European Commission

How to apply the Impact Assessment tool on Research and Innovation

A practical guide

Research and Innovation

How to apply the Impact Assessment tool on Research and Innovation - A practical guide

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How to apply the Impact Assessment tool on Research and Innovation

A practical guide

2017 Directorate-General for Research and Innovation

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The full report can be downloaded from
http://ec.europa.eu/research/index.cfm?pg=publications&lg=en .

1 Contents

R&I tool: the stepwise approach

1.Public consultation

- Include specific questions on innovation, emerging technologies, and impacts on companies.
- Be aware of possible biases (e.g. lack of new firms among respondents).

2.Potential impacts

Impacts on innovation can happen at **company** level and in various phases from research to commercialisation. They can also be measured at national and **EU**-levels.

3. Legislative choices

Legislative design impacts innovation pathways, thus:
- consider flexibility options in the design of the initiative;
- try to obtain room for time-bound experimentation (sunset clauses, derogations).

4. Apply

There are various forms which may convene such as:
- experimentation or sunset clauses or outcome-oriented legislation;
- top runner approach or test of alternatives.

1 PURPOSE OF THE GUIDE

The Directorate-General for Research and Innovation defines and implements European research and innovation (R&I) policy.

The Better Regulation Guidelines adopted in May 2015 provide a dedicated 'Research and Innovation Tool' on how to assess the innovation impacts of options for new legislative proposals. The Tool provides specific guidance on designing innovation-friendly legislation. Systematic application of the 'Research and Innovation Tool' would allow consider innovation needs thoroughly before adoption of the legislative proposal in line with the "innovation principle". This would challenge regulatory bottlenecks that hamper innovation and contribute to the Commission's objectives.

This practical guide is aimed at officials in the European Commission. It applies the tool to case studies on recently adopted sectoral regulations in the Energy, Food, Health, Transport and Water sectors.

The guide is structured as following:

- A guide on how to use the 'Research and Innovation Tool'; this includes an overview of methods and sources and a step-by-step guide.
- The application of the tool on recently adopted sectoral regulations in the Energy, Food, Health, Transport and Water sectors.

2 INNOVATION AND REGULATION

2.1 Types of EU legislation

The Commission Staff Working Document entitled 'Better regulations for innovation-driven investment at EU level'[1] provides an in-depth analysis of how the regulatory environment at EU level can hamper or stimulate innovation. The importance of a

[1]https://ec.europa.eu/research/innovation-union/pdf/innovrefit_staff_working_document.pdf

high quality and cost-effective regulatory framework has been confirmed for fast growing firms as well as for the innovation behaviour of traditional firms. As the document points out there is no simple causal relationship between innovation behaviour and the regulatory environment, but this link has to be examined on a case-by-case basis.

There are three types of EU legislation:

- **Legislative proposals**, such as regulations, directives, and decisions;
- **Non-legislative initiatives**, which comprise a number of so-called 'soft' regulations such as 'recommendations', voluntary agreements (self-regulation or co-regulation), but also technical standards.
  It also contains other instruments related to demand-side policies (taxes, subsidies, incentives, labelling schemes, etc.).
- **Implementing and delegated acts;** while the former include implementation measures, delegated acts allow amending, supplementing, or deleting non-essential elements of the legislative acts. Implementing acts are used in a wide range of policy areas such as energy labelling or authorisation of certain type of food additives.

2.2 Types of innovation

Innovation is a multifaceted phenomenon and depending on its sources a variety of types can be distinguished showing that innovation is not limited to new product development. For the purposes of this Guide, we highlight the following innovation types:

- **Technological innovations** "comprise new products and processes and significant technological changes of products and processes. An innovation has been implemented if it has been introduced on the market (product innovation)" (OECD, 2002[2]).
- **Non-technological innovation,** "Innovation has both technological and non-technological aspects. The commercialisation of new products often requires the development of new marketing methods. Similarly, a new production technique will increase productivity only if supported by changes in organisation. Marketing and organisational innovations, therefore, are important dimensions of many firms' innovation activities, particularly in services" (OECD, 2009[3]).
- **Service innovation** "comprises new or significantly improved service concepts and offerings as such, irrespective of whether they are introduced by service companies or manufacturing companies, as well as innovation in the service process, service infrastructure, customer processing, business models, commercialisation (sales, marketing, delivery), service productivity and hybrid forms of innovation serving several user groups in different ways simultaneously" (European Commission, 2012[4]).
- **Social innovation** can be defined as 'the development and implementation of new ideas (products, services and models) to meet social needs and create new social relationships or collaborations. It represents new responses to pressing social demands, which affect the process of social interactions. It is aimed at improving human well-being' (European Commission, 2013[5]).

3 Applying the R&I tool

The following sections provide guidance on the different steps. Not all steps may be needed at all times. The R&I tool **should be applied a la carte**.

4 Step 1: Broaden consultation to capture research & innovation

The tool starts with the public consultation. The public online stakeholder consultation can be designed according to the relevant needs: if the new measure, for example, is on an emerging technology, it is useful to design specific questions to companies but also to other stakeholders such as consumer groups and other civil society organisations. They should include questions on potential impacts on research and innovation, on emerging techniques and technologies, impacts on companies planning to scale up in size but also the views of relevant other stakeholder groups.

Different surveys are developed for different types of stakeholders. This allows for more targeted questions and results can potentially

[2]http://www.oecd.org/innovation/inno/frascatimanualproposedstandardpracticeforsurveysonresearchandexperimentaldevelopment6thedition.htm

[3]http://dx.doi.org/10.1787/sti_scoreboard-2009-41-en

[4]http://ec.europa.eu/enterprise/policies/sme/regional-sme-policies/documents/no.4_service_innovation_en.pdf

[5]http://s3platform.jrc.ec.europa.eu/documents/20182/84453/Guide_to_Social_Innovation.pdf

be used and transformed into indicators if questions are introduced that ask for quantifiable information. If companies are targeted, the following questions[6] can be envisaged:

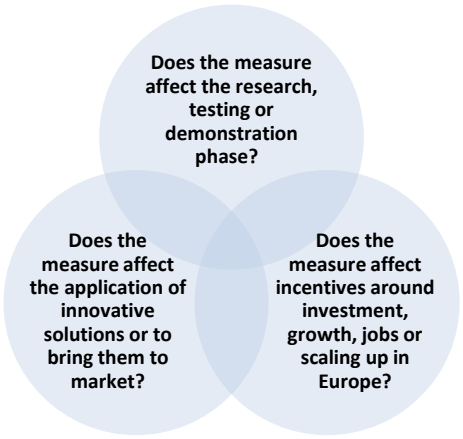
- Has your organisation introduced a product innovation in the past three years? (Y/N)
- Would the new regulation/intervention stimulate you to conduct more research and innovation activities?
- Would the [new intervention] affect innovation in your sector? (Y/N)
- If yes, where would that be? (Y/N options for the sub-questions:)
  - Testing, piloting, demonstrating
  - Market entry (will extend/limit competition)
  - Price (will affect prices in the sector)
  - Product characteristics
  - Market formation (diffusion, commercialisation potential)
- What would be the impact on your innovation activities following the adoption of the regulation?
- Would the new regulation hinder/stimulate co-operation with other partners in the innovation process?
- Would the new regulation affect the time of your development of innovative technologies/solutions?
- Is the regulation adapted in a timely way to technological progress?
- Would the regulation potentially give rise to legal uncertainties related to your research and innovation activities?
- Are you planning to scale up any introduced product or process innovation and do you think that the intervention would have a negative/positive impact on these activities of yours?

5 STEP 2: ASSESS POTENTIAL IMPACTS ON RESEARCH AND INNOVATION

The indicative set of questions below can help assess whether the proposed initiative affects research and innovation.

[6]Questions should be adapted to the individual assessment.

Figure 1 Questions to assess potential impacts on research and innovation



Source: Better regulation toolbox (2017), Tool#21
Layout: Technopolis Group

These three questions are the main pillars of a **scoping exercise** which is equally the focus of the problem analysis part of the IA. If the assessment concludes that the proposed measure has an impact on research and innovation, further analysis should be carried out in the comparison of the policy options.

