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Study on the costs and benefits of innovation-sensitive legislation

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Study on the costs and benefits of innovation-sensitive legislation

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ABSTRACT

The study on the costs and benefits of innovation-sensitive legislation aims on the one hand to analyse the use of the Tool #21 (on Research and Innovation) of the Better Regulation Toolbox, and on the other hand to provide a step-wise operational guidance on assessing innovation impacts. With this aim, the analysis goes beyond the analysis of impacts of regulation on innovation to highlight links between innovation and the broader context in which it occurs.

Ultimately, this aims to provide a systematic approach for those engaged in planning and implementing impact assessments, to raise awareness and provide examples of how innovation impacts can be factored in impact assessments of legislation.

The guide is based on empirical analysis of existing impact assessments - mainly at the EU-level. More than 30 impact assessments were screened and 15 analysed in greater detail including the Commission's published impact assessments, support studies, and the Regulatory Scrutiny Board's opinions. Four dedicated case studies and interviews served for further insights. Among the findings is that innovation is treated implicitly in most impact assessments. Very often, innovation impacts are included under economic impacts and in this area, the corresponding benefits are calculated in terms of economic growth, the effect on jobs or the decrease of environmental pressures. Supported by the case studies, quantifying the impacts of/on innovation is challenging – partly due to the unpredictable nature of innovation, but also due to practical issues such as limited availability of data and confidentiality issues. Yet, EU as well as national policymakers could benefit from sharing examples more widely.

RÉSUMÉ

L'étude sur les coûts et les avantages d'une législation sensible à l'innovation vise d'une part à analyser l'utilisation de l'outil n° 21 (Recherche et Innovation) de la boîte à outils "Mieux légiférer", et d'autre part à fournir un guide opérationnel pas à pas pour l'analyse des impacts sur l'innovation. A cet égard, cette étude va au-delà de l'analyse des impacts de la réglementation sur l'innovation et souligne les liens entre l'innovation et son contexte.

Enfin, il s'agit de proposer une approche systématique pour ceux qui sont impliquées dans la planification et la mise en œuvre des analyses d'impact, de sensibiliser et de fournir des exemples sur la façon de mieux prendre en compte les impacts de l'innovation dans les analyses d'impact de la législation.

Le guide est basé sur l'étude empirique des analyses d'impact existantes, principalement au niveau de l'Union Européenne. Plus de 30 analyses d'impact ont été passées en revue et 15 d'entre elles ont été analysées plus en détail, notamment les analyses d'impact publiées par la Commission, les rapports d'appui et les avis des comités de contrôle de la réglementation. Quatre études de cas spécifiques et des entretiens ont permis d'approfondir la réflexion. Parmi les conclusions, il ressort que l'innovation est traitée de manière implicite dans la plupart des analyses d'impact. Très souvent, elle est incluse dans les impacts économiques et, dans ce domaine, les avantages sont calculés en termes de croissance économique, d'effet sur l'emploi ou de diminution des pressions environnementales. Comme le montrent les études de cas, la quantification des impacts de l'innovation ou sur l'innovation est un défi - en partie du fait de la nature imprévisible de l'innovation, mais aussi à cause de problèmes pratiques tels que la disponibilité limitée des données ou les problèmes de confidentialité. Pourtant, les décideurs politiques européens et nationaux pourraient bénéficier d'un partage plus large de ces expériences.

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Abbreviations

BERD	Business Expenditure in Research and Development
BR	Better Regulation
CBA	Cost Benefit Analysis
CUA	Cost Utility Analysis
DG CNECT	Directorate-General for Communications Networks, Content and Technology
DG ENV	Directorate-General for the Environment
DG ENER	Directorate-General for Energy
DG RTD	Directorate-General Research and Innovation
EC	European Commission
EPIRARE	European Platform for Rare Disease Registries
ERNs	European Reference Networks
EC	European Commission
EU	European Union
FP	Framework Programme
IA	Impact Assessment
INSERM	French National Institute of Health and Medical Research
IRDiRC	International Rare Disease Research Consortium
JRC	Joint Research Centre
MS	Member States
OECD	Organisation for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
OMPs	Orphan medicinal products
NGO	Non-Governmental Organisation
QoL	Quality of Life
R&D	Research and development
R&I	Research and innovation
RDI	Research, Development and Innovation
rNPV	Risk-adjusted Net Present Value
RoI	Return on Investment
RSB	Regulatory Scrutiny Board
SDG	Sustainable Development Goals
STI	Science Technology and Innovation
TFP	Total factor productivity
UWWTD	Urban Waste-Water Treatment Directive

1. Executive summary

Purpose and scope of the study

In April 2021, the Commission adopted a Communication on Better Regulation, which aims to introduce several improvements into evidence-based policy making practice at EU level.

Concretely, the Commission expects to re-model numerous tools of the Better Regulation toolbox to give a more prominent role to foresight, and update techniques to assess green, digital, geopolitical, and socio-economic trends.

The revision of the Tool #21 (which is renumbered Tool #22 in the updated Better Regulation toolbox[1]) fits into this framework.

Tool #21 of the Better Regulation toolbox focuses on "Research & Innovation" to "provide clear guidelines for analysing the interaction between new or revised EU legislation (including spending programmes) and innovation." Overall, the tool aims "to make legislative proposals more forward-looking and innovation-friendly." In order to promote the tool in its application, a practical guideline on "How to apply the Impact Assessment tool on research and innovation" was published in 2017.[2]

With the tool and in line with the innovation principle, DG RTD is promoting the analysis of impacts on research and innovation in legislative proposals. In 2019, the tool and its use were analysed by Renda and Simonelli (2019)[3], also indicating areas for clarification.

In light of the above, the purpose and scope for this study is twofold:

(1) by analysing if and how the Tool #21 was and is used so far in impact assessments and evaluations and their support studies, the study wants to understand its use, potential limitations, and areas to improve.

(2) the second aim is to provide methods to identify and measure the impacts of innovation-sensitive legislation *on* innovation.

This study thus demonstrates through existing examples, how approaches can be improved and how (expected) innovation effects could be included in impact assessments and to some extent into evaluation studies.

Background

Regulation is defined by the OECD as "the diverse set of instruments by which governments set requirements on enterprises and citizens. Regulations include laws, formal and informal orders and subordinate rules issued by all levels of government, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers." (OECD, 1997).

The study uses the OECD definition and thus treats EU-level Regulations as specific forms of rules. Yet, in the EU context the study equally refers to legislation as a process and as

[1] See https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

[2] EC (2017): How to apply the impact assessment tool on research and innovation. A practical guide, see: https://op.europa.eu/en/publication-detail/-/publication/26a243e6-f5ba-11e7-b8f5-01aa75ed71a1/language-en

[3] Renda, A., Simonelli, F. (2019): Study supporting the interim evaluation of the innovation principle.

an overarching term for formal legal provisions. Thus, regulation and legislation are used interchangeably throughout the report.

The impact of regulation on innovation has been discussed in the academic literature for quite some time and has been taken up by policy circles. Blind (2012) classified three types of regulations, namely:

- Regulations targeting the promotion of innovation.
- General regulation without the dedicated goal to promote innovation.
- Regulations affecting companies' strategies and activities but not necessarily affecting (positively) their innovation activities.

More and more, policymakers at EU-level and to some extent at country level aim to address the interlinkages between innovation and regulation in a more systematic way. In this respect, the Better Regulation (BR) principles and tools of the European Commission serve as key guidelines. The European Commission also encourages the Member States to establish their own national Better Regulation strategies and to perform impact assessments that resemble the scope of the EC's own assessments.

Much has been achieved not only in the EU but also in the OECD context, particularly in terms of methodological guidelines, systematic reviews of countries' regulatory systems and recommendations since the mid -1990s.[4]

Yet, in spite of this progress, experimental instruments like those proposed in Tool#21 are not widely found – perhaps also due to a lack of systematic review[5]. It seems that there is a lack of appropriating new functions to regulation and some difficulties in finding ways to anticipate new, innovation-conducive regulation or respond with adequate regulation to new technological instances such as the data economy. There is a perceived risk that new regulations may not enable useful and wanted innovation that serves the public interest while existing regulation may become outdated and not respond to the new challenges.

Relationship between regulation and innovation

The lessons from the existing body of literature suggest that the relationship between regulation and innovation is not simple or straightforward.

The literature analysing the effects of regulation on innovative activities emphasises the need to take account of the **systemic nature of innovation activities and the difficulties in attributing innovation effects to regulation**. The innovation literature also suggests that regulation is but **one of the factors influencing innovation**. Based on the innovation system approach, innovation evolves within a system in which many interconnected factors play a role (e.g., framework conditions, technological capabilities, culture).

4 OECD (2019), Better Regulation Practices across the European Union, OECD Publishing, Paris, https://doi.org/10.1787/9789264311732-en; updated work is expected to be published in summer 2022. For an overview at national level see also: EPRS (2020): Better regulation practices in national parliaments. PE642.835. A very detailed, public handbook on better regulation and impact assessment exists in Austria with the Handbuch wirkungsorientierte Folgenabschätzung (BMF 2013).

5 For example, In a study of EY for the German BMWE 2020 on experiemental regulation, more than 50 sandboxes in 25 countries were identified and three projects from France, Denmark, and Japan further analysed. See EY (2020): Gutachten für das Bundesministerium für Wirtschaft und Energie: Reallabore Überblick über international regulatorische Ansätze und ihre Umsetzbarkeit in deutsches Recht. SV 113/19/ RV Recht Reallabore.

- Evidence from environmental regulation showed that regulation played an important role in stimulating innovation when considering the **type of innovation** (or technical direction).
- Depending on the context, regulation can both enable and hinder innovation activity.
- Regulation may have **system-level effects**, for example, by shifting investment opportunities to different actors.
- Regulation rarely explicitly addresses innovation. In many cases regulations affect innovation indirectly and in an unintended way.
- Various empirical studies on the impact of different types of regulation on innovation present a rather **heterogeneous picture both regarding the type of regulation and the sectors which benefit – or not**.

Empirical findings show that the innovation effects of regulation vary by industry and technological area. These studies also show **differences between short- and long-term impacts**. The short-term impacts of regulations are often negative for innovation behaviour and the costs of innovation. This is mainly due to adjustments needed to comply with a new rule. In contrast, the long-term implications of forcing or encouraging their adoption and accelerating the uptake of innovations and their spillover benefits are rather positive.

Methodology

The study is based on desk research, case studies and interviews. Given the political priorities of the green and digital transformation, there was a thematic focus for choosing the case studies with an emphasis on digitalisation, the green transition, health, and mobility.

The methodological approach for the study was based on five pillars:

1. A systematic **analysis of potential recent cases** – based on desk research and the search of dedicated websites and databases followed by validating interviews.
2. A selection process based on a multicriteria analysis which considered empirical evidence as well as the needs of the European Commission.
3. Development of concise and well-structured **cases studies** that provide insights on the use of the Tool #21 as well as potential improvements.
4. Exemplary pathways providing guidance on measuring the impacts of innovation.
5. Critical assessment and suggestion of robust indicators for monitoring and evaluating.

For the systematic screening of the identified regulation, the study has screened more than 30 pieces of legislation and analysed in detail 15 EU-level and three national level cases.

Operational guidance on assessing innovation impacts

The operational guide **for the quantification of costs and benefits of innovation effects** wants to be a hands-on guide for practitioners. The guidance is made of six steps, as follows:

- Step 1: Identify the type of regulation and its relation to innovation
- Step 2: Map actors and their modalities of compliance

- Step 3: Understand the impact of regulation on innovation and innovation impacts on society, environment, health, economy, competitiveness, etc.
- Step 4: Identify data/information needs
- Step 5: Design suitable methods to collect and analyse the data
- Step 6: Validate results.
-

Findings and conclusions

By means of comparing the analysed cases, a number of findings emerge:

- Several of the cases concerned **impact assessments of amended legislative proposals or evaluations of existing legislation** for which (at least) one initial impact assessment and/or evaluation study already existed. They can therefore build on available, already collected data. Contrary, impact assessments for completely new proposals may struggle to collect new data from scratch.
- Environmental, transport and mobility-related studies tend to use a wealth of data.
- Innovation is predominantly treated implicitly. Digital-related studies clearly mention innovation, while health-related studies tend to focus on social impacts.
- Regarding the **quantification of costs and benefits**, the most frequently calculated benefits are about economic growth (GDP), the effect on jobs, and the decrease of environmental pressures.
- The support studies vary in terms of degree of **use of sophisticated methods –** the choices are a function of **available data.**
- The heterogeneity of the selected cases highlights the **cross-cutting and multidimensional relationship between innovation and regulation**: regulation can affect innovation in various ways, and the emergence of new innovations is presenting challenges for the regulators in all sectors.
- As highlighted by the case studies, quantifying the impacts of/on innovation is challenging – partly due to the unpredictable nature of innovation, but also due to practical issues (e.g., availability of data, confidentiality issues).
- There is **no established set of methods** to assess the impacts on/of innovation. Moreover, innovation is only one of the several policy goals of legislation. Various methods have been developed to estimate the impacts of innovation, for example, the link between innovation and productivity or the growth of total factor productivity (TFP) due to R&D investment. Most of the research that measures the returns to R&D (at the micro or macro levels) **relies on a production function framework**, where the output is related to the stock of R&D (or knowledge capital).
- The methods used to capture the relations between innovation, productivity and regulation are dependent on the availability of resources to collect/purchase data and conduct the analysis. The empirical and data collection methods are **highly labour intensive and thus costly**.
- Further methodological questions concern econometric modelling - it is facing several issues related to **endogeneity**, uncertainties in the choice of **the lag structure** and the **limitations** regarding the use of cross-sectional data.
- Somewhat problematic is the limited variety of credible data sources.

Considerations for EU policymakers

The intelligence collected during the development of the study leads to a number of considerations for improvement in view of potential changes to the Tool #21. Overall, the availability of the Tool #21 (or similar) and its wider dissemination to the national level would help to envisage and assess impacts more systematically. Improvements can be thought of, for example:

1. By providing and sharing concrete examples (at EU or national level) on the use of Tool #21 and on the assessment of impacts on innovation (including Cost-Benefit Analyses (CBAs)).
2. When using the CBA, results could be improved with access to more recent and specific data, such as R&D costs of market authorisation holders, and a better means to value the additional period of market exclusivity.
3. For a more systematic study of possible unintended negative impacts innovation could have, more theory-driven studies may be envisaged. They can treat innovation as the – possibly unobserved – outcome of interest and develop a (quasi)causal model (a series of mechanisms and impact pathways) of how the proposed changes to the regulation might influence innovation positively or negatively.
4. In the future, Member States and the European Parliament may require a broader range of quantitative and qualitative evidence for the political evaluation of regulatory proposals, particularly in the context of the green and digital transformations. Yet, for the time being, it is often the basic economic costs and benefits that constitute the main criterion for the political evaluation of legislative proposals. Innovation is more a precursor of these results of interest than the result of the interest itself. Yet, the concept of future-proof legislation bringing forward the need for adaptability to scientific and technological progress combined with the industrial strategy supporting the twin transition of industrial ecosystems increases the need for quantitative evidence on innovation.

2. Résumé exécutif

Objectif et portée de l'étude

En avril 2021, la Commission a adopté une communication sur l'amélioration de la réglementation, qui vise à introduire différentes améliorations dans la manière d'élaborer les politiques publiques fondées sur des données probantes au niveau de l'UE.

Plus concrètement, la Commission prévoit de refondre différents outils de la boîte à outils "Mieux légiférer" afin de donner un rôle plus important à la prospective, et d'actualiser les techniques d'évaluation et mieux prendre en compte les évolutions environnementales, numériques, géopolitiques et socio-économiques.

La révision de l'outil n° 21 (qui est renommé outil n° 22 dans la boîte à outils "Mieux légiférer" actualisée) s'inscrit dans ce cadre.

L'outil n° 21 de la boîte à outils "Mieux légiférer" se concentre sur la "recherche et l'innovation" afin de "fournir des lignes directrices claires pour analyser les interactions entre la législation européenne nouvelle ou révisée (y compris les programmes de dépenses) et l'innovation". Globalement, l'outil vise à "rendre les propositions législatives tournées vers l'avenir et plus favorables à l'innovation." Afin de promouvoir l'outil dans son application, un guide pratique intitulé "Comment appliquer l'outil d'analyse d'impact sur la recherche et l'innovation" a été publié en 2017.

Avec cet outil, et conformément au principe d'innovation, la DG RTD encourage l'analyse des impacts sur la recherche et l'innovation dans les propositions législatives. En 2019, l'outil et son utilisation ont été analysés par Renda et Simonelli (2019), indiquant également les domaines à clarifier.

L'objectif et la portée de cette étude sont doubles:

(1) en analysant si et comment l'outil 21 a été et est utilisé jusqu'à présent dans les analyses d'impact, les évaluations et leurs rapports d'appui, l'étude entend comprendre son utilisation, ses limites potentielles et les domaines à améliorer.

(2) le second objectif est de fournir des méthodes pour identifier et mesurer les impacts de certains types de régulations tenant compte de l'innovation sur l'innovation elle-même.

Cette étude démontre donc, à partir d'exemples existants, comment les approches peuvent être améliorées et comment les effets (attendus) sur l'innovation pourraient être inclus dans les analyses d'impact et, dans une certaine mesure, dans les études d'évaluation.

Contexte

La réglementation est définie par l'OCDE comme "l'ensemble diversifié d'instruments par lesquels les gouvernements fixent des exigences aux entreprises et aux citoyens. Les réglementations comprennent les lois, les ordonnances formelles et informelles et les règles subordonnées émises par tous les niveaux de gouvernement, ainsi que les règles émises par des organismes non gouvernementaux ou d'autorégulation auxquels les gouvernements ont délégué des pouvoirs de réglementation". (OCDE, 1997).

L'étude utilise la définition de l'OCDE et englobe donc les règlements au niveau de l'UE en tant que formes spécifiques de règles. Cependant, dans le contexte de l'UE, l'étude fait également référence à la législation en tant que processus et en tant que terme général pour les dispositions juridiques formelles. Les termes "règlement" et "législation" sont donc utilisés indifféremment dans le rapport.

L'impact de la réglementation sur l'innovation fait l'objet de discussions dans la littérature académique depuis un certain temps et a été repris par les cercles politiques. Blind (2012) a classé trois types de réglementations, à savoir :

- Les réglementations visant à promouvoir l'innovation.
- Les réglementations générales sans objectif dédié à la promotion de l'innovation.
- Les réglementations affectant les stratégies et les activités des entreprises mais n'affectant pas nécessairement (positivement) leurs activités d'innovation.

De plus en plus, les décideurs politiques au niveau de l'UE et, dans une certaine mesure, au niveau national, cherchent à aborder les liens entre l'innovation et la réglementation de manière plus systématique. À cet égard, les principes et les outils du programme "Mieux légiférer" de la Commission européenne servent des lignes directrices essentielles. La Commission européenne encourage également les États membres à établir leurs propres stratégies nationales d'amélioration de la réglementation et à réaliser des analyses d'impact dont la portée ressemble à celle des évaluations de la CE.

De nombreux progrès ont été réalisés non seulement dans l'UE mais aussi dans le contexte de l'OCDE, notamment en termes de lignes directrices méthodologiques, d'examens systématiques des systèmes réglementaires des pays et de recommandations depuis le milieu des années 1990.[6]

Malgré ces progrès, les instruments expérimentaux comme ceux proposés dans l'Outil n° #21 sont rarement abordés de manière systématique.[7] Il semble qu'il y ait un manque d'appropriation des nouvelles fonctions de la réglementation et des difficultés sur la manière d'anticiper une nouvelle réglementation propice à l'innovation ou de répondre avec une réglementation adéquate aux nouvelles instances technologiques telles que l'économie des données. Il existe un risque perçu que les nouvelles réglementations ne facilitent pas une innovation utile et souhaitée servant l'intérêt public, tandis que la réglementation existante peut devenir obsolète et ne pas répondre aux nouveaux défis.

Relation entre réglementation et innovation

Les enseignements tirés de l'ensemble de la littérature existante suggèrent que la relation entre la réglementation et l'innovation n'est pas simple ou directe.

La littérature analysant les effets de la réglementation sur les activités innovantes souligne la nécessité de prendre en compte **la nature systémique des activités d'innovation et les difficultés à attribuer les effets de l'innovation à la réglementation**. La littérature sur l'innovation suggère néanmoins que la réglementation n'est qu'un des facteurs influençant l'innovation. Selon l'approche du système d'innovation, l'innovation évolue au sein d'un système dans lequel de nombreux

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[6] 6 OECD (2019), Better Regulation Practices across the European Union, OECD Publishing, Paris, https://doi.org/10.1787/9789264311732-en; la publication des résultats actualisés est prévue pour l'été 2022. Pour une vue d'ensemble au niveau national, voir également: EPRS (2020): Better regulation practices in national parliaments. PE642.835. Un manuel public très détaillé sur l'amélioration de la réglementation et l'analyse d'impact existe en Autriche avec le ' Handbuch wirkungsorientierte Folgenabschätzung' (BMF 2013).

