensure that the parties subject to the screening decision have the right to seek an effective judicial remedy against that screening decision.

8. Each Member State shall ensure that an annual report is made public, and includes information on relevant legislative developments in that Member State and aggregated and anonymised data on the foreign investments screened, including the outcome of screening decisions, nationalities, or countries of establishment, as applicable, of parties to the foreign 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.

9. Member States shall ensure that a foreign investment subject to a prior authorisation requirement as referred to in paragraph 15 is filed by the applicant requesting an authorisation with the screening authority and is screened before the foreign investment is completed.

10. Member States shall ensure that their screening authorities, where applicable and without undue delay, inform the person who made the filing of the completeness of that filing.

11. Member States shall ensure that their screening authorities are 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 foreign investment where required or failure to comply with mitigating measures.

12. Member States' screening authorities and the Commission shall make publicly available the contact details through which stakeholders may submit information concerning foreign investments in a confidential manner.

13. Adequate procedures shall be provided for the notification of foreign investments through the cooperation mechanism pursuant to Article 5.

14. Before adopting a decision to authorise a foreign investment subject to mitigating measures or to prohibit or 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.

15. Each Member State shall ensure that its screening mechanism imposes a prior authorisation requirement for foreign investments where the Union target established in its territory:

(a) develops, produces or commercialises items listed in Annex I to Regulation (EU) 2021/821;

(b) develops, produces or commercialises goods or technology listed in the Annex to Directive 2009/43/EC;

(c) produces, conducts research in or develops semiconductor or quantum technologies referred to in Annex I to this Regulation, or conducts research in or develops artificial intelligence technologies referred to in that Annex;

(d) is active in the transport, energy or digital infrastructure sectors and is considered critical pursuant to a risk-based targeted assessment that takes into account national security and vital societal functions in light of the essential services provided by that Union target and that is performed by the Member State in which that Union target is established;

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

(f) constitutes one of the following entities:

(i) a central counterparty, namely a 'CCP' as defined in Article 2, point (1), of Regulation (EU) No 648/2012 of the European Parliament and of the Council[33];

(ii) a central securities depository, as defined in Article 2(1), point (1), of Regulation (EU) No 909/2014 of the European Parliament and of the Council[34];

(iii) an operator of regulated markets, within the meaning of Article 4(1), point (18), and Article 4(1), point (21), of Directive 2014/65/EU;

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33 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 (OJ L 201, 27.7.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/648/oj).

34 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 (OJ L 257, 28.8.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/909/oj).

(iv) an operator of payment systems, withing the meaning of Article 2, point (a), of Directive 98/26/EC of the European Parliament and of the Council[35], and designated as such pursuant to Article 10(1) of that Directive, with the exclusion of payment systems operated by central banks;

(v) any other systemically important institution within the meaning of Article 131(3) of Directive 2013/36/EU;

(vi) a global provider of specialised financial messaging services; or

(g) 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.

16. Member States may decide to apply the screening mechanism to foreign investments falling within the scope of this Regulation other than those referred to in paragraph 15. Where Member States decide to apply the screening mechanism to such foreign investments, this Regulation shall apply to the screening of those foreign investments.

17. Paragraph 15 does not apply to greenfield investments.

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[35] 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 (OJ L 166, 11.6.1998, p. 45, ELI: http://data.europa.eu/eli/dir/1998/26/oj).

Chapter 3

The cooperation mechanism on foreign investments likely to negatively affect security or public order

SECTION I

NOTIFICATION OF FOREIGN INVESTMENTS

Article 5

Notification of foreign investments

1. Member States shall notify the other Member States and the Commission through the cooperation mechanism of any foreign investment in a Union target established in their territory to which Article 4(15) and any of the following criteria apply:

   (a) 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 board directors or managers;

(b) 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;

(c) 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 that, 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 other Member States and the Commission 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 either of the following conditions are met:

(a) the Union target is active in a project or programme of Union interest, as listed in Annex II;

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

3. Member States shall notify the other Member States and the Commission 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.

4. Foreign investments notified pursuant to paragraph 1 shall not be notified pursuant to paragraph 2 or paragraph 3.

5. A host Member State shall notify the other Member States and the Commission of any foreign investment that falls within the scope of its screening mechanism but is not covered by paragraph 1, 2 or 3 of this Article, 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 two or more entities in different Member States which are covered by Article 4(15), points (a) to (g). Any such notification shall be duly justified.

Article 6

Content and procedures for notification of foreign investments

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 other Member States and the Commission:

(a) within 15 calendar days of the filing for foreign investments meeting the criteria 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 where Article 5(3) applies;

(d) without undue delay after making the decision to notify a foreign investment in accordance with Article 5(5).

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 requirements set out in point (a) of this Article, it shall discuss with the other Member States concerned, inter alia, whether the conditions set out in Article 5 are met; at the request of a Member State, the Commission may participate in such discussions;

(c) if the filing concerns a foreign investment that meets the conditions set out in Article 5(1), (2) or (5), the Member States concerned shall endeavour to send their notifications through the cooperation mechanism on the same day;

(d) the Member States concerned shall coordinate closely throughout the process and, in particular, 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.

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 provide 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 II, on grounds of security or public order; or

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

The Commission may issue an opinion regardless of whether any Member State has provided comments.

3. 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.

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

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

Article 9

Intention to provide comments or issue an opinion

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

(a) that Member State shall inform the notifying Member State of its intention to provide comments no later than 15 calendar days from the receipt of a notification pursuant to Article 5;

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

Article 10

Additional information

1. When informing the notifying Member State of their intention to provide comments or issue an opinion, Member States and the Commission may request information from the notifying Member State in addition to the information referred to 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 for a comment provided by the notifying Member State pursuant to Article 8(3).

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(3), or for the Commission to issue an opinion pursuant to Article 8(2) or Article 8(5) or in response to a request pursuant to Article 8(3);

(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 paragraph 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.

6. Where the notifying Member State receives two or more requests for additional information about the same notified foreign investment, it shall endeavour to provide all the requested additional information simultaneously.