The checklist of the R&I Tool provides an indicative set of questions to assess whether the proposed initiative affects research and innovation.

Question set 1:

Does the measure affect the research, testing or demonstration phase?

The first set of questions is related to the impact in the first phase of development such as the generation of new ideas, their adaptation and application, the co-operation, the establishment of R&D infrastructures, the testing, piloting or demonstrating phase. To this end, one needs to explore what are the main research and innovation needs in the sector and which of those needs might be affected by the proposed intervention.

The following dimensions should be considered for this question. While some can be addressed simply by EC colleagues themselves (sources are detailed in section 5.3), some aspects can also be formulated as questions for the public consultation or be addressed through external studies.

- Which research, technological areas and industry sectors are potentially related to the proposed new regulation?

  Check: Eurostat R&D statistics, Key enabling technologies Observatory

- Which key research institutions and research centres are potentially affected?

  Check: Cordis, Research and Innovation Observatory

- Who are the main research and innovation stakeholders potentially affected?

  Check: Eurostat R&D and CIS data

- Which research and technological clusters are potentially affected?

  Check: European Cluster Observatory Data

This question can also explore how a new regulation would fit with existing ones (is it complementary, does it address aspects which have not been tackled so far, or would the new regulation conflict with existing ones?).

In case the IA is not related to a possible review of existing legislation, answering this question requires a screening of regulation, which has been laid out in the Regulatory Screening[7] already.

A short recap of the process:

- Identify relevant existing regulation in the field;
- Narrow down the selection and assess the relevance for innovation for example through expert workshops or interviews;
- Identify relevant data that can establish a link between regulation and innovation (e.g., patent data, trade data) which is also used for analysing the broader context;
- Use case studies to identify where a given regulation is seen as a barrier.

This question addresses underlying factors (incentives and choices) as well as resources from a company perspective. In the area of knowledge it departs from the company-perspective and adds public sector research and infrastructures.

Question set 2:

Does the measure affect the application of innovative solutions or to bring them to market?

The second set of questions relate to the market entry and commercialisation of innovative solutions such as to the pace of innovation, the introduction of future innovative solutions, and to administrative burden related to the commercialisation of innovations.

If the intervention directly or indirectly addresses innovation in the **private sector**, the following key indicators can be collected through available sources or, if it concerns expected/potential/future developments, the stakeholder consultation and external studies can be used to provide insights. The policy intervention can be put into perspective based on data collected through e.g. workshops, interviews, surveys. The following questions will help to identify how the measure affects innovation in the sectors:

- Which industry sectors are addressed directly and indirectly?
- Who are the main innovation stakeholders?
- What are key features of the industry structure (i.e. are there several or only a few small or large firms? Are there dominant firms?)

  Check: Eurostat Structural business data

  Indicator: Number of firms by firm size and by sector

- What is the innovation potential in the (these) sectors? What are the innovation trends and challenges?

  Check: Patent data (Eurostat, OECD, EPO/USPTO)

  Indicator: Evolution of patents in relevant patent classes

- Is there technological or other innovation types in the sector(s)?

  Check: Eurostat Patent statistics at NACE level and by country or ESPACE, the direct search at the European Patent Office.

  Indicator: Absolute number of patent applications for the past 5-10 years; average annual growth of applications for the past 5-10 years by industry sector.

  Check: Eurostat Community Innovation Survey: Enterprises by specific types of innovation, NACE Rev. 2 activity and size class [inn_cis8_spec]

  Indicators: Number or share of enterprises that developed goods, services, process innovations, marketing or organisational innovation (various breakdowns possible).

If it directly or indirectly addresses **public sector research** stakeholders, the following aspects and indicators could be relevant:

[7] https://ec.europa.eu/research/innovation-union/pdf/RegulatoryScreening_short_guide.pdf

- Identification of the key public sector organisations: Which organisations are addressed directly and indirectly? How many people are affected potentially?

  Check: Eurostat, Data on HRST at national level [hrst_st_ncat]

  Indicator: Employed HRST by category, sex, age and NACE Rev. 2

Question set 3:

Does the measure affect incentives around investment, growth, jobs or scaling up in Europe?

The third set of questions relates to the longer-term impacts such as investments, growth, jobs and scaling up. Specific areas to explore include if the new measures affect innovation incentives and choices for R&D investments, if it may lead to a difference in innovation investment incentives in the EU compared to third countries, or if it leads to societal innovation.

This set of questions asks about potentials and as such can make use of qualitative aspects which can be addressed in the stakeholder consultation as well as in external studies, or quantitative analysis which is typically the source of projections.

The set of questions addresses mainly the effects on companies and markets. The impact area matrix below indicates the various areas where an intervention can typically impact markets.

Table 1 Impact area matrix

Impact area	Type of intervention	Expected impact	Indicator(s)	Data source(s)
Goods and services	• Product regulation • Price regulation • Consumer safety regulation	- Price caps reduce innovation incentives + Minimum prices secure minimum turnover and decrease risks; - non-regulated prices allow monopoly pricing	Share of companies who introduced new to the market products in the past three years	CIS (broken down by country and sector)
Market conditions	• Market entry regulation • Antitrust • M&A	- Prohibits market entry of potentially innovative newcomers +Reduces competition for incumbents, e.g. for infant industries - Dominant (innovative) companies have limited incentives to invest further in R&D + Allows competitors to enter the market and put pressure on dominant companies - M&A restrictions limit takeover pressure and incentive to innovate +M&A allows efficient takeover of innovative firms + M&A restrictions protect management from short-term market pressures	Herfindahl index Share of SMEs within the sector	Number of companies in sector: Eurostat or private company databases such as ORBIS or AMADEUS Market share calculation: ORBIS or AMADEUS M&A: M&A Research Catalyst
Administra-tive burden	• Regulation	- Additional compliance costs	Nr of days to register a new company	eGovernment Report
Rewards	• IPR regulation	+ Provides security and incentivises tangible innovation + incentive to invest in R&D due to monopoly rights	Nr of patent applications/ Growth of patent applications at EPO	Eurostat; EPO: espacenet
Indirect effects in other sectors	• Health and safety regulation • Environmental regulation • Competition law	- Reduces rents for innovators + Creates incentive to develop new processes with higher work safety + Creates incentive for new eco-friendly products and processes by creating temporary market barriers (Porter Hypothesis) - Compliance costs limits R&D budget - Prohibits R&D Cooperation + Increases and secures incentives to invest in innovation	Technological spillover: Number/growth of patents with IPCs in initial class and other destined field Growth of 'green' goods	EPO: espacenet Eurostat: PATSTAT
Human resources	• Employment legislation	+ Job security - Higher adjustment costs	e.g.: Job vacancy rate (JVR) by sector	Eurostat: Labour Force Survey (LFS), Job vacancy

Impact area	Type of intervention	Expected impact	Indicator(s)	Data source(s)
Financial resources	• Liability law • Bankruptcy laws	+ Increases acceptance and diffusion among consumers - Too high liability reduces incentives to develop new products + Increases confidence of creditors to invest in innovation - Restriction to acquire external funds for risky investments		
Firm size	• Market entry regulation • Competition law	*See above Market conditions*		
Generation of new ideas	• Direct measure	+ increases knowledge pool within an organisation/country	Scientific publications	Scopus, Web Of Science
Co-operation	• Competition law		Share of BERD/HERD	Eurostat, OECD

Source: EC (2015), Blind (2012); compilation: Technopolis Group

5.1 Interpreting the findings

The analysis of existing data and, in particular, longer-term trends in the past can be good predictive means for future developments. Innovation and research behaviour of firms tend to remain relatively stable but if there were external shocks – e.g. an important policy initiative that benefitted particular sectors or technologies, this may show with patent data, R&D investments, employment data etc. The question one needs to address is thus, were there fluctuations in growth or was the rate constant? What caused the changes?

Examples:

- *Phasing out regulation* on incandescent light bulbs (which is being implemented throughout many regions of the world with differing phasing-out starting years) will most likely show in R&D expenditure, patent, and trade data.
- *Bans* are likely to have the most obvious direct and measurable effects while other types of regulation are less likely to produce clear effects (evidence: trade data).