[7] Par exemple, dans une étude réalisée par EY pour le BMWE 2020 en Allemagne sur la réglementation expérimentale, plus de 50 sandboxes ont été identifiés dans 25 pays, dont trois projets en France, du Danemark et du Japon ont fait l'objet d'une analyse plus approfondie. Voir EY (2020) : Expertise pour le ministère fédéral de l'économie et de l'énergie : Reallabore Überblick über international regulatorische Ansätze und ihre Umsetzbarkeit in deutsches Recht [Reallabore Aperçu des approches réglementaires internationales et de leur applicabilité en droit allemand]. SV 113/19/ RV Recht Reallabore

facteurs interconnectés jouent un rôle (par exemple, les conditions cadres, les capacités technologiques, la culture).

- Les données relatives à la réglementation environnementale ont montré que la réglementation jouait un rôle important pour stimuler l'innovation lorsque le **type d'innovation** (ou l'orientation technique) est pris en compte.
- Selon le contexte, la réglementation peut à la fois favoriser et entraver l'activité d'innovation.
- La réglementation peut avoir des **effets au niveau du système**, par exemple en déplaçant les opportunités d'investissement vers différents acteurs.
- La réglementation aborde rarement l'innovation de manière explicite. Dans de nombreux cas, les réglementations affectent l'innovation indirectement et de manière non intentionnelle.
- Différentes études empiriques sur l'impact de différents types de réglementation sur l'innovation présentent un tableau plutôt hétérogène, tant en ce qui concerne le type de réglementation que les secteurs qui en bénéficient - ou non.
- Les résultats empiriques montrent que les effets de la réglementation sur l'innovation varient selon l'industrie et le domaine technologique. Toutefois, si l'on passe au niveau sectoriel, on constate des différences marquées. Ces études montrent également **des différences entre les impacts à court et à long terme**. Les impacts à court terme des réglementations sont souvent négatifs en ce qui concerne les comportements liés à l'innovation et les coûts de cette dernière. Ceci est principalement dû aux ajustements nécessaires pour se conformer à une nouvelle règle. En revanche, les implications à long terme en forçant ou en encourageant leur adoption et en accélérant l'adoption des innovations et leurs retombées sont plutôt positives.

Méthodologie

L'étude est basée sur de la recherche documentaire, des études de cas et des entretiens. Compte tenu des priorités politiques de la transformation verte et numérique, le choix des études de cas s'est fait selon une approche thématique mettant l'accent sur la numérisation, la transition verte, la santé et la mobilité.

L'approche méthodologique de l'étude reposait sur cinq piliers :

1. Une **analyse systématique de cas potentiels récents** - basée sur une recherche documentaire et la consultation de sites web et de bases de données spécialisés, suivie d'entretiens de validation.
2. Un processus de sélection basé sur une analyse multicritères qui a pris en compte les preuves empiriques ainsi que les besoins de la Commission européenne.
3. L'élaboration **d'études de cas** concises et bien structurées qui donnent un aperçu de l'utilisation de l'outil ainsi que des améliorations potentielles.
4. Des exemples de cheminement fournissant des conseils sur la mesure des impacts de l'innovation.
5. Évaluation, critique et suggestion d'indicateurs robustes pour le suivi et l'évaluation.

Pour l'examen systématique de la législation identifiée, l'étude a passé en revue plus de 30 actes législatifs et analysé en détail 15 cas au niveau de l'UE et trois au niveau national.

Guide opérationnel pour l'évaluation des impacts de l'innovation

Le guide opérationnel pour **la quantification des coûts et des avantages des effets de l'innovation** se veut un guide appliqué pour les praticiens. Il comprend les six étapes suivantes:

- - Étape 1 : Identifier le type de réglementation et sa relation avec l'innovation.
- - Étape 2 : Cartographier les acteurs et leurs modalités de conformité.
- - Étape 3 : Comprendre l'impact de la réglementation sur l'innovation et les impacts de l'innovation sur la société, l'environnement, la santé, l'économie, la compétitivité, etc.
- - Étape 4 : Identifier les besoins en données/informations.
- - Étape 5 : Concevoir des méthodes appropriées pour collecter et analyser les données.
- - Étape 6 : Valider les résultats.

Constatations et conclusions

La comparaison des cas analysés permet de faire un certain nombre de constatations :

- Plusieurs des cas concernaient **des analyses d'impact de propositions législatives modifiées ou des évaluations de la réglementation existante** pour lesquelles (au moins) une première analyse d'impact et/ou des études d'évaluation existaient déjà. Elles peuvent donc s'appuyer sur des données disponibles et déjà collectées. Au contraire, les analyses d'impact de propositions totalement nouvelles peuvent avoir des difficultés à collecter de nouvelles données.
- Les études liées à l'environnement, aux transports et à la mobilité ont tendance à utiliser une grande quantité de données.
- L'innovation est principalement traitée de manière implicite. Les études liées au numérique mentionnent clairement l'innovation, tandis que les études liées à la santé ont tendance à se concentrer sur les impacts sociaux.
- En ce qui concerne **la quantification des coûts et des bénéfices**, les avantages les plus fréquemment calculés concernent la croissance économique (PIB), l'effet sur l'emploi et la diminution des pressions environnementales.
- Les études de soutien varient en termes d'utilisation ou de **degré d'utilisation de méthodes sophistiquées** - les choix sont faits en fonction des **données disponibles**.
- L'hétérogénéité des cas sélectionnés met en évidence la **relation transversale et multidimensionnelle entre l'innovation et la réglementation**: La réglementation peut affecter l'innovation de diverses manières, et l'émergence de nouvelles innovations pose des défis aux régulateurs dans tous les secteurs.
- Comme le soulignent les études de cas, il est difficile de "quantifier" les impacts de l'innovation ou sur l'innovation - en partie en raison de la nature imprévisible de l'innovation, mais aussi pour des raisons pratiques (par exemple, la disponibilité des données, les questions de confidentialité).
- Il n'existe **pas d'ensemble de méthodes établies** pour évaluer les impacts sur/de l'innovation. De plus, l'innovation n'est qu'un des nombreux objectifs politiques de la régulation. Diverses méthodes ont été développées pour estimer les impacts de

l'innovation, par exemple, le lien entre l'innovation et la productivité ou la croissance de la productivité totale des facteurs (PTF) due à l'investissement en R&D. La plupart des recherches qui mesurent les rendements de la R&D (aux niveaux micro ou macro) **s'appuient sur un cadre de fonction de production**, où la production est liée au stock de R&D (ou capital de connaissances).

- Les méthodes utilisées pour saisir les relations entre l'innovation, la productivité et la réglementation dépendent de la disponibilité des ressources pour collecter/acheter les données et mener l'analyse. Les méthodes empiriques et de collecte de données sont **très exigeantes en main-d'œuvre et donc coûteuses**.
- D'autres questions méthodologiques concernent la modélisation économétrique - elle est confrontée à plusieurs problèmes liés au caractère **endogène**, aux incertitudes dans le choix de la **structure de décalage** et aux **limitations** concernant l'utilisation de données transversales.
- La variété limitée de sources de données crédibles est également problématique.

Considérations pour les décideurs de l'UE

Les renseignements recueillis au cours de l'élaboration de l'étude conduisent à un certain nombre de considérations pour l'amélioration en vue de modifications potentielles de l'outil n° 21. Dans l'ensemble, la disponibilité de l'outil n° 21 (ou d'un outil similaire) et sa diffusion plus large au niveau national aideraient la considération et l'évaluation des impacts de manière plus systématique. Des améliorations peuvent être envisagées, par exemple :

1. En fournissant et en partageant des exemples concrets (au niveau européen ou national) sur l'utilisation de l'outil n° 21 et sur l'évaluation des impacts sur l'innovation (y compris les analyses coûts-avantages (ACB)).
2. Lors de l'utilisation de l'ACB, les résultats pourraient être améliorés par l'accès à des données plus récentes et plus spécifiques, telles que les coûts de R&D des détenteurs d'autorisation de mise sur le marché, et un meilleur moyen d'évaluer la période supplémentaire d'exclusivité commerciale.
3. Pour une étude plus systématique des éventuels impacts négatifs involontaires que l'innovation pourrait avoir, des études basées sur la théorie peuvent être envisagées. Elles peuvent traiter l'innovation comme le résultat d'intérêt - éventuellement non observé - et développer un modèle (quasi) causal (une série de mécanismes et de voies d'impact) de la manière dont les changements proposés à la réglementation pourraient influencer positivement ou négativement l'innovation.
4. Compte tenu des transformations verte et numérique, un plus large éventail de preuves quantitatives et qualitatives pourraient jouer un rôle croissant dans l'évaluation politique des propositions de réglementation par les États membres et le Parlement européen. D'autre part, pour les États membres et le Parlement européen, ce sont encore souvent les coûts et avantages économiques de base qui constituent le principal critère d'évaluation politique des propositions législatives. L'innovation est davantage un précurseur de ces résultats d'intérêt que le résultat de l'intérêt lui-même. Pourtant, le concept de législation à l'épreuve du temps, qui met en avant la nécessité de s'adapter aux progrès scientifiques et technologiques, combiné à la stratégie industrielle soutenant la double transition des écosystèmes industriels, accroît le besoin de données quantitatives sur l'innovation.

3. Introduction

This report is the final deliverable of the "**Study on the costs and benefits of innovation-sensitive legislation**" (specific request RTD/2020/SC/012), which was commissioned by the Directorate General for Research and Innovation (DG RTD) of the European Commission under the multiple service framework contract (2018/RTD/A2/OP/PP-07001-2018, Lot 3).

The report is structured as follows: following this introduction in Chapter 1, as well as the purpose and the scope of the study, **Chapter 2** provides the relevant background, including a typology of regulations. In **Chapter 3** we include a short summary of the methodology - a more extensive description is included in Annex A. **Chapter 4** provides an overview of the findings against the research questions, conclusions, and key recommendations to improve the application of the Tool #21 in the future.

The report is accompanied by **annexes** providing complementary or more detailed information with:

- A. Methodology (overview of the methodology applied)
- B. Analysis of cases (methodology behind the choice of the four case studies)
- C. Case studies (full version of the four case studies)
- D. Further inputs on the recommendations on indicators
- E. 'Operational Guidance' on how to assess the costs and benefits of innovation-sensitive legislation.

3.1 Purpose and scope of the study

In April 2021, the Commission has adopted the Communication on Better Regulation: Joining forces to make better laws.[8] It aims to introduce several improvements into evidence-based policy making practice at EU level (and specifically inviting the European Parliament and the Council to follow this quest).

In the words of EC Vice-President Šefčovič, this is a further stepping up effort to "simplify EU legislation and reduce its burden, while making better use of strategic foresight and supporting sustainability and digitalisation.''

Through a renewed involvement of stakeholders and a closer collaboration with institutions at regional and national level, as well as social partners, the Commission expects to re-model numerous tools of the Better Regulation toolbox in order to give a more prominent role to foresight, and update techniques to assess green, digital, geopolitical and socio-economic trends.

The revision of the Tool #21 (which is renumbered Tool #22 in the updated Better Regulation toolbox of November 2021) fits into this framework.[9]

Specifically, Tool #21 of the Better Regulation toolbox focuses on "Research & Innovation" to "provide clear guidelines for analysing the interaction between new or

8 https://ec.europa.eu/info/files/better-regulation-joining-forces-make-better-laws_en

9 Since the interviews and work for this study were completed before the publication of the revised Better Regulation toolbox, we still refer to Tool#21 throughout the text.

revised EU legislation (including spending programmes) and innovation." Overall, the tool aims "to make legislative proposals more forward-looking and innovation-friendly." In order to promote the tool in its application, a practical guideline on "How to apply the Impact Assessment tool on research and innovation" was published in 2017.

With the tool, DG RTD is supporting the analysis of impacts on research and innovation – in line with the innovation principle, in legislative proposals.[10] Recently, the tool and its use were analysed by Renda and Simonelli (2019)[11], also indicating areas for clarification.

The purpose and scope for this study is twofold:

(1) by analysing if and how the Tool 21 was and is used so far in impact assessments and evaluations and their support studies, the study wanted to understand its use, potential limitations, and areas to improve.

(2) The study also aimed to provide methodologies to help measuring the impacts of innovation-sensitive legislation *on* innovation outputs.

What is meant with the latter? In impact analyses, the current Better Regulation guidelines and toolbox require the analysis of impacts (economic, social, and environmental). If a cost-benefit analysis is required or planned, specific tools provide guidance (Tools #57-60). The formal quantification of costs and benefits is frequently limited to the cost side. In fact, Tool #59 recognises that "*The classification of benefits is not as well-developed as for costs not least because they are often the objective of the initiative, are initiative specific and are difficult to classify*." Therefore, much of formal cost-benefit analysis addresses the costs. Analysing the effects of regulation on innovation thus tends to address the administrative costs for introducing new legislation but does not include wider effects of the (new) rule on innovation.

This study thus wants to demonstrate on existing examples, how approaches can be improved and how (expected) innovation effects could be included in impact assessments and to some extent into evaluation studies. The obvious focus is on the EU-level but there are a number of country-level attempts to improve the law-making process (including forward-looking analysis) so that both EU and national levels are considered[12].

The study is based on desk research, case studies and interviews to further inform on difficulties and suggested improvements. Given the political priorities of the green and digital transformation, there was a thematic focus for choosing the case studies with an emphasis on digitalisation, the green transition, health, and mobility.

[10] The innovation principle is to be understood as a principle of sustainable innovation. It can be described as follows: "EU policy and legislation should be developed, implemented and assessed in view of encouraging innovations that help realise EU's environmental, social and economic objectives, and to anticipate and harness future technological advances".

[11] Renda, A., Simonelli, F. (2019): Study supporting the interim evaluation of the innovation principle.

[12] For example V. Salminen, K. Halme (2020): Innovation-friendly regulation: Current state and good practices.

4. The impact of legislation on innovation

4.1 Background

The impact of legislation on innovation has been discussed in the academic literature for quite some time and has been taken up by policy circles.[13] With the Better Regulation guidelines policymakers at EU-level have an instrument to include innovation aspects in impact assessments, yet innovation is only one among many factors that assessments can consider (or not). At the national level, the degree of systematic analyses is even lower and awareness about the innovation effects of legislation is only gradually increasing. In this respect, the Better Regulation (BR) principles and tools of the European Commission are key guidelines that can also serve the national level as a source of inspiration. In fact, the European Commission also encourages the Member States to establish their own national Better Regulation strategies and to perform impact assessments that resemble the scope of the EC's own assessments.

While predominantly designed for the European Commission processes, the Better Regulation guidelines of the European Commission are also influenced by national experiences such as the UK, Sweden, Germany, or the Netherlands. Several EU Member States and some third countries such as the UK, Switzerland, and Canada are active in developing further Better Regulation processes. Much has been achieved not only in the EU but in the OECD context since the mid 1990s, particularly in terms of methodological guidelines, systematic reviews of countries' regulatory systems and recommendations.[14]

In a recent publication by NESTA[15], the authors note different narratives on regulation – but not much change: the narrative of 'regulation is burdensome' and 'red tape' is dating back to the 1990s and is still ongoing.[16] Another strand led to focussing on the downside risks innovation can entail in the absence of regulation. An example is given with the financial crisis of 2008: the lack of regulation of the (formerly praised) financial markets and the effects of mis-regulation led to innovative, but in the end dangerous financial instruments and the collapse of the market.

Having witnessed the downside of absent regulation, the above-mentioned narrative has lost some weight and at present, regulation is seen as "*a potential guardian of the efficient functioning of markets and public safety*" (p10). An example for the need of regulation in highly innovative environments is mentioned for instance for large digital platforms. So far, they grew by and large under the radar of regulative action and generated also unintended and unwanted social and economic side effects. They impact the economy and social life alike, creating markets on their own and transforming many industries. While these transformations could be seen as an urgent call for regulation, NESTA concludes that the regulative processes remain conservative in the sense that there is not much experimentation of new and needed regulation. A growing attention for

13 For example: Blind, K. (2012): The Impact of Regulation on Innovation, Nesta Working Paper 12/02; Pelkmans/Renda (2014): Does EU regulation hinder or stimulate innovation?, CEPS Special Report No. 96; EC (2016): Better regulations for innovation-driven investment at EU level. Commission Staff Working Document

14 EPRS (2020): Better regulation practices in national parliaments. PE642.835

15 NESTA (2019): Renewing regulation. 'Anticipatory regulation' in an age of disruption.

16 At the EU-level, there was for example the High-level group on Administrative Burdens ('Stoiber Group') created in 2007. The 2021 Communication on Better Regulation proposes the "one in one out" principle for legislation to reduce the regulative burden.

new tools such as regulatory sandboxes and other forms of experimentation could however change this.[17]

Examples of countries applying an innovation principle (see Annex B, 11), regulatory sandboxes, or other instruments are not yet systematically analysed but identified cases are instructive (see the example of the Finnish Act on Transport Services, one of the case studies in Annex B, 12) for testing new legislation or providing testbeds for innovation in a defined setting. Applying for example sunset clauses to legislation would either end the legislation if it has served its purpose or enable adaptation to new needs - be it due to technical, economic, or social change.

Yet, experimental instruments like those proposed in Tool#21 are not yet widely found in real life. Appropriating new functions to regulation is challenging and so is finding how to respond with adequate regulation to for instance, the new reality of the platform economy.[18] There is a perceived risk that new regulations may not enable useful innovation that serves the public interest while existing regulation may seem to be outdated and not responding to the new challenges. On the other hand, new tools such as regulatory sandboxes and other forms of experimentation to make legislation more agile and future-proof are spreading. However, the still limited implementation experience does not yet allow drawing firm conclusions on their potential.

When it comes to impact assessments a positive development can be observed. According to the OECD's 2018 Regulatory Policy Outlook[19], the type of innovation-related impact assessments by the number of countries requiring/performing them for new regulation, has considerably increased between 2014 and 2017.

4.2 Types of regulations

Regulation is defined by the OECD as "the diverse set of instruments by which governments set requirements on enterprises and citizens. Regulations include laws, formal and informal orders and subordinate rules issued by all levels of government, and rules issued by non-governmental or self-regulatory bodies to whom governments have delegated regulatory powers." (OECD, 1997).

Blind (2012) classified three types of regulations, namely:

1. Regulations **targeting the promotion of innovation**. This includes for example intellectual property regulation, which impacts companies and their innovation behaviour directly.

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[17] See for example EY 2020, OECD 2020. The growing interest is also manifested through the Council Conclusions 16/11//2020 (13026/20), see: https://www.consilium.europa.eu/en/press/press-releases/2020/11/16/regulatory-sandboxes-and-experimentation-clauses-as-tools-for-better-regulation-council-adopts-conclusions/. In the latest version of the Better regulation toolbox (Nov 2021), Tool #69 provides for further guidance on regulatory sandboxes and their relevance for policymaking.

[18] Among the key functions of law is legal certainty. Implicitly, certainty is associated with a long-term perspective. A laboratory environment as meant to describe a regulatory sandbox, experimentation or testbeds represents a deviation from common understandings about law. Yet, experimental legislation concerns the process and tool for regulation. From an economic perspective, experimentation aims at mitigating economic risks. From a legal perspective, the nature of the risks is potentially much broader, since the law has a protection function in the real world (e.g. consumer safety, fundamental rights). See for example the blog entry of K. Yordanova (2019): The shifting sands of regulatory sandboxes for AI. https://www.law.kuleuven.be/citip/blog/the-shifting-sands-of-regulatory-sandboxes-for-ai/

[19] OECD (2018): Regulatory Policy Outlook 2018.

2. General regulation **without the dedicated goal to promote innovation**. This is the dominant type. Regulation in this category targets health and safety, or environmental protection, but also market regulations are integrated in this type. General regulations have a direct impact on companies. Because of the regulation, they need to modify existing products (incremental innovation effect) or introduce radical product or process innovations. This has potential effects on the environmental pressures but also on consumers and society.
3. The third type concerns regulations affecting companies' strategies and activities but **not necessarily affecting (positively) their innovation activities**. Here, reporting requirements and the often labelled 'administrative burden' -type of regulation is meant.

Blind further distinguished economic, social, and institutional types of regulations and their positive and negative effects on innovation (Figure 1). This categorisation and the previous distinction between innovation-targeted or general regulations are useful to bear in mind when speaking about innovation-sensitive legislation.

This classification of regulations by type and objectives increases the understanding of the most common expected positive and negative effects. Its use in empirical cases illustrates the highly contextual nature of both regulatory and innovation domains. This in turn can lead to rather diverse impact pathways, which capture different relevant impacts.

