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**COMMISSION STAFF WORKING DOCUMENT**  
**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT**

*Accompanying the documents*

**COMMUNICATION FROM THE COMMISSION**  
**Approval of the content of a draft for a Communication from the Commission –**  
**Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the**  
**European Union to horizontal co-operation agreements**

**COMMISSION REGULATION (EU) .../... of XXX on the application of Article 101(3)**  
**of the Treaty on the Functioning of the European Union to certain categories of research**  
**and development agreements**

**COMMISSION REGULATION (EU) .../... of XXX on the application of Article 101(3)**  
**of the Treaty on the Functioning of the European Union to certain categories of**  
**specialisation agreements**

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Executive summary sheet
Impact assessment accompanying the revised Horizontal Block Exemption Regulations (“HBERs”) and the revised Guidelines on horizontal co-operation agreements (“Horizontal Guidelines”)
A. Need for action
What is the problem and why is it a problem at EU level?
<p>The evaluation confirmed that the HBERs and Horizontal Guidelines are useful tools that greatly facilitate the self-assessment of horizontal agreements under EU competition law. However, the evaluation also identified certain areas where the rules do not function well or as well as they could. Therefore, it was deemed relevant to revise the HBERs and Horizontal Guidelines following an impact assessment of the proposed changes. Two main problems were identified.</p> <p>Firstly, the evaluation showed that <b>small and medium-sized enterprises (‘SMEs’) find it difficult to self-assess the compliance of their R&amp;D and specialisation agreements with Article 101 of the Treaty using the HBERs</b>. R&amp;D and specialisation cooperation is important for SMEs, as cooperation with other SMEs or with larger firms may provide them with access to resources, funding and knowledge. Compliance uncertainty in relation to a potential R&amp;D or specialisation cooperation may lead to the cooperation being abandoned, with the consequence of missed opportunities and innovation delays. SMEs reported that they have particular difficulties with applying the definitions in the HBERs, defining relevant markets and calculating market shares, and with interpreting the conditions for exemption in the Regulation on the application of Article 101(3) of the Treaty to certain categories of research and development agreements (‘R&amp;D BER’). Therefore, SMEs are often dependent on the availability of costly external support in order to assess the compliance of their cooperation with competition law.</p> <p>Secondly, there is a concern that <b>innovation competition may not be adequately protected</b> in certain cases where companies enter into R&amp;D agreements for which it is not possible to calculate market shares. The safe harbour in the R&amp;D Block Exemption Regulation applies to R&amp;D agreements where the parties to the agreement have a combined market share not exceeding 25% on the market(s) for products or technologies that will be improved, substituted or replaced by the products or technologies resulting from the joint R&amp;D. However, companies may also enter into <b>R&amp;D agreements for the purpose of developing products or technologies that will not improve or replace existing products or technologies but will create an entirely new market</b>. Such R&amp;D agreements are currently treated in the R&amp;D BER as agreements between non-competitors and they can therefore benefit from the block exemption without any condition relating to the competitive dynamic at the R&amp;D level. However, companies do compete at the R&amp;D stage to win the race to bring products and technologies to the market. Therefore, in specific cases R&amp;D agreements relating to the development of products or technologies that will create an entirely new market could restrict innovation competition without meeting the conditions of Article 101(3) of the Treaty.</p>
What should be achieved?
<p>The general objective of the initiative is to make it easier for companies to cooperate in ways that are economically desirable and without adverse effects from the point of view of competition policy. In parallel, the initiative also aims to simplify administrative supervision by the Commission, National Competition Authorities and national courts.</p>
What is the added value of action at EU level (subsidiarity)?

Pursuant to Article 3 of the Treaty, the EU has exclusive competence to establish competition rules necessary for the functioning of the internal market. The HBERs provide a safe harbour from EU competition law, which can only be granted at EU level. As regards the necessity and added value of adopting revised HBERs, rather than allowing the HBERs to expire, the evaluation indicates that the HBERs simplify self-assessment and increase legal certainty for companies entering into R&D and specialisation agreements, as well as providing a common framework for the application of Article 101 of the Treaty to these types of agreements by NCAs and national courts.