5.2 Innovation indicators

Innovation measurement is often limited to R&D investment (inputs) and patents (outputs). These are limited proxies. Innovation activities can lead to patent applications but a large share of innovations remain non-patented. Thus, looking only at patents is thoroughly underestimating innovation activities. There are also companies who do not invest in innovation but are innovative (see data from the Community Innovation Surveys, OECD 2010). In addition to the various indicators provided through the Community Innovation Survey, the following table lists a few suggestions such as intangible investments or new products.

Several indicators serve different purposes: they can for example be an input but also an output or impact indicator. For example, R&D expenditure is typically used as input indicator, but how much a company or country may spend on R&D may also depend on other factors, thus it can also be an impact indicator.

5.3 Methods and sources

This section focuses on the methods and sources that can be used for obtaining the relevant information and data needed to provide a better understanding on the "Factors affecting R&I" (Step I of the tool) and "How do these interventions affect the innovation capacity of firms" (Step II of the tool). The various sources are captured in section 5.3. The overview of methods and data sources could be useful in identifying all relevant R&I aspects in the problem definition of the impact assessment. This can be seen as complementary to the stakeholder consultation.

5.3.1 Desk research

The Eurostat database contains dedicated sections, where more general secondary data can be found as well as specific industry related data.

The section on **Industry, trade and services** which includes the "Structural Business statistics" provides relevant information on business demography and various data breakdowns on:

- The number of firms/new firms (in a given NACE 2-digit level sector by country and year).

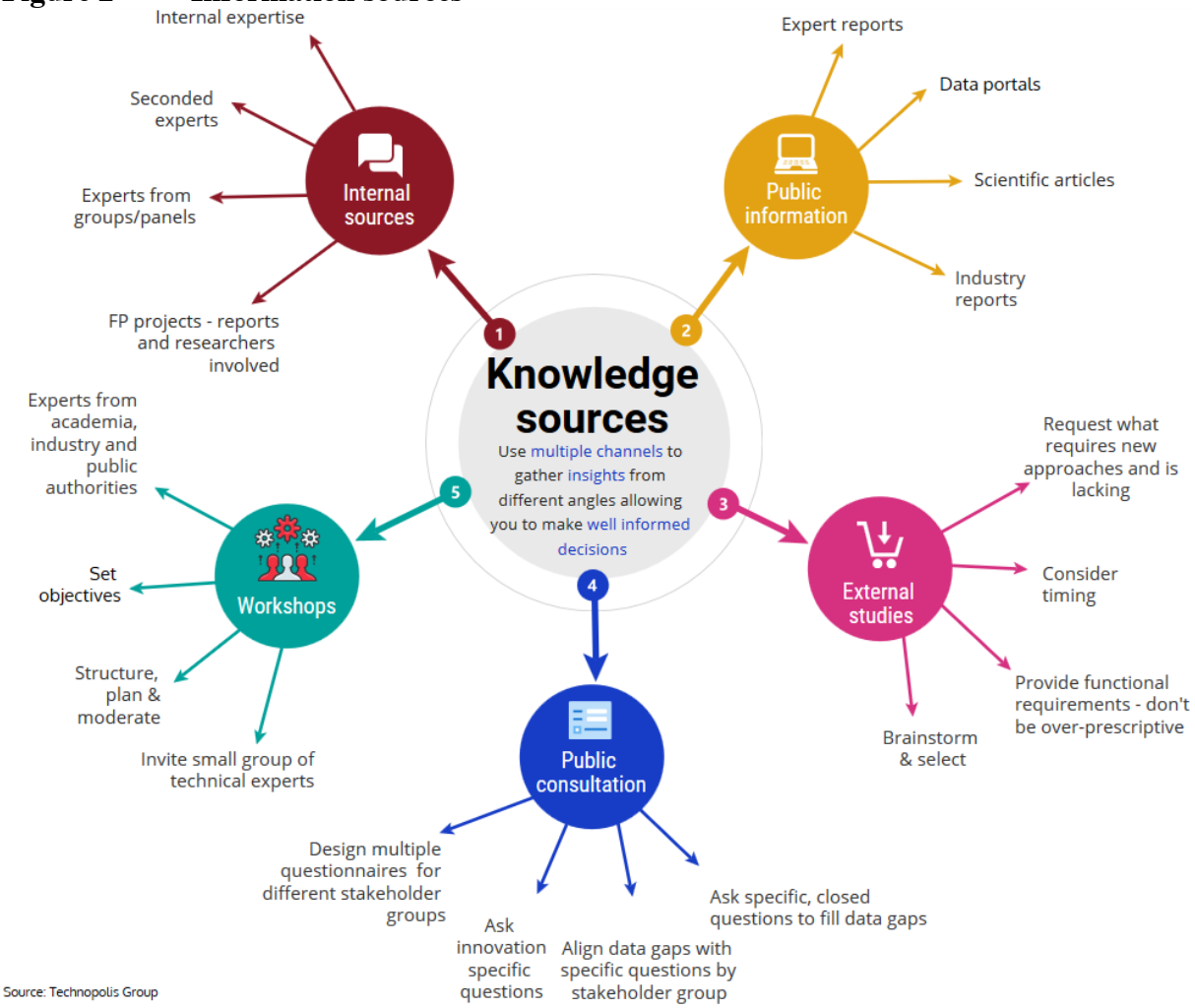
- The employment figures (by NACE sector, country and year).

This can be used as source of indicators for relevance/irrelevance of a given industry and it can also show differences at MS-level.

The section on **Science and Technology** offers several types of indicators such as:

- R&D statistics broken down to expenditure and personnel.
- GBAORD – Government budget appropriations by socio-economic objective (NABS).
- Community Innovation Survey – based on bi-annual surveys, this data source allows distinguishing innovating from non-innovating firms. There is a large core set of indicators available over a long period while other indicators are ad-hoc; this is a particularly **rich data source for firm-level information** (publicly aggregated at industry-level).
- Human resources in Science and Technology (HRST) – includes stock and flows of HRST by year, country and sector. You can check how many researchers or R&D personnel are working in a given NACE 1-digit level industry, by sector (such as public or private), or country.
- Intellectual property rights – this section includes available data on European patent office (EPO) patent applications as well as USPTO granted patents. Other IPR such as trademarks and designs are equally available. Data is available at NACE-level.

Figure 2 Information sources



Source: Technopolis Group

Some of the data is also available at **regional level** (NUTS1 or NUTS2-level).

There are other public and private data sources which provide data on a general level, or dedicated sources. Examples that bring together general data are:

- OECD : Main Science and Technology Indicators
- UN : Statistics Division
- EU : Open Data Portal
- EU: European Data Portal
- Statista

While the entry points above have the advantage that most often EU-28 MS are addressed, there are several sources that provide data and information for a limited set of indicators and/or countries. More specific data can be found within:

- Global entrepreneurship monitor (provides long-term information on entrepreneurial behaviour and attitudes of individuals and the national context and its impact on entrepreneurship);
- Intan-Invest.net (data on intangible investment).

5.3.2 Internal sources

The EC services have access to monitoring data collected by spending DGs. A first check could be the project titles and short summaries of FP7 and Horizon 2020 research projects under the various priorities in Corda. This may identify a limited set of projects, and speaking to the relevant project officers may allow identifying reports, data sources, or individual participants that could be addressed for further insights.

5.3.3 External studies

There are limits in collecting the information in a timely and cost-effective manner. Therefore, one of the main information sources in IA exercises are dedicated studies through external service providers.

Trying to obtain information from external sources can take substantial lead time.

However, it is an opportunity to incorporate innovation related tasks in the terms of reference (ToR). The specific questions should be developed following the initial check of publically available data and specific objectives of the intervention planned.

Tasks could for example include:

- Identification of innovation trends within the sector; main trends in the past ten years and future trends;
- Identification of drivers and barriers to innovation. Which regulatory barriers hamper (technological/organisational/ marketing) innovation;
- Identification of good/bad-practice examples at MS-level of EU-law transposition and its impact on innovation.

Service providers need to develop a sound approach in terms of methods, timing, and resources. The task descriptions in the TOR provide the framework - therefore it is important to describe the expected outputs ("functional requirements"), but not to be too prescriptive in terms of the methodology/approaches to be used.