Figure 1 Types of regulations and their effects on innovation

Type of regulation	Positive effects	Negative effects
Economic		
Competition	Increases incentive to invest in innovation	Reduces rents for innovators Reduces R&D co-operation
Antitrust	Competitive pressure by market entrants	
Merger & Acquisitions	Restrictions protect management from short term market pressure	M&A restrictions limit takeover pressure and innovation incentives
Market entry	Can protect infant industries	Restricts market entry of (innovative) newcomers
Price regulation	Minimum prices decrease risk	Price caps reduce innovation incentive
Natural monopolies/ public enterprises	Stability allows for long time-horizons	Monopoly results in low incentives, e.g. to innovate
Social		
Environmental protection	Creates incentive for new eco-friendly products and processes by creating temporary market barriers (Porter Hypothesis)	Compliance costs limit R&D budget
Workers health and safety protection	Creates incentive to develop new processes with higher work safety	Compliance costs limit R&D budget
Product and consumer safety	Increases acceptance/demand for new products among consumers	Compliance costs limit R&D budget

Type of regulation	Positive effects	Negative effects
Institutional		
Liability	Increases acceptance and diffusion among consumers	Too high liability reduces incentives to develop new products
Employment protection legislation	Job security	Higher adjustment costs, e.g., in case of an economic downturn
Immigration	More competitive/flexible job market	Integration costs
Bankruptcy	Increased confidence of creditors to invest in innovation	Restriction to acquire external funds for risky investments
Intellectual property rights	Additional incentives to invest in R&D due to monopoly rights	Restricts development and diffusion of new technologies

Source: Adapted from Blind 2016

4.3 Relationship between regulation and innovation

The impact of regulation on innovation activity has been a topic of academic research for decades (e.g., Porter, 1990; Porter and van der Linde, 1995; Pickmann 1998, Ashford and Hall, 2011). The lessons from the existing body of literature suggest that the relationship between regulation and innovation is not simple or straightforward.

The literature analysing the effects of regulation on innovative activities emphasises the need to take account of the **systemic nature of innovation activities and the difficulties in attributing innovation effects to regulation**. The relation between regulation and innovation was highlighted by Porter (1995), suggesting that strict environmental regulations could induce efficiency and encourage innovations that help improve commercial competitiveness. Empirical evidence from the Community Innovation 2008 survey (it contained the environmental innovation module), showed that the regulatory factor plays an important role in introducing environmental innovations. The innovation literature nevertheless suggests that regulation is but **one of the factors influencing innovation**. Based on the innovation system approach, innovation evolves within a system in which many interconnected factors play a role (e.g., framework conditions, technological capabilities, culture).

Evidence from environmental regulation showed that regulation played an important role when considering the **type of innovation**. Early regulation for example fostered end-of-the pipe technologies. Later regulation and measures, such as environmental management schemes, energy and material cost-saving measures directed the innovations towards introducing cleaner production technologies or adopting resource efficient measures (Frondel 2007, Fleiter 2013).

Depending on the context (i.e., company profile, sector, economic climate, wider policy framework), **regulation can both enable and hinder innovation activity**. Regulation may be supportive and foster innovation for example by reducing investment risks by harmonising regulatory frameworks across Europe, or by providing a common reference framework for new materials and products. In terms of barriers, compliance costs or the lack of clear regulatory targets are often considered a burden by businesses.

Regulation may have **system-level effects**, for example, by shifting investment opportunities to different actors. Under the European Green Deal or the digital transformation priorities, this may happen and as such drive innovation, and may create

new job opportunities. On the other hand, these innovations may have transformative impacts and lead to or support the decline of existing industries and the loss of existing jobs.

Regulation rarely explicitly addresses innovation. In many cases **regulations affect innovation indirectly and in an unintended way.** This renders the assessment challenging.

A clear taxonomy determining the direct and indirect innovation effects of a given regulation does not exist. Similarly, there is no clear view on how regulations affect innovation processes. Numerous case studies suggest some effects but so far, the creation of stylised facts that can serve as a basis for a congruent analysis appears as difficult to achieve.

In 2008, BERR[20] developed a framework of six drivers, which determine the impact of regulation on innovation, and which is currently included in the Tool #21 under Step 3 – Address legislative design considerations.

4.4 Regulatory impacts by type of regulation

Empirical evidence could be used to better understand which type of regulation affects innovation behaviour within economic sectors.

Empirical findings show that the innovation effects of regulation vary by industry and technological area (Frondel et al. 2007; Kammerer 2009). Based on the Community Innovation Survey, several sectors indicated to what extent they introduced environmental innovation in response to regulation. In transport, mining, and construction about one third of companies indicated innovation behaviour due to regulation. In energy generation about 40% of companies, or in the water sector, about half of the firms were affected and reacted with innovation. The influence from the prospect of future regulation (expected regulation) was strikingly high in these industry sectors too.

According to a survey Technopolis conducted for DG RTD on regulatory impacts[21] and economic effects of EU legislation on innovation, overall, among the different types of legislation, several (e.g. standardisation, labelling, or environmental protection regulation) are not perceived as a barrier and as such do not have a major effect on innovation (see Figure 2). Overall, the main barrier was not regulation per se but **conflicting requirements of different regulations**.

However, broken down to the sectorial level, there are marked differences. Dedicated sectoral policies are in general seen as a driver, but in several sectors such as agriculture, forestry, and fisheries, the manufacturing of chemicals, pesticides and other agrochemical products, water, and food industries they are perceived as a barrier. Product safety regulation, environmental protection regulation, and labelling which are equally more often perceived as a driver, are a barrier in a variety of sectors such as

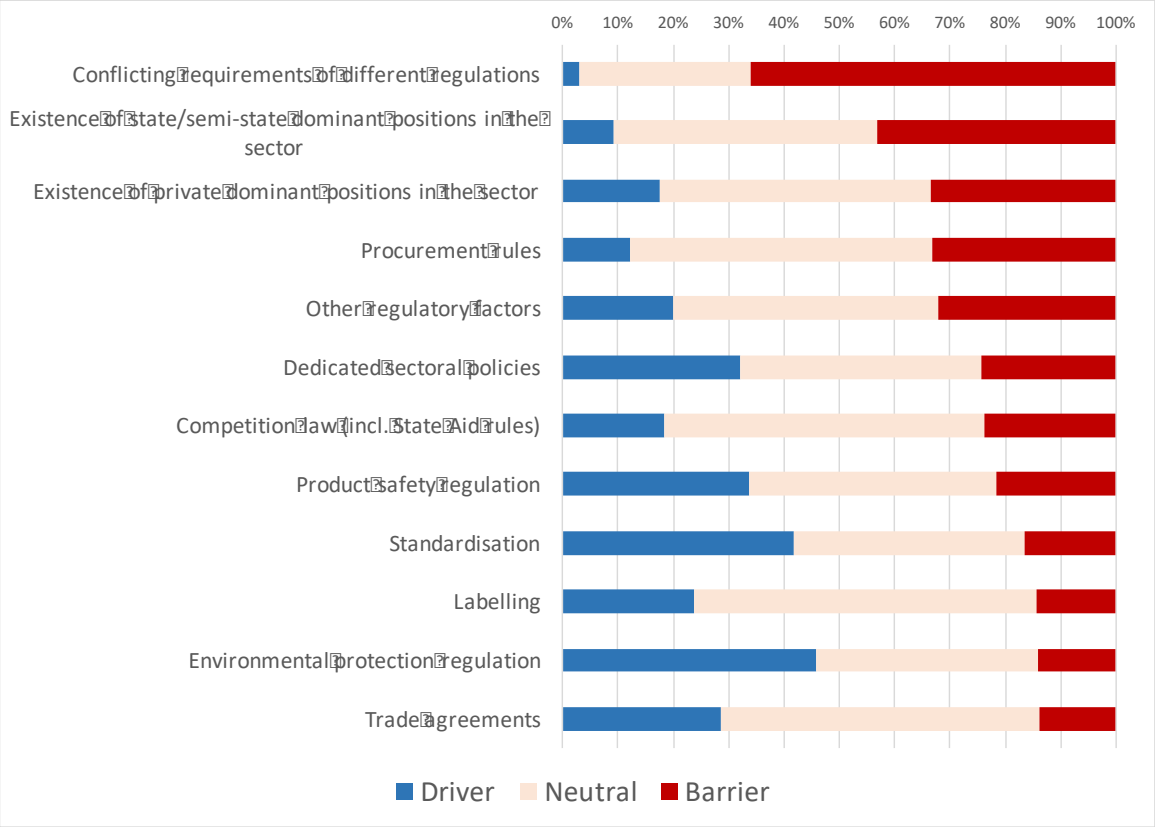
[20] BERR (2008): Regulation and Innovation: Evidence and policy implications. The factors considered were: Prescriptive vs. outcome-based regulation, Stringency, Timing, Compliance costs, Regulatory uncertainty, and Interactions with other government policies

[21] Technopolis Group (2016:) Assessing the Impacts of EU Regulatory Barriers on Innovation

manufacturing of food products, chemicals, pharmaceuticals, metals, health, and construction.

In summary, various empirical studies[22] on the impact of different types of regulation on innovation present a rather heterogeneous picture both regarding the type of regulation and the sectors which benefit – or not.

Figure 2 Overview of impact of regulation on innovation, all industry (2016)



Source: Technopolis 2016

4.5 Short-term versus long-term impacts

Empirical studies also show differences between short- and long-term impacts. The short-term impacts of regulations are often negative for innovation behaviour and the costs of innovation. The long-term implications of forcing or encouraging the adoption and acceleration of the uptake of innovations and their spillover benefits are much more beneficial. In fact, in the longer-term perspective, the costs of implementing a regulation have been fully written-off and are no longer seen as a cost or burden of a regulation.

22 For example, Ollinger, M., Fernandez-Cornejo, J. (1998): Innovation and regulation in the pesticide industry; EC (1998): The Impact of EU Regulation on Innovation of European Industry ; Mahdi, S. (et al) (2002): Regulation and Innovation in the Chemical Industry; Kuhlmann. S. (et al) (1998): Regulation und künftige Technikentwicklung. Springer (incl. a case of the German wind energy regulation).

This does however not apply to the "Type III" – regulations (see 4.2 above), which oblige companies to constant reporting. These are typically costs, which do not cease to exist.

Blind (2012) noted that the impacts are not time invariant. Earlier studies have found slightly more negative impacts, whereas more recent investigations tended to reveal more positive implications especially in relation to environmental regulations. Furthermore, most quantitative studies about the impact of regulations were not able to distinguish between the influence of changes in the legislation (on innovation activities) and of their enforcement and the related compliance of companies.[23]

4.6 Innovation in the EU policy cycle

The Council conclusions on research and innovation friendly regulation of May 2016 stressed that, "when considering, developing or updating EU policy or regulatory measures, the 'Innovation Principle' should be applied, which entails taking into account the impact on research and innovation". Among others, the innovation principle aims to reduce the EU innovation deficit. It ensures that when EU legislation is being considered, its impact on innovation is assessed. It is therefore key to foster both research and innovation at EU level. The European Commission as well as Member States recognise the importance of this principle. The European Political Strategy Centre, an in-house expert group under the previous Juncker Commission issued in 2016 a policy-note on the Innovation Principle[24] describing "An innovation principle means ensuring that whenever policy is developed, the impact on innovation is fully assessed. The principle should provide guidance to ensure that the choice, design and regulatory tools foster innovation, rather than hamper it."

Innovation is among the types of impacts that must be identified in the impact assessments and assessed if they prove to be significant. Constraints on the practice, as the note further writes "often have to do with insufficient available data, limited ability to quantify results or limited comparability of different options". The innovation principle calls for a systematic and holistic analysis of the impacts of regulatory proposals on innovation activities. This implies an assessment of economic, environmental, and social costs, "even if they are often hard to quantify."

In ex-post evaluations, the Better Regulation guidelines ask explicitly for an analysis of economic, social, and environmental impacts. Unfortunately, the ex-ante as well as the ex-post analysis is hampered by the complexity of the innovation process and most of the time, a direct, explicit and quantifiable contribution of a given regulation on (measurable) innovation effects remain rare. This is also since a lot of legislation is not primarily intended to foster innovation but has different objectives. Perhaps as a by-product, innovation happens, but there can be many other factors that contribute. A notable exception is perhaps the evaluation of the Orphan Regulation (see Annex B, 13): while the Regulation dates prior to rigorous impact assessment practice at EU-level, it is one of the few identifiable innovation-sensitive regulations. There is a clear economic situation before and after the introduction of the Regulation which was addressed in the first ex-post evaluation.

[23] See for example, Crépon et al (1998). On the rate of innovation as well as type of innovation based on French labour market regulation data, see also Aghion et al 2021.

[24] EPSC (2016): Towards an Innovation principle endorsed by the Better Regulation. Issue 14, 30.06.2016

5. Methodology overview

The methodological approach for the study was based on five pillars:

1. A systematic analysis of recent cases[25], – based on desk research and the search of dedicated websites and databases, followed by validating interviews to identify suitable case studies.
2. A selection process based on a multicriteria analysis, which considered empirical evidence as well as the needs of the European Commission.
3. Development of concise and well-structured cases studies that provide insights on the use of the tool as well as potential improvements.
4. Exemplary pathways providing guidance on measuring the impacts of innovation.
5. Critical assessment and suggestion of robust indicators for monitoring and evaluation.

The detailed description of the methodology can be found in Annex A. Methodology.

5.1 Conceptual framework

The theoretical concepts on the impact of regulation on innovation and the impact of innovation can be summarised in a conceptual framework as shown in Figure 3. A regulatory framework co-exists with the innovation system. It influences directly or indirectly innovation stakeholders, processes, as well as research and innovation activities. Other factors – the framework conditions – exert various influences too. This mix of regulation and wider framework conditions are impacting *on* the innovation system and its stakeholders and the whole leads to innovation outputs (i.e., the effects of regulation *on* innovation).

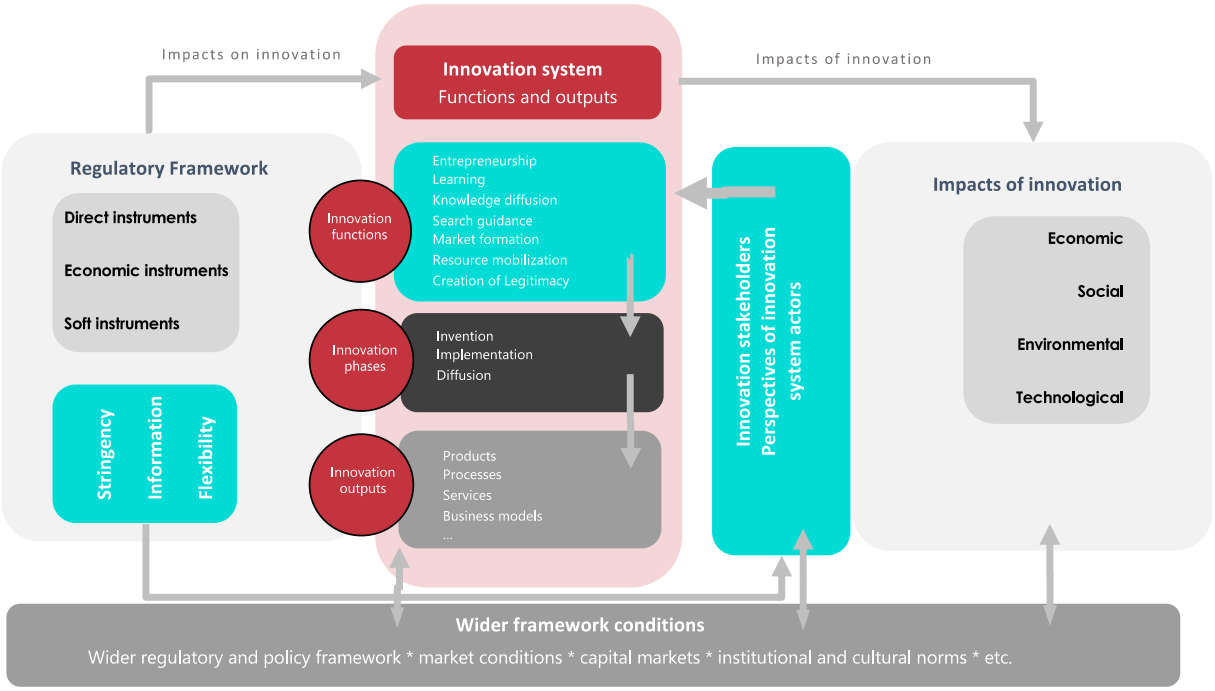
These innovations have also wider socio-economic impacts, which are covered on the right-hand side of the figure, covering the angle of *impacts of innovation*.

In a 'classical' impact assessment exercise or under a fitness check, the quantification is concentrated on costs and benefits of the new regulation on various stakeholders. Measuring the impacts on innovation is a complex task: the complexity or interrelatedness of regulation, innovation, framework conditions in combination with a time dimension (which is not depicted in the figure but needs to be considered too), impede the identification, attribution and measurement of direct and indirect effects. Nevertheless, impact assessments include forward-looking elements, and they address economic, environmental, and social impacts (as indicated for example in Tool #19 of the Better Regulation toolbox).[26]

[25] Initially, cases were chosen to be from 2017 onwards. However, given clear limitations, the study team chose to expand the timespan of the considered impact assessment and evaluation studies in order to encompass more, relevant innovation-sensitive regulation cases.

[26] In the latest edition of the BR (Nov. 2021), Tool #19 'Identification of impacts' is part of Chapter 2 on how to carry out an impact assessment .

Figure 3 Conceptual framework



Source: Technopolis Group

5.2 *Findings of the screening analysis*

Following the identification and analysis of several impact assessments, evaluations and their supporting studies of potentially innovation-relevant legislation in the Inception phase (see for more details Annex A), the study team summarised reflections and observations on the current state of the application of the Tool #21 as follows:

- Several of the cases were not new but concerned **impact assessments of amended legislative proposals or evaluations of existing legislation** for which at least one initial impact assessment was conducted, and/or evaluations of previous versions existed. Thus, for some studies, a chain of impact assessment, legislation, evaluation, impact assessment, legislation, evaluation etc. existed. Typically, the study team considered the latest revision. In some cases – in particular in transport- and digital-related studies – a number of earlier studies and cumulative data efforts served as input to the next study (evaluation or impact assessment). This renders the analysed cases highly data driven.
- **Environmental, transport and mobility-related studies shine with a wealth of data** – sometimes it is difficult to find a red thread with all the data and evidence provided in the support studies. In these areas, studies benefit from a lot of available environmental and economic data. They equally tend to include advanced modelling.
- **None of the screened legislations aimed directly at the promotion of innovation activities**. Cases such as the Novel Food Regulation practically ignored innovation and focused entirely on safety aspects in its 2008 revision (the Regulation dates back prior to the introduction of impact assessments).
- **Innovation is predominantly treated implicitly**. Almost all studies analyse economic impacts and focus on growth and employment. Whether or not the growth and employment effects are due to new business opportunities, business models and

the delivery of new products and services, induced or at least supported through the legislation remains by and large a "non-treated black box".

- **Digital-related studies** – in particular the latest studies, **clearly mention innovation**. In this area, innovation is mainly induced through the technological opportunities promoted or enabled through the novel legislation (e.g., the European Data Act).
- **Health-related studies focus on social impacts** – in particular safety aspects. Economic effects play – if any - a minor role.
- Although most of the analysed studies aim at some kind of quantification of costs and benefits, they vary in level of detail. The most often calculated benefit is on economic growth (GDP), the effect on jobs, and the decrease of environmental pressures.
- Highly **sophisticated or less sophisticated methods are used in several support studies**. The depth of the latter may be a function of the budget – obviously, data can be collected but it has a price in terms of time and resources. Therefore, more difficult and costly systematic collection means are hardly included. In studies where data is available (e.g., transport, environment) it is used in often complex models. In other cases, such as fragmented product markets, where data is much less readily available this would require a substantial and costly collection effort which may not have been anticipated when the support study was planned. Also, in this initial planning phase, a substantial collection effort in a small or fragmented market may not seem to be proportionate.

5.3 Characteristics of the case studies

Four case studies were selected. Despite a common structure, the selected case studies have many different characteristics. Three of the cases relate to EU-level legislation, whereas the *Finnish Act on Transport Services* is a national case. While the Finnish Act can be seen as an example of an economic regulation, the *Orphan Regulation* and the *Directive on Urban Waste-water Treatment* are viewed as social regulation, and the *Directive on Re-use of Public Service Information* can be seen as an institutional regulation aimed at promoting innovation (see Figure 1). The thematic focuses of the cases cover mobility, health, digitalisation and the environment.