## **B. Solutions**

### **What are the various options to achieve the objectives? Is there a preferred option?**

The baseline for each of the two areas that are the subject of the impact assessment is to maintain the rules and guidance set out in the 2010 HBERs and Horizontal Guidelines (**baseline scenario** for both areas).

Options to **facilitate the application of the HBERs by SMEs**: **Option 1** would provide a specific exemption in both HBERs for agreements concluded by SMEs. The exemption would be subject to certain criteria developed specifically for SMEs to avoid the need for them to define relevant markets or calculate market shares when assessing their agreements. **Option 2** would limit or remove, for R&D agreements concluded by SMEs, the access condition(s) in Articles 3(2) and 3(3) of the R&D BER that require the parties to such agreements to provide full access to the final results of the joint R&D, as well as access to pre-existing know-how in order to benefit from the block exemption. **Option 3** would expand the scope of the Specialisation BER by extending the definition of unilateral specialisation to include agreements entered into between more than two companies. This would be particularly relevant for SMEs, since, due to their size and limited resources, an effective specialisation may require the cooperation of more than two parties.

The **preferred option is Option 3**. This option would be combined with the introduction of clarifications in the Horizontal Guidelines. Option 3 comes closest to meeting the objectives of ensuring effective protection of competition and providing adequate legal certainty. The expansion of the scope of the Specialisation BER under **Option 3** and the clarifications will also contribute to simplifying administrative supervision by the Commission, NCAs and national courts.

Options regarding the **potentially inadequate level of protection for innovation competition**: **Option 1** would introduce a new threshold for the exemption of R&D agreements for which it is not possible to calculate market shares at the time the agreement is concluded. This threshold would be linked to the competitive dynamic at the R&D level, i.e. the level of residual competition at R&D level. **Option 2** would maintain the exemption of R&D agreements for which it is not possible to calculate market shares at the time the agreement is concluded, subject to the other conditions set out in the R&D BER (e.g. conditions relating to access to the R&D results, absence of hardcore restrictions, etc.) without introducing any new threshold. However, Option 2 would insert a new provision in the R&D BER referring to the power of the Commission and NCAs to withdraw the benefit of the exemption in cases where an individual R&D agreement does not fulfil the conditions of Article 101(3) of the Treaty, in particular where it eliminates innovation competition. The preferred option is **Option 2**. Option 2 would come closest to meeting the objectives of ensuring the effective protection of competition and providing legal certainty, without creating administrative and compliance costs that would be disproportionate to the identified problem.

### What are the different stakeholders' views? Who supports which option?

Various consultations took place in relation to the policy options for the HBERs: a consultation on the inception impact assessment; an open public consultation based on an online questionnaire; targeted questionnaires on specific issues; a targeted consultation of national competition authorities; three expert reports; a workshop on R&D and specialisation agreements; an open public consultation based on the publication of draft revised HBERs and draft revised Horizontal Guidelines, and a workshop on the revision of the R&D Block Exemption Regulation. All categories of stakeholders have generally welcomed the review of the HBERs and Horizontal Guidelines.

As regards the options to **facilitate the application of the HBERs for SMEs**, only few stakeholders provided views. The experts that were consulted argued against the introduction of a **specific exemption for R&D and specialisation agreements concluded by SMEs (Option 1)** and the **limitation or removal of the conditions in the R&D BER for R&D agreements concluded by SMEs (Option 2)**. NCAs indicated that they lacked experience to express a clear preference. The expansion of the **definition of unilateral specialisation agreements** to include more than two parties (**Option 3**) was tested via the publication of the draft revised texts and received general stakeholder approval from the stakeholders that submitted views.