7. Where two or more notifying Member States receive requests for additional information about a multi-country notification, they shall endeavour to provide all of the requested information simultaneously.

Article 11

Provision of comments and issuing of opinions

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

2. The Commission shall:

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

   (b) send the opinions referred to in Article 8(2), point (b), and in Article 8(5) to all Member States.

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

   (a) where a Member State makes known its intention to provide comments on a notified foreign investment without requesting additional information from the notifying Member State, the respective comments shall be provided to the notifying Member State within a reasonable timeframe, and in any event no later than 20 calendar days from the receipt of the notification of the foreign investment;

(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, that opinion shall be issued to the notifying Member State within a reasonable timeframe, and in any event no later than 30 calendar days from the receipt of the notification of the foreign investment;

(c) where a Member State makes known its intention to provide comments on a notified foreign investment and requests additional information from the notifying Member State, those comments shall be provided to the notifying Member State within a reasonable timeframe, and in any event no later than 15 calendar days from the receipt of the additional information;

(d) where the Commission makes known its intention to issue an opinion on a notified foreign investment and requests additional information from the notifying Member State, that opinion shall be issued to the notifying Member State within a reasonable timeframe, and in any event no later than 25 calendar days from the receipt of the additional information.

4. The notifying Member State shall communicate to the other Member States and the Commission any substantial new information or circumstances relevant for the assessment of a foreign investment already notified pursuant to Article 5. If that information or those circumstances are communicated before the respective deadline set out in paragraph 3 of this Article, 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.

5. The notifying Member State shall adopt its screening decision only after the relevant deadline set out in paragraph 3, points (a) to (d), has expired.

6. Where, due to exceptional circumstances, the notifying Member State considers that its security or public order requires the adopting of a screening decision before the expiry of the relevant 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 provide comments or issue an opinion expeditiously. That procedure shall not be invoked to serve purely commercial interests of the applicant requesting the authorisation.

7. When providing comments or issuing an opinion pursuant to this Article, the Member States or the Commission, as applicable, shall consider whether such comments or opinion should be protected as 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

Consideration 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(5), it shall give due consideration to that comment or opinion.

2. Following the receipt of comments or an opinion, and at the request of a Member State having provided 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 provided comments and the Commission; or

(b) the Commission, where no comments were provided.

Where the comments or the 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.

3. The screening decision shall be adopted by the Member State undertaking the screening.

4. Following the receipt of comments pursuant to Article 8(1) or an opinion pursuant to Article 8(2) or Article 8(5), the notifying Member State shall notify to the Member States concerned and to the Commission, no later than seven calendar days from the date of entry into force of the screening decision, the operative part of its screening decision as well as a summary of the main reasons thereof in view of the provided comments or issued 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 provide duly justified comments to a host Member State on a foreign investment which has not been notified through the cooperation mechanism, where the Member State providing those comments:

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

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

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

2. The Commission may issue a duly justified opinion to a host Member State on a foreign investment which has not been notified through 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 II, on grounds of security or public order; or

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

3. The Commission shall:

(a) send opinions meeting the conditions set out in paragraph 2, points (a) and (c), 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 paragraph 2, point (b), to all Member States.

4. Member States, before providing 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.

5. Before providing comments or issuing 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.

6. Any request for information pursuant to paragraph 5 shall be:

(a) duly justified;

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

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

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

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

7. The host Member State shall provide the information requested by the other Member States or the Commission pursuant to paragraph 5 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.

8. Comments provided 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 timeframe, and in any event no later than 20 calendar days from the receipt of the information pursuant to paragraph 7.

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

9. 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 provided comments and the Commission thereof.

10. If, following the information referred to in paragraph 9, a Member State that provided comments so requests, the host Member State shall organise a meeting with the Member States that provided comments and with the Commission or, if the Commission so requests, a meeting with the Commission alone where only the Commission issued an opinion.

11. Where, following a meeting as referred to in paragraph 10, the host Member State decides not to screen the foreign investment, it shall inform Member States that provided 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 provided 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.

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

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

SECTION III

REQUIREMENTS FOR ENSURING 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 objective 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 other Member States or the Commission.

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 adopted. This includes having at their disposal, in any relevant instrument, including their screening mechanisms, the necessary legal means and powers to consider concerns expressed or likely effects 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 Article 13(2).

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 decisions. Where mitigating measures in a screening decision require compliance by undertakings established in other Member States, the Member State that adopted that screening decision and other relevant Member States shall endeavour 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 cooperation mechanism, a host Member State imposes penalties in accordance with Article 4(11), it shall, where appropriate, notify the Commission and the Member States that provided comments on that foreign investment within a reasonable timeframe.

Article 15

Information requirements

1. Member States shall ensure that information provided in the notification referred to in Article 5 or pursuant to Article 13(7) includes:

   (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;

   (b) the ownership structure of the foreign investor and, where applicable, of the corporate group of which the foreign investor forms part;

   (c) 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 or is completed;

   (d) the 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;

(e) 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;

(f) where applicable, details about the participation of the Union target in projects or programmes of Union interest, as listed in Annex II;

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

(h) 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 advisory procedure referred to in Article 29(2).

3. 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 and Article 10(1) and (2). The requested information shall be provided to the host Member State within 15 calendar days of the request. The host Member State may extend that deadline as it deems appropriate in light of the complexity or quantity of the requested information.

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

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

6. Where the information referred to in paragraphs 1 and 3 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 other Member States and the Commission.

Article 16

Information-gathering assistance

1. The host Member State and the Commission may request another Member State to gather information from a natural person residing or a legal person established in its territory, provided that the natural or legal person concerned 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 or a legal person established in another Member State's territory, provided that the natural or legal person concerned is likely to possess the information in question. Provided that the Member State in whose territory the natural person resides or the legal person is established has been informed by the Commission and does not, within a reasonable timeframe, 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 of this Article shall be relevant and strictly necessary for assessing a foreign investment pursuant to Article 19 and the request for assistance in gathering information pursuant to paragraph 1 or 2 of this Article 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.