Three of the four cases can be considered as examples of regulation specifically targeting the promotion of innovation, while the *Directive on Waste-water Treatment* is more of a general regulation without the dedicated goal to promote innovation, although there is also a clear link to innovation.

Also, the 'impact mechanisms' (ways the regulation may affect innovation) vary from case to case. In the *Finnish Act on Transport Services*, there is a clear focus to create new and to develop existing mobility services by introducing requirements for opening data. In a sense, the *Directive on Re-use of Public Service Information* can be seen to have a somewhat similar logic, albeit on a much more general level going beyond the mobility/transport sector. The *Orphan Regulation* bears a strong social aspect by focusing on ensuring the same quality of treatment to patients with rare diseases, but at the same time, has a notable innovation dimension by providing incentives for industry to develop and market orphan medicinal products. Similarly, the *Directive on Urban Waste-water Treatment* is an example of social regulation which also includes incentives for developing new innovative solutions for waste-water treatment.

Table 1 Overview of characteristics of selected cases

Case	Level	Thematic field	Type of regulation	Relationship to innovation	Impact mechanism(s) / logic (regarding innovation)
The Finnish Act on Transport Services	National	Mobility/ transport	Economic (especially regarding public transport agencies)	Targeting the promotion of innovation activities	Includes requirements to open mobility data and data interfaces to support the development of Mobility-as-a-Service (MaaS)
Regulation (EC) No 141/2000 (the Orphan Regulation)	EU	Health	Social (improving public health and reducing health inequality)	Innovation-sensitive since ultimate social goal is achieved through innovation only	Ensuring the same quality of treatment to patients with rare diseases and restoring the equilibrium between supply (industry) and demand (patients with rare diseases) by providing incentives for industry to develop and market orphan medicinal products.
Directive on Re-use of Public Sector Information (Directive 2013/37/EU)	EU	Digital	Institutional regulation (access to data)	Targeting the promotion of innovation activities	Fostering the growth of the digital economy and the creation of digital-economy jobs, stimulating "digital innovation, especially with regard to artificial intelligence" and the development of new products and services.
Directive on Urban Waste-water Treatment (Directive 91/271/EEC)	EU	Environment	Social (environmental protection)	General regulation without the dedicated goal to promote innovation	Protecting the environment from the effects of the pollution from waste-water by improving the environmental performance of waste-water treatment (thus creating demand for new waste-water treatment innovations).

Source: own compilation

The use of the Tool #21 as well as CBA also varies between the cases. In none of the cases the Tool #21 was explicitly used. However, it shall be noted that some of the cases pre-date the introduction of Tool #21. Also, the utilisation of CBA in the cases varied rather significantly: for example, regarding the *Finnish Transport Act*, no particular CBA was conducted, though the Government Proposal included some references to studies in other contexts where CBA was utilised. The modelling and quantitative assessment of the *Directive on Urban Waste-water Treatment* was considered limited, whereas in the cases of *Re-use of Public Sector Information* and the *Orphan Regulation*, the usage of CBA was rather extensive.

Table 2 Use of Tool #21 and CBA in the case studies.

Case	The use of Tool #21	Use of CBA	Notes on Cost Benefit Analysis	Methods /sources
The Finnish Act on Transport Services	No (national case, predates Tool #21)	No (but references to CBA studies in other contexts)	A national need to develop more robust methods for RIA in Finland has been identified (Audit Committee Report).	Literature review, desk research of earlier studies in similar context.
Regulation (EC) No 141/2000 (the Orphan Regulation)	Implicit, original regulation & IA predate Tool #21	Yes, as far as possible in accordance with EU guidelines	Health benefits not monetised but expressed in terms of Quality-adjusted Life Years (QALYs)	CBA, literature review, data analysis, targeted consultation
Directive on Re-use of Public Sector Information (Directive 2013/37/EU)	No explicit use of Tool #21[27]	CBA of different policy options for revising the Directive	CBA for each policy package relative to business as usual (BAU) performed with respect to their effectiveness, efficiency, proportionality, legal feasibility and coherence, and practical, technical and political feasibility	CBA, legal data analysis, costs typology, desk research, interviews, survey and open public consultation.
Directive on Urban Waste-water Treatment (Directive 91/271/EEC)	Implicit	The assessment of the efficiency criteria includes a CBA	Limited modelling or quantitative assessment	Desk research, modelling of impacts, stakeholder consultations, open public consultation. Assessment of the efficiency criteria included a CBA.

Source: own compilation

[27] Instead, extensive reference is made to the Better Regulation agenda and Tool #63 on multi-criteria analysis (Tool #62 in the 2021 edition of the Toolbox) is explicitly used.

6. Findings, conclusions, and recommendations

This section aims to give an overview of the lessons learned. We first look at each of the developed case studies and then, provide insights from a cross-sectoral analysis. These considerations may help understanding potential useful changes to #Tool 21, in order to improve future quantifications of costs and benefits of innovation-sensitive legislation.

6.1 Findings from the case studies

Orphan Regulation

The scope of the analysis regarding the *Orphan Regulation* was seen as appropriate, as many of the stakeholders and stakeholder groups were engaged in the consultations. Additionally, a cost benefit analysis was conducted. The fact that the sponsors of orphan medical products (companies) were unwilling or unable to disclose information about R&D costs relating to specific orphan medical products in the consultations led the evaluators to use more general corporate R&D expenditure data and the wider academic literature for analysis instead of precise data.

An improved access to up-to-date and specific data on R&D costs of market authorisation holders could improve different CBA analyses in the future. For example, if company data on R&D costs, production, marketing and distribution costs, pricing and revenues from individual products were to be available, they could be used to show how these factors influence the decisions of companies. However, there are several challenges involved with using confidential corporate information in such analyses.

Re-use of PSI

Regarding the good practices and lessons learned in the *Directive on Re-use of Public Sector Information*, especially the broad stakeholder input and the solicitation of expert opinion should be emphasized. In addition to the almost one hundred interviews conducted, there were also several surveys and workshops held.

Although one of the important objectives of the Directive was the promotion of innovation, the Evaluation and Impact Assessment did not attempt to directly analyse its actual innovation effects. However, the chosen methodology was essentially appropriate. Under ideal circumstances (e.g., more time and resources), the analysis could have been pushed a bit further by performing a more systematic study of the possible unintended negative innovation impacts. In the interviews conducted for the present study, it was brought up that while the promotion of innovation is always present when considering the effectiveness of policy measures, currently the innovation effects are rarely assessed directly. The reasons behind this were seen to be two-fold: firstly, innovation effects remain difficult to quantify and secondly, for Member States and the European Parliament, it is often the basic economic costs and benefits that constitute the overriding criterion by which regulatory proposals are politically assessed.

Finnish Act on Transport Services

The Finnish Act on Transport Services has been identified as a good example of innovation-friendly regulation. This was mostly due to technology-neutrality and innovation-enabling legislation being the key guiding principles in the legislation drafting phase. Another focus area was customer-orientation as there was a notable emphasis on customers' and citizens' needs and the quality of transport services. A very concrete good practice was the establishment of the *Transport Market Forum* by the Ministry of Transport and Communications. The forum was set up to facilitate discussion among transport service providers and other actors on the effects of the Transport Services Act, as well as being responsible for supporting the monitoring of the effects of the Transport Services Act.

Even though the Finnish Transport Act specifically aimed to impact innovation, the assessment of these impacts remained limited and on a general level. While the act was drafted before Tool #21 was introduced, it is likely that utilising the Tool #21 or some other similar method would have considerably helped to assess the impacts in a more systematic manner. Therefore, by providing and sharing concrete European or national level examples of using the Tool #21 and assessing the impacts on innovation – including Cost Benefit Analyses – the Commission could significantly help the Member States in assessing the impacts of both EU-based regulation and national regulation.

Urban Waste-water Treatment

The evaluation of the Directive can be considered a good practice example. It combined a range of quantitative and qualitative methods. As often in environmental studies, there was use of an established impact model which did not include innovation impacts. Innovation impacts were addressed through a patent analysis, and a large expert group. The latter enabled the integration of academic as well as industry insights.

As a key good practice and important for the then following impact assessment was the comprehensive integration of supporting sources in the EC. The lead DG brought together various supporting entities such as the JRC, expert groups, obtained and provided access to projects from the Executive Agency for SMEs (EASME) and other relevant studies. This pool of resources was beyond the initial evaluation support study budget and provided a wide evidence basis.

6.2 Findings from cross- case studies analysis

The heterogeneity of the selected cases highlights **the cross-cutting and multidimensional relationship between innovation and legislation**: regulation can affect innovation in various ways, and the emergence of new innovations is presenting challenges for the regulators in all sectors. This, understandably, raises expectations for assessing the impact on/of innovation.

As highlighted by the case studies and in the consulted academic literature, **quantifying the impacts of/on innovation is by no means easy**. Some of the challenges are related to the unexpected nature of innovation, while some are more practical (e.g., availability of data, confidentiality issues).

Despite some good examples and lessons, **there is no generally established set of methods to assess the impacts on/of innovation**. It should also be kept in mind that innovation is only one of the many – and in most cases subordinate – policy goals of legislation. Therefore, the resources available for assessing the impacts of/on innovation are likely to be restricted.

More specifically, in terms of **impacts on innovation**: a review of the empirical literature related to the impact of regulatory instruments on innovation and productivity provided no consistent picture in matters of a particular/common methodological approach or impact itself (e.g., Blind, 2012).

From a methodological perspective, various methods have been developed to estimate the **impacts of innovation**, for example, the link between innovation and productivity. A very common approach relates the growth of total factor productivity (TFP) to R&D. Most of the research that measures the returns to R&D (the micro or macro levels) relies on a production function framework, where the output is related to the stock of R&D (or knowledge capital). Many scholars draw on the work of Griliches (1979,1992, 1994) and his estimations of R&D elasticity based on a production function, as well as on studies derived from Crepon et al. (1998) who proposed a conceptual and analytical framework relating R&D, innovation, and productivity.

The methods used to capture the relations between innovation, productivity and regulation are highly dependent on the **availability of resources** to collect/purchase data and conduct the analysis. The empirical and data collection methods are highly labour intensive and thus costly.

Further methodological questions concern econometric modelling - it is facing several issues related to **endogeneity**[28], uncertainties in the choice of the lag structure and the limitations regarding the use of cross-sectional data.

Somewhat problematic is the limited variety of credible data sources: economists in their studies tend to rely on the same sources such as patent data from Patstat, R&D related data from the Community Innovation Survey (CIS) or aggregated data from the OECD database. This limits their research perspectives and also possible narratives.

The Tool #21 can help identify the relevant issues and questions, but further efforts are needed to refine methodologies, test new methods, and disseminate good practices for robust impact assessments – both at EU and national level.

[28] The correlation between the explanatory variable and the error term.

7. Development of recommendations on monitoring and evaluating impact indicators on and of innovation

The development of recommendations on indicators follows the conceptual framework (see Figure 3). Furthermore, we differentiate between the indicators and monitoring approaches related to indicators of innovation on the one hand and indicators measuring the various impacts of innovation on the other hand. Related to the indicators of innovation, we differentiate further between different levels of analyses, since legislation impacts not only the macro level (e.g., Blind 2012), but due to its sectoral character also the sector (meso level) and eventually the organisational level (see McEntaggart et al. 2020).

7.1 Innovation indicators

In a first step, we screened the most relevant sources for the definition of innovation, but also examples of innovation scoreboards and innovation indexes. This was complemented by the insights of the recent literature review by Dziallas and Blind (2019) on innovation indicators, along the different phases of the innovation process.

Based on these insights complemented with the restricted input from the analysed case studies, we derived a condensed list of indicators, which we propose for the performance of ex ante impact assessments and ex post evaluations of legislation with implications on innovation.

We structure the list of indicators along the linear research and innovation process, i.e. we present first indicators for the input and then for the output, which are complemented by indicators related to changes of market structures.

Research and Innovation Input Indicators

In order to generate innovations, companies have to carry out different activities. In the narrow sense, these are research and development defined by the Frascati Manual (OECD 2015). However, complementary to these activities, which are mainly conducted by researchers, machines and other tangible or intangible assets as well as financial and commercial activities related to an innovation for the firm are necessary (see Table 1 from the Oslo Manual). Finally, following research and development, additional activities are relevant to eventually commercialize the results of the research and development efforts.

Box 1: Types of activities of relevance to innovation (OECD/Eurostat 2018)

- Research and experimental development activities
- Engineering, design, and other creative work activities
- Marketing and brand equity activities
- Intellectual property related activities
- Employee training activities
- Software development and database activities
- Activities related to the acquisition or lease of tangible assets
- Innovation management

Source: own compilation

We follow the logic of the OECD and propose the following indicators related to the input into research and development and ultimately innovation:[29]

Table 3 R&D and innovation input indicators

Indicators	Level of Analysis	Data Sources
Expenditures of companies for research and development[30]	Country	Eurostat incl. EIS and CIS, OECD
	Sector	Eurostat incl. CIS, EU Industrial R&D Investment Scoreboard; specific company surveys
	Micro	Eurostat CIS micro data; interviews
Expenditures of companies for innovation related activities	Country	Eurostat incl. EIS and CIS, OECD
	Sector	Eurostat CIS, specific surveys
	Micro	Eurostat CIS micro data; interviews
Personnel working in research and development[31]	Country	Eurostat incl. EIS, OECD
	Sector	Eurostat CIS, EU Industrial R&D Investment Scoreboard; specific surveys
	Micro	Eurostat CIS micro data; interviews

Source: own compilation

Research Output Indicators

Following the input into research and innovation activities, we can rely on two indicators, which measure immediately the output of the above activities, although these indicators are not necessarily related to innovation.[32] On the one hand, **scientific publications** are a well-established indicator in particular for basic, but also applied research (see for the current state of the art Glänzel et al. (2019). In addition, it has to be mentioned that

[29] Dziallas and Blind (2019) reveal 82 indicators based on their comprehensive review of the literature. Unfortunately, for most of them no data is available, i.e. it has to be collected via interviews or company surveys. However, some of them are significantly influenced by legislation, e.g., time to market. Therefore, it makes sense to consider some of them in ex ante impact assessments or ex post evaluations of legislation.

[30] In theory, we could further differentiate between basic and applied research. However, this differentiation is in general challenging. Furthermore, companies being in the focus of impact assessments and evaluations are less active in basic research. Therefore, we do not recommend a differentiation between basic and applied research. Depending on the legislation to be analysed, also the expenditures of the public research organisations and universities have to be considered.

[31] Personnel for innovation activities are not appropriate because they are often not only involved in innovation related activities.

[32] In addition to scientific publications and patents, **standards** have been meanwhile accepted as output indicators of research projects already under Horizon 2020, and were also included in the OECD Oslo Manual (OECD/Eurostat 2018). See for a detailed discussion about standardisation and standards as innovation indicators Blind (2019). For specific regulations, the complementary analysis of related standards including their diffusion might be justified in the context of ex-ante impact assessments and ex post evaluations.

more than 90% of the scientific publications are published by authors working in universities and public research organisations (see Krieger et al. 2020 for Germany). However, in some areas scientific publications by authors with company affiliations are significantly higher and very relevant for companies' innovation strategies, e.g., in pharmaceuticals.

Complementary to scientific publications, **patents** (both applications and granted patents) are well-established indicators to measure in particular the output of applied research (see also for the current state of the art Glänzel et al. (2019). Therefore, the large majority of patents are applied by companies, which are in the focus of ex ante impact assessments and ex post evaluations. In contrast to the input indicators, in particular patent applications[33] allow very fine-grained analyses of the R&D output in specific technologies. In addition, publication and patent data can be aggregated at the country, at the sector, at the organisational level and even at the individual level, which is in general not needed or relevant. If legislation might have an influence on collaboration in R&D, the subcategories of co-publications and co-patents might be used as indicators to assess its impacts.[34]

Table 4 R&D output indicators

Indicators	Level of Analysis	Data Sources
Scientific publications	Country	Google Scholar, Web of Science, Scopus
	Micro	Web of Science, Scopus
	Individual	
Patent applications	Country	European Patent Office
	Sector[35]	
	Micro (Organisation)	
	Individual	
Open Source software	Country	Open Source repositories, like GitHub
	Micro (organisation)	
	Individual	

Source: own compilation

[33] Granted patents are preferable from a qualitative perspective - due to the examination process; however because of the still significant delays from application to patent award, they are less suitable for timely analyses.

[34] Another specific type of patents (standard essential patents (SEPs) are fundamental for the implementation of standards, mainly in the area of information and communication technologies. They are in general of a higher value (Rysman and Simcoe 2008) and often generate licensing revenues. For European telecommunication standards, they can be searched for in the database provided by ETSI (European Telecommunications Standards Institute) https://ipr.etsi.org/. Commercial database providers collect and provide the declarations of a large set of standard setting organisations. Therefore, they might be considered in ICT related legislation, e.g. in the area of mobile communications.

[35] The concordance between IPC and NACE classes can be used to construct sector-level indicators. See Neuhäusler et al. (2019).

Since patents are not granted for software as such, they are not an appropriate indicator for the output of software development.[36] Recent studies (e.g., Blind et al. 2021) show that individual developers, but also companies make significant contributions to Open Source software repositories, which eventually turn out to foster economic growth in the EU. The differentiation of contributions by countries is possible, but not perfect because account holders do not always reveal their geographic location. Many large companies, as well as universities and research organisations have accounts at Open Source repositories. However, they might contribute also through individual developers. Therefore, the measurement of contributions at the organisational level is very likely incomplete. Nevertheless, this output of R&D activities might become more relevant in the future.

Innovation Output Indicators

Based both on the input into the research, development and innovation process, but also their outputs (i.e. publications, patents and software), companies and other organisations might generate an innovation defined as "a new or improved product or process (or combination thereof) that differs significantly from the unit's previous products or processes and that has been made available to potential users (product) or brought into use by the unit (process)" (OECD/Eurostat 2018).

Whereas in the third edition of the Oslo Manual, the distinction was made between product, process, marketing and organisational innovation, the new fourth edition just distinguishes between product and business process innovation. In turn, business process innovation is further differentiated into six different subcategories. A first indicator of innovation outputs is the share of companies claiming to have introduced one or several of these types of innovations in the last three years. Secondly, the share of turnover based on new products and services related to companies' total turnover is an important and well-established indicator. Both are used for example in the European Innovation Scoreboard 2021. The latter can be even further differentiated between the turnover of innovations, which are just new for the company, new to the market and even new to the world. This distinction might be relevant for impact assessments and evaluations of legislation, because they can have different impacts on radical or incremental innovations, e.g., as recently revealed by Aghion et al. (2021).

The indicators related to product and business process innovations are in general based on the data collected within the Community Innovation Survey, which is based on companies as the unit of observation. However, we can consider also additional indicators derived from databases, such as those already elaborated for scientific publications and patents. In particular, the registration of trademarks and designs offer additional options for assessing ex ante or evaluating ex post the impacts of legislation by focusing on specific classes, like for patents, or on specific companies. They can help to complement information from the CIS on product and service innovation on the one hand and business process innovation in the area of marketing, sales and aftersales support on the other hand. In addition, both indicators weighted by the GDPs of the Member States are already included in the European Innovation Scoreboard 2021 as Intellectual Assets under Innovation Activities (European Commission 2021), but also in the Global Innovation Index launched by WIPO (Cornell University et al. 2020).

Another novel source for indicators for administration and management innovations as a subcategory of business process innovations are the certifications related to international management system standards. Conceptually, Armbruster et al. (2008) introduced them

[36] Computer-implemented inventions can be patented. Therefore, patent data can be used as shown by Neuhäusler and Frietsch (2019).

as intra-organisational procedural innovation without providing empirical evidence. Meanwhile, Cornell University et al. (2020) introduced both the number of quality management certificates ISO 9001 divided by countries' GDP as indicators under knowledge impact and the number of environmental management standards ISO 14001 also divided by countries' GDP under ecological sustainability.[37] However, we propose to use this data source as base for constructing indicators of organisational innovations both on country, but also sector-level. In addition, web mining could be used to identify relevant companies and other organisations (see Mirtsch et al. 2021), which can then be interviewed in a later stage.

Legislation is not only affecting existing companies, but also start-ups.[38] Consequently, indicators in particular related to start-ups are necessary.[39] However, detailed data about start-ups are not available in Eurostat, besides the birth- and death-rates by Member State in general or differentiated by sectors.[40] Also at the level of Member States official data is often not provided by the national statistical offices. Therefore, researchers are using Crunchbase, which is claiming to be the leading database in this area.[41]

Due to limited data availability regarding start-ups both at the EU and the Member State level, both the European Innovation Scoreboard (European Commission) and the Global Innovation Index released by WIPO (Cornell University et al. 2021) use venture capital by GDP as indicator based on venture capital deals provided by Thomson Reuters and Invest Europe. Whereas in addition data is available at the micro level, i.e. the deal level, systematic sector level data is - according to our searches - not available. However, the OECD provides data differentiated by seed stage, start-up and other early-stage vs later stage venture.[42]

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37 In addition, Orcos et al. (2018) show the important role of institutions, which include regulations, on the diffusion of the ISO 14001 certificates. ISO 27001 on IT security is in some countries also directly linked to national regulations (Mirtsch et al. 2021b). Therefore, the data on these certificates should be considered in the ex-ante assessment or ex post evaluations of related regulations.