5.3.4 Consultation Methods

There are different sources and methods that can be used by the DG and external service providers to consult stakeholders.

Table 2 below gives an overview of advantages and disadvantages of each method.

Table 2 Advantages/disadvantages of consultation methods

Method	Advantage	Disadvantage
Workshop	• conveys the messages and input from a larger set of stakeholders • identifies main trends, drivers and barriers, etc. • feedback on reliability and quality of results	• needs substantial effort to identify mixed set of limited set of relevant participants • critically depends on the limited number of workshop participants
Focus group	• targeted, small group steers and validates on a specific item	• needs substantial effort to identify mixed set of relevant participants • possible bias
Interviews	• counterbalance input from public consultation • provide new insights otherwise not yet covered	• requires sound development of interview questions and selection of interview partners • possible bias
Sectoral survey	• has a wide outreach to get feedback from a large audience • provides new insights otherwise not yet covered	• survey fatigue • needs targeted, well-formulated and short questions • difficult identification of counterfactual group • substantial effort to obtain reasonable response rate

Source: Technopolis Group

Figure 3 Step 2 checklist

6 STEP 3: ADDRESS LEGISLATIVE DESIGN CONSIDERATIONS

This section addresses legislative measures and their designs. This step of the R&I tool includes questions on flexibility, regulatory costs, and future-impacts of legislation. It serves as a check list for Step 4.

The various questions ask for a holistic analysis when new legislation is proposed. These questions summarise potential impacts on innovation which may not always play a prominent role in impact assessments.

7 STEP 4: APPLY TOOLS TO LEVERAGE THE POTENTIAL OF INNOVATION AND REDUCE NEGATIVE IMPACTS

To enable a faster market entry without jeopardizing consumer safety, there are legal options which are, so far, not widely used but could potentially decrease the time lag between regulation and innovation. This is discussed under the term 'experimental legislation'. Where it is a legal option, it can be used for example to 'test' how an innovative service or product should be regulated. It is a means to collect 'hard' evidence while testing new laws and regulations on a small scale and for a limited period before permanent laws – applicable to the entire population - are enacted.[8]

The following approaches are distinguished in the tool:

- **Experimentation clauses** – provide a temporary legal framework allowing for new technologies or concepts to be tested. They are useful when one does not know (enough) about the effectiveness of new rules. They function as a derogation to the applicable law.
- **Outcome-oriented legislation** - sets a measureable 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. This principle is key in innovation procurement ('functional procurement') since it leaves room for innovative concepts and ideas. The same is true for legislation. However, it can only be applied when planned legislation aims at specific targets, for example energy efficiency.
- **Sunset legislation/clauses** – are '*provisions in a regulation that sets a time limit on a new piece of regulation such that it actually expires, in whole or part, after a fixed period'* (Mandelkern Group Report 2001). The clause is usually linked to a review before the expiry date. Its main advantage is that it forces the legislature to analyse the effects of a particular law or regulation after its implementation.

Sunset legislation has been experimented in the US, Australia, and Germany[9].

Ex-ante assessments often include checking the adequacy to include a sunset clause. This can, de facto, mean requesting for evaluation after a given period. Depending on the results of the evaluation, it can lead to the termination of the measure.

- **Test of alternatives** – is a means to ensure that e.g. technical solutions which have negative side effects require an alternative testing to reach an objective. In practice, this approach may be time consuming and costly since technical solutions often require meeting established technical standards. If they are absent, innovative alternatives need time to obtain approval.[10]
- **Top-runner approach** – is a product-related environmental policy approach aiming at market uptake of the most environmentally friendly or resource efficient and/or energy efficient technology within a certain product group. The 'best available' product on the market is declared standard. This has to be met by other products within a certain time span. The approach thus promotes technical progress and accelerated diffusion of environmentally friendly products.

[8]Legislative experiments are modelled from natural experiments, following their set-up with a randomly chosen test group and a control group. This form can be found in variants in form of living labs, model projects, pilots, etc. Legislative experiments are means to collect evidence through e.g. monitoring. These data which can be used to inform on future processes and outcomes (Veit/Jantz, 2010, van Gestel/van Dijck, 2011).

[9]See Jantz/Veit 2010 in their expert report, which analyses the experience with sunset legislation in the US, Australia, Germany and Switzerland.

[10]See for example 4silence.nl. This Dutch start-up developed an innovative traffic noise reduction approach by 2012. In the absence of technical standards pilots were enabled through regional road authorities which proved the technology and set the ground for including it in legislation. By 2016, a team of acoustic experts from various public and private organisations worked on the technical standard which sets the new approach as an acknowledged method. This is required in order to commercialise the product more widely.

The concept of experimental legislation shares a number of features with other approaches. They all aim to provide a small-scale testing ground before a new regulation is implemented. Throughout the test, information ("evidence") is collected which supports the decision-making.

Table 3 recaps the advantages and disadvantages and provides legal aspects as well as examples. It also includes a current example of innovation-friendly regulation in the area of energy.

Example:

An example of EU-level legislation which falls under this heading is **Directive 1999/85/EC** introducing the possibility of applying on an experimental basis a reduced VAT rate on labour-intensive services to create jobs. The Directive was tested in a limited number of Member States. At the end of the four-year test, the EC concluded based on the Member States' reports, that there was no causal link between a reduced VAT and creation of jobs.

Nevertheless, in 2009, the Council adopted Directive 2009/47/EC which allows on a permanent basis the optional use of reduced VAT rates for certain labour-intensive local services.

