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REGULATORY SCRUTINY BOARD OPINION

European Innovation Act

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EUROPEAN COMMISSION
REGULATORY SCRUTINY BOARD

Brussels,
RSB

Opinion

Title: Impact assessment / European Innovation Act

Overall 2nd opinion: NEGATIVE

(A) Policy context

The European Innovation Act aims to remove barriers that hinder the proper functioning of the Single Market and prevent EU innovative companies from scaling up. It proposes establishing cross-sectoral framework conditions to facilitate the commercialisation of research results, strengthen collaboration between industry, academia and the public sector, and improve access to markets and infrastructures. In doing so, it seeks to create a more coherent regulatory, policy, and investment environment across the EU.

(B) Key issues

The Board notes the significant changes in the range of the proposed measures, clarifications of the context and scope of the initiative, and improvements to the presentation of the report.

However, the Board maintains its negative opinion, because the revised report still contains the following significant shortcomings:

(1) There are apparent overlaps with the public procurement Directives and the report lacks the assessment of the coherence with the upcoming revision of the public procurement rules. The subsidiarity and proportionality of the measures in the area of public procurement are not demonstrated.

(2) The analysis of impacts focusses on innovative companies while the measures covering the definitions of innovative companies, startups and scaleups have been discarded and the proposed measures in this initiative are not limited to specific company categories. This makes the overall analysis incomplete and potentially misleading.

(3) Some measures are not sufficiently specified to allow for their assessment. The analysis of costs and benefits of the specific measures is not adequate.

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(C) What to improve

(1) The relation to the EU public procurement framework remains ambiguous. On the one hand the report claims that the scope is restricted to the areas outside of the public procurement Directives' remit (i.e. below the established financial thresholds and covering also the exempted sectors), on the other hand some proposed measures seem to go beyond the pre-commercial procurement. In view of the upcoming revision of the EU public procurement framework, the rationale and the value added for supplementing it with additional elements in the European Innovation Act should be better assessed and justified, also in the light of stakeholders' concerns. The establishment of mandatory innovation procurement targets would extend to public procurement at large, which could create an overlap with the public procurement framework, add legal complexity and unnecessary administrative burden which is not sufficiently analysed in the report. In addition, the inclusion of public procurement below the financial thresholds established in the EU framework (currently subject to national procurement law) in the measures proposed by the European Innovation Act requires further analysis in terms of their proportionality and subsidiarity.

(2) In the revised report the measures for 'operationalising the definitions of innovative companies, startups and scaleups' have been discarded, arguing that the proposed measures would apply to all companies. Yet the issue of establishing the definitions of such companies in the overall innovation framework remains unresolved: the report refers to the forthcoming EU level company definition whereas the analysis of impact of the measures focusses heavily on innovative companies. However, the potential consequences resulting from overlaps with the existing definitions of SMEs, micro-companies and small mid-caps are not assessed. Furthermore, the impact on legal certainty for companies as well as the impact on establishing a threshold in terms of innovation spending for SMEs should be analysed.

(3) Several of the options and measures analysed, (including measures 1, 2, 5, 7 and 8), are not specified at a sufficient level of detail. This makes it difficult to assess what impacts would follow from introducing these measures, including their feasibility, effectiveness, efficiency and proportionality.

(4) The report should investigate the indirect effects of some measures that may have significant consequences. For instance, the costs of mandatory innovation procurement targets and other measures related to procurement are not limited to the administrative and adjustment costs of establishing the targets. The report would need to assess whether the fact that the targets would have to be met may lead to procuring (innovative) products and services at higher costs. Similarly, the EU preference in private and public procurement outside the EU procurement framework may induce higher costs to public and private stakeholders, which are not properly analysed in the report. The risk that preset or too narrow definitions and principles for sandboxes could lead to the exclusion of some potentially beneficial experiments should also be assessed.

(5) The magnitude(s) of the benefits alleged to result from several of the proposed measures, (including measures 1, 2 and 3), are neither sufficiently assessed nor credibly demonstrated. The assumptions behind such benefit estimates are not always robust.

(6) Given the above, the report does not provide a sufficient evidence base to be informative for the decision making.