38 See for example the qualitative analysis of innovation within start-ups related to the introduction of the General Data Protection Regulation by Martin et al. (2019).

39 Like in the Global Innovation Index released by WIPO, start-ups can be also perceived as impacts of innovation. However, we consider start-ups as a specific type of innovation, e.g. like a business model innovation, which are immediately impacted by regulations.

40 The OECD provides also the share of start-ups up to the age of two years, but only for two countries. In the Global Innovation Index, new business intensity defined as new registrations per thousand population 15–64 years old based on World Bank data is provided. However, both indicators are not explicitly linked to innovation.

41 See for example the significant impact of the change in public procurement regulations favouring Open Source software on the creation of start-ups in France revealed by Nagle (2019).

42 See: https://stats.oecd.org/Index.aspx?DataSetCode=VC_INVEST

Table 5 Innovation output indicators

Indicators	Level of Analysis	Data Sources
• Product innovation • Goods • Services • Goods and services include knowledge-capturing products, and combinations thereof • Includes the design characteristics of goods and services	Country	Eurostat incl. EIS and CIS, OECD
	Sector	Eurostat CIS, specific surveys
	Micro	Eurostat CIS micro data; interviews
• Share of turnover with product innovation (new to the company, new to the market, new to the world)	Country	Eurostat incl. EIS and CIS, OECD
	Sector	Eurostat CIS, specific surveys
	Micro	Eurostat CIS micro data; interviews
• Business process innovation • Production of goods and services • Distribution and logistics • Marketing, sales and aftersales support • Information and communication systems • Administration and management • Product and business process development	Country	Eurostat incl. EIS and CIS, OECD
	Sector	Eurostat CIS, specific surveys
	Micro	Eurostat CIS micro data; interviews
• Trademarks application	Country	EUIPO https://euipo.europa.eu/ohimportal/en/trade-marks
	Sector[43]	
	Micro (organisation)	
	Individual	EUIPO
• Design applications	Country	EUIPO https://euipo.europa.eu/ohimportal/en/designs
	Micro (organisation)	
	Individual	
• ISO Certificates	Country	ISO survey https://www.iso.org/the-iso-survey.html
	Sector	
	Micro	Organisation's website for identification and follow-up interviews
• Start ups	Country	Crunchbase[44]/Dealroom[45]/ Eutopia[46]/Cleantech[47]/ Pitchbook[48]
	Sector	Crunchbase
	Micro	

[43] In contrast to the concordance between patent and sector classifications, a matching between trademark classifications and sector classifications is not available. However, the so-called NICE classification https://www.wipo.int/classifications/nice/en/ allows a crude matching to sectors.

[44] See: https://www.crunchbase.com

[45] See: https://dealroom.co

[46] See: https://www.eutopiagreen.com

[47] See: https://www.cleantech.com

[48] See https://pitchbook.com

Indicators	Level of Analysis	Data Sources
• Venture capital	Country	EIS, GII, OECD
	Micro	Thomson Reuters; Invest Europe, Crunchbase
• Change in company population	Country	Eurostat https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=bd_9ac_l_form_r2&lang=en
	Sector	

Source: own compilation

In the last years, the scope of innovation has been extended beyond companies. Consequently, the OECD has not only widened the definition of innovation, but also included a chapter on innovation beyond the business sector including the governmental sector, non-profit institutions and even households and individuals. Unfortunately, data and therefore indicators are only available to a limited extent, e.g., through national surveys. The future of measuring innovation in the public sector is currently being discussed, e.g., in the OECD (2019). For the ex-ante assessment and ex post evaluation of regulation, the inclusion of impacts beyond the business sector has to be considered when relevant to obtain a complete picture.

Indicators on the Impact of Innovation

Following the review of innovation indicators, we consider in the second chapter indicators related to the impact of innovation. The analysis of the various examples of innovation scoreboards and innovation indexes was the starting point. Whereas the OECD Science, Technology and Innovation Scoreboard provides no indicators on the impact of innovation, we find in the European Innovation Scoreboard by the European Commission and the Global Innovation Index released by WIPO different impacts of innovation, which we have consolidated in the following table.

Employment impacts are measured by the shares of knowledge-intensive or innovative enterprises. Innovation is a source for productivity growth. Therefore, the growth rate of real GDP per person employed provides a measure of labour productivity. Complementary to countries' shares of high-tech and medium-high-tech manufacturing, sales impacts are based on shares of medium and high-tech product exports[49], knowledge-intensive services exports and sales of new and improved products.

In addition, the Global Innovation Index released by WIPO addresses creative outputs separately to knowledge outputs. Here - in one subcategory - intangible assets, like the already presented trademark and design applications, but also global brand values and ICTs and organisational model creation based on survey data are listed. In a second subcategory, creative goods and services including cultural and creative services exports, national feature films produced, entertainment and media markets, printing publications and other media output and finally creative goods exports are listed. In a third and last category of online creativity, the number of generic top-level domains, country-code top-level domains, Wikipedia yearly edits, and mobile app creation are presented. These impact dimensions and indicators might become more relevant in the future, when legislation will affect digital markets.

[49] The GII relies on the share high tech exports, but also ICT exports compared to the broader approach applied in the EIS. In addition, it includes the intellectual property receipts received by countries according to the balance of payments.

Finally, innovation has significant impacts on all dimensions of sustainability. Therefore, we can argue that innovation has an influence on all 17 Sustainable Development Goals (SDGs). Since the EC policies and priorities refer very much to these goals, one could link innovation related monitoring and evaluation indicators to the SDGs. Consequently, a starting point for the selection of indicators of the impacts of innovations could be the global indicator framework for Sustainable Development Goals developed by the Inter-Agency and Expert Group on SDG Indicators (IAEG-SDGs). The global indicator framework includes 231 unique indicators. Since twelve indicators repeat under two or three different targets, the total number of indicators listed in the global indicator framework of SDG indicators is 247 (see Annex,

List 1). However, for illustration purposes, in the following table we present only the impacts on environmental sustainability included in the European Innovation Scoreboard 2021 (European Commission 2021).[50] This subcategory is measured by resource productivity defined as domestic material consumption in relation to the GDP, the air emissions by fine particulate matter in industry and the share of patents in environment-related technologies.[51] In principle, the latter indicator can be further differentiated by sectors, but also by organisations.

However, both in the long run and depending on the type of regulation, the impact of innovation on sustainability has to be widened beyond the current set of indicators used by the European Innovation Scoreboard and the Global Innovation Index. This can simply be explained with the fact that both include a limited set which does not represent the relevant SDGs. Therefore, the immediate next step for those involved in policy planning should be an assessment of the appropriateness of the 231 indicators listed in the Annex. However, eventually these indicators will have to be adapted depending on upcoming requirements and options, but also in relation to the focus of the regulation to be investigated.

Table 6 Innovation impact indicators

Impacts	Indicators	Level of Analysis	Data Sources
Employment	Employment in knowledge-intensive activities	Country	EIS
		Sector	Eurostat[52]
		Micro	Interviews
	Employment in innovative enterprises	Country	EIS
		Sector	Eurostat, CIS
		Micro	Interviews
Growth	Growth rate of GDP per person engaged[53]	Country	The Conference Board Total Economy Database Output, Labour and Labour Productivity https://www.conference-board.org/data/economydatabase/

50 The GII has also a subcategory on ecological sustainability based on three sub-indicators referring to GDP per energy use, environmental performance and ISO 14001 certificates.

51 It could be argued that the environmental related technologies are an output of R&D activities and are therefore not an impact of innovation.

52 Since knowledge-intensive activities are defined as all NACE Rev.2 industries at 2-digit level, where at least 33% of employment has a tertiary education degree, the construction of indicators for these sectors should be feasible.

53 For the OECD countries, data on multifactor productivity is available https://stats.oecd.org/Index.aspx?DataSetCode=PDB_GR.

Impacts	Indicators	Level of Analysis	Data Sources
		Sector[54]	National statistics
	High-tech and medium-high-tech manufacturing	Country	United Nations Industrial Development Organization (UNIDO)
		Sector[55]	
	Medium and high-tech product exports	Country	EIS
		Sector	Eurostat[56]
		Micro	Interviews
	Knowledge-intensive services exports	Country	EIS
		Sector	Eurostat[57]
		Micro	Interviews
	Sales of new or improved products ("product innovations")	Country	EIS
		Sector	Eurostat
		Micro	Interviews
Environment	Resource productivity (measured as domestic material consumption (DMC) in relation to GDP)	Country	EIS
		Micro	Interviews
	Air emissions by fine particulate matter (PM2.5) in Industry	Country	EIS
		Micro	Interviews
	Development of environment-related technologies	Country	EIS
		Sector[58]	OECD Green Growth database
		Micro (Organisation)	

Source: own compilation

7.2 Conclusions and recommendations

Need for guidance and exchange on impact assessment for policymaking at EU and national level

The use of Tool #21 (or similar) can greatly help to assess impacts more systematically. By providing and sharing concrete examples (at EU or national level) on the use of Tool #21 and on the assessment of impacts on innovation (including CBAs), b. Both the Commission and the Member States can significantly strengthen their capabilities to assess innovation impacts of legislation (see the Finnish *Transport Act*).

Furthermore, any impact assessment at EU level directly contributes to supporting impact assessments at national level as these assessments are often also the basis for assessments at national level.

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54 Sector-specific analyses are possible, e.g. for the US. Data across OECD or EU Member States are not available.

55 Since the values of high-tech and medium-high-tech manufacturing are based on a subset of sectors of the International Standard Industrial Classification ISIC, the construction of indicators for these sectors should be feasible.

56 Since the value of medium and high-tech exports is based on a sample of SITC Rev.3 products, which can be converted into NACE, the construction of indicators for these sectors should be feasible.

57 Since the value of exports of knowledge-intensive services is based on a set of specific service sectors, the construction of indicators for these sectors should be feasible.

58 The concordance between IPC and NACE classes can be used to construct sector-level indicators. See Neuhäusler et al. (2019).

Need for more appropriate data collection methodologies

When using the CBA, results could be improved with access to more recent and specific data, e.g., R&D costs of market authorisation holders, and a better means to value the additional period of market exclusivity (see the case of the Orphan Regulation).

Need for a more theory-driven approach

To better understand possible unintended negative impacts legislation could have on innovation, more theory-driven studies may be envisaged, which can treat innovation as the – possibly unobserved – outcome of interest and develop a (quasi)causal model (a series of mechanisms and impact pathways) of how the proposed changes to the legislation might influence innovation positively or negatively (see the PSI Directive).

The validity of the theorised mechanisms and pathways could be tested through stakeholder interviews and/or rigorously selected case studies. The likely size of the effect of the different mechanisms and the overall net effect could therefore, at least qualitatively, be measured.

However, this theory-driven approach would not necessarily be able to deliver hard quantitative estimates for innovation effects (whether measured as patents, new products/services or business processes, R&D expenditure, etc.). Yet, it could enable policy makers to better identify regulatory design options that promise either particularly strong positive or limited negative innovation effects (including unintended ones).

Nevertheless, this approach may not be proportionate in all cases. If promoting innovation remains a concern for policymakers, the effects of innovation are rarely explicitly considered in the formulation of legislation. The main reasons are that the effects of innovation are difficult to quantify ex ante. Impact analyses should however produce evidence on the effects of innovation combining qualitative and quantitative evidence where possible and a methodological design validating results obtained.

Quantitative evidence could also play an increasing role in the political evaluation of regulatory proposals by Member States and the European Parliament. On the other hand, for the legislators it is often the basic economic costs and benefits - in terms of GDP, jobs, number of businesses, compliance / administrative expenses and change in revenue, among others - which constitute the main criteria in a political evaluation of legislative proposals. Innovation is more a precursor of these results of interest than the result of the interest itself. As there are established methodologies and data sources for the estimation of these key criteria, impact assessments tend to remain focused on them.

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9. Annex A. Methodology

For the completion of the study, the study team developed three work packages, which were articulated in tasks as described in the table below.

Table 7 Structure of the workplan, in Work Packages and Tasks

Work Package	Task
Inception	Task 1 - Identification of cases
	Task 2 – Selection of case studies
Implementation and analysis phase	Task 3 – Case studies
	Task 4 – Development of operational guidelines including quantification
	Task 5 – Development of recommendations on monitoring and evaluating impact indicators on and of innovation
Finalisation	Task 6 – Final study reporting
	Task 7 – Presentation of findings, conclusions, and recommendations in a workshop

9.1 Identification of cases

The study team identified relevant impact assessments and evaluations of innovation-sensitive legislation, which served as basis for the selection of case studies. In particular, the webpages of the Regulatory Scrutiny Board were used to identify EU-level impact assessments and evaluations. Relevant support studies were then identified in the EU Publications Office.

In order to identify national studies, the repositories of SIPER and FTEval were screened as well as websites in a number of countries. The countries were selected following the OECD's iREG survey.

Table 8 List of repositories consulted/screened

Repository	Short description	URL link	Approach and results
List of IA and opinions of RSB	Includes Staff working documents (SWD) of 190 studies as well as accompanying opinions of the RSB since 2016	https://ec.europa.eu/transparency/regdoc/?fuseaction=ia	Preselection of most likely relevant DGs Focus on 'new' legislative proposals Analysis and appraisal
EU Publications	Repository of all publications of the European Union	https://op.europa.eu/en/web/general-publications/publications	Search for term "Impact assessment", filtered by years (>2015) Search for contracted support studies of impact assessments and evaluations as well as other relevant support activities/publications (e.g.., JRC, expert groups)
SIPER	Repository of research and innovation policy evaluations, EU and OECD countries	http://si-per.eu/	Search for relevant studies since 2010

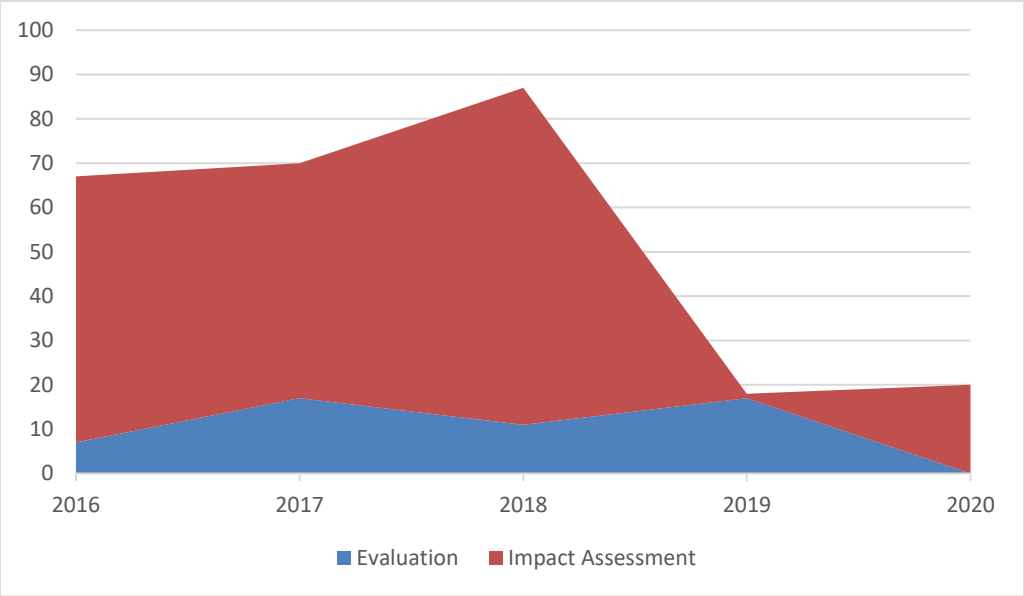
Repository	Short description	URL link	Approach and results
Fteval	Repository of the Austrian Platform for Research and Technology Evaluation, Austrian and other. mainly European countries' evaluations	https://repository.fteval.at	Search for relevant studies - negative on individual studies
iREG	Dataset covering 38 OECD countries and their survey results	https://qdd.oecd.org/subject.aspx?Subject=GOV_REG	Use of report and underlying dataset for the selection of national cases checking

Source: own compilation

9.2 Systematic screening of EU-level legislation

The relevant starting point for the identification of legislative proposals at EU-level was the Regulatory Scrutiny Board (RSB) (or, before 2015, the Impact Assessment Board). The Board examines impact assessments, developed during the preparation of new initiatives and major retrospective evaluations of a single policy or law. Furthermore, the Board scrutinises fitness checks of multiple policies and laws.

Figure 4 RSB work 2016-2020 (1)



Source: RSB Annual review 2019, transparency register
(1) the reports are only published once the proposal is adopted.

Among the 190 impact assessments the Board scrutinised between 2016-2019, and the ones publicly available for 2020, the study team considered several DGs as potentially important for the provision of a relevant case.

Table 9 Overview of assessments covered by the RSB by selected DGs

DG	CLIMA	CNECT	ENER	ENV	GROW	MOVE	SANTE	Sum
RSB studies 2016-2020	6	13	13	7	15	18	3	75
New regulations	2	7	1	1	4	2	1	18
Proposals amending or repealing existing legislation	4	4	12	3	8	8	2	41
New directives				1	2			3
Proposals amending or repealing existing legislation		2		2	1	8		13

Source: RSB, extraction Technopolis Group

Out of the 75 assessments from the selected DGs, not all were proposals for a new Directive or Regulation. In fact, 21 (28%) concerned proposals for 'new legislation', whereas the remaining ones were either 'repealing', 'amending', 'supplementing', 'pursuant to', or a 'recast' of existing legislation. Among the latter, DG ENER included several regulations on individual household appliances, which all had to be adapted to the *Ecodesign Directive*.

At first sight, almost none of the identified examples aims to promote innovation activities nor do they have explicit innovation-related objectives. However, several of the legislative proposals have innovation effects. In various cases, they are either excluded or only implicitly covered. For instance, the support study for the proposed Regulation on '*Minimum requirements for water reuse*' writes "*not factored into the analysis is the potential for innovation to be called forward by the measures, in terms of the design of products and the implementation of new business models designed to foster more sustainable consumption patterns (for example, deposit refund schemes for refillable cups)*." (ICF Support study, p.15).

Yet, the SWD includes several innovation effects in greater detail – but does not attempt to quantify them. The insights are collected through a variety of qualitative means such as targeted stakeholder consultation and a support study by the JRC. The RSB summarised: *by teaming up with other Directorate-Generals (DG REGIO and DG RTD) specific aspects have been assessed, namely the impacts on innovation and territorial impacts. Significant effort was put into the collection of evidence and where possible, triangulation was performed to cross check the validity and robustness of information. Nevertheless, it was not feasible to arrive at monetised and quantified impacts on all aspects. In these cases, a qualitative assessment was performed. The Impact Assessment builds on detailed data on water scarcity and droughts in Europe, as well as future projections and a cost-benefit analysis of the use of treated waste water for agricultural irrigation. The modelling assumptions were based on expert judgements. The choice of options and the underlying scientific work developing minimum quality requirements was discussed with Member States and stakeholders in the context of the Common Implementation Strategy under the Water Framework Directive and adapted accordingly*.

In case of the data proposals (*Data Governance Act* and the *Regulation on Free flow of non-personal data*), both are presented as legislation having the power to transform Europe's competitiveness level in this area through enabling massive innovation and business opportunities. An interesting exception is the SWD on the proposed *Regulation setting CO_2 emission performance standards for new heavy-duty vehicles*. The CBA of the

latter focussed on broader economic effects; the interesting methodology concerned the integration and analysis of about 50 technological devices or designs – modules new to current heavy-duty vehicles – with differing emission-lowering effects. Some of the technological devices were on the market but not yet standardly included in these trucks, some were in pilot phases, while others were in a design study phase (for example, concerning the shape of the front, back, top, etc.). For each of the existing but also potentially future devices, the CO_2 emission reduction was calculated.

The analysis of the legislative proposals reviewed by the RSB (2016-2020) identified the following elements:

- Only one quarter of the available assessments concerns new legislative proposals with impact assessments.
- The majority of legislation concerns revisions. The original dates back in time and has possibly undergone one or more revisions.
- Any revision and the supporting official impact assessment may have benefitted from (multiple) evaluation and/or impact assessment support studies.
- For the initial legislation, it may not be any more feasible to locate a Commission impact assessment or a support study (at least prior to 2003).
- New legislation passing the RSB (2016-2020) is mostly not innovation-sensitive *in the strict sense*. However, several support studies as well as the impact assessment reports by the EC are acknowledging explicitly or implicitly that the legislative proposal affects innovation directly or indirectly. Nevertheless, a quantification of the effects tends to implicitly be integrated in the quantification of economic effects such as GDP growth or jobs.

