

TOOL #21. RESEARCH & INNOVATION

1. INTRODUCTION

This research and innovation Tool provides clear guidelines for analysing the interaction between new or revised EU legislation (including spending programmes) and innovation. In addition, it outlines a series of design considerations and operational instruments that can be used to make legislative proposals more forward-looking and innovation-friendly. The Tool is not limited to looking at impacts on technological innovation but can also be used to look at other forms of innovation such as social, business model and public sector. Other tools in the Toolbox can also be used to identify and assess impacts flowing from innovation.

The assessment of the potential impact of legislation on research and innovation starts with the type of legislation and its overall objectives. Please consider whether, and to what extent, the initiative may have positive or negative impacts on research and innovation capacity at the firm, sector or EU level. For example:

- (1) In creating (or reducing) barriers to innovation or weakening (or strengthening) the incentives for investing in innovation.
- (2) Creating opportunities or incentives for innovation that could better support the achievement of policy objectives.
- (3) Affecting specific research and innovation regulation (e.g. patent law, technology transfer legislation) or spending programmes. These will have an effect on the incentives and rewards, as well as perhaps the location choice of research, development and market entry.

DG Research and Innovation is available to support the analysis, provide further guidance and help in the design of EU initiatives at the request of, and in cooperation with, the lead DG. The Scientific Advice Mechanism (SAM)¹⁸⁴ can also play a role in cases where the scientific understanding and interpretation of evidence is critical to making policy choices; this latter mechanism complements the routine assistance of the JRC in better regulation work.

2. THE STEPWISE APPROACH

Step (1) Broaden consultation to capture the research and innovation angle

Depending on the extent to which solving the problem is likely to have significant impacts on innovation and research, questions on these aspects should be a central element of the consultation strategy (for which separate guidance exists¹⁸⁵). The public online stakeholder consultation should include questions on potential impacts on research and innovation, on emerging techniques and technologies and on impacts on companies

¹⁸⁴ <https://ec.europa.eu/research/sam/index.cfm>

¹⁸⁵ See Tools #53, #54, and #55 on Stakeholder consultation

scaling-up in size.¹⁸⁶ The public consultation should reach out to relevant stakeholders, in particular start-ups.

There is a risk that this sort of consultation exercise will predominantly identify the views of existing and incumbent firms and therefore may not fully take into account the impact on or possible creation of new business models, new firms or new technologies and services. This should be taken into account in the analysis of responses received.¹⁸⁷ This risk can also be mitigated by targeted consultation with research and innovation ecosystem actors, for instance through round tables, focus group meetings, hearings etc. DG RTD will help to identify key stakeholders and facilitate engagement.

Step (2) Assess potential impacts on research and innovation

The checklist below provides an indicative set of questions to assess whether the proposed initiative affects research and innovation¹⁸⁸.

Impact on research and innovation	Y/N
<i>Does the measure affect the research, testing or demonstration phase?</i>	
Does the intervention impact the generation of new ideas , their adaptation and application (e.g. from the knowledge base to industry)?	
Does it affect the cooperation (e.g. circulation of data, research results or researchers) between public and corporate R&D ?	
Does the proposed intervention potentially affect the establishment of, access to and functioning of R&D infrastructures ?	
Could the measure add or ease an administrative burden to testing, piloting or demonstrating new goods, services and products?	
Could compliance costs and time for the development of innovative technologies/solutions be affected?	
Does the intervention provide an equal playing field for public and private actors?	
<i>Does the measure affect application of innovative solutions or to bring them to market?</i>	
Is the intervention in an area with a relatively fast pace of innovation ?	
Could the initiative affect the introduction of future innovative solutions that may better achieve its policy objectives?	
Could the measure affect the innovation dynamics of specific markets ?	
Could the measure add or remove an administrative burden to bringing new goods, services and products on the market?	
Will the proposed initiative stimulate multi-disciplinary scientific research?	

¹⁸⁶ See COM(2016) 733; Europe's next leaders: the Start-up and Scale-up Initiative which contains actions to help start-ups and scale-ups that are also linked to SME and internal market impacts.

¹⁸⁷ See Ashford/Renda, 2016. <https://www.ceps.eu/publications/aligning-policies-low-carbon-systemic-innovation-europe>

¹⁸⁸ See Tool #20 on *Competiveness* for guidance on how to quantify the impact of legislation on the capacity of enterprises to innovate.