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(4) and (6) shall apply *mutatis mutandis*.

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 provided, 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 Union and national 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, online EU portal and secure database

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 other 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 (the ‘online EU portal’). The online EU portal shall be operational no later than 12 months from that request.

3. The online EU portal shall be used in Member States that requested its establishment pursuant to paragraph 2. It shall also be used in Member States which, after the establishment of the online EU portal, so request. The online EU portal shall no longer be used 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 where the online EU portal is used shall only be made through an online form available on the online EU portal. That form shall include the information required under Article 15(1).

5. By 12 months from the request referred to in paragraph 2 of this Article, the Commission shall set out, by means of implementing acts, the arrangements for the functioning of the online EU portal and update those arrangements thereafter as necessary. Those implementing acts shall be adopted in accordance with the advisory 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 through 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 secure 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 under 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;

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

Points (a) to (c) of the first subparagraph of this paragraph shall only apply where the information referred to in those points has not been previously provided pursuant to Article 15(1) or where it has changed since the notification.

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

9. By … [15 months from the date of entry into force of this Regulation], the Commission shall provide, by means of implementing acts, technical guidance to Member States concerning the implementation of paragraphs 7, 8 and 11 of this Article, and update that technical guidance thereafter as necessary. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 29(2).

10. By … [12 months from the date of entry into force of this Regulation], the Commission shall upload to the secure 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.

11. By … [18 months from the date of entry into force of this Regulation], Member States shall upload to the secure database the information at their disposal about the outcome of their screening mechanisms under 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.

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

Chapter 4
Foreign investments likely to negatively affect security or public order

Article 19

Determination of likely negative effect on security or public order

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

(a) a project or programme of Union interest, as listed in Annex II;

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

(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 of the European Parliament and of the Council[36], taking into account the relevant Union-level coordinated security risk assessments carried out in accordance with Article 22 of Directive (EU) 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, 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;

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[36] Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive) (OJ L 333, 27.12.2022, p. 80, ELI: http://data.europa.eu/eli/dir/2022/2555/oj).

(g) the protection of electoral processes;

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

(i) the protection of food security, including farming when the Union target possesses or operates more than 10.000 ha of farmland;

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

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

(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:

(i) is likely to 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) is likely to facilitate the development of a third country's military capabilities;

(iii) is likely to 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 to Regulation (EU) 2021/821 or items included in Annex I to Directive 2009/43/EC;

(iv) has made a foreign investment that was previously screened by a Member State and not authorised or only authorised subject to mitigating measures which were significantly or repeatedly not complied with; to determine that, 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;

(v) has already been involved in activities negatively affecting the security or public order in a Member State; or

(vi) has engaged in illegal or criminal activities, including the circumvention of Union restrictive measures adopted pursuant to Article 29 TEU and Article 215 TFEU;

(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 is established in a third country identified as having significant strategic deficiencies in its national regime on anti-money laundering and on countering the financing of terrorism in accordance with Article 29 of Regulation (EU) 2024/1624 of the European Parliament and of the Council[37];

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

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

3. 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.

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[37] Regulation (EU) 2024/1624 of the European Parliament and of the Council of 31 May 2024 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing (OJ L, 2024/1624, 19.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1624/oj).

4. 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.

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 elements it considers relevant to the foreign investment and, where applicable, in the light of comments provided 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, it shall adopt a screening decision:

(a) authorising the foreign investment subject to mitigating measures; or

(b) prohibiting or ordering the unwinding of the foreign investment.

The screening decision referred to in the first subparagraph shall 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 likely negative effect on security or public order.

3. The host Member State shall only adopt a screening decision prohibiting or ordering the unwinding of the foreign investment where the likely negative effect on security or public order cannot be adequately addressed through other means.

4. The mitigating measures referred to in paragraph 1, first subparagraph, point (a), shall be sufficient to resolve the foreign investment's likely negative effect on security or 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;

(c) conditions on access to sensitive technologies or information;

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

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

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

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

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

Chapter 5
Final and transitional provisions

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 (the 'group of experts'), which provides advice and expertise to the Commission, shall continue to engage in discussions regarding foreign investment screening. The group of experts shall share best practices and lessons learnt, and exchange views on emerging trends and issues of common concern related to foreign investments. The Commission shall seek the advice of the group of experts 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 the group of experts 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 or public order.

Article 23

Public transparency requirements

1. The Commission shall make publicly available a list of Member States' screening mechanisms no later than three months from the deadline referred to in Article 3(2), first subparagraph. That list shall contain the contact details referred to in Article 4(12), 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. To the extent that 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 filing 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 through the cooperation mechanism;

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

   (f) the origin of the foreign investors and their beneficial owners and the sector of activity of the targets of the foreign investments screened, authorised, subject to mitigating measures, prohibited or unwound, respectively;

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

(h) the number of comments provided 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).

2. By … [1 January of the calendar year following that during which this Regulation starts to apply], 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, and update the form thereafter as necessary. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 29(2).

3. 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 ensures the anonymity of specific transactions.

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

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 with Regulation (EU) 2018/1725 and to the extent that 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 controllers in accordance with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 for the processing of operational personal data under this Regulation.

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

Article 26

Evaluation

1. The Commission shall evaluate the functioning and effectiveness of this Regulation by … [four years and six months from the date of entry into force of this Regulation] and every five 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(15) 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.

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, as set out in Annex II, 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 for 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 set out in Annex III, to take account of changes in the circumstances relevant to 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;

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

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

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

(f) 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;

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

(h) 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 IV and at the same time to replace the reference to that Annex in Article 19(1), point (h), 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 Regulations (EC) No 1394/2007 and (EU) No 536/2014 and repealing Regulations (EC) No 141/2000, (EC) No 726/2004 and (EC) No 1901/2006.

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 not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or Council opposes such extension not 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 either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 29

Committee procedure

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 in 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), 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.

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(2), Article 15(2), Article 18(1) to (6), Article 18(9) to (12), 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 …,

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

ANNEX I

Technology areas relevant for the common minimum scope pursuant to Article 4(15)

1. Semiconductor technologies, meaning any technology or know-how related to:

   (a) 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;

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

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

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

   (e) 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;

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

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

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

(a) quantum computing;

(b) quantum communications;

(c) quantum sensing.