9.3 Methods for identification of national-level legislation

Given that the previous step only covered assessments that were brought to the attention of the RSB, the study team tried to identify in parallel other assessments through

- going through own studies
- checking of websites of typical EU-level support study providers
- a search of the Publication's Office online resources
- individual national ministries or key organisations' websites
- informal contacts to national level organisations.

Systematic screening of national-level legislation

The OECD report on 'Better regulation practices across the European Union' (OECD 2019) and its underlying survey of the EU-Member States (GOV_Reg data), was used for analysing the countries' use of Better Regulation. Two survey items were analysed to identify which countries could have interesting national cases. The relevant survey questions are:

- When developing primary laws, are regulators required to include assessments of the following: Impact on innovation? (1A15_P)
- When developing subordinate regulation, are regulators required to include assessments of the following: Impact on innovation? (1A15_S)

- Are evaluations of existing primary laws made publicly available over the internet? (3D7_P)
- Are evaluations of existing subordinate regulations made publicly available over the internet? (3D7_S)

Out of the EU-27, 8 countries (30%) never require the assessment of innovation impacts in primary law, nine also not for subordinate law. 13 countries (48%) indicate this requirement 'for all primary law' while the remaining six countries (2%) indicate that this is required 'for some primary law'.

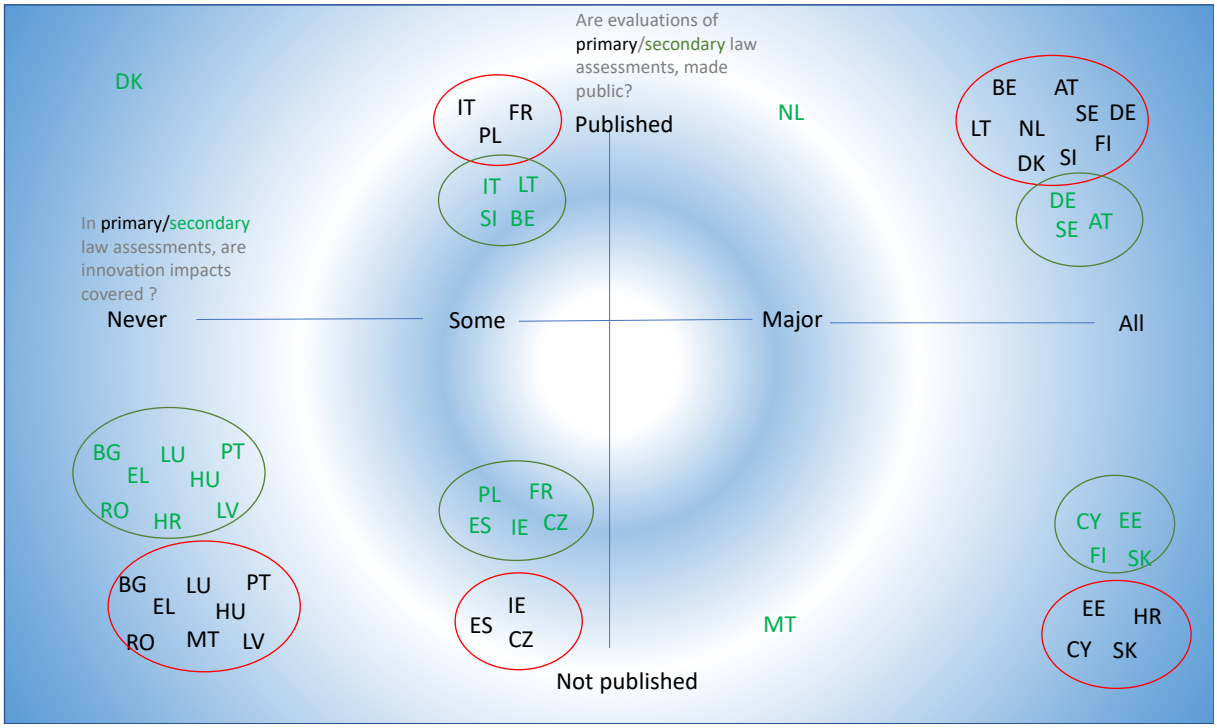
Seven countries (26%) also indicate that this is a requirement 'for all subordinate law' and two 'for major subordinate law', one third of the countries has requirements only 'for some subordinate law' and as mentioned above, also one third of the countries does not have this requirement and also does not include these types of impacts.

The following Figure 5 summarises the EU-MS and their requirements.

In the upper right corner are all the countries, which look at innovation impacts in their primary (secondary (in green)) law and publish the evaluation studies on the web. In the opposite lower left are eight countries, which neither require the checking of innovation impacts nor publishing of relevant evaluation studies. The OECD report on this data however contains an additional caveat: while on paper requirements may exist, if they are fulfilled remains to be seen.

For the identification of national cases, this limits the chances to identify public information to a limited number of countries in the case of primary law, and results in even more limits in the case of secondary law.

Figure 5 Analysis of EU-MS requirements in terms of capturing innovation impacts and publication habits



Data: OECD iREG survey, analysis and graph: Technopolis Group

The OECD study provided a number of relevant **qualitative insights** that explain the difficulty to find evaluation studies of regulation. In fact, even if many EU-MS have broad requirements to conduct regulatory impact assessments "*it is worth noting that there is a gap between commitment and the extent to which it occurs in practice*" (OECD 2019, p. 74). Not only do the MS provide for exceptions to the rule but the OECD notes a worrying fact that the requirements for secondary law seems to be much more relaxed. At the same time, this subordinate law brings primary law into life and regulates citizens and businesses alike.

Whether or not an assessment (full or simplified) is carried out depends on a number of factors – 60% of the EU countries use a proportionality test while Lithuania and Italy have a threshold test.

The study team then tried to identify cases in the identified countries (DE, AT, FI, SE, DK, BE, NL, SI and LT) – although for Lithuania and Slovenia, the language barrier was too high.

Similar to EU-level identification tools, the team:

- checked websites of individual national ministries or key organisations
- used informal contacts and
- in the case of Finland, searched the relevant public website.

The full list of the cases considered for the selection of the case studies and the reasoning is included in Table 10. The final selection was made in agreement with the EC services.

9.4 Selection of case studies

The implementation and analysis phase covers the tasks centred around the case studies, detailed methodological work on the quantification of innovation impacts, and the development of a step-by-step operational guideline for the use in further impact assessments and evaluation studies.

Initially planned for obtaining a better understanding of the use of #Tool21, scoping interviews with EC staff were deemed better placed to finalise the case studies or to obtain a more general appreciation of the tool by EC-level staff involved in impact assessments and evaluations. The interviews with EC staff had the purpose of:

- Explaining whether and why terms of references for support studies include/do not include innovation
- Identifying the needs/the level of detail a new guideline on CBA should entail
- Understanding what impedes the (explicit) use of Tool #21 in evaluations and impact assessments of relatively new innovation-sensitive legislation.

Following the selection of the cases and their initial screening results, the study team:

- Collected all relevant documents (impact assessment study/evaluation, opinion of RSB or national opinions (as publicly available), support (background) studies
- Identified responsible project officer/lead unit as well as study authors (names, emails, phone numbers)
- Further refined the interview guidelines.

The identification and analysis of innovation impacts in the selected cases studies required a thorough analysis of the relevant documents, such as the background or 'support' studies and their annexes. They were a major source for the case studies

together with further documents and interviews with the relevant lead DG. The following structure was used for the development of the case studies.

Box 2: Case study template

Title of the regulation				
Study reference				
Geographic level	EU		Country	
Type of study	Impact assessment, Evaluation		Evaluation	
Author & Affiliation				
Checked by				

General background of the legislation

- History of the legislation
- Responsible organisation
- Type of regulation
- Sectors addressed
- Scope of regulation
- Objectives
- Implementation of the regulation

Overview of the impact assessment and support study

- Role and focus of the support study
- Overview of the support study implementation

The use of Tool 21

- Explicit use of the tool
- Implicit use of tool

Impact on innovation

- Impacts assessed
- Model and methods used

Impact of innovation

- Impacts assessed
- Model and methods used

Good practices and lessons learned

- Good practices
- Replicability of the study (resource intensity, timing, data requirements)
- Other lessons

Opportunities

- Scope of the analysis
- Data collection methods
- Use of data
- Case selection and design of the analysis
- Use of indicators to monitor innovation impacts in the short, medium, and long term

Alternative Models

Development of operational guidelines

Under Task 4, the study team developed an operational guidance to support the systematisation of quantification of costs and benefits of future impact assessments and evaluations by the European Commission.

The final version of the operational guidance is integrated as Annex D and published equally as a separate document.

The process towards developing the operational guide included:

- The critical review of Tool #21 (degree of guidance, such as relevant examples or links to other Better Regulation Guidelines Tools, typologies of costs and benefits, etc.).
- The analysis of the developed case studies (examples on how the innovation angle in a study could have been examined in greater depth).
- Interviews with relevant methodology experts.

Quantification of impacts

Under Task 4, the study team aimed to select cases to assess the impacts of and on innovation using both quantitative and qualitative methods.

More specifically, it was envisaged to showcase a range of quantitative methods that were used and indicating the minimum of empirical evidence that can be collected systematically in several IAs and evaluations (e.g., the case of monetisation of costs and monetisation/quantification of benefits) and an application using macro or micro modelling to assess the impact of and on innovation.

None of the screened or further analysed cases proved to be ideal. Those in transport and mobility for example are built on existing models. They typically include a large range of environmental data and look predominantly at environmental effects. In other areas, the data basis is much more scant, and the costs and benefits are addressed using qualitative information. However, the broad analysis suggested a number of good and inspiring approaches.

Development of recommendations on monitoring and evaluating impact indicators on and of innovation

The development of recommendations on indicators to monitor the impact of regulation on and of innovation follows the conceptual model. The study team differentiated between the indicators and monitoring approaches related to innovation indicators on the one hand, and indicators measuring the various impacts of innovation on the other hand.

The study team argue that innovation has an influence on all 17 Sustainable Development Goals (SDGs). Consequently, a starting point for the selection of indicators of the impacts of innovations could be the global indicator framework for Sustainable Development Goals developed by the Inter-Agency and Expert Group on SDG Indicators (IAEG-SDGs).[59]

The global indicator framework includes 231 unique indicators. Since twelve indicators repeat under two or three different targets, the total number of indicators listed in the global indicator framework of SDG indicators is 247.

However, a more focused approach would differentiate between input, throughput, output and impact indicators. Since regulations have not only impacts on innovation (in the short and medium and long run), but trigger in a second step also impacts of innovation (long-term impacts), the study team differentiates between input and throughput indicators as indicators measuring regulations' impact on innovation, whereas output and impact indicators measure the output and the impacts of these regulation-induced innovations.

- **Input indicators** are human capital measured by different indicators, like the share of tertiary education, number of PhDs. Another important input is knowledge, which is

[59] See: https://unstats.un.org/sdgs/indicators/indicators-list/

difficult to measure. Options could be stock of scientific knowledge measured by scientific publications complemented by the stock of applied and granted patents and the stocks of standards. The stock of software could be measured by GitHub repositories. These stock indicators have to be expanded to flow indicators, like private and public R&D spending.

- **Throughput indicators** reflect the immediate results of R&D activities, like scientific publications, patent applications, meanwhile also standards released (Blind 2019). Regarding the human capital, one can use PhDs completed within public funded R&D projects.
- **Output indicators** generated by the regulation-triggered innovations are product and business process innovations of companies (OECD/Eurostat 2019). Further indicators reflecting the different stages in innovation processes are reviewed by Dziallas and Blind (2019). On the sector level and in case of very generic regulations also at the macro level, traditional production volumes and value, added value, employment, and exports were considered.
- **Impact indicators of innovations could be in principle all the above-mentioned indicators** related to the 17 SDGs. However, major impacts of innovation should be the welfare and well-being of citizens, but also the adequate protection of the environment, including tackling global climate change. In addition, innovation can help to achieve the reduction of poverty, securing of food security, healthy lives, and inclusion.

Once the data collection and analysis activities (Task 3-6) were concluded, the resulting information was synthesised through a process of data triangulation and integrative analysis.

9.5 Analysis of cases

For the systematic screening of the identified legislation, the study team developed a screening template and analysed in detail 15 EU-level and three national level cases.

For each of the identified potential EU-level cases, the study team screened the identified cases on the following information:

- **Expected impact of the legislation**: considering the broader impact of the legislation, such as on competitiveness, the environment, etc.
- **Thematic field**: the field the specific legislation belongs to, such as environment/green transition, health, digitalisation, or transport
- **Type of study**: was it an impact assessment support study or an evaluation support study
- **Responsible organisation**: the institution requesting the study (at European Commission level, the specific DG)
- **Support study**: the (most often) contracted support study for the proposals/evaluation
- **Regulation type:** based on the classification of Blind (2012), five cases were classified as promotion of innovation activities, eight as general regulations without explicit innovation-related objectives and three regulations were classified as affecting companies' strategies but not their innovation activities. However, it was observed that none of the cases is as clear-cut as the typology suggests, and even the ones classified as innovation-sensitive included this aspect rather implicitly.

- **Application of Tool #21:** we checked if the assessments used the Tool #21 explicitly or implicitly and if the studies followed a similar approach with:
  - a stakeholder consultation
  - the assessment of potential impacts on research and innovation
  - considerations for the legislative design and its impacts.
- **Quantitative analysis methodologies**: more specifically, whether the study included or entailed:
  - CBA analysis
  - Cost typologies
  - Comments regarding the benefits of the used typologies (e.g., turnover, profitability of enterprises after the introduction of a regulation)
  - Econometric analysis and models used
  - Limitations (methodological, data related if mentioned)
  - Datasets/data sources
  - Issues regarding accessibility of data.

In addition, for each individual case, a short appraisal of its relevance as potential in-depth case study was provided. Only case studies on evaluations and impacts assessments whose quantitative and qualitative evidence (including data) would be available and/or accessible were selected.

Table 10 List of detailed analysed cases

Regulation	Thematic field	Study Title	Year	Type of regulation (1)	Component of #Tool21				Quantitative methodologies	Qualitative methodologies
					1. stakeholder consultations	2. assessment of potential impacts	3. considerations for legislative design and impacts	4. investigation of means to reduce negative impacts on innovation		
Drinking Water Directive (DWD)	Environment/ Green transition	Study supporting the revision of the EU Drinking Water Directive	2016		x		x		CBA	Desk research, Literature review, Interviews, Case studies, Survey, Workshops, Open Public consultation
Regulation on minimum requirements for water reuse	Environment/ Green transition	SWD IA on a proposal for a regulation on minimum requirements for water reuse	2018		x	x	x	x	CBA, Hydro modelling	Workshops, Open Public consultation
EU Timber Regulation (EUTR)	Environment/ Green transition	Impact Assessment Study for the Revision of the Product Scope of the EU Timber Regulation	2019		x		x		CBA	Desk research, Literature review, Workshops, Open Public consultation
Regulation on CO_2 emissions standards for Heavy Duty Vehicles	Environment/ Green transition	Support for preparation of the impact assessment for CO_2 emissions standards for Heavy Duty Vehicles	2018		x				CBA	Literature review, Interviews, Survey, Workshops
Directive 2006/66/EC on batteries and accumulators and waste	Environment/ Green transition	Study report in support of evaluation of the Directive 2006/66/EC on batteries and accumulators and	2019		x		x	x	no formal, quantitative CBA; CBA is mentioned in the	Literature review, Interviews, Survey, Workshop, Open Public consultation.

Regulation	Thematic field	Study Title	Year	Type of regulation (1)	Component of #Tool21				Quantitative methodologies	Qualitative methodologies
					1. stakeholder consultations	2. assessment of potential impacts	3. considerations for legislative design and impacts	4. investigation of means to reduce negative impacts on innovation		
batteries and accumulators		waste batteries and accumulators							'Efficiency" section based on qualitative and some quantitative information	Study analyses several measures and sub-measures (options) applying innovation principle
Directive 2009/33 on Clean Vehicles (CVD)	Mobility	Impact Assessment study for the review of Directive 2009/33 on the Promotion of Clean and Energy-Efficient Road Transport Vehicles	2017		X	x	x		CBA	Desk research, Literature review, Interviews, Survey, Workshops, Open Public consultation
EU Paediatric Regulation (EC) No 1901/2006)	Health	Study on the economic impact of the Paediatric Regulation, including its rewards and incentives	2016			x			CBA	Interviews, Survey, database, stakeholder consultation
Novel food regulation EC 258/97 (4))	Health	Draft report on Impact assessment for a regulation replacing regulation (EC) No 258/97 on novel foods and novel food ingredients (Com (2007) 872 final)	2007		x					Open Public Consultation

Regulation	Thematic field	Study Title	Year	Type of regulation (1)	Component of #Tool21				Quantitative methodologies	Qualitative methodologies
					1. stakeholder consultations	2. assessment of potential impacts	3. considerations for legislative design and impacts	4. investigation of means to reduce negative impacts on innovation		
GDPR	Digital	Economic impact assessment of the proposed European General Data Protection Regulation	2013		x	x		x	CBA	Desk research, Literature review, Interviews, Survey
Directive 96/9/EC on the legal protection of databases	Digital	Study in support of the evaluation of Directive 96/9/EC on the legal protection of databases	2017		x	x			Similar to CBA	Desk research, Literature review, Interviews, Survey, Workshops
Regulation on European data governance (Data Governance Act)	Digital	SWD IA on a proposal for a regulation on a European data governance	2020		x	x			CBA, Multi-Criteria Analysis	Several support studies using desk research, case studies, interviews, surveys, workshops, open public consultation, targeted consultation
Directive 2003/98/EC on the re-use of public sector information (PSI Directive)	Digital	Study to support the review of Directive 2003/98/EC on the re-use of public sector information	2018		x	x	x	(x)	CBA, Legal data analysis, Costs typology	Desk research, Interviews, Survey, Open public consultation
Construction Products Regulation (EU) No 305/2011	Other	Supporting study for the Review of the Construction Products Regulation: Impact Assessment	2018		x	x				Survey, Workshops, Open Public Consultation

Regulation	Thematic field	Study Title	Year	Type of regulation (1)	Component of #Tool21				Quantitative methodologies	Qualitative methodologies
					1. stakeholder consultations	2. assessment of potential impacts	3. considerations for legislative design and impacts	4. investigation of means to reduce negative impacts on innovation		
European Union Governmental Satellite Communications (EU GOVSATCOM)	Other	Study in support of the Impact Assessment of an EU GOVSATCOM initiative	2017		x	x		x	CBA	Desk research, Literature review, Interviews, Workshops, Open Public Consultation
Directive 2006/42/EC on Machinery	Other	Evaluation of Directive 2006/42/EC on Machinery	2017		x	x			CBA	Desk research, Literature review, Interviews

Notes and colour coding:

aimed at promotion of innovation activities

general regulations without explicit innovation-related objectives

regulations affecting companies' strategies but not their innovation activities

(1) we included the Novel Food Regulation in our initial analysis since it suggests innovation activities and thus, innovation sensitive legislation. However, this aspect seems to not have been the focus of the evaluations and succeeding impact assessments.

10. Annex B. Case studies

This annex includes four case studies, namely:

- The Finnish "Transport Act"
- Regulation (EC) No 141/2000 on Orphan Drugs
- Directive 2003/98/EC on the Re-use of public sector information
- Directive 91/271/EEC on Urban waste-water treatment

A national case was developed using the Finnish Transport Act as example. During the Finnish presidency, Better Regulation was a priority and therefore, a review of the Innovation Principle was performed. The case study thus includes an overview of that previous study, followed by the Transport case. Since it is a case in the national context, the case study template was slightly amended when needed.

The three EU-level cases are examples in the priority areas environment, digital, and health.

11. Case 1a - Innovation Principle and innovation impact assessment in Finland

11.1 General context

In recent years, innovation-friendly regulation has become part of the Finnish policy agenda, and regulation is increasingly seen as one tool for innovation and industrial policy. In the *National Roadmap for Research, Development and Innovation* the use of innovation-friendly regulation is mentioned as one action point for promoting the access of new innovations and business models to markets. The roadmap also calls for a more systematic assessment of the impacts of regulation on research and innovation, and for increasing legislation authorities' competences in foresight, innovation, and markets.[60] The Innovation Principle was also one of the key themes during the Finnish EU Presidency in 2019, during which a High-Level Conference on the Innovation Principle was organised in December 2019.