Figure 4 The process of experimental legislation

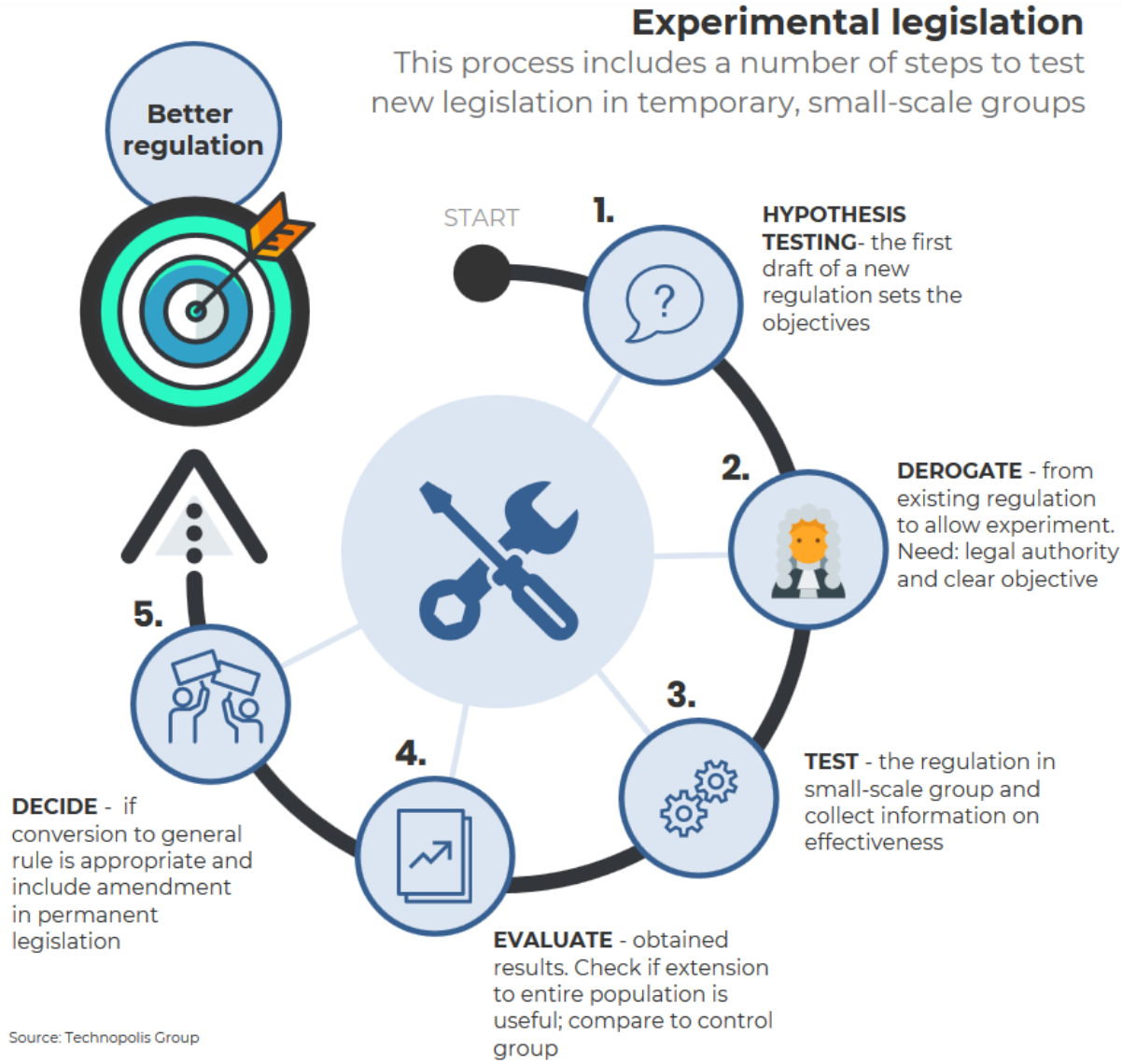


Table 3 Legislative approaches

Type	Advantages	Disadvantages	Legal aspects	Examples/appraisal
Experimental legislation	Allows legislators to submit new rules to a reality check ; Testing effectiveness of rules ; Testing effectiveness on small-scale basis ; Produces information : source of evidence ; Alternative to precautionary approach ; Avoids regulatory delays ; Opportunity to legislators to have iterative learning;	Potentially, citizens do not take them into account due to temporary character and inherent uncertainty	Potential violation of fundamental principles of law (legal certainty and equal treatment); Not always enabled through constitution or case law; Not widely used due to lack of information/ training of lawmakers; Aims at continuity, helps for long-lasting problems and incremental improvements in products and services	Dutch experimental dynamic speed-limit regulation (2009-2012) (Evaluatie praktijkvoeren Dynamische Maximumsnelheden 2010); Germany: "Autopilot-law" (legislation on self-driving cars), February 2017. The law will be reviewed in 2 years since aspects on liability and data protection are not fully resolved. The law was possible following a change of the Vienna Convention on Road Traffic; Highly useful for environmental legislation
Outcome oriented legislation	Sets a measureable objective without prescribing the exact mechanisms; Allows for flexibility;	Potentially, citizens do not take them into account due to temporary character and inherent uncertainty		
Sunset legislation/ sunset clauses	Allow for adaptation of rule; Determine expiry of unnecessary / outdated acts; Help avoiding overregulating a sector and unnecessary burden; Impose expiry of regulation that do not keep up with latest state of technology; Can be used to temporarily stimulate innovation (e.g. through temporary tax credits)	Costly for the administration (review requirements, burden of proof to demonstrate that regulation is not necessary); If no ending is planned, more likely to be extended quasi automatically (US) or incremental modification (AU); General sunset clauses did not proof to be efficient and effective (at US federal states level); Potentially high compliance cost	Used where legislation did not pass parliament, (e.g. presidential decree) Mainly US (agencies, programmes) and Australia; Used for temporary or rapidly evolving problems; Sunset needs to be adapted to technology life cycle	In Germany review (after 5 years) is required in majority of the federal states legislative acts. At state level, only in contested areas (e.g., freedom of information act, fight against terrorism); Switzerland introduced a mandatory evaluation of new legislation in 2000; Sunset can be incorporated in instruments providing an incentive such as temporary tax credits
Test of alternatives	Development of better solution	Time consuming; Expensive	Testing may require prior approval and thus exemptions from legislative rules	Dutch case of allowing a pilot testing of innovative traffic noise reduction technology (see 4silence.nl)
Top Runner Approach	Best available technology standard; Helps create new market and diffusion of energy efficient devices; Incentive to develop energy efficient devices	Once very high level of efficiency is achieved, often 'unproportional' high development costs to achieve further efficiency level.		Ecodesign directive, energy consumption labelling (energy star)

Type	Advantages	Disadvantages	Legal aspects	Examples/appraisal
Legislative experiments	Checks existing laws in real world Gather information/ evidence Limit uncertainties Small scale	See legal aspects	Arbitrary selection conflicts with principal of legal certainty.	Germany: Praxistests, Modellversuche
Living Labs /Prooftuinen/ pilot projects	Policy experiment testing policy effects on human behaviour; Small scale testing; Inclusion of citizens; Allows for collection of evidence		Requires legal backing for derogation; Includes experimental legislation	Netherlands, Belgium (Flanders), Denmark, etc. see : http://www.openlivinglabs.eu/ https://www.iminds.be/en/gain-insights/digital-health/innovation/validation-lab/care-living-labs https://vito.be/en/energy/smart-energy-city-and-district-planning/vision-development-and-test-projects
Innovation-friendly legislation	Introduces a flexibility element	If not-binding, the opportunity may not be taken	If legally binding, a revision may be introduced in order to adapt the element (e.g., according to technological progress)	Clean energy package: https://ec.europa.eu/energy/en/topics/energy-strategy-and-energy-union/clean-energy-all-europeans

Source: Ranchordas (2014), Veit/Jantz (2010); van Gestel/van Dijck (2011), own research;
Compilation: Technopolis Group

Examples from the **Clean Energy for All Europeans package** as proposed by the Commission[11]:

Priority access to the grid for RES in the **new Electricity Market Design Directive**.
Article 11, paragraph 2:

When dispatching electricity generating installations, transmission system operators shall give priority to generating installations using renewable energy sources or high efficiency cogeneration from small generating installations or generating installations using emerging technologies to the following extent:

(a) generating installations using renewable energy sources or high-efficiency cogeneration with an installed electricity capacity of less than 500 kW; or

(b) demonstration projects for innovative technologies.

Article 25 of the **new Renewable Energy Directive** is setting a minimum target for renewable energy in the transport sector to boost innovative low-carbon technologies and create a level playing field - advanced biofuels and biogas produced from feedstock listed in Annex IX, renewable liquid and gaseous transport fuels of non-biological origin, and renewable electricity

[11] Still under discussion in the EP and the Council.

8 SECTORAL APPLICATIONS

The following table can be used to structure and summarise the analysis and findings based on indicators, data sources, and methods. In this section, five examples on the application of the guide are provided. For this application, the main focus is step 1 and 2 of the R&I tool.

Does the measure affect the research, testing or demonstration phase?	**Relevant (y/n)**	**Data sources/ Methods**	**Indicators**	**Main findings**
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 **co-operation** (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**[12]?				
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?				
Does the measure affect the application of innovative solutions or to bring them to market?				
Is the intervention in an area with a relatively **fast pace of innovation**?				
Could the intervention 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?				
Does the measure affect incentives around investment, growth, jobs or scaling up in Europe?				
Could the measure 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 measure lead to **societal innovation**?				

[12]"*Research infrastructure means facilities, resources and related services that are used by the scientific community to conduct top-level research in their respective fields and covers major scientific equipment or sets of instruments; knowledge-based resources such as collections, archives or structures for scientific information; enabling Information and Communications Technology-based infrastructures such as Grid, computing, software and communication, or any other entity of a unique nature essential to achieve excellence in research*" (ERIC, 2010).

8.1 Sectoral application: Energy

The energy example looks at the changes proposed by the European Commission to the 2010 **Energy Labelling Directive and Ecodesign Directive**.

The public consultation included the following question on innovation: "has the correct level of ambition in minimum ecodesign requirements product energy efficiency classification been set for implementing measures and voluntary agreements for the following product groups, taking into account economic technical potential, innovation and market developments?"

The problem addressed by these Directives is that products can have a negative impact on the environment depending on how they are produced, used and disposed.

The Impact Assessment (IA)[13] conducted in 2015 identified the following problems in the implementation of the Directives:

- most products are now in the top classes of the energy label, it is difficult for consumers to distinguish between models;
- the introduced energy labels of « A+ », « A++ » and « A+++ » were less effective as planned;
- non-compliance of the Directives, partly due to weak enforcement of national market surveillance authorities, leads to a loss of about 10% of envisaged energy savings.