3. 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:

(a) general-purpose AI models as defined in Article 3, point (63), of Regulation (EU) 2024/1689 of the European Parliament and of the Council[1] or AI systems based on such models suitable for the development of space or defence application; or

(b) general-purpose AI models with systemic risk within the meaning of Article 51 of Regulation (EU) 2024/1689 or AI systems based on such models.

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[1] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).

ANNEX II

Projects or programmes of Union interest

1. Preparatory Action on Preparing the new EU GOVSATCOM programme

   Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union, and in particular Article 58(2), point (b), thereof (OJ L, 2024/2509, 26.9.2024, ELI: http://data.europa.eu/eli/reg/2024/2509/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 (2014-2020) 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 2021-2025

Council Regulation (Euratom) 2025/1304 of 23 June 2025 establishing the Research and Training Programme of the European Atomic Energy Community for the period 2026-2027 complementing Horizon Europe – the Framework Programme for Research and Innovation and repealing Regulation (Euratom) 2021/765 (OJ L, 2025/1304, 3.7.2025, ELI: http://data.europa.eu/eli/reg/2025/1304/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, 2024/1679, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1679/oj).

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

Regulation (EU) 2022/869 of the European Parliament and of the Council of 30 May 2022 on guidelines for trans-European energy infrastructure, amending Regulations (EC) No 715/2009, (EU) 2019/942 and (EU) 2019/943 and Directives 2009/73/EC and (EU) 2019/944, and repealing Regulation (EU) No 347/2013 (OJ L 152, 3.6.2022, p. 45, ELI: http://data.europa.eu/eli/reg/2022/869/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).

[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.

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).

12. European Defence Industrial Development Programme

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).

13. Preparatory Action on Defence Research

Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union, and in particular Article 58(2), point (b), thereof.

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).

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 L 135, 23.5.2023, p. 123, ELI: http://data.europa.eu/eli/dec/2023/995/oj).

18. European Defence Industry Programme (EDIP)

Regulation (EU) 2025/2643 of the European Parliament and of the Council of 16 December 2025 establishing the European Defence Industry Programme and a framework of measures to ensure the timely availability and supply of defence products ('EDIP Regulation') (OJ L, 2025/2643, 29.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2643/oj).

19. 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).

20. EU4Health Programme

Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/522/oj).

21. 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.

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, 2024/1041, 8.4.2024, ELI: http://data.europa.eu/eli/reg_del/2024/1041/oj).

ANNEX III

Technology areas relevant to risk assessments pursuant to Article 19

a. Biotechnologies:

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

b. Advanced connectivity, navigation and digital technologies:

- secure digital communications and connectivity, such as RAN & Open RAN (Radio Access Network) and 6G
- cyber security technologies including 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

c. Submarine fibre-optic cables

d. Advanced sensing technologies:

– electro-optical, radar, chemical, biological, radiation and distributed sensing

– magnetometers, magnetic gradiometers

– underwater electric field sensors

– gravity meters and gradiometers

e. 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

f. Aerospace technologies

g. 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

h. Robotics and autonomous systems:

– drones and vehicles (air, land, surface and underwater)

– robots and robot-controlled precision systems

– exoskeletons

– AI-enabled systems

i. 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

– digitally controlled micro-precision manufacturing and small-scale laser machining/welding

ANNEX IV

List of critical medicines

ATC level 5	ATC description[1]	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

[1] The Anatomical Therapeutic Chemical (ATC) 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).

ATC level 5	ATC description[1]	Route of administration
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	
A12CC02	MAGNESIUM SULFATE	intravenous, intramuscular use
	A16A - Other alimentary tract and metabolism products	
A16AB02	IMIGLUCERASE	intravenous use
	B - Blood and blood forming organs	
	B01A - Antithrombotic agents	
B01AA03	WARFARIN	oral use
B01AB01	HEPARIN	haemodialysis, intraarterial, intravenous, subcutaneous use
B01AB02	ANTITHROMBIN III	intravenous use
B01AC04	CLOPIDOGREL	oral use
B01AC16	EPTIFIBATIDE	intravenous use
B01AD02	ALTEPLASE	intravenous use
B01AD11	TENECTEPLASE	intravenous use
B01AE07	DABIGATRAN	oral use
	B02A - Antifibrinolytics	
B02AA02	TRANEXAMIC ACID	oral, intravenous use

ATC level 5	ATC description[1]	Route of administration
	B02B - Vitamin K and other hemostatics	
B02BA01	PHYTOMENADIONE	intramuscular, intravenous, oral use
B02BB01	HUMAN FIBRINOGEN	intravenous use
B02BD01	HUMAN PROTHROMBIN COMPLEX	intravenous use
B02BD02	HUMAN COAGULATION FACTOR VIII	intravenous use
B02BD03	FACTOR VIII INHIBITOR BYPASSING ACTIVITY	intravenous use
B02BD04	HUMAN COAGULATION FACTOR IX	intravenous use
B02BD05	HUMAN COAGULATION FACTOR VII	intravenous use
B02BD07	HUMAN COAGULATION FACTOR XIII	intravenous use
B02BD08	EPTACOG ALFA	intravenous use
	B03B - Vitamin B12 and folic acid	
B03BA03	HYDROXOCOBALAMIN	intravenous, intramuscular, subcutaneous, oral use
	B05A - Blood and related products	
B05AA01	ALBUMIN	intravenous use
B05AA02	PLASMA PROTEIN FRACTION	intravenous use
	B05B - IV solutions	
B05BB01	POTASSIUM CHLORIDE	intravenous use
B05BC01	MANNITOL	intravenous use
	B05X - IV solution additives	
B05XA01	POTASSIUM CHLORIDE	intravenous use
B05XA05	MAGNESIUM SULFATE	intravenous use