<i>Does the measure affect incentives around investment, growth, jobs or scaling up in Europe?</i>	
Could the legislation change the innovation incentives and choices for R&D investments?	
Could the intervention lead to a difference in innovation investment incentives in the EU compared to third countries?	
Could the intervention create or influence a preference for keeping a firm size below a certain limit?	
Could the intervention affect the incentives for companies to scale up in Europe?	
Will the proposed initiative lead to societal innovation?	

If the assessment leads to the conclusion that the proposed initiative has an impact (positive or negative) on research and innovation, further analysis on the specific impacts should be carried out of the policy options. Services should elaborate further on what the expected impacts are in the impact assessment report¹⁸⁹. DG RTD will support in developing an evidence base for policy options and the relation with innovation through the screening of relevant projects funded by Union RTD programmes. In specific cases, RTD can also provide additional assistance through short-term service contracts.

Step (3) Address legislative design considerations

The overall interaction between a policy option and innovation depends on a range of factors, including regulation design, implementation and enforcement. This section will help you to understand (i) the potential impact of the design of your proposal on research and innovation behaviours and outcomes, (ii) how to mitigate negative impacts on research and innovation and (iii) how innovation can be leveraged to better achieve policy objectives. Questions may not be relevant for all types of policies.

The table below describes a number of ways in which regulation and innovation interact. The description of each issue is followed by a series of questions designed to facilitate further reflection on whether and how it might be relevant to the options being considered in the impact assessment.

If you answer 'yes' to a question, please consider what steps you can take to maximise R&I capacities and the potential of innovation to achieve policy objectives. Where possible, the table points to specific instruments in Step 4 that can be applied to address the identified challenge. These are, however, by no means the only instruments that can be used.

¹⁸⁹ See Tool #8 on the *Format of the IA report*.

Legislative design considerations	Y/N	Relevant tools
<p style="text-align: center;"><i>Flexibility and future-proofing¹⁹⁰</i></p> <p>As far as possible legislation should remain open to innovative solutions that will help to achieve the policy objective of the measure being considered. It should aim for technology neutrality, and seek to avoid lock-in to one particular technology solution or technique. As a general rule, the less prescriptive and detailed a measure is, the more room it leaves for potential innovation. Very prescriptive and detailed regulation can create barriers to entry for innovative solutions, even if the innovation could contribute to policy goal of regulation.</p>		
Does the measure give operators as much flexibility as possible while ensuring that the policy objective will be met? Has the impact on innovation of the proposed measure been examined in the context of the proportionality test?		
Does the proposed measure contain targets? Is it designed to allow for the possibility of emerging technologies or processes that could better meet or exceed these targets?		2, 4, 5
Are any definitions used such that they will not become outdated with the appearance of new innovations?		3
Are provisions included that will allow for regular updates of the measure in case of rapid technological developments?		3
Is the legislation being proposed to address a time-specific issue?		3
Is the proposed measure adaptable to technological and scientific progress throughout the new sciences developments?		
<p style="text-align: center;"><i>Compliance costs</i></p> <p>All compliance costs divert resources from other purposes, potentially including research and innovation. Compliance costs may also discourage innovation if they fall disproportionately on innovators compared to incumbents, for example because of the costs of testing and obtaining authorisation. Testing and authorisation processes for regulatory compliance may require spending on research – this is sometimes considered "defensive" R&D as opposed to R&D that itself aims to develop new technologies, processes or products.</p>		
Have you taken steps to reduce the likelihood that the compliance costs of the policy option will divert resources from R&I activities?		2, 4, 5
Does the policy option seek to achieve a balance between requirements for "defensive" R&D and incentives for R&D into novel solutions?		4, 5
Have you taken steps to reduce unjustified variation in compliance costs between incumbents and potential innovators?		1, 2, 4, 5
Have you taken steps to ensure that compliance costs do not create a particular obstacle for innovative SMEs?		1

¹⁹⁰ EU legislation is future proof if it is proactive and forward-looking and provides the maximum legal clarity and certainty (Future Proof Legislation, EESC Opinion, 2016).