These problems do not only affect energy and environmental savings targets, but also affect consumers as their energy bills are not reduced as much as envisaged.

Thus, the objective of the IA was to update the policy framework so that it continues to ensure the functioning of the internal market, reduces high energy consumption and other negative environmental impacts of products. In addition, the envisaged update of the framework aimed to ensure that:

- a relevant update is useful and easy-to-understand for consumers; that it can be enforced easily and appropriately;
- the policy is simple, apt for purpose, robust to future developments, and cost-effective;
- it remains in line with international obligations.

Although innovation impacts were not directly covered in this IA, decisions regarding the composition of the Energy Labelling Directive and Ecodesign Directive can affect industries' product strategies. More information in this regard can be found in the study analysing the impact of the Ecodesign and Energy Labelling directives on R&D and Technological Innovation[14].

The following recaps what the IA addressed in terms of the block of questions included in the R&I tool.

[13]Commission Staff Working Document. Impact Assessment. Accompanying the document. Proposal for a Regulation of the European Parliament and the Council setting a framework for energy efficiency labelling and repealing Directive 2010/30/EU, SWD(2015) 139 final.

[14]https://ec.europa.eu/energy/sites/ener/files/documents/201405_ieel_product_innovation.pdf

Does the measure affect...	Main findings	Data sources/Methods	Indicators
The research, testing or demonstration phase?	• The directives reduce the commercial and financial risk of innovation for some of the product sectors. • Industry stakeholders are strongly involved, especially in the design of regulations due to the framework directives. If regulations are set in a way that the requirements can be met easily, this can hinder innovation. • Estimated administrative and compliance costs for manufacturers would be €7-12 million per year.	• Research study • stakeholder consultation • available data • ecodesign impact accounting model, incorporating the data from all preparatory studies and impact assessments done for ecodesign and energy labelling • Market surveillance data would be a good source	Potential indicator: Number of new to the market products by product groups The Commission's in-house Administrative Burden Calculator was used to calculate administrative costs for businesses
The application of innovative solutions or to bring them to market?	• Especially the Ecodesign Directive sets minimum standards and products that do not meet them cannot be sold and need to be taken off the EU market. • The Directives does not support single technological options, but the reduction of energy consumption and other environmental impacts. A single technological option may in the extreme lead to a single technological solution. • Increasing costs for innovation may arise due to specific Ecodesign regulations for certain projects, if these regulations are quite strict and require new and innovative products.		
Incentives around investment, growth, jobs or scaling up in Europe?	• positive impact on revenues both for larger businesses and SMEs.	• Secondary research, • stakeholder consultation	New products on the market (CIS), new jobs created (CIS),

8.2 Sectoral application: Food

Regulation (EC) No 258/97 on novel foods and food ingredients concerns food that was not consumed to a significant degree in the EU before 15 May 1997 (date of entry into force of the Regulation). In practice, novel foods are newly developed – innovative - foods and food produced by new technologies that might have a possible impact on food (most discussed new technologies have been those producing recombinant DNA or irradiation technology) as well as (exotic traditional) foods that have been imported from outside the EU. Novel food and novel food ingredients have to undergo a pre-market safety assessment and authorisation.

Stakeholder consultations in 2002 on a Commission discussion paper and subsequent evaluation have underlined the importance of and the need to develop and update the Regulation.

The main problems that were found in the implementation of the 1997 Regulation were:

- Traditional food which was not on the EU market before 1997, but for which there is information on safe use outside the EU, is also subject to the safety assessment procedure. Third countries perceive this as an unjustified barrier to trade for their traditional foods.
- The safety assessment and product authorisation procedure takes too long.
- The lengthy decentralised procedure duplicates the work and often generates unnecessary delays in the authorisation process.
- The authorisation decision is only addressed to the applicant. Others are only able to market the same food after notifying the Commission through an additional administrative procedure.
- Assessing and authorising the same substances within different legal frameworks causes repetition and creates an additional administrative burden.
- The general implementation of the Novel Food Regulation needs to be improved.
- Furthermore, there was a need for legal clarifications and updating.

As the Regulation focuses on novel foods that are the results of a costly and long-term research and innovation processes, the problems encountered had a direct impact on the private company's innovation behaviour, mostly because of the long authorisation processes and the uncertainties this brought about. This had a negative impact on the competitiveness of companies in the food sector.

The four major policy actions that have been the subject of the impact assessment[15] are:

1. Adjusted safety assessment and management for traditional food from third countries.
2. Safety assessment and authorisation procedure.
3. Authorisation decision.
4. Submission of application for several food uses.

For each policy action a number of options were presented.

Input was received through a stakeholder consultation and meeting in 2003, consultation of member States authorities in working group meetings in 2005-2006, an Interactive Policy Making (IPM) online consultation in 2006 and subsequent stakeholders consultations in 2006.[16]

The online questionnaire of 2006 asked for detailed data on markets, imports, employment, product shares, innovation costs, regulative aspects on time and costs, and regulative burden. Impact of various options including innovation and research was equally addressed.

[15] Commission staff working document (2008). Impact assessment for a Regulation replacing Regulation (EC) No 258/97 on novel foods and novel ingredients. Brussels [COM(2007) 872 final] [SEC(2008) 13]

[16] The questionnaire is included as Annex 4 here : https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_impact-assessment_en.pdf

Does the measure affect...	Main findings	Data sources/Methods	Indicators
The research, testing or demonstration phase?	• The impact on Innovation and research is measured for a number of options proposed for each Policy Action (PA). Two (of the four) proposed options for PA1 are expected to have a positive impact on innovation. A third option is expected to have a negative impact. • Option 2 for PA2 is expected to have a positive impact on I&R. • As the current Regulation does not have a highly beneficial impact on innovation and research, any improvement proposed for the authorisations process under PA3 already have a positive – for some options a significant – impact. • I&R would benefit from simplification (PA4)	• Mainly stakeholder consultation (most response from food industry); • in-house data collection; • IA results were investigated and valorised by several expert panels	The IA mentions the following indicators: - the "R&I efforts" as an indicator for PA1. - the "economics and attractiveness of new product development", "encouragement of innovation" are indicators for PA2. - the "food industry's enthusiasm for innovation and research", - the "administrative burden for new product development and market access" and "the overall efficiency of the safety assessment procedure" for PA4. The indicators are derived from the stakeholder consultation. Sometimes conclusions are added based on other sources. The CIS holds a number of Innovation and Research indicators that can be used for monitoring the R&I activities. In addition to this IA, the European parliament has done a complementary assessment that focuses on a number of key aspects of the 2013 proposal[17]
The application of innovative solutions or to bring them to market?	• The – in most cases positive - impact on product development of the several options under each PA was measured for all PAs. • As product development is closely linked to research and innovation, product development was reported under the heading 'Impact in Innovation and research'. Product development was mentioned under 'Impact on competitiveness, markets, trade and investment flows (including third countries)' • The revision is especially focused at simplifying the regulatory process (especially PA4) and to enable the applicants to apply for an approval by a single application covering novel food and food uses regulated under various regulatory frameworks.	• Stakeholder consultation, • in-house data collection. • IA results were investigated and valorised by several expert panels	The IA explores the effects of several types of authorisations

[17] These key aspects are: scope of 'Novel Food' definition, the efficiency and impact of the central authorization procedures on the various parties, the role of national authorities and agencies in the centralized system, and the proposed Regulation's coherence with other EU regulatory requirements.

Does the measure affect...	Main findings	Data sources/Methods	Indicators
	• PA3 is specifically focused at market admission. In the current regulation the authorisation decision is linked to the applicant, thus allowing only this applicant to market the novel food in the EU. Others who also want to market the food have to make additional administrative notification (simplified procedure). However, the main issue here deals with research that is invested in the innovative food (by the applicant) that could be covered by protecting the data presented in the application. The applicant wants to have a temporary 'monopoly'		
Incentives around investment, growth, jobs or scaling up in Europe?	One of the options for PA3, is Option 3: Generic authorisation plus data protection for certain foods	Stakeholder consultation	Data protection for a certain period

8.3 Sectoral application: Health

The following practical example of the application of the guide to the field of health uses the **Medical Devices regulatory framework**:

- Council Directive 90/385/EEC on active implantable medical devices (AIMDD);
- Council Directive 93/42/EEC on medical devices (MDD); and
- Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (IVDD).