11.2 Findings on the status of innovation-friendly regulation in Finland

In 2019-2020, the Finnish government commissioned a study to support the national implementation of the Innovation Principle, and to assess the status and good practices of innovation-friendly regulation. The study, conducted by a study team led by 4FRONT, was published in May 2020. Based on the findings, it offered recommendations on how to develop the regulatory environment and related processes (e.g., to assess the impact on and of innovation) in Finland. [61]

According to the study, the significance of innovation-friendly regulation has been widely recognised in various ministries. Yet, there are major variations in the degree to which the innovation perspective has been taken into account in legislation. Also, the interpretation of 'innovation-friendliness' varies across, and within, ministries. The lack of declared principles or definitions regarding innovation-friendly regulation was seen as a significant bottleneck. [62]

The study concluded that although 'innovation-relevant' regulation can be identified in all administrative branches, the assessment of impacts on (or of) innovation has been occasional and unsystematic. An analysis of government proposals issued in 2018 confirmed that taking the innovation perspective into account in the ex-ante assessments remains case-specific and unstructured. To improve impact assessment of/on innovation effects, there is a need for a more clearly defined framework, and of structured and concrete tools (such as Tool #21 or similar 'checklists', see more below). [63]

In the report, officials stressed that the regulators need to consider many different 'impact categories', and impact on innovation is often not the most important or relevant aspect to assess. In addition, if more time and personnel resources are allocated to impact assessments, less resources can be allocated to other stages of legislative drafting. For these reasons, it is essential to effectively prioritise and identify the

[60] The National Roadmap for Research, Development and Innovation. https://minedu.fi/en/rdi-roadmap

[61] Salminen et al (2020) *Innovation-friendly regulation: Current state and good practices.* Publications of the Government's analysis, assessment and research activities 2020:27, Prime Minister's Office. In Finnish. Executive Summary of the final report available also in English.

[62] Ibid.

[63] Ibid.

proposals and types of legislation essential for innovation, and to focus resources on these cases. [64]

As for stakeholder engagement, good practices and methods for stakeholder engagement were identified in many ministries and agencies. However, the consultations often only take place towards the end of the drafting process. Furthermore, the study highlighted the significance of different alternative and softer methods co-existing with or supporting legislation. In fact, instead of legislation itself, implementation and interpretation of legislation were seen as bigger challenges for innovation-friendly regulation. The findings emphasised the need to develop 'advisory' regulation (e.g. help-desks or other advisory services for helping companies to navigate the regulatory environment) as well as implementation and dialogue practices. Building shared understanding and defining common goals for regulation emerged as a key factor. [65]

11.3 Regulatory Impact Assessment in Finland

Regulatory Impact Assessments (RIA) are mandatory for all government proposals. RIAs are conducted according to the national guidelines, published in 2007 by the Ministry of Justice. The guidelines are an important hands-on tool and point of reference for government officials responsible for impact assessments, and basically all impact assessments follow the structure of these guidelines. The guidelines distinguish between four main categories of impacts: economic impacts, impacts on public authorities, environmental impacts and other societal impacts. Impacts on companies is defined as one sub-category under the economic impacts.[66] The guidelines are set to be updated by the end of 2021.

Currently, impacts on/of innovation are not specified as a self-standing own (sub-)category in the guidelines. However, as part of the section discussing the impacts on companies, the guidelines highlight the important role of R&D activities and innovation for companies' competitiveness and productivity, and maintain that as part of the assessment of impact on companies, the impacts on companies investments in R&D activities should be assessed. The guidelines also emphasise the importance of continuity of the regulation for R&D investments.[67] Overall, the section discussing the impacts on innovation is very limited and remains on a general level. Building on the national guidelines, some sectoral ministries have developed their own (more specific) guidelines for impact assessment. The Ministry of Employment and the Economy (MEE) is responsible for developing the tools and guidance for assessing the impacts on companies, and is currently developing approaches for assessing impacts on innovation in a more systematic manner (see below).

Regarding the impact assessment of EU legislation, the national guidelines refer to the European Commission Impact Assessment Guidelines. However, the (Finnish) guidelines highlight that EU-level impact assessments do not necessarily take sufficiently into account the specific conditions and context in the Member States, and therefore it is important to monitor the relevant EU regulations and assess their impacts on national level. Furthermore, the guidelines instruct to utilise the impact assessments conducted

[64] Ibid.

[65] Ibid.

[66] Oikeusministeriö (2007) Säädösehdotusten vaikutusarviointi: Ohjeet. Oikeusministeriön julkaisut 2007:6. [Impact assessment of government proposals: Guidelines. Ministry of Justice publications 2007:6 (in Finnish).

[67] Oikeusministeriö 2007, p. 20.

by the Commission and other Member States when assessing the impacts of EU-driven regulations.[68]

Overall, according to OECD and national studies, the quality of legislation in Finland is high, and the RIA system efficient and well organised. However, there are also clear needs for improvement especially regarding ex-post evaluations but also regarding the RIA.[69] Specifically – and importantly for innovation-friendly regulation, the assessment of alternatives for regulation, as well as the lack of robust ex-post evaluations, experiments and Randomised Controlled Trials (RCTs) have been identified as areas for improvement.[70] There is also need for developing RIA methods such as the use of Cost-Benefit-Analysis (CBA). In fact, according to a recent report by the Audit Committee of the Finnish Parliament, CBAs have been very rarely used in Finland. The Audit Committee also pointed at the need to develop more robust methods for RIA in Finland.[71] No examples of CBA in the context of impact on companies or innovation were identified as part of this case study.

11.4 Assessing impacts on/of innovation and use of Tool #21 – recent developments and lessons

Based on the findings of Salminen et al (2020) the assessment of impacts on/of innovation has been very limited and occasional in Finland. In fact, as highlighted by Salminen et al. (2020), there is a need for structured and concrete tools such as Tool #21 or similar 'checklists' to improve the assessment of the impact of legislation on innovation. Until recently, the overall awareness of the impact of legislation on innovation (or the Tool #21) has been very limited across ministries in Finland. This finding was further validated with interviews as part of this case study.

According to the interviewed MEE representatives, the Tool #21 is seen as a useful and helpful tool, also for the national context (with some adjustments). However, to better integrate the innovation perspective into the RIA processes, the Tool (or at least some elements of it) should be integrated into national RIA guidelines (see above). It is also seen that the tools and guidelines should be supported with a clear (high-level) mandate, sufficient resourcing and share of good practices and use-cases. The interviewees also highlighted that innovation is only one category, and there are increasing needs to include (other) new impact 'categories' in the guidelines. This calls for very simple and effective ways to (1) identify the most relevant cases and (2) conduct impact assessments for these cases. Any support from the European Commission (especially for hands-on cases and examples) was seen highly valuable.

In early 2021, based on the lessons and recommendations of the previous study (Salminen 2020), the Ministry launched a pilot project to develop new approaches for assessing the impact of legislation on research and innovation. The pilot includes two hands-on cases (and a possible third case in autumn 2021). As part of the cases, also the Tool #21 will be considered. The lessons from these cases will be used to refine the guidelines on assessing impacts on innovation as part of the broader update of national RIA guidelines by the end of 2021.

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[68] Oikeusministeriö 2007, p. 20.

[69] See. e.g. OECD (2010). Better Regulation in Europe: Finland 2018. OECD Publishing, Paris.; OECD (2015). OECD Regulatory Policy Outlook 2015, OECD Publishing, Paris.; OECD (2018a). OECD Regulatory Policy Outlook 2018. OECD Publishing, Paris; Salminen 2020.

[70] See e.g., Salminen 2020.

[71] Keinänen, A. & Pajuoja, J. (2020). Miten vaikutusten arviointia voitaisiin parantaa? Vaikutusarviointi ja sen kehittämistarpeet suomalaisessa lainvalmistelussa. Eduskunnan tarkastusvaliokunnan julkaisu 1/2020 (in Finnish).

12. Case 1b - The Finnish Act on Transport Services

Title of the regulation	**Finnish Act on Transport Services**			
Study reference	Several studies			
Geographic level	EU		Country	
Type of study	Impact assessment		Evaluation	

12.1 Act on Transport Services: General background of the regulation

History of the legislation

Finland conducted a major reform of transport sector legislation in 2016-2019, resulting into a new Transport Service Act (in three parts, 2016, 2017, 2019) as well as modifications to 58 other acts. The implementation of the legislation is currently in progress.

One key aim for the reform was to "create conditions for the adoption of new technologies, digitalisation and business models within the transport sector", leading to better, more efficient as well as environment- and customer-friendly transport services. Fostering the Finnish Mobility-as-a-Service (MaaS) ecosystem was especially mentioned.[72]

For the purposes of this case study, a key regulation is the Act on Transport Services (320/2017)[73], which was introduced in 2017, as well as the preceding government proposal in 2016.[74] One part of the Act (§4 in Chapter 2) is related to the inter-operability of data and opening of data interfaces of transport operators. In practice, the regulation requires the actors to provide (other service providers) access to their data.

Responsible organisation

Finnish Ministry of Transport and Communications.

Type of regulation

The regulation has elements of different types of regulations. It is directly linked to several aspects of economic regulation, such as competition and market entry, as well as public enterprises and monopolies. It has also elements of social regulation, such as environmental protection and consumer safety, as well as institutional regulation (intellectual property rights and data ownership).

Promoting innovation (new transport services and business models, especially MaaS solutions) is one of the key goals of the regulation.

[72] Government proposal 161/2016. https://www.finlex.fi/fi/esitykset/he/2016/20160161#idp447426528

[73] Act on Transport Services (Laki liikenteen palveluista) 320/2017. https://www.finlex.fi/fi/laki/alkup/2017/20170320

[74] Government proposal 161/2016. https://www.finlex.fi/fi/esitykset/he/2016/20160161#idp447426528

Sectors addressed

The Act addresses several different sectors and organisations, most importantly transport service providers (public and private), but also public authorities and other stakeholders.

Scope of regulation

The renewed transport code ('liikennekaari') addressed the transport sector in a broad manner; however, the specific government proposal (161/2016) focuses on the road transport sector. This includes the taxi sector, as well as the public transport sector and freight transport sector. The focal point of the proposal was to introduce notable deregulation in the aforementioned sectors and thus enable new, more competitive, cost-efficient and innovative services that utilise the possibilities of digitalisation, as well as decreasing the administrative burden of the transport actors.

Objectives

The objective of the proposal is to consolidate key elements of the legislation regarding transport services into one act. The aim is to produce the lightest, most consistent and technology-neutral regulation possible by repealing the legislation on the road transport market, which was previously divided into several different acts, and thus consolidating the key elements into one act.

Some of the high-level concrete objectives of the proposal are:

- Data interoperability. This is said to stimulate demand by informing customers about the available services in an easy and extensive manner. The availability of information relevant to mobility services is strengthened by obliging providers of such services to open their essential information in a machine-readable form through an open interface.
- Interoperability of ticket and payment systems. The idea is that in the future, individual transport service providers and intermediaries could offer either separate single journeys or, as a result of a service-integrated combination, different chained or packaged mobility services for their own customers.
- Simplifying and harmonising regulation in freight and passenger transport, including taxis. This is seen to better facilitate entry into the market and their overall operation, as well as creating conditions for new business models and the utilisation of new innovations.

Implementation of the legislation

During the preparation of the Transport Services Act, the Parliament of Finland demanded the Government to closely monitor the effects of the new legislation and, if necessary, take steps to change the regulations. The Parliament requested the Government to submit a written report to the Transport and Communication Committee on the effects of the Act – and the possible needs for amendment – by the end of 2018. A longer-term monitoring and impact report was also to be submitted to the Committee by the end of 2022.[75]

Stemming from these demands, the Ministry of Transport and Communications arranged a permanent *Transport Market Forum* to facilitate discussion among transport service providers and other actors on the effects of the Transport Services Act and the functioning of the market. This Forum is also responsible for supporting the monitoring of

[75] Parliamentary Reply EV 27/2017, https://www.eduskunta.fi/FI/vaski/EduskunnanVastaus/Sivut/EV_27+2017.aspx (in Finnish).

the effects of the Transport Services Act. The aim of the Forum is to create a common understanding of the roles and activities of different transport actors and the opportunities offered to the industry by the Transport Services Act. However, the Forum does not make decisions on the interpretation of the provisions of the Act, as this role is reserved for The Finnish Transport and Communications Agency Traficom. Traficom also monitors and reports on the effects of the Act.[76]

12.2 Overview of the impact assessment and support study

Role and focus of the support study

There is no specific support study directly linked to the government proposal; however, the proposal includes references to several different studies and reports in the section reviewing the anticipated effects. Regarding effects on households, Statistics Finland's household Consumption Survey and an American study *Shared mobility and the transformation of public transit*, prepared for the American Public Transport Association, are referenced.[77] As regards estimating the effects on companies, three studies are referenced: Traficom's (Finnish Transportation and Communications Agency) *Transport market in Finland*[78], *Report on Finnish logistics 2014*[79] (commissioned by the Finnish Transport Agency) and a study done by PricewaterhouseCoopers on the liberalisation of the taxi market.

When presenting the anticipated effects on both public finance and the national economy, multiple reports and studies are referenced. These include the European Commission's *To develop and validate a European passenger transport information and booking system across transport*[80], which appears to be the most relevant reference in the light of methods used and its comprehensiveness. However, the study considers factors affecting the potential of Multimodal Information and Ticketing Systems (MMITS) in the EU, and therefore is not limited to the Finnish case. In addition to this report, references are made to the Internet of Things (IoT) survey by the Confederation of Finnish Industries and a journal article focusing on co-evolution of three megatrends.[81]

Finally, when scrutinising other anticipated societal effects, two OECD reports are referenced, the first one focusing on market reforms[82] and the other one on competition policy[83]. Additionally, a panel presentation from the OECD 2015 Global Forum on Competition is mentioned.

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[76] Ministry of Transportation and Communications, https://www.lvm.fi/-/liikennemarkkinafoorumi-keskustelemaan-liikennepalvelulain-vaikutuksista-1002155 (in Finnish).

[77] Shared-Use Mobility Center (2016). Shared mobility and the transformation of public transport. https://www.apta.com/wp-content/uploads/Resources/resources/reportsandpublications/Documents/APTA-Shared-Mobility.pdf

[78] Pöllänen, et al. (2015): *Liikenteen markkinat Suomessa*. https://arkisto.trafi.fi/filebank/a/1452675021/34e771ac250db32ab331b2d71ae92ffc/19497-Liikennemarkkinat_raportti_2015-12-10.pdf (in Finnish).

[79] Solakivi et al. (2014): *Logistiikkaselvitys 2014.* https://www.utupub.fi/bitstream/handle/10024/101919/KRe-1_2014.pdf?sequence=2&isAllowed=y (in Finnish).

[80] Eisenkopf, et al (2014): *To develop and validate a European passenger transport information and booking system across transport modes*. https://ec.europa.eu/transport/sites/default/files/themes/its/studies/doc/20140812-july9thversion-awtfinalreport.pdf

[81] Watanabe, Naveed & Neittaanmäki (2016): Co-evolution of three mega-trends nurtures un-captured GDP – Uber's ride-sharing revolution. *Technology in Society* 46, 164–185.

[82] Nicoletti & Scarpetta (2005): *Product Market Reforms and Employment in OECD Countries.* https://www.oecd-ilibrary.org/economics/product-market-reforms-and-employment-in-oecd-countries_463767160680

[83] OECD (2014): *Factsheet on how competition policy affects macro-economic outcomes*. https://www.oecd.org/daf/competition/2014-competition-factsheet-iv-en.pdf

Overview of the support study implementation

The studies do not include any systematic assessment or cost benefit analysis of effects of or on innovation, but several references are made to innovation and technology impacts. The European Commission report regarding the Multimodal Information and Ticketing Systems (MMITS) in the EU includes a cost benefit analysis in section six of the report which deals with the economic assessment of the MMITS. However, the focus in this analysis is on the economic effects that are approached through a perspective on safety, mobility, and environment. Methodology-wise the national (Finnish) reports referenced in the proposal typically rely on literature reviews, interviews and especially surveys, and cost benefit analysis methods are not used.

12.3 The use of Tool 21

Explicit use of tool

The Tool #21 was not explicitly used. The proposal and regulation predate the introduction of the tool.

Implicit use of tool

There is implicit use of the tool as described in the sections below.

Step 1 Broaden consultation to capture the research and innovation angle

During the preparation phase of the proposal, in addition to the typical consultation of stakeholders by written commentary, the Ministry of Transportation and Communications organised a number of public stakeholder events to inform about the project, gather information and discuss the advantages and disadvantages of different solutions. Project material and video recordings of the events were available on the Ministry's website. Extensive discussions also took place with various stakeholders interested in the project.

These activities complemented the typical written consultations of the stakeholders, which came in abundance, as over 240 different parties provided their views. These included different industry and interest organisations, companies and entrepreneurs, as well as public sector representatives including different provincial and municipal actors. The different views presented in the consultations are reviewed in section five of the Government proposal.

In the aforementioned study, which aimed to develop regulatory environment and processes in Finland, these actions to involve stakeholders to the process were highlighted as an important part of the drafting phase. Additionally, it is reported that emphasis was also given to clear communication. However according to an official interviewed for the report, it could have still been improved.[84]

Step 2 Assess potential impacts on research and innovation

As part of the legislation drafting, an ex-ante impact assessment was conducted (mandatory process in Finland for all legislation). In line with general guidance on regulatory impact assessment, the assessment covered various areas of impact (e.g., impact on economy, environment, etc.). Impact on innovation was especially addressed as part of the assessment of economic impacts (specifically under the title of impact on companies).

Step 3 Address legislative design considerations

Flexibility and technology-neutrality were important principles in the legislation drafting. As a result, some details were consciously left out of the act to leave room for interpretations as new technologies emerge in the future. It was also specifically mentioned that the regulation will be reviewed. The proposal highlights the technology-

[84] Salminen et al. 2020, 86.

neutrality as a desired feature in a few contexts. A very concrete example is the proposed change to remove the requirement of taximeter in taxies. The proposal discusses that, for example, satellite-navigation based solutions could be more precise than mechanical taximeters, but the usage of such solutions was not possible during the previous legislation.

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

The proposal does not include temporary or experimental legislation, however some references are made to the Government Programme, which included a broad goal to create a *culture of experimentation* in Finland that would enable seeking new solutions and taking a leading role in, for example, digital transport solutions. Deregulation is said to bring new opportunities for transport operators to develop their activities and take advantage of innovations such as the use of electronic platforms.

12.4 Impact on innovation

Impacts assessed

As part of the assessment, it was, for example, concluded that the requirements on open data interfaces will result into new company networks which, in turn, further promote the production of new mobility services, innovations and digitalisation. It was also highlighted that it is difficult to assess impact on innovation ex-ante, but the information available indicates that open data is important for innovation activity. The overall idea behind the proposal was therefore to increase the ways and methods to create and provide new transportation solutions – in the proposal, it is estimated that so called mode-specific regulation (own regulation to each mode of transport) has led to a certain market rigidity, which has hampered the self-regulation of the market that is inherent in effective competition.

The proposal states that it is not the government's task to create new innovations and competitive operating models in passenger transport or other industries, as it is primarily the task of private companies. The task of the government is to create, through regulation, an environment in which companies can provide new value-added services to consumers with their innovative solutions, and thus contribute to growth of productivity. A balance should be struck between government regulation and the market so that regulation adequately protects consumer rights and other socially important interests.

In the proposal it is estimated that as a result of the market liberalisation, new innovative solutions will be created. This is seen to create more value for the customer in many ways, as a result of which the turnover of companies operating in the sector may increase. However, as the proposal states, there is a fundamental asymmetry in the impact assessment of market liberalisation: the losses of traditional activities resulting from market opening are measurable, but the benefits are visible only in the long run as a result of the complete economic development process and cannot be demonstrated in advance.

Model and methods used

The impact assessment regarding innovation was largely based on previous studies and stakeholder consultations (discussions, interviews, some surveys). It should be noted that many of the studies referenced are not limited to the particular Finnish case in hand, as presented previously.

12.5 Impact of innovation

Impacts assessed

The impact of innovation is primarily approached in the proposal through the possible economic and environmental effects achieved. The lowering of the entry threshold to the market and open data sources are estimated to create new services and thus change people's consumption behaviour in relation to mobility services. This would then facilitate the desirable switch from using own cars to public transport. This shift would improve road safety and reduce traffic congestion as well as environmental damage. Additionally, where public transport reduces the need to use private cars, land use becomes more efficient, as parking spaces and roads do not have to be built for such a large number of cars.