ATC level 5	ATC description[1]	Route of administration
	B06A - Other hematological agents	
B06AB01	HUMAN HEMIN	intravenous use
B06AC01	COMPLEMENT C1 ESTERASE INHIBITOR	intravenous, subcutaneous use
	C - Cardiovascular system	
	C01A - Cardiac glycosides	
C01AA05	DIGOXIN	oral, intravenous use
	C01B - Antiarrhythmics, class I and III	
C01BB01	LIDOCAINE	parenteral use
C01BB02	MEXILETINE	oral use
C01BC04	FLECAINIDE	oral use
C01BD01	AMIODARONE	intravenous use
	C01C - Cardiac stimulants excl cardiac glycosides	
C01CA02	ISOPRENALINE	intravenous use
C01CA03	NOREPINEPHRINE	intravenous use
C01CA04	DOPAMINE	intravenous use
C01CA07	DOBUTAMINE	intravenous use
C01CA24	EPINEPHRINE	endotracheopulmonary, intracardiac, intraosseous, intramuscular, intravenous, subcutaneous use
C01CA26	EPHEDRINE	intravenous, intramuscular, subcutaneous use
C01CE02	MILRINONE	intravenous use

ATC level 5	ATC description[1]	Route of administration
	C01D - Vasodilators used in cardiac diseases	
C01DA02	GLYCERYL TRINITRATE	intravenous, sublingual use
	C01E - Other cardiac preparations	
C01EB10	ADENOSINE	intravenous use
	C02A - Antiadrenergic agents, centrally acting	
C02AB01	METHYLDOPA (levorotatory)	oral use
C02AB02	METHYLDOPA (racemic)	oral use
C02AC01	CLONIDINE	intramuscular, intravenous, subcutaneous, oral use
	C02D - Arteriolar smooth muscle, agents acting on	
C02DD01	SODIUM NITROPRUSSIDE	intravenous use
	C03C - High-ceiling diuretics	
C03CA01	FUROSEMIDE	intravenous, intramuscular use
	C07A - Beta blocking agents	
C07AA05	PROPRANOLOL	oral use
C07AG01	LABETALOL	intravenous use
	C08C - Selective calcium channel blockers with mainly vascular effects	
C08CA06	NIMODIPINE	intravenous, intracisternal use
	C08D - Selective calcium channel blockers with direct cardiac effects	
C08DA01	VERAPAMIL	intravenous use

ATC level 5	ATC description[1]	Route of administration
	G - Genito urinary system and sex hormones	
	G02A - Uterotonics	
G02AB01	METHYLERGOMETRINE	intramuscular, intrauterine, intravenous, subcutaneous use
	G03X - Other sex hormones and modulators of the genital system	
G03XB01	MIFEPRISTONE	oral use
	H - Systemic hormonal preparations, excl sex hormones and insulins	
	H01B - Posterior pituitary lobe hormones	
H01BA01	ARGIPRESSIN	intramuscular, intravenous, subcutaneous use
H01BA02	DESMOPRESSIN	intramuscular, intravenous, subcutaneous use
H01BB02	OXYTOCIN	intramuscular, intravenous use
H01BB03	CARBETOCIN	intramuscular, intravenous use
	H02A - Corticosteroids for systemic use, plain	
H02AA02	FLUDROCORTISONE	oral use
H02AB04	METHYLPREDNISOLONE	intraarticular, intrabursal, intradermal, intralesional, intramuscular, intravenous, periarticular, rectal use
H02AB06	PREDNISOLONE	oral use
H02AB09	HYDROCORTISONE	intraarticular, intramuscular, intravenous, oral use

ATC level 5	ATC description[1]	Route of administration
	H03B - Antithyroid preparations	
H03BA02	PROPYLTHIOURACIL	oral use
H03BB01	CARBIMAZOLE	oral use
H03BB02	THIAMAZOLE	oral use
	H04A - Glycogenolytic hormones	
H04AA01	GLUCAGON	intramuscular, intravenous, nasal, subcutaneous use
	J - Antiinfectives for systemic use	
	J01A - Tetracyclines	
J01AA02	DOXYCYCLINE	oral use
	J01C - Beta-lactam antibacterials, penicillins	
J01CA01	AMPICILLIN	intramuscular, intravenous use
J01CA04	AMOXICILLIN	oral, intravenous, intramuscular use
J01CE01	BENZYLPENICILLIN	intraarticular, intramuscular, intrapleural, intrathecal, intravenous use
J01CE02	PHENOXYMETHYLPENICILLIN	oral use
J01CE08	BENZATHINE BENZYLPENICILLIN	intramuscular use
J01CF02	CLOXACILLIN	intravenous, intramuscular use
J01CF05	FLUCLOXACILLIN	inhalation, intraarticular, intramuscular, intrapleural, intravenous, oral use
J01CR02	AMOXICILLIN, CLAVULANIC ACID	oral, intravenous use
J01CR05	PIPERACILLIN, TAZOBACTAM	intravenous use

ATC level 5	ATC description[1]	Route of administration
	J01D - Other beta-lactam antibacterials	
J01DC02	CEFUROXIME	oral use
J01DD01	CEFOTAXIME	intramuscular, intravenous use
J01DD02	CEFTAZIDIME	intramuscular, intravenous use
J01DD04	CEFTRIAXONE	intramuscular, intravenous, subcutaneous use
J01DD08	CEFIXIME	oral use
J01DD52	CEFTAZIDIME, AVIBACTAM	intravenous use
J01DF01	AZTREONAM	intramuscular, intravenous use
J01DH56	CILASTATIN SODIUM, IMIPENEM, RELEBACTAM	intravenous use
J01DI54	TAZOBACTAM, CEFTOLOZANE	intravenous use
	J01E - Sulfonamides and trimethoprim	
J01EA01	TRIMETHOPRIM	oral use
J01EE01	CO-TRIMOXAZOLE	oral, intravenous use
	J01F - Macrolides, lincosamides and streptogramins	
J01FA01	ERYTHROMYCIN	intravenous use
J01FA09	CLARITHROMYCIN	intravenous use
J01FA10	AZITHROMYCIN	intravenous, oral use
J01FF01	CLINDAMYCIN	intramuscular, intravenous use
	J01G - Aminoglycoside antibacterials	
J01GB01	TOBRAMYCIN	inhalation, intramuscular, intravenous use
J01GB03	GENTAMICIN	intramuscular, intravenous, subconjunctival use
J01GB06	AMIKACIN	intramuscular, intravenous use