An Impact Assessment (IA) was conducted in 2012 to update the regulatory framework for Medical Devices, dating from the 1990s[18]. In the current legal framework, medical devices are not subject to a pre-market authorisation by a regulatory authority. Instead, they need to pass a conformity assessment which, for medium and high risk devices, involves an independent third party, called a "Notified Body". Once certified, devices bear the CE marking and can circulate freely in the EU/EFTA countries and Turkey, meaning that the internal market for medical devices comprises 32 countries.

According to the Commission, the current Medical Devices regulatory framework needs to be amended because it is necessary to improve the level of protection of public health for all European patients and users, and at the same time, prevent Member States from adopting varying product regulations that could result in further fragmentation of the internal market. Also, due to imprecise legal requirements and different levels of expertise, human resources and powers of the competent authorities, the level of control exercised over Notified Bodies and over the medical devices placed on the market is also fragmented. The main systemic problems with the current regulation that the IA tries to address are: the oversight system of Notified Bodies, post-market safety, transparency and traceability of products, access to external expertise and management of the regulatory system.

The revision of the regulatory framework is interesting for the purpose of this guide because one of its objectives (overall objective C) is "to provide a regulatory framework which is supportive for innovation and the competitiveness of the European medical device industry". The other two overall objectives are as follows:

- Objective A: To ensure a high level of protection of human health and safety; and
- Objective B: To ensure the smooth functioning of the internal market.

The IA discards both a no EU action (baseline scenario) and a fundamental change

[18] SWD(2012) 274 final. Available from: http://eur-lex.europa.eu/resource.html?uri=cellar:487acc33-213b-4fdf-bdbb-8840209a8807.0001.04/DOC_2&format=PDF

(marketing authorisation of medical devices) options, and recommends an evolution of the current framework that reinforces the current regime keeping the same legal approach. The following analysis of the application of the R&I Tool has been carried out examining the preferred options selected for each of the above objectives.

Does the measure affect...	Main findings	Data sources/Methods	Indicators
The research, testing or demonstration phase?	According to the IA, the new Regulation is especially focused at simplifying the regulatory process (especially PA4).	• Secondary research • Stakeholder consultation	The IA could have further analysed the impact of preferred policy options on: • Size of the market • Average life-cycle of medical devices • Reinvestment in R&D • Time to market for new products • Faster pre-market assessment • Development of combination products • Comparison with other developed countries
The application of innovative solutions or to bring them to market?	• The IA considers how policy options may affect innovation, especially on potential delays to get new products in the market. • The proposed changes do not aim at directly incentivising the entry of new offers in the market and does not affect the conditions of the incumbent. However, the new proposed legislation aims at simplifying and at the same time make more rigorous the way by which new products pass their conformity assessment. These could have an impact in the entry of new products in the market. • The IA recognises that preferred policy option 1G (notification requirement regarding new applications for conformity assessment and possibility for ex ante control) may "slow down the access of new products to the market but only case-by case under the responsibility of the MDEG [Medical Device Expert Group] where it has identified a concern". The IA adds that "it would however require that the review process does not lead to unreasonable delays and does not become the rule rather than the exception" • The analysis of the cost and benefits of the preferred policy options establishes neutral or decreased costs (including administrative burden) in most	• Secondary research • Stakeholder consultation • Assessment of new offers in the market due to simplified procedure	• Comparison with other developed countries in terms of innovation indicators such as the ones listed above. • Qualitative data from interviews, consultations or surveys with key stakeholders in the sector. • Compliance costs • Costs of required tests • Adaptation costs • Administrative costs associated to single submission

Does the measure affect...	Main findings	Data sources/Methods	Indicators
	of the cases, with some proposed changes leading to increased administrative costs to manufacturers (for example product traceability). • The proposed changes would only affect unsafe products taken out of the market.		
Incentives around investment, growth, jobs or scaling up in Europe?	Data analysed for the IA shows that the EU medical devices sector is very innovative in comparison to the sector in the US and Japan. The revision of the regulatory framework responds to legal needs, harmonisation of the internal market and patient safety issues.	• Secondary research • Stakeholder consultation	• Size of the market • Average life-cycle of medical devices • Reinvestment in R&D • Time to market for new products • Faster pre-market assessment • Development of combination products • Comparison with other developed countries • Other possible indicators not included: • Number of patents • R&D expenditure

8.4 Sectoral application: Transport

The R&I tool is being applied to the proposal for the "Regulation of the European Parliament and of the Council setting CO2 emission performance standards for new heavy-duty vehicles". Unlike other well-established legislation in transport sector, this proposal focuses on a new aspect, as CO2 emissions from HDV have so far not been regulated. This offered an interesting field to test the innovation principle and to foster future-proof and innovation-friendly legislation.

This last proposal is the completion of a 3-step process to complete the defined Strategy Communication on reducing Heavy-Duty Vehicle fuel consumption and CO2 emissions (May 2014 COM(2014)285) and the Commission's strategy for low-emission mobility (July 2016 COM(2016)501). Main policy objectives are:

1) Reduce the climate impact of HDVs in a cost-effective, technology and competitively neutral manner.

2) Contribute to the improvement of the competitiveness of HDV manufacturers.

3) Facilitate a reduction in the total cost of ownership for transport operators, most of which are SMEs.

The process in still ongoing, but some interesting lessons can be shared.

Does the measure affect...	Main findings	Data sources/Methods	Indicators
The research, testing or demonstration phase?	• A limited number of main incumbent actors account for 90% of all sales in Europe. EU producers not only manufacture the engines but also the complete vehicle.	• Sector data • Internal sources • R&I projects (Cordis)	

Does the measure affect...	Main findings	Data sources/Methods	Indicators
	• While the fuel efficiency of HDVs has improved over past decades, the rate of the efficiency improvement has been around 1% per year.		
The application of innovative solutions or to bring them to market?	• While the majority of companies directly affected are large vehicles manufacturers, stakeholders include operators and logistics companies (mostly SMEs and micro-enterprises). • Market barriers are present, and there is a lack of market uptake of the most cost effective technologies. Penetration level of technologies also hampered by the lack of transparency. • Additional cost for the deployment of CO_2 reducing technology in HDVs. • Measure shall help overcome of missing opportunity: transport operators and clients miss possible fuel savings and reduced fuel bills. • Small revenue margins in the sector, increase of costs are at least to some extent passed on to operators and consumers.	• Sector data • Other development countries reports • Broaden stakeholders consultation • Studies ongoing on current and future technological developments	• Qualitative data from stakeholders consultation strategy. • Costs of technologies and payback time • Comparison with other developed countries
Incentives around investment, growth, jobs or scaling up in Europe?	• EU HDV manufacturers face increasing global competitive pressures, and the sector need to keep up with the technological improvements in these markets to preserve market position and its leading role in vehicle fuel efficiency. • The EU competitive position would be strengthened with respect to other manufacturers by increased regulatory pressure that improves fuel efficiency.	• Sector data • Broaden stakeholder consultation	• Time to market and payback time • Comparison with other developed countries (in particular USA and China) • Reinvestment in R&D

LESSONS LEARNT

WHAT	WHEN
• *Remind the importance of 'innovation principle' (in particular for the Impact Assessment study) and briefly illustrate the use of the R&I tool*	*ASAP, 1st ISG meeting*
• *Propose to write specific questions on technological issues*	*Consultation strategy definition*
• *Broaden consultation to 'new entrants' and to R&I actors (verify previous FP7 and H2020 projects consortia via corda).* • *Support participation to consultation*	*Consultation strategy definition*
• *Propose at least one different/alternative approach to be examined in the IA*	*Inception Impact Assessment (and ToR definition in case of external studies)*
• *'Top runner' and of 'Eco-innovation' approaches*	*Proposed*
• *Investigation of both available and close to market technological developments*	*Proposed*

8.5 Sectoral application: Water

In 2017, the European Commission is preparing a new legislative instrument on quality of reused waste water for irrigation and groundwater recharge. There were two online public consultations in 2014[19] and 2016/17[20] which addressed various aspects. For example, respondents were asked about the benefits of water reuse. Among the various options provided, the innovation potential in the water sector was considered the second most-often mentioned benefit.

In order to get expert opinions in the short time period that was available for this exercise DG RTD organised a workshop with water reuse experts in May 2017. The methodological approach includes a wider scope of policy options than the options assessed in the Impact Assessment report since the exact options to be included in the impact assessment were not yet defined in the moment when the methodology was decided. Furthermore, DG RTD intended to test the R&I Tool on a wider range of generic policy options and obtain experience on how practical and useful the R&I tool is.

The options discussed at the workshop were the combination of generic options that are applicable for all EU policy initiatives and specific options corresponding to possible elements of policy as identified by preparatory studies. The discussed options were:

Generic options:

- **mandatory**, i.e. Member States are obliged to comply with the legal requirements stipulated in the law; or
- **voluntary**, i.e. Member States are advised or incentivised to implement certain measures but are not strictly obliged to do so. They usually take the form of EU recommendations, guidance or communications.

Specific options:

1. **Targets** for Member States, e.g. what proportion of waste water should be reused;
2. Measures to **prevent trade barriers** (harmonization of rules or mutual recognition of national rules);
3. **Limit values for control of hazardous substances in the treated waste water for reuse**. These can be set to protect **either public health**, e.g. microbiological pathogens or hazardous substances that may enter food chain, or **prevent environmental damage**, e.g. overload of nutrients that may cause eutrophication of surface water bodies, degradation of soil or pollution by hazardous substances that have negative impact on terrestrial and aquatic ecosystems.
4. Measures to address **public health risks** by application of risk management systems (public health risk management requirements);
5. Measures to address **environmental risks** by risk management systems (environmental risk management requirements);
6. **Governance and economic aspects**, i.e. who is responsible for delivery of the requirements and who pays for what and how much;
7. **Technology**, e.g. is any particular technology or technique required (explicitly or implicitly).

The workshop focused mainly on options 3, 4 and 5 and the links among them. Option 1 was eliminated as not acceptable at the EU level and option 2 was included as an overarching component of options 3 and 4. Options 6 and 7 have been also assessed.

Below is a summary of the impacts of mandatory requirements. The outcome suggests that if the tool questions are addressed through a qualitative setting (workshop), the discussion allows for a rather flexible format which does not necessarily follows each and every question, but nevertheless provides valuable insights. The following table omits the columns on data sources/methodology and indicators.

[19] results are included in http://ec.europa.eu/environment/consultations/pdf/Water%20Reuse.pdf

[20] http://ec.europa.eu/environment/water/pdf/WaterReuse2ndConsultation-Report-and-Annex-COM.pdf

Does the measure affect...	Main findings
The research, testing or demonstration phase?	Mandatory EU minimum quality requirements are seen as innovation-friendly if some conditions are met. Positive impacts will only be realised if a balanced scope of parameters and appropriate stringency of limit values is found. If too many parameters and very stringent limit values become obligatory, this can discourage the application of water reuse and the driving effect for innovation would disappear. If these are too low and easy to achieve with the conventional technology it will not provide additional drivers for innovation compared to the current situation • They can stimulate and drive R&I in technologies and solutions that will help to reach the limit values of defined parameters. They will boost R&I at all phases driven by the needs to demonstrate technical performance, efficiency and reliability of conventional and new technologies (filtration, disinfection, membranes, advanced oxidation, etc.), economic viability of water reuse projects, and social and environmental benefits • New and innovative ways of monitoring will be stimulated, in particular online (continuous) monitoring, development of new microbiological and chemical indicators. New analytical methods will be developed for instance for pathogens (based on RNA-ribonucleic acid analysis) or effect based analysis for chemicals (bioassays). Setting standards for online monitoring techniques will produce an incentive to bring more R&D results to the market. • Minimum quality requirements will establish a stable market and speed up application of innovative solutions and exploiting existing results; • It will positively affect cooperation between public and corporate R&D throughout Europe. Large demonstration projects applying results of public and private research will be necessary to validate water reuse schemes' performances;
The application of innovative solutions or to bring them to market?	• The harmonization of quality requirements (parameters and limit values) and procedures will provide innovative companies the opportunity to scale up. • This option will reduce compliance costs and time for the development of innovative technologies/solutions due to the need to meet the challenges within the deadlines set by the legislation. • It will also stimulate social innovation, better cooperation between stakeholders, multidisciplinary research, improved public education, integrated and holistic approach to water resource management, sustainable development and the application of the circular economy concept in the water sector.
Incentives around investment, growth, jobs or scaling up in Europe?	• It will create the necessity for all stakeholders in the reuse field to envision new ways to treat, distribute, control quality of reclaimed water and manage public acceptance.

9 ANNEX 1: SOURCES

9.1 Public data sources

- Eurostat: Database
- OECD : Main Science and Technology Indicators
- UN : Statistics Division
- EU : Open Data Portal
- EU : European Data Portal
- Statista
- Global Entrepreneurship Monitor

9.2 Private data sources

- Bureau van Dijk: AMADEUS and ORBIS (company data, including financial sheets, R&D expenditure etc.) but also databases on M&A: M&A Research Catalyst
- Elsevier: Scopus (scientific publications)
- Clarivate: Web of Science (scientific publications)
- Clarivate: Derwent World Patent Index (patents)

9.3 Literature

Blind, K. (2012): The Impact of Regulation on Innovation. MIoUR

EC (2015): Better regulation toolbox

Jantz, B, Veit, S. (2010: Gutachten: Bessere Rechtsetzung durch Befristungs- und Evaluationsklauseln? Bertelsmann Stiftung.

OECD (2010), Measuring Innovation: A New Perspective, OECD

Mandelkern Group (2001): Mandelkern Group on Better Regulation. 2001

Ranchordas, S. (2014): Constitutional Sunsets and Experimental Legislation. A Comparative Perspective, Elgar Monographs in Constitutional and Administrative Law, Edward Elgar

van Gestel, R., van Dijck, G. (2011) : Better regulation through experimental legislation, European Public Law, 3, pp 539-553

10 ANNEX 2 : TOOL #21. RESEARCH & INNOVATION

10.1 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)[21] 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.

10.2 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 exists[22]). 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 scaling-up in size.[23] 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.[24] 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.

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21 https://ec.europa.eu/research/sam/index.cfm

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

23 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.

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

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 innovation[25].

Impact on research and innovation	Y/N
Does the measure affect the research, testing or demonstration phase?	
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?	
Does the measure affect application of innovative solutions or to bring them to market?	
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?	
Does the measure affect incentives around investment, growth, jobs or scaling up in Europe?	
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 report[26]. 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.

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

[26] See Tool #8 on the *Format of the IA report*.

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.

Legislative design considerations	**Y/N**	**Relevant tools**
Flexibility and future-proofing[27] 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.		
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?		
Compliance costs 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.		
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

[27] 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).

Regulatory certainty and clarity 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 adaption to scientific and technological progress on the other?		3
Timing and stringency 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?		
The single market and harmonisation and interactions with other policies 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 #15[28] 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.

[28] See Tool #18 on *The choice of policy instruments*

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 measureable 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

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).

10.3 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"[29] and the Report on the screening of the Regulatory Framework[30].

- 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.

[29] https://ec.europa.eu/research/innovation-union/pdf/innovrefit_staff_working_document.pdf .

[30] https://ec.europa.eu/research/innovation-union/pdf/KI-04-13-129-EN-N-RegulatoryScreening.pdf .

- 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.

10.4 Support[31]

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

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

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The Better Regulation Guidelines provide specific guidance on designing innovation-friendly legislation through a dedicated 'Research and Innovation Tool' on how to assess the innovation impacts of options for new legislative proposals.

This practical guide is aimed at officials in the European Commission. It provides more details on the use of the tool and applies it to case studies on recently adopted sectoral regulations in the Energy, Food, Health, Transport and Water sectors.

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