The proposal states that based on a moderate scenario, the changes are estimated to generate a total annual benefit of 13,1 billion euros in the EU. In Finland, the benefit would be 193,1 million euros annually. The study only considers the benefits to existing users and businesses.[85]

12.6 Good practices and lessons learned

According to Salminen et al (2020), the Finnish Transport Act can be seen as good example of innovation-friendly regulation. Technology-neutrality and innovation-enabling legislation were key principles in the legislation's drafting. Specific attention was paid on *not* to regulate technological solutions in order to ensure that the regulation will not be outdated when technologies emerge. Another important principle was customer-orientation: The Act emphasised customers' and citizens' needs and the quality of transport services as the primary objective, even if it might introduce new requirements or administrative burden on incumbent companies. This highlights the fact that innovation-friendly regulation does not always mean *less* regulation, and sometimes more stringent regulation can be used as a driver for promoting innovation.

Due to the profound impacts of the Act on the transport services market, high-level political and ministry-level mandate was essential for conducting the reform. In addition, taking into account the challenges and unpredictability of large-scale reforms, the regulation was implemented in phases, with the aim of refining the regulation based if needed.

The Act is also a good example of how regulators could aim to support emergence of new innovations by introducing *new* regulation (instead of just reducing existing regulation). In fact, regarding the opening of service interfaces, the Finnish regulation goes beyond the EU-level minimum requirements. The aim was to support the development of new MaaS solutions.

The engagement of different stakeholders was very active during the preparation of the Act, and specific (although probably not sufficient) attention was paid to communicating the process and content in a user-friendly manner. Here, the above-mentioned *Transport Market Forum* can be identified as a good practice. Also, the importance of self-regulation (in parallel with legislation) as well as strategic level discussion and roadmaps (prior to the regulation) were highlighted.

Despite some good practice and lessons, the case also highlights the importance of the implementation phase in innovation-friendly regulation. Especially the larger public operators have been reluctant to open their data interfaces in the given schedule, resulting into legal disputes and penalty fines for transport operators. The issue was already raised in the preparatory phase and there were some calls for including better incentives for transport operators for opening their data. There has also been some

[85] The calculation is referenced to the European Commission report presented earlier (Eisenkopf et al. 2014)

disagreement among stakeholders, whether the opening of interfaces would have been better achieved with self-regulation instead of legislation. Retrospectively it could be argued that, although the stakeholder consultation was broad and extensive, an *even* broader and *more* extensive discussion during the *earlier* phase might have ensured a smoother implementation process.

Finally, it should be noted that there is yet no strong evidence on the long-term impacts of the Act, and to what extent the Act will help to stimulate new MaaS innovations, remains to be seen.

12.7 Opportunities

As highlighted in Part 1 of the case study, the assessment of impact of/on innovation is still unsystematic and new methods and tools are needed for better assessing the impact of legislation on innovation. This applies also to the Finnish Act on Transport Services: despite the fact that the Act specifically aims to impact innovation, the assessment of these impacts remains limited and on a general level. Also, the impacts of alternative regulation strategies (e.g., role of self-regulation) for innovation could have been explored.

It is likely that utilising the Tool #21 (or similar) would already have considerably helped to assess the impacts in a more systematic manner (the Act was drafted before the tool was introduced). By providing and sharing concrete (EU or national level) examples of using the Tool #21 and assessing the impacts on innovation (including CBAs), the Commission would significantly help the Member States in assessing the impacts of both EU-based regulation and national regulation. Also, any EU-level impact assessments directly help to support the impact assessments on national level as these assessments are often also the basis of national-level assessments.

13. Case 2 Regulation (EC) No 141/2000 - the Orphan Regulation

Title of the regulation	Regulation (EC) No 141/2000 (the Orphan Regulation)			
Study reference	De Jongh, T. et al. (2019) Study to support the evaluation of the EU Orphan Regulation			
Geographic level	EU		Country	
Type of study	Impact assessment		Evaluation	

13.1 General background of the regulation

History of the legislation

Prior to 2000, there was insufficient knowledge of rare diseases and their impact. Likewise, there was limited detailed information on the activity of businesses in this space. In a 1995 Council Resolution on orphan medicines, the Council of the European Union called upon the European Commission "*to look into the situation of 'orphan' drugs in Europe and, if necessary, make appropriate proposals with a view to improving access to medicinal products intended particularly for people suffering from rare diseases*".[86]

Following consultation with Member States, industry and patient organisations, the Commission subsequently developed a proposal (COM/98/0450 final) for an EU Regulation on orphan medicinal products.[87] This proposal set out the rationale for an EU regulation highlighting three main points as follows:

- There is a "whole series of diseases that affect relatively few people" (approximately 5,000 diseases) for which no medication or other diagnosis, prevention or treatment is available
- The pharmaceutical industry is reluctant to develop medicinal products to treat these diseases owing to the high costs of R&D and low return on investment (because of small patient numbers) and thus such medicinal products are known as 'orphan products'
- It is not acceptable that certain individuals are denied the benefits of medical progress just because the condition they suffer from affects only a small number of people. It is therefore up to the public authorities to provide the necessary incentives.

The EU Orphan Regulation (EC) No 141/2000 was officially adopted by the European Parliament on 16 December 1999. A further implementing Regulation (EC) No 847/2000 was adopted by the European Commission the following year.

Responsible organisation

DG SANTE and the European Medicines Agency (EMA) have overall responsibility for the Regulation.

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[86] The Council of the European Union. (1995). Council Resolution of 20 December 1995 on orphan drugs (95/C). *Official Journal of the European Communities*, *350*(3). Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31995Y1230(03)&from=EN.

[87] The European Commission. (1998). Proposal for a European Parliament and Council Regulation (EC) on orphan medicinal products 98/0240. Brussels: European Commission.

Type of regulation

The Orphan Regulation is a social legislation designed to improve public health and reduce health inequality. It offers a set of incentives and regulatory rewards for orphan product developers ('sponsors'), aimed at addressing issues underpinning the market failures described above. It is a 'Type 3' regulation as per Knut Blind's taxonomy since it is designed to change companies' strategies and increase levels of R&D investment for rare diseases.

Sectors addressed

The pharmaceutical sector is the main sector addressed by the Regulation.

Scope of regulation

Any medical product intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that affects no more than 5 in 10,000 persons in the EU, and where there is no satisfactory alternative falls within the scope of the Orphan Regulation.

Objectives

The general objective of the Regulation is to ensure a high level of health protection for all. The specific objectives are:

- To ensure the same quality of treatment to patients with rare diseases
- To restore the equilibrium between supply (industry) and demand (patients with rare diseases)
- To provide incentives for industry to develop and market orphan medicinal products
- To ensure better functioning of the internal market and preserve fair competition
- To encourage innovation.

Implementation of the regulation

The Regulation explicitly encourages developers to invest in the R&D and marketing of innovative medicines for rare diseases through the various incentives described below.

The EMA Committee for Orphan Medicinal Products (COMP) is responsible for assessing and recommending orphan designation of medicines for rare diseases and includes representatives from all Member States as well as scientific experts to ensure there is sufficient competence to assess different therapeutics and different disease areas.

The COMP has had to work hard to cope with the evolution in the underlying science (e.g. the growth in advanced therapies and personalised medicine, new trial designs).

13.2 Overview of the impact assessment and support study

Role and focus of the support study

The support study reviewed the objectives and design of the Regulation and assessed to what extent it has proven effective, efficient, and relevant. The time period to be covered was 2000 to 2017. Additionally, it examined the internal coherence between the Regulation at the level of the EU, as well as external coherence with national policies and initiatives in EU Member States. The EU added value of the Regulation was also reviewed along with the Regulation's achievements, shortcomings, and challenges.

Overview of the support study implementation

The study drew upon existing data sets as well as the collection of new data. A comprehensive analysis of available literature and of data provided by the European Medicines Agency was performed. A targeted consultation, using surveys and interviews, was conducted with 5 distinct groups of stakeholders: 1) representatives of national public authorities in EU Member States, 2) sponsors of orphan medicinal products, 3) developers of generic medicines, 4) patient and consumer organisations, and 5) academic researchers and experts. Additionally, IQVIA[88] sales data and additional secondary sources were used to estimate the costs associated with the Regulation and to conduct a high-level cost-assessment.

13.3 The use of Tool 21

Explicit use of the tool

The original regulation and impact assessment (IA) predate Tool 21.

Implicit use of tool

There is implicit use of the tool as described in the sections below.

Step 1 Broaden consultation to capture the research and innovation angle

Primary data for the support study was collected from targeted stakeholder groups using a series of interviews and online administered surveys. The targeted stakeholder groups included representatives of sponsors of orphan medicinal products and developers of generic orphan medicines and their respective industry associations as well as academic experts so as to capture the developments and current status of R&I related to orphan medical products. Moreover, an online public consultation was conducted to solicit input from individuals with a personal experience with rare diseases (patients and carers) and from health care professionals.

Step 2 Assess potential impacts on research and innovation

The consultations included questions about the impacts of the Orphan Regulation and its incentives on research and innovation including the extent to which the Regulation had influenced the intensity and direction of R&D activities in the 'orphan' space. This included collection of data and evidence to help assess whether the regulation had encouraged companies to (i) increase their R&D investment related to rare diseases and (ii) increase the number of innovative medical products they brought to market.

Step 3 Address legislative design considerations

The regulation was designed to be flexible – it is agnostic in terms of the diseases that can be targeted, the innovation being developed, and the companies involved in the R&I activity.

Furthermore, since the legislation was an EU Regulation, it had the benefit of not needing to be transposed into national legislation – as with a Directive – and meant that the legislation would be applicable in all Member States as soon as it would enter into force. The proposal further set harmonised criteria for defining a rare disease and introduced a Community procedure for designating orphan medicinal products. There was also an annual contribution from the Community budget allocated specifically to allow applicants

[88] IQVIA is a company specialising in using data, technology, and advanced analytics, and has databases of real world data from the pharmaceutical sector.

to be exempt from paying all or part of the fees associated with the services provided. It was assumed the fee might constitute a serious obstacle in its own right to the development of at least some orphan drugs. These fee waivers and provision for protocol assistance / advice were particularly designed for SMEs, explicitly to reduce the compliance costs on developers and to avoid problems that particularly affect SMEs.

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

The principal measure to leverage the potential of innovation and reduce negative impacts on innovators (companies) is the 'market exclusivity': the EU Orphan Regulation grants developers of designated orphan medicines exclusive marketing rights throughout the EU single market for a 10-year period upon marketing authorisation. In general, EMA approved branded medicines enjoy 8 years protection against generic entrants, with the additional 2-year's market exclusivity expected to increase revenue sufficiently to reduce or overcome the market failures surrounding the development of medicines for rare diseases.

The Regulation also allows Member States to introduce their own additional incentives for placing orphan medicines on the market, within the framework of their own powers and responsibilities, such as R&D tax credits.

13.4 Impact on innovation

Impacts assessed

The external evaluation of the Regulation found that the number of orphan medicines on the market in at least one EU Member State increased from 48 in 2008 to 129 in 2016. On average 21 (range 18 to 24) out of 131 orphan medicines were developed between 2012 and 2017 as a direct result of the Regulation.

The Orphan Regulation has also enabled faster availability of orphan medicines in the EU market. The average time to market has reduced by as much as 9 months.

The economic value of the market exclusivity reward for a limited sample of 16 orphan products was on average 30% of total turnover. Further, the reward may result in 10 to 20% increase in revenue potential for an average orphan medical product. This is likely to incentivise R&D investment in the area of rare diseases. It was calculated that in the period 2000-2017, developers spent an additional €10bn on R&D relating to rare diseases compared to what was projected to have happened without the regulation.

Model and methods used

The review of the regulation entailed a cost-benefit analysis as far as possible in accordance with EU guidelines.[89] The model however differed in that health benefits were not monetised but expressed in terms of Quality-adjusted Life Years (QALYs). Societal costs and health impacts were assessed by comparing the "situation with the EU Orphan Regulation" to the "situation without the EU Regulation" (comparator situation). The following cost and impact data were assessed in the CBA:

- Impact of the EU Orphan Regulation (compared to the comparator situation). This estimate was based on data from IQVIA
- Impact on accessibility into extra sales volumes and extra use of orphan medicines in the EU, resulting in extra turnover for industry. IQVIA sales data for orphan medicines in the EU and the estimated economic value of the market exclusivity reward were used for this dimension

[89] European Commission, Better Regulation Toolbox, Tool #52, Methods to Assess Costs and Benefits. 2017; European Commission, Guide to Cost-Benefit Analysis of Investment Projects, December 2014.

- Impact of extra use of orphan medicines on health care costs, based on available literature
- Health impact on patients with rare diseases due to the treatment with the new orphan medicines, according to data from Health Technology Assessment reports
- Health care costs as divided between public and private financing sources
- Impact of the extra use of orphan medicines on non-health costs of disease, based on literature review.

The economic value of the market exclusivity reward was estimated based on two dimensions: (1) the monetary impact of the reward for the society as a whole and (2) the comparator situation i.e., the situation before the Orphan Regulation was introduced. Using a group of 16 orphan medicines, the economic value of the reward was calculated based on (a) the actual development of the revenues of the originator company; (b) the applicable comparator situation and (c) the market dynamics after the expiry of the exclusivity rights.

The methodology applied is described in adequate detail in the study report and is replicable depending on access to the relevant data. For instance, IQVIA data are not publicly available but access can be negotiated. The CBA entailed the compilation of substantial primary and secondary data and required around 50 staff days to carry out and around €30 000 in data costs.

13.5 Impact of innovation

Impacts assessed

Major innovations in medical products over the years have made the assessment process more challenging for the COMP, requiring more specialist scientific advice and more time to debate issues. Changes such as the advent of personalised medicine and use of biomarkers are posing fundamental challenges as regards the key criteria for orphan designation. Similarly, use of novel trial designs is raising questions as to the evidence base regulatory agencies and health technology assessors can consider acceptable for decision-making.

In terms of societal impacts, the accumulated health impact realised from authorised orphan medicines is estimated at 240,000 to 500,000 quality-adjusted life years (2000-2017). However, not all of this impact can be attributed to innovation encouraged by the Orphan Regulation. With this caveat in mind, it should be noted that findings for 24 orphan medicines show that the average incremental cost-effectiveness ratio is €110,000, with a weighted average of €54,000 per quality-adjusted life year.

Model and methods used

The impact of innovation was estimated qualitatively in the evaluation and was based on data collected from the literature review and stakeholder consultations.

The methodology used is standard and readily replicable. Around 20 to 30 staff days would be needed to replicate the approach.

13.6 Good practices and lessons learned

Good practices

The Regulation provides a good example of the conscious use of a pan-EU regulation to provide a combination of intersecting measures: clear criteria for orphan designation, central / common assessment of applications for designation, provision of scientific advice ahead of applications (e.g. protocol assistance), fee reductions and waivers and

meaningful market rewards (e.g. market exclusivity), to incentivise private actors to change their behaviour and address a market failure through increased R&I activity.

Replicability of the study (resource intensity, timing, data requirements)

The search queries for the literature selection and screening and the steps of the portfolio analysis are provided in the study annex. For the cost-benefit analysis a specific (paid) database was used. Again, description of the various steps to identify the relevant drugs is described in the annex. However, it will not be possible to replicate the study since the underlying raw data points of the costs and benefits are not provided in an accessible format, so that it is not clear what has been calculated to come to the included figures. Yet, a similar study with the same elements (surveys, database use etc.) is possible with potentially highly similar results.

In terms of data requirements, paid access to a specific database would be needed.

R&I activity could be addressed through additional use of databases such as patent data (e,g., PATSTAT) or analysis of start-ups (Crunchbase, Dealroom). Use of the databases is fee-based.

13.7 Opportunities

Scope of the analysis

The scope of the analysis was appropriate; the right stakeholders and stakeholder groups were engaged in the consultations and the relevant questions were asked e.g., in relation to the implementation and impact of the regulation. Further, CBA was conducted.

Data collection methods

The number and diversity of stakeholder groups involved meant that it was quite challenging for the study team to ensure comprehensive feedback from all groups. It is possible that certain perspectives were underrepresented in the support study.

Sponsors of orphan medical products (businesses) were unwilling or unable to disclose information about R&D costs relating to specific orphan medical products in the consultations.

Use of data

Given the challenges in collecting the relevant data via a survey, the study team had to use more general corporate R&D expenditure data and the wider academic literature for analysis, which meant that findings were not based on the most recent and specific data.

Case selection and design of the analysis

The limited number of instances where generic medicines were brought to market after expiry of the orphan market exclusivity meant that estimates of the financial value of the additional period of market exclusivity had to rely on a small, potentially un-representative, sample of products.

Use of indicators to monitor innovation impacts in the short, medium, and long term

The EMA monitoring arrangements do not extend to tracking market authorisation holders' research investments or EU / Global research and innovation activities relating to rare diseases more generally. Such indicators would be useful to monitor innovation impacts more closely and over time.

Alternative Models

The CBA methodology was appropriate. However, the results could be improved with access to more recent and specific data, e.g. R&D costs of market authorisation holders, and a better means to value the additional period of market exclusivity. For example, if company data on R&D costs, production, marketing and distribution costs, pricing and revenues from individual products were available, they could show how these factors influence the decisions of companies to start or continue the development process of new orphan medicines, and how the rewards (public research, protocol assistance, fee waivers, market exclusivity) influence these decisions.

14. Case 3 Directive 2003/98/EC on the Re-use of public sector information

Title of the regulation	Evaluation and Impact Assessment of the Directive on Re-use of Public Sector Information (Directive 2013/37/EU)			
Geographic level	EU		Country	
Type of study	Impact assessment		Evaluation	

14.1 General background of the regulation

History of the legislation

The Directive on Re-use of Public Sector Information (the "Directive", "DRPSI") was first passed in 2003 (Directive 2003/98/EC). It was amended for the first time in 2013, with new rules on (i) making data re-usability the default, (ii) adopting the principle of marginal-cost charging, (iii) including cultural data in the scope of the Directive, and (iv) making data available in a machine-readable format(Directive 2013/37/EU).[90] In 2017 the Commission commissioned an Evaluation of the (revised) Directive, including policy recommendations and an Impact Assessment of possible further changes. This Evaluation, formulation of Recommendations and Impact Assessment was contracted to a study team led by Deloitte and is referred to here as the "Support Study" (SMART 2017/0061). Said study team is referred to as the "Contractor". The Directive was then further amended in 2019 (Directive 2019/1024 EU).

Responsible organisation

Directorate-General for Communications Networks, Content and Technology (DG CNECT)

Support study supplier ("Contractor")

Study team consisting of Deloitte, Open Evidence, wik CONSULT, time.lex, Spark Legal Network, and The Lisbon Council.

Additional support/background studies

Since the original Directive was passed in 2003, a number of studies of the Directive and/or PSI Re-use and market development in general were performed. Most of these are referred to in the Support Study. They include:

- Fornefeld, M., Boele-Keimer, G., Recher, S., Fanning, M. (2009): "Assessment of the Re-use of Public Sector Information (PSI) in the Geographical Information, Meteorological Information and Legal Information Sectors" (not referred to in the Support Study), Düsseldorf: Micus Management Consulting

[90] Support Study, p. 16; Wirtz, H. (2014): "Die Änderung der PSI-Richtlinie. Fortschritt oder Rückschritt?, DuD: Datenschutz und Datensichterheit 6, pp. 389–393, https://link.springer.com/content/pdf/10.1007/s11623-014-0146-1.pdf ; European Commission (2018): "Evaluation Accompanying the document Proposal for a Directive for a Directive of the European Parliament and of the Council on the re-use of public sector information", SWD(2018) 145 final, Brussels: 25.04.2018

- Vickery, G. (2011): "Review of recent studies on PSI re-use and related market developments", Paris: Information Economics, http://ec.europa.eu/newsroom/document.cfm?doc_id=1093
- Shakespeare, S. (2013): "Shakespeare Review. An Independent Review of Public Sector Information", HRM Department for Business, Innovation & Skills, BIS/13/774, https://www.gov.uk/government/publications/shakespeare-review-of-public-sector-information
- De Vries, M., Kapff, L., Achiaga Negreiro, M., Wauters, P., Osimo, D., Foley, P., Szkuta, K., O'Connor, J., Whitehouse, D. (2011): "Pricing of Public Sector Information Study (POPSIS). Models of supply and charging for public sector information (ABC) - final report", SMART 2010/0046, Brussels: Deloitte and others. https://ec.europa.eu/digital-single-market/en/news/pricing-public-sector-information-study-popsis-models-supply-and-charging-public-sector
- IDC and Open Evidence (2017): "European Data Market Study. Final Report", SMART 2013/0063. https://a2528ba5-a-c3c32646-s-sites.googlegroups.com/a/open-evidence.com/download/repository/SMART20130063_Final%20Report_030417_2.pdf?attachauth=ANoY7crh-yrOIYwe-lpXMMgkV2w2lOxH9NxL8o0Fgz3a7uaVP-vFuE3kVSEnXAOtzucAHnp9bl0Jiq_kOLI71xad68c7dTHH-YXf9of6Ypy8-gt_2sk8B-wuHnZDfwSdKBlFW_R2ApepjVylPg_WjBