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WORKING PAPER

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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Telecommunications and Information Society
Subject:	Options paper for the policy orientation debate on the Artificial Intelligence Act, prepared by the incoming CZ Presidency in view of the discussion in WP Telecom on 5 July 2022.

Delegations will find in the Annex an options paper for the policy orientation debate on the Artificial Intelligence Act, prepared by the incoming CZ Presidency in view of the discussion in WP Telecom on 5 July 2022.

Presidency options paper for the policy orientation debate on the Artificial Intelligence Act
WP Telecom, 5 July 2022

INTRODUCTION

In preparation for the drafting of the second compromise and in line with the declared ambition of reaching a General Approach at the December Telecom Council meeting, the CZ Presidency would like to obtain the views of the delegations on possible ways ahead on some of the main outstanding issues in relation to the proposal for a **Regulation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)**.

With a view to the WP Telecom meeting on 5 July, the CZ Presidency has identified **four high-level outstanding issues** which require a more thorough discussion and where receiving directions from the Member States would be crucial to move the negotiations to the next level. Each issue is briefly presented below, together with **corresponding policy options**.

During the discussions at the WP Telecom on 5 July, delegations will be requested to indicate their preferred options. Depending on the circumstances, presented options can also be cumulated. Based on these discussions, the CZ Presidency will aim to redraft the relevant parts of the compromise proposal and present it before the end of July, in view of obtaining written comments on the entire second compromise proposal by 2 September 2022.

The Presidency has based its work on the progress report issued by the FR Presidency (document 8576/22) and on the comments raised by delegations in previous meetings, as well as on the delegations' written comments.

Delegations are invited to use the latest consolidated version of the compromise proposal, namely document 10069/22, as the basis for their preparations and interventions.

DISCUSSION TOPICS

1. DEFINITION OF AN AI SYSTEM AND DELEGATED ACTS IN RELATION TO ANNEX I

A large number of the Member States still consider the definition of an AI system to be too broad and ambiguous, notably as it would possibly include also more classical/simple software systems that are not associated with what is understood as AI. There are also concerns among the Member States that some elements of such an important part of the Regulation (notably Annex I) could be amended by the Commission through delegated acts. The two issues are linked. At the same time, there is a need to make sure that the definition is future-proof and that the legal framework can react accordingly to the developments in the market.

The Presidency seeks the views of delegations on:

A. Scope of the definition/what is AI for the purpose of the AI Act:

- **Option 0:** Go back to the Commission's proposal.
- **Option 1:** Keep the definition of an AI system as proposed in the current compromise text (document 10069/22). The definition builds on the Commission's proposal and adds some elements of clarification, such as the inclusion of elements of "learning", "reasoning" and "modelling" in Art. 3(1).
- **Option 2:** Narrow down the definition of an AI system to systems developed through machine learning techniques and knowledge-based approaches.
- **Option 3:** Narrow down the definition of an AI system to systems developed through machine learning techniques.

B. Delegation of powers to the Commission:

- **Option 0:** Under Options A.0 and A.1 above, maintain the status quo (the Commission can update Annex I through delegated acts).
- **Option 1:** Under Options A.0 and A.1 above, incorporate Annex I in Art. 3 (the Commission cannot update the list of techniques and change can happen only through the ordinary legislative procedure).
- **Option 2:** Under Options A.2 and A.3 above, Annex I is removed. Techniques are explained in recitals and/or the definition clarifies what is machine learning and knowledge-based approaches for the purpose of the AI Act directly in Art 3. The Commission may be empowered to adopt implementing acts to further specify techniques under each category and keep them updated.