<i>Regulatory certainty and clarity</i>		
Regulatory uncertainty can hamper investment, including investment in R&I, because it increases risk and potentially also the cost of finance. Regulatory uncertainty can take different forms. It may be caused by real or perceived instability: is the regulator likely to change the regulatory framework in the foreseeable future? It may also be caused by a gap or lack of clarity in regulation, when it is unclear whether or not an innovation would comply. There are trade-offs between the need to reduce regulatory uncertainty and the need to maintain flexibility.		
Will the proposed measure minimise regulatory uncertainty?		
Does the policy option create clarity concerning the classification and treatment of emerging technologies where possible?		1, 2
Will the proposed measure expire at a certain date or is there a date fixed for its review and possible modification? If so, does it strike the right balance between providing regulatory certainty on the one hand and the possibility for adaptation to scientific and technological progress on the other?		3
<i>Timing and stringency</i>		
There is a balance to be struck with regard to the stringency of regulations. On the one hand, a regulation that is overly stringent or imposes requirements within an unrealistic timeframe may encourage the market to use existing solutions. This can hamper investment and the deployment of solutions. On the other hand, the need to meet ambitious standards can stimulate radical innovation, provided regulation leaves sufficient time and is sufficiently stable to allow the market to develop new solutions.		
Does the initiative introduce new requirements within a timeframe that is in line with the market's investment and innovation cycle?		
<i>The single market and harmonisation and interactions with other policies</i>		
A lack of harmonisation between Member States, and even between EU Member States and other countries, can discourage investment in the development of innovative solutions and create barriers to market access. The creation of a well-functioning single market can encourage investment in the scaling up of innovations.		
Will the proposed measure help to ensure a harmonised approach across the EU? Will it effectively address any identified problems created by differences in implementation in different Member States?		
Could the implementation of the legislation result in inconsistent requirements or regulatory practices between Member States in relation to innovative solutions?		
Is the proposed initiative aligned with requirements at the international level (e.g. international standards)?		
Does the proposal consider potential interactions with cross-sectoral legislation or requirements governing different sectors?		

Step (4) Apply tools to leverage the potential of innovation and reduce negative impacts

This section provides a non-exhaustive list of instruments and approaches that can be used to improve the design of your legislation to make it more innovation friendly and to leverage innovation to better achieve your policy objectives. These options have specific characteristics that need to be taken into account on a case-by-case basis in order to assess their case-specific relevance and opportunity.

DG RTD can provide additional expertise and practical guidance to help you to apply these tools.

Please also refer to Tool #15¹⁹¹ for support in assessing whether the choice of different policy instruments (e.g. directives versus regulations) could allow you to achieve better outcomes for innovation.

1. Experimentation clauses

An experimentation clause enables the authorities tasked with implementing and enforcing the legislation to exercise a degree of flexibility in relation to innovative technologies, products or approaches, even if they do not conform to all existing legal requirements.

Experimentation clauses can be appropriate when detailed product or technological characteristics have to be defined in legislation, but the policy goal could be met in the future by different, innovative solutions. They may also be proposed with the express intention of encouraging innovation and experimentation. A sophisticated experimentation clause is sometimes referred to as a regulatory sandbox – a framework that allows innovations to be tested in a real-world environment subject to regulatory safeguards and support.

The **Framework Directive on the Approval of Motor Vehicles** (2007/46/EC) defines the process by which Member States certify that a vehicle model meets EU safety, environmental and production requirements. Article 20 (*Exemptions for new technologies or new concepts*) allows Member States, subject to authorisation from the Commission, to approve technologies or concepts even though they do not meet certain requirements. Pending the Commission decision on whether to authorise the exemption, the Member State may grant provisional approval that is valid only on its territory. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007L0046&from=FR>

2. Outcome-oriented legislation

Outcome-oriented legislation sets a measurable objective without prescribing the exact mechanisms by which the objective is to be achieved. It gives concerned organisations the flexibility to decide how to achieve the objective.

Outcome-oriented legislation should, in principle, be the preferred option unless there is a clear need to define the exact mechanisms by which the objective is to be achieved. It avoids creating a situation of lock-in to a particular technology or approach, and creates a more level playing field for innovative technologies or approaches to compete against incumbents.

The **Regulation on personal protective equipment** (2016/425) lays down requirements for the design and manufacture of personal protective equipment to ensure the protection of the health and safety of users. The technical specifications listed in Annex II of the Regulation do not prescribe the specific technology or materials to be used provided they do not adversely affect the health or safety. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0425>

¹⁹¹ See Tool #18 on *The choice of policy instruments*

3. Sunset clauses

Sunset clauses terminate or repeal some or all provisions of a legal text after a specific date, unless further legislative action is taken to extend them. They can be used to ensure that legislation does not become an obstacle to innovation in rapidly changing market or technological environments. They can also serve as a tool for legislative experimentation, as they allow the lawmaker to test a new legal approach or regulatory framework for new technologies in a clearly delimited way. The risk of regulatory uncertainty must however also be taken into account when considering their use.