ATC level 5	ATC description[1]	Route of administration
	J01M - Quinolone antibacterials	
J01MA02	CIPROFLOXACIN	intravenous use
J01MA12	LEVOFLOXACIN	intravenous use
	J01X - Other antibacterials	
J01XA01	VANCOMYCIN	intraperitoneal, intravenous, oral use
J01XA02	TEICOPLANIN	intramuscular, intravenous use
J01XB01	COLISTIN	inhalation, intrathecal, intravenous use
J01XD01	METRONIDAZOLE	intravenous use
J01XX01	FOSFOMYCIN	intravenous use
	J02A - Antimycotics for systemic use	
J02AA01	AMPHOTERICIN B	intravenous use
J02AC01	FLUCONAZOLE	intravenous use
J02AC04	POSACONAZOLE	intravenous use
J02AC05	ISAVUCONAZOLE	intravenous, oral use
	J04A - Drugs for treatment of tuberculosis	
J04AB02	RIFAMPICIN	oral use
J04AB04	RIFABUTIN	oral use
J04AC01	ISONIAZID	oral use
J04AK01	PYRAZINAMIDE	oral use
J04AK02	ETHAMBUTOL	oral use
J04AK05	BEDAQUILINE	oral use
J04AM02	ISONIAZID, RIFAMPICIN	oral use
	J04B - Drugs for treatment of lepra	
J04BA02	DAPSONE	oral use

ATC level 5	ATC description[1]	Route of administration
	J05A - Direct acting antivirals	
J05AB01	ACICLOVIR	intravenous use
J05AB06	GANCICLOVIR	intravenous use
J05AB14	VALGANCICLOVIR	oral use
J05AD01	FOSCARNET	intravenous use
J05AF01	ZIDOVUDINE	intravenous, oral use
J05AF05	LAMIVUDINE	oral use
J05AF06	ABACAVIR	oral use
J05AF09	EMTRICITABINE	oral use
J05AG01	NEVIRAPINE	oral use
J05AR02	ABACAVIR, LAMIVUDINE	oral use
	J06B - Immunoglobulins	
J06BA01	HUMAN NORMAL IMMUNOGLOBULIN	intravenous, subcutaneous use
J06BA02	HUMAN NORMAL IMMUNOGLOBULIN	intravenous use
J06BB01	HUMAN ANTI-D IMMUNOGLOBULIN	intramuscular, intravenous use
J06BB02	HUMAN TETANUS IMMUNOGLOBULIN	intramuscular, subcutaneous use
J06BB04	HUMAN HEPATITIS B IMMUNOGLOBULIN	intramuscular, intravenous, subcutaneous use
J06BB05	HUMAN RABIES IMMUNOGLOBULIN	intramuscular use

ATC level 5	ATC description[1]	Route of administration
	J07A - Bacterial vaccines	
J07AE01	CHOLERA VACCINE (inactivated)	oral use
J07AH07	MENINGOCOCCAL GROUP C VACCINE	intramuscular use
J07AH09	MENINGOCOCCAL GROUP B VACCINE	intramuscular use
J07AJ51	DIPHTHERIA, TETANUS, PERTUSSIS VACCINE (inactivated, whole cell)	intramuscular, subcutaneous use
J07AJ52	DIPHTHERIA, TETANUS, PERTUSSIS VACCINE (purified antigen)	intramuscular, subcutaneous use
J07AM51	DIPHTHERIA, TETANUS VACCINE	intramuscular, subcutaneous use
J07AP03	TYPHOID VACCINE (polysaccharide)	intramuscular, subcutaneous use
	J07B - Viral vaccines	
J07BA02	ENCEPHALITIS (Japanese, whole virus, inactivated)	intramuscular use
J07BB01	INFLUENZA VACCINE (various forms, strains)	intramuscular use
J07BB02	INFLUENZA VACCINE (various forms, strains)	intramuscular, subcutaneous use
J07BC01	HEPATITIS B VACCINE	intramuscular, subcutaneous use
J07BC02	HEPATITIS A VACCINE	intramuscular, subcutaneous use
J07BC20	HEPATITIS A AND B VACCINE	intramuscular, subcutaneous use
J07BD52	MEASLES, MUMPS, RUBELLA VACCINE	intramuscular, subcutaneous use
J07BD54	MEASLES, MUMPS, RUBELLA, VARICELLA VACCINE	intramuscular, subcutaneous use
J07BF03	POLIOMYELITIS VACCINE (trivalent)	intramuscular, subcutaneous use
J07BG01	RABIES VACCINE	intradermal, intramuscular, subcutaneous use

ATC level 5	ATC description[1]	Route of administration
J07BH02	ROTAVIRUS PENTAVALENT VACCINE	oral use
J07BK01	VARICELLA VACCINE (live)	intramuscular, subcutaneous use
J07BL01	YELLOW FEVER VACCINE	intramuscular, subcutaneous use
J07BM01	PAPILLOMAVIRUS VACCINE	intramuscular use
J07BM02	PAPILLOMAVIRUS VACCINE	intramuscular use
J07BM03	HUMAN PAPILLOMAVIRUS VACCINE (9-valent)	intramuscular use
	J07C - Bacterial and viral vaccines, combined	
J07CA01	DIPHTHERIA, TETANUS, POLIOMYELITIS VACCINE	intramuscular, subcutaneous use
J07CA02	DIPHTHERIA, TETANUS, PERTUSSIS, POLIOMYELITIS VACCINE	intramuscular, subcutaneous use
J07CA06	DIPHTHERIA, TETANUS, PERTUSSIS VACCINE	intramuscular, subcutaneous use
J07CA12	DIPHTHERIA, TETANUS, PERTUSSIS, POLIOMYELITIS, HEPATITIS B VACCINE	intramuscular use
	L - Antineoplastic and immunomodulating agents	
	L01A - Antineoplastic agents	
L01AA01	CYCLOPHOSPHAMIDE	intramuscular, intravenous, oral use
L01AA02	CHLORAMBUCIL	oral use
L01AA03	MELPHALAN	intraarterial, intravenous, oral use
L01AA06	IFOSFAMIDE	intraarterial, intravenous use