2. HIGH-RISK AI SYSTEMS CLASSIFICATION, USE CASES AND DELEGATED ACTS IN RELATION TO ANNEX III

Some Member States expressed doubts with regard to the classification of AI systems as high risk on the broad terms of Annex III, leading to concerns that such an approach may capture AI systems that are not likely to cause serious fundamental rights violations or other significant risks. In this respect, there have been calls to include only those use cases in Annex III that are clearly defined and identifiable and based on impact assessment. Some Member States have also expressed concerns about the empowerment of the Commission to adopt delegated acts in relation to Annex III, including the fact that the Commission can only add use cases (no power to remove use cases). At the same time, effective protection and practical possibility to adjust the regulatory framework to market developments are essential to achieve the goals of the AI Act.

The Presidency seeks the views of delegations on:

A. List of uses cases in Annex III

- **Option 0:** Keep the list as proposed in the current compromise text (document 10069/22).
- **Option 1:** Delete certain use cases. If so, which ones and why?
- **Option 2:** Add more use cases. If so, which ones and why?

- **Option 3:** Sharpen wording of the use cases so as to make sure that they are clearly defined and/or not too broad encompassing. If so, which ones and why? What changes are needed?

B. Classification rules for standalone high-risk AI systems

- **Option 0:** Keep the text of Article 6(3) as it is in the current compromise text (document 10069/22). The burden for providers would be eased if the wording of individual use cases is sharpened as per Option A.3 and/or the number of use cases reduced under Option A.1.
- **Option 1:** In order to ensure that the Regulation applies only to cases with significant risk/adverse impact, strengthen the risk-based approach by adding another horizontal layer on top of the high-risk classification made by the legislator in relation to Annex III, more specifically by adding some high-level criteria for evaluating the significant risk that may be further specified by conferring the power to the Commission to specify them through delegating or implementing acts. This option would require providers to make a self-assessment based on those high-level criteria and could require further guidance.
- **Option 2:** In order to ensure that the Regulation applies only to cases with significant risk, strengthen the risk-based approach by adding another horizontal layer on top of the high-risk classification made by the legislator in Annex III, more specifically by introducing a provision in relation to Annex III as follows:
    - if an output of a system is a *decision (fully automated process)*, an AI system referred to in Annex III is always high-risk;
    - if the output of a system is *something else (elements of information to be used by a human in making a decision)*, an AI system is high-risk only if that output can lead to a *significant risk/an adverse impact for health, safety, fundamental rights* or, in other words, *be considered significant for the type of an action/a decision at stake in the use case*.
    - The Commission could be conferred the power to adopt an implementing act to establish uniform conditions in the Member States for the implementation of the concept of 'significance of AI-generated information'.

  Option B.2 would likely be easier for providers and would apply only to those AI systems for which the output of the system is not already explicitly identified in Annex III (e.g. 1(a), 2(a), 6(a), etc.). Guidance on classification of software as medical device by MDCG[1] and on risk framework for software as medical device by

[1] Medical Device Coordination Group (MDCG) provides advice to the Commission and assists the Commission and the Member States in ensuring a harmonised implementation of medical devices Regulations (EU) 2017/745 and 2017/746.

IMDREF[2] can be a starting point to articulate concept of "significance" of information provided by an AI system.

C. Delegation of powers to the Commission

- **Option 0:** Keep the delegation of powers to the Commission together with certain provisions clarifying the involvement of the Member States in the process as drafted in the current compromise text (document 10069/22).
- **Option 1:** Delete the Commission's empowerment: change only possible through the ordinary legislative procedure.
- **Option 2:** Keep the delegation of powers to the Commission as per Option C.0 but add empowerment for the Commission to delete use cases as well (not only to add), under certain well-specified conditions, ensuring an equivalent level of protection.

3. GOVERNANCE AND ENFORCEMENT

Some Member States have suggested that an overly decentralized national-level governance framework could pose limitations to effective enforcement in cyberspace across the Union, notably due to insufficient capacities and know-how at the level of national authorities to implement and enforce AI rules effectively. At the same time, some emphasized a need for a certain level of flexibility for national law and specificities. While enforcement of some Union rules in the cyberspace might have proved challenging in the past, it is also to be reminded that scope and enforcement mechanism envisaged by the AI Act proposal is different from some recently adopted legislation where more centralized elements were introduced. Delegating enforcement powers to a more central level also requires careful practical and budget implications considerations.

The Presidency seeks the views of delegations on:

[2] International Medical Device Regulators Forum (IMDRF).

A. Governance and enforcement

- **Option 0:** Keep the approach included in the current compromise text (document 10069/22) which builds on the Commission´s proposal and on the Market Surveillance Regulation (2019/1020, MSR) already applicable to products incorporating AI. This means that Member States are primarily in charge, with elements of coordination (AI Board) and intervention (Union safeguard procedure – Art. 66). Under this option the national authority in the country where the AI system is used would be in a position to launch investigations and enforce the Regulation in cases of abuse.
- **Option 1:** Incorporate explicitly further elements to support Member States´ capacity:
    i. The Commission could be mandated to designate one or more Union Testing Facilities[3] for AI under Article 21 Market Surveillance Regulation (Testing Experimentation Facilities under the Digital Europe Programme could be considered for this purpose);
    ii. Creation of a centralized pool of experts to support enforcement by Member States upon request (if not already part of Union Testing Facilities) – existing Union funding possibilities or financing by Member States themselves would need to be explored;
    iii. Foresee emergency mechanism to support market surveillance activities – in case of urgency (e.g. cross-border mutual assistance under MSR or "ordinary" support by a pool of experts being too slow/ineffective) and upon request by (three) Member States, Commission to adopt a decision to fast-track support for Member States enforcement activities (re-direct/prioritize use of experts/Union testing facilities) with a view to assess compliance of an AI system.
- **Option 2:** Further strengthen the role of the AI Board:
    i. Provide advice to and assist also national authorities (not only the Commission);
    ii. Along the model Art. 105 Medical Devices Regulation, include a more detailed list of tasks, including of direct relevance for enforcement by the Member States (such as assessment, designation and monitoring of notified bodies, issuing of guidance and coordination of market surveillance activities).
- **Option 3:** Give the Commission power to, under certain well-defined exceptional circumstances, launch a direct investigation and enforcement. This could only be envisaged for AI systems under Annex III – it implies considerate practical and

[3] According to Art. 21 MSR, Union Testing Facilities shall, among others, carry out test of products covered by Union harmonization legislation (like the AI Act) at the request of market surveillance authorities, the Commission or the Union Product Compliance Network and provide independent technical or scientific advice. Art. 34 MSR foresees an information and communication system for the exchange of information among market surveillance authorities in relation to their activities. Chapter VI MSR (Art. 22-24) already foresees mechanisms for cross-border mutual assistance among market surveillance authorities of different Member States (access to information, adoption of enforcement measures).

financial implications. If this option was to be retained, it would be necessary to specify the budgetary resources and procedural safeguards.

4. NATIONAL SECURITY EXCLUSION

It appears that a vast majority in the Council strongly supports an explicit exclusion of national security from the scope of the AI Act as included in the document 10069/22. At the same time, there are calls that further clarifications of this concept are still needed.

The Presidency seeks the views of delegations on Art. 2(3):

- **Option 0:** Keep the text as it is in the current compromise text (document 10069/22): *"This Regulation shall not apply to AI systems developed or used exclusively for military or national security purposes"*.
- **Option 1:** Delete "exclusively" from Option 0. This could create some ambiguity in the interpretation as to which AI systems are excluded and which ones are not.
- **Option 2:** Reformulate as follows: *"This Regulation shall not apply to AI systems placed on the market or put into service exclusively for military or national security purposes"*. The development phase is anyway out of scope. When the system is placed on the market or put into service for military or national security purposes it remains out of scope.
- **Option 3:** Build on Option 2 and delete 'exclusively': *"This Regulation shall not apply to AI systems placed on the market or put into service for military or national security purposes"*. The development phase is anyway out of scope. When the system is placed on the market or put into service for military or national security purposes it remains out of scope. Like Option 1, this option could create some ambiguity in the interpretation as to which AI systems are excluded and which ones are not.