The **European Union Agency for Network and Information Security** (ENISA) was created in 2004 for an initial period of five years. Article 25 of Regulation (EC) No 460/2004 specified that its operations must be evaluated in order to determine whether its mandate should be extended. Under Regulation (EU) 526/2013, ENISA received a new seven year mandate, with a possibility of extension following an evaluation (Article 32, 36). The temporary mandates reflect the rapid evolution of information and communication technologies, the changing threat landscape and the evolution of Union policy in this field.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:165:0041:0058:EN:PDF>

4. Test of alternatives

A test of alternatives requires applicants for regulatory approval to consider potential alternatives, and to justify why their chosen solution is the optimal way to meet the policy goals underlying regulation. Applied rigorously, the requirement to examine alternatives has the potential to encourage innovation and the search for new approaches to existing goals.

A test of alternatives may be relevant when projects, products or technologies have a negative impact on a core regulatory objective like consumer or environmental protection or even fail to meet standards, but a regulator nonetheless has reason to approve due to their wider benefits. In such cases, a test of alternatives can help to ensure that the desired wider benefit is achieved using the best available technology.

The **Environmental Impact Assessment Directive** (2011/92/EU) defines the environmental impact assessment to be applied by Member States when authorising projects likely to have significant effects on the environment. Article 5 specifies that developers must submit an outline of the main alternatives they have studied, and explain the reasons for their choice, taking into account the environmental effects.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0092&from=EN>

5. Top-runner approach

The top-runner approach refers to legislative provisions that envisage the updating of a requirement in order to reflect higher performance levels that have become possible because of scientific or technological progress. If an innovation achieves a higher performance level, then that performance level becomes the new requirement. The top-runner approach encourages innovation by rewarding first movers, since other market operators are obliged to adopt that innovation – or seek their own innovation that performs equally well or better.

The **Industrial Emissions Directive** (2010/75/EU) aims to protect human health and the environment by reducing harmful industrial emissions. Member State authorities may grant operating permits for industrial installations only if those installations do not

exceed certain emission levels. The emission levels are set according to what can be achieved by Best Available Techniques, as defined in a Commission Implementing Decision. Article 74 provides for the periodic updating of the Best Available Techniques and the acceptable emissions level in accordance with scientific and technological progress.

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32010L0075&from=EN>

Combining different approaches and instruments

In practice legislation may combine different instruments and approaches.

For example, the Industrial Emissions Directive (2010/75/EU) includes provisions that correspond to the top-runner approach (Article 74), outcome-oriented legislation (Article 15, paragraph 2) and an exemption mechanism (Article 15, paragraph 5).

REACH (Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) combines the test of alternatives with the top-runner approach (Articles 55, 60 and 61).

3. INFORMATION SOURCES

Further information on how to screen initiatives/legislation from the innovation perspective; and detailed examples of where innovation acts as a barrier or driver for innovation are presented in the “Better Regulation for Innovation Driven Investment at EU level”¹⁹² and the Report on the screening of the Regulatory Framework¹⁹³.

- [Towards an Innovation Principle Endorsed by Better Regulation](#). EPSC Strategic Note, Issue 14, 30 June 2016.
- **Assessing the Impacts of EU Regulatory Barriers on Innovation**, Technopolis, 2017.
- [Regulatory screening: A short guide on the innovation effects of regulation](#). DG RTD 2014.
- [Better regulations for innovation-driven investment at EU level](#). DG RTD 2016.
- **The impact of regulation on innovation**. Blind, K., NESTA working paper, 2012.
- **How can EU Legislation enable and/or disable innovation?** J. Pelkmans, A. Renda. European Commission, 2014.
- **Regulation and Innovation: evidence and policy implications**. BERR Economics Paper N4. 2008.
- [Regulation and R&I policy: comparing Europe and the USA](#). Renda, European Commission, June 2016.

¹⁹² https://ec.europa.eu/research/innovation-union/pdf/innovrefit_staff_working_document.pdf.

¹⁹³ <https://ec.europa.eu/research/innovation-union/pdf/KI-04-13-129-EN-N-RegulatoryScreening.pdf>.

4. SUPPORT¹⁹⁴

- Information about the content or application of this tool: RTD-BR@ec.europa.eu.

¹⁹⁴ For further background material and examples, please consult DG RTD intranet page <http://intranet-rtd.rtd.cec.eu.int/evaluation/impact-assessment.php>.