ATC level 5	ATC description[1]	Route of administration
L01AB01	BUSULFAN	intravenous, oral, subcutaneous use
L01AB02	TREOSULFAN	intravenous use
L01AC01	THIOTEPA	intramuscular, intrapericardial, intraperitoneal, intrapleural, intravascular, intravenous use
L01AX04	DACARBAZINE	intravenous use
	L01B - Antimetabolites	
L01BA01	METHOTREXATE	epidural, intraarterial, intraarticular, intrabursal, intracoronary, intradiscal, intramuscular, intrathecal, intravenous, oral, periarticular, perineural, rectal, retrobulbar, subconjunctival, subcutaneous, transdermal use
L01BB02	MERCAPTOPURINE	oral use
L01BB03	TIOGUANINE	oral use
L01BB05	FLUDARABINE	epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, oral, perineural, retrobulbar use
L01BC01	CYTARABINE	intramuscular, intrathecal, intravenous, subcutaneous use
L01BC02	FLUOROURACIL	intraarterial, intraarticular, intramuscular, intraperitoneal, intrapleural, intravenous use
L01BC05	GEMCITABINE	intravenous use

ATC level 5	ATC description[1]	Route of administration
	L01C - Plant alkaloids and other natural products	
L01CA01	VINBLASTINE	epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use
L01CA02	VINCRISTINE	epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use
L01CB01	ETOPOSIDE	epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, oral, perineural, retrobulbar use
L01CD01	PACLITAXEL	intravenous use
L01CE01	TOPOTECAN	intravenous, oral use
	L01D - Cytotoxic antibiotics and related substances	
L01DB01	DOXORUBICIN	intravenous, intravesical use
L01DB02	DAUNORUBICIN	intravenous use
L01DB03	EPIRUBICIN	epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, intravesical, perineural, retrobulbar use
L01DB06	IDARUBICIN	intravenous use
L01DB07	MITOXANTRONE	intrapleural, intravenous use
L01DC01	BLEOMYCIN	intraarterial, intramuscular, intraperitoneal, intrapleural, intratumoral, intravenous, subcutaneous use
L01DC03	MITOMYCIN	intravenous, intravesical use

ATC level 5	ATC description[1]	Route of administration
	L01E - Protein kinase inhibitors	
L01EA03	NILOTINIB	oral use
L01EC02	DABRAFENIB	oral use
L01EC03	ENCORAFENIB	oral use
L01EE01	TRAMETINIB	oral use
L01EL01	IBRUTINIB	oral use
	L01F - Monoclonal antibodies and antibody drug conjugates	
L01FA03	OBINUTUZUMAB	intravenous use
L01FB01	INOTUZUMAB OZOGAMICIN	intravenous use
L01FC01	DARATUMUMAB	intravenous, subcutaneous use
L01FF01	NIVOLUMAB	intravenous, subcutaneous use
L01FF02	PEMBROLIZUMAB	intravenous use
L01FF03	DURVALUMAB	intravenous use
L01FX02	GEMTUZUMAB OZOGAMICIN	intravenous use
L01FX05	BRENTUXIMAB VEDOTIN	intravenous use
L01FX17	SACITUZUMAB GOVITECAN	intravenous use
	L01X - Other neoplastic agents	
L01XA01	CISPLATIN	epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use
L01XA02	CARBOPLATIN	epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use

ATC level 5	ATC description[1]	Route of administration
L01XA03	OXALIPLATIN	epidural, intrabursal, intracoronary, intradiscal, intramuscular, intravenous, perineural, retrobulbar use
L01XB01	PROCARBAZINE	oral use
L01XF01	TRETINOIN	oral use
L01XJ01	VISMODEGIB	oral use
L01XX05	HYDROXYCARBAMIDE	oral use
L01XX23	MITOTANE	oral use
L01XX24	PEGASPARGASE	intramuscular, intravenous use
	L02B - Hormone antagonists and related agents	
L02BA01	TAMOXIFEN	oral use
	L03A - Immunostimulants	
L03AB11	PEGINTERFERON ALFA-2A	subcutaneous use
L03AX03	BCG VACCINE (various forms)	intravesical use
L03AX13	GLATIRAMER	intraarticular, intravenous, periarticular, subcutaneous, transdermal use
L03AX16	PLERIXAFOR	subcutaneous use
	L04A - Immunosuppressants	
L04AA03	ANTILYMPHOCYTE IMMUNOGLOBULIN (horse)	intravenous use
L04AA04	ANTITHYMOCYTE IMMUNOGLOBULIN (rabbit)	intravenous use
L04AC02	BASILIXIMAB	intravenous use

ATC level 5	ATC description[1]	Route of administration
L04AC03	ANAKINRA	subcutaneous use
L04AD01	CICLOSPORIN	intravenous, oral use
L04AD02	TACROLIMUS	intravenous, oral use
L04AH01	SIROLIMUS	oral use
L04AX02	THALIDOMIDE	oral use
L04AX03	METHOTREXATE	oral use
	M - Musculo-skeletal system	
	M01C - Specific antirheumatic agents	
M01CC01	PENICILLAMINE	oral use
	M03A - Muscle relaxants, peripherally acting agents	
M03AB01	SUXAMETHONIUM	intramuscular, intraosseous, intravenous use
M03AC04	ATRACURIUM	intravenous use
M03AC09	ROCURONIUM	intravenous use
M03AC11	CISATRACURIUM	intravenous use
	M03C - Muscle relaxants, directly acting agents	
M03CA01	DANTROLENE	intravenous use
	N - Nervous system	
	N01A - Anesthetics, general	
N01AH01	FENTANYL	epidural, intramuscular, intravenous use
N01AH03	SUFENTANIL	epidural, intravenous use
N01AH06	REMIFENTANIL	intramuscular, intravenous use

ATC level 5	ATC description[1]	Route of administration
N01AX03	KETAMINE	intramuscular, intravenous use
N01AX10	PROPOFOL	intravenous use
N01AX14	ESKETAMINE	intramuscular, intravenous use
	N02A - Opioids	
N02AA01	MORPHINE	epidural, intramuscular, intravenous, subcutaneous use
	N02B - Other analgesics and antipyretics	
N02BE01	PARACETAMOL	intravenous use
	N03A - Antiepileptics	
N03AA02	PHENOBARBITAL	intramuscular, intravenous, oral use
N03AB02	PHENYTOIN	intramuscular, intravenous, oral use
N03AD01	ETHOSUXIMIDE	oral use
N03AE01	CLONAZEPAM	oral use
N03AF01	CARBAMAZEPINE	oral use
N03AG01	VALPROIC ACID	intravenous, oral use
N03AG04	VIGABATRIN	oral use
	N04A - Anticholinergic agents	
N04AA02	BIPERIDEN	intramuscular, intravenous use
	N05A - Antipsychotics	
N05AD01	HALOPERIDOL	intraarticular, intramuscular, intravascular, intravenous, oral use
N05AH03	OLANZAPINE	intramuscular use
N05AN01	LITHIUM	oral use

ATC level 5	ATC description[1]	Route of administration
	N05B - Anxiolytics	
N05BA01	DIAZEPAM	intramuscular, intravenous, rectal use
N05BA06	LORAZEPAM	intramuscular, intravenous use
	N05C - Hypnotics and sedatives	
N05CD08	MIDAZOLAM	intramuscular, intravenous, subcutaneous, rectal use
N05CM18	DEXMEDETOMIDINE	intravenous, subcutaneous use
	N06A - Antidepressants	
N06AX27	ESKETAMINE	nasal use
	N06B - Psychostimulants, agents used for ADHD and nootropics	
N06BC01	CAFFEINE	intravenous, oral use
	N07A - Parasympathomimetics	
N07AA01	NEOSTIGMINE	intramuscular, intravenous, subcutaneous use
	N07X - Other nervous system drugs	
N07XX02	RILUZOLE	oral use
	P - Antiparasitic products, insecticides and repellents	
	P01A - Agents against amoebiasis and other protozoal diseases	
P01AB01	METRONIDAZOLE	intravenous use
	P01C - Agents against leishmaniasis and trypanosomiasis	
P01CX01	PENTAMIDINE	inhalation, intramuscular, intravenous use

ATC level 5	ATC description[1]	Route of administration
	P02C - Antinematodal agents	
P02CA03	ALBENDAZOLE	oral use
	R - Respiratory system	
	R03A - Adrenergics, inhalants	
R03AC02	SALBUTAMOL	inhalation, nasal, oral use
	R03B - Other drugs for obstructive airway diseases, inhalants	
R03BB01	IPRATROPIUM	inhalation, oral use
	R03C - Adrenergics for systemic use	
R03CA02	EPHEDRINE	intramuscular, intravenous, subcutaneous use
R03CC02	SALBUTAMOL	intramuscular, intravenous, subcutaneous use
	R05C - Expectorants, excl combinations with cough suppressants	
R05CB01	ACETYLCYSTEINE	intravenous use
R05CB13	DORNASE ALFA (DESOXYRIBONUCLEASE)	inhalation use
	S - Sensory organs	
	S01E - Antiglaucoma preparations and miotics	
S01EB01	PILOCARPINE	ocular use
S01EB09	ACETYLCHOLINE	intraocular use
S01EC01	ACETAZOLAMIDE	oral use
	S01F - Mydriatics and cycloplegics	
S01FA04	CYCLOPENTOLATE	ocular use

ATC level 5	ATC description[1]	Route of administration
	S01L - Ocular vascular disorder agents	
S01LA01	VERTEPORFIN	intravenous use
	S02A - Antiinfectives	
S02AA15	CIPROFLOXACIN	oral use
	S03A - Antiinfectives	
S03AA07	CIPROFLOXACIN	oral use
	V - Various	
	V03A - All other therapeutic products	
V03AB06	SODIUM THIOSULFATE	intravenous use
V03AB14	PROTAMINE	intravenous use
V03AB15	NALOXONE	intramuscular, intravenous, subcutaneous use
V03AB17	METHYLTHIONINIUM	intravenous use
V03AB23	ACETYLCYSTEINE	intravenous use
V03AB25	FLUMAZENIL	intravenous use
V03AB33	HYDROXOCOBALAMIN	intramuscular, intravenous, oral, subcutaneous use
V03AB34	FOMEPIZOLE	intravenous use
V03AB35	SUGAMMADEX	intravenous use
V03AB37	IDARUCIZUMAB	intravenous use
V03AC01	DEFEROXAMINE	intramuscular, intraperitoneal, intravenous, subcutaneous use
V03AE01	POLYSTYRENE SULFONIC ACID	oral use
V03AF01	MESNA	intravenous, oral use

ATC level 5	ATC description[1]	Route of administration
V03AF02	DEXRAZOXANE	intravenous use
V03AF03	FOLINIC ACID	intramuscular, intravenous use
V03AF07	RASBURICASE	intravenous use
	V04C - Other diagnostic agents	
V04CF01	TUBERCULIN	intradermal use
	V09G - Cardiovascular system	
V09GA04	ALBUMIN (Technetium, 99mTc)	intravenous use
V09GB02	ALBUMIN (Iodine, 125I)	intradermal, intratumoral, intravenous, subcutaneous use
	V10X - Other therapeutic radiopharmaceuticals	
V10XX03	RADIUM (223RA) DICHLORIDE	intravenous use

A statement has been made with regard to this Regulation and can be found in OJ C, …, ELI: …[+].

[+] OJ: Please insert the OJ reference of the statement, including the ELI.