Regarding the options on the **potentially inadequate level of protection for innovation competition**, stakeholders generally expressed a clear preference for Option 2. **Option 1**, namely a new threshold linked to the competitive dynamic at R&D level for R&D agreements for which it is not possible to calculate market shares would, in principle, increase the protection of competition, by reducing the possibility that this category of R&D agreements may benefit from the safe harbour in cases where the agreement would harm innovation competition. However, based on the results of the impact assessment, this would come at the cost of more complex self-assessments and less legal certainty for business envisaging entering into this category of R&D agreements. **Option 2** would maintain the current level of legal certainty for this category of R&D agreements, while raising awareness of the possibility that in certain scenarios such agreements may harm innovation competition, in which case competition authorities may withdraw the benefit of the block exemption.

### C. Impacts of the preferred option

#### What are the benefits of the preferred option?

The main benefit of the preferred option as regards **facilitating the application of the HBERs for SMEs** is that it would increase legal certainty by keeping the market share thresholds and adding further guidance on the application of these thresholds, the hardcore restrictions and the conditions for exemption in the Horizontal Guidelines. Moreover, this option would preserve competition in the market.

The main benefit of the preferred option as regards the **potentially inadequate level of protection for innovation competition** is that it would raise awareness of the possible competition concerns, while maintaining legal certainty. Therefore it would not create administrative and compliance costs that would be disproportionate to the identified problem.

#### What are the costs of the preferred option?

The preferred option as regards **SMEs** will lead to a decrease in costs, thanks to the expansion of the concept of specialisation agreements to include more parties than currently foreseen and also thanks to the enhanced legal certainty and clarifications inserted in the Horizontal Guidelines.

The preferred option as regards <b>protecting innovation competition</b> is not likely to increase administrative or compliance costs for companies.
<b>What are the impacts on SMEs and competitiveness?</b>
<p>The preferred options for <b>SMEs</b> and <b>innovation competition</b> would have the advantage that companies would be able to continue to rely on the same rules and would not have to adapt to any new legislation and would benefit from added legal certainty in the form of clarifications on the application of the HBERs in the Horizontal Guidelines.</p> <p>The expansion of the concept of unilateral specialisation would recognise the economic reality that it is sometimes necessary to cooperate with more than one other party to obtain sufficient economies of scale to be competitive. This will have an important impact on SMEs, facilitating market entry and reducing risks that they may be less able to counter than their larger rivals. The negative impacts on the internal market are limited, as the combined market share threshold of 20% does not change.</p> <p>In addition, the new provision in the R&amp;D BER referring to the power of the Commission and NCAs to withdraw the block exemption, together with the additional guidance on the scenarios in which this power is likely to be used, will raise awareness of this power and the risks involved in concluding agreements that harm competition at the R&amp;D level.</p>
<b>Will there be significant impacts on national budgets and administrations?</b>
Overall, the initiative would not have significant practical implications as regards the antitrust enforcement work of national authorities. This is because it would not fundamentally alter the core structure and framework of assessment provided by the HBERs (e.g. the concepts of hardcore restrictions and the market share thresholds). Furthermore, the initiative as such would not have any impact on national budgets.
<b>Will there be other significant impacts?</b>
Beyond the direct impact on businesses, competition and the internal market, each of the preferred options is expected to also generate indirect impacts for consumers, who will benefit from more innovation and choice if competition at R&D level is maintained. Furthermore, the market share thresholds, conditions for exemption and lists of hardcore restrictions will ensure that the efficiencies stemming from R&D and specialisation agreements will reach final consumers and will outweigh any possible harm.
<b>Proportionality</b>
The preferred option for each area of the rules would be proportionate, as it avoids going beyond what is necessary to readjust the scope of the HBER safe harbour.
<b>D. Follow-up</b>
<b>When will the policy be reviewed?</b>
These initiatives are planned to be in place for 12 years. The Commission will monitor the functioning of the revised rules on an ongoing basis, through its own enforcement practice and that of the NCAs; by monitoring questions of interpretation that arise before the national and Union courts, and through informal contacts with stakeholders. No later than June 2031, the Commission will take stock of the functioning of the revised rules and draw up an evaluation report, inter alia on the basis of the information gathered through this monitoring.