<table>
<tr><td colspan="2"><u>(D) Conclusion</u>

The Board’s opinion is as a rule final. The lead Service can seek political guidance on whether, and under which conditions, this initiative may proceed further.</td></tr>
<tr><td>Full title</td><td>European Innovation Act</td></tr>
<tr><td>Reference number</td><td>PLAN/2024/2791</td></tr>
<tr><td>Submitted to RSB on</td><td>20 February 2026</td></tr>
<tr><td>Date of RSB meeting</td><td>Written procedure</td></tr>
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Title: Impact assessment / European Innovation Act

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(A) Policy context

The European Innovation Act aims to remove barriers that hinder the proper functioning of the Single Market and prevent EU innovative companies from scaling up. It proposes establishing cross-sectoral framework conditions to facilitate the commercialisation of research results, strengthen collaboration between industry academia, and the public sector, and improve access to markets, and infrastructures. In doing so, it seeks to create a more coherent regulatory, policy, and investment environment across the EU.

(B) Key issues

The Board notes the additional information provided and commitments to make changes to the report.

However, the Board gives a negative opinion because the report contains the following serious shortcomings that the lead Service must address:

(1) The scope of the intervention is not clear.

(2) The problems, their scale and their drivers are not well identified and are not supported with the appropriate evidence.

(3) The report lacks a clear logic of the intervention. The objectives are not S.M.A.R.T.. The policy measures are not clearly defined and it is not demonstrated that they address those problems at their roots causes.

(4) The report does not provide sufficient evidence supporting the feasibility, effectiveness and efficiency of many of the proposed policy measures; their proportionality is not sufficiently assessed.

(5) The report does not appropriately assess the external coherence of this initiative with other horizontal initiatives contributing to the European competitiveness and functioning of the Single Market.

(6) The level of administrative burden is not sufficiently analysed.

(C) What to improve

(7) The report must clarify the scope of the intervention. It should better set the context of the initiative and other initiatives that the Commission is preparing in parallel, that delineate the scope of the European Innovation Act and could potentially support or complement it. A better description of the scope will enable to strictly base the impact assessment on problems identified inside this scope.

(8) Currently most of the problems and problem drivers overlap. The report should better differentiate between the presented problems and their drivers, striving to identify root causes as exhaustively as possible. The report should then transparently consider what can be addressed better by parallel or future initiatives. The large divergence in the identified issues among Member States is not analysed. The problem identification should be corroborated by evidence and should focus on the issues that cannot be solved at the national/regional or local level, that have a cross-border dimension and could be addressed at the EU level. The specificities of innovative companies as opposed to SMEs should be explained and supported by evidence. The report does not provide compelling evidence that support the rationale for regulating sandboxes at the EU level, rather than proposing general guidance.

(9) The logic of the intervention is not well established in the report. Once the problems and their drivers are better identified, the general and specific objectives should be aligned and narrowed down to the adjusted scope of the intervention. Formulating a general objective that is too multifaceted and vast makes it hardly possible to demonstrate causal links between the intervention and the future results. The specific objectives, selected based on a refined problem definition, should be S.M.A.R.T. to clearly understand what is expected to be achieved and to enable the assessment of the impact of the policy options.

(10) The report should propose policy measures that are based on evidence demonstrating that they can solve the underlying problems/drivers and achieve the desired objectives. The feasibility of those measures should be checked upfront. Many of the measures proposed in the report are not well specified, often relying on terms that may be subject to interpretation, or are simply not fully defined. It is therefore not possible to assess their feasibility, effectiveness, efficiency, and proportionality. The evidence supporting the effectiveness of some measures is incomplete or missing. The causal links between a measure and the problem drivers it is intended to address are often not established.

(11) More specifically, the feasibility of establishing a common and future proof definition of an innovative company across different sectors should be demonstrated better. The feasibility and consequences of establishing a common definition of a startup, scaleup and an innovative company and their co-existence with the established definitions of SMEs, micro companies, and small mid-caps, should be discussed in the report in view of possible overlaps as regards access to (EU) funding or any other special treatment of such companies. The report should analyse the risk that the proposed policy measures and their implementation could add more burdens than benefits.

(12) The report should better analyse the external coherence with other horizontal initiatives contributing to improving European competitiveness by promoting innovation and functioning of Single Market. The report should assess the coherence with the simplification agenda (Omnibus IV); measure 2 and the supporting recommendation should describe how they would be implemented. It should discuss the coherence of the proposals on public procurement and in particular the revision of the public procurement rules, in light of the concerns of stakeholders. The discussion on the external coherence should also cover the coming European Research Area act and the “28th regime for innovative companies”.

(13) The report should be clear on what success will look like; targets and benchmarks for the specified monitoring indicators should be introduced.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.

Full title	European Innovation Act
Reference number	PLAN/2024/279
Submitted to RSB on	23 December 2025
Date of RSB meeting	28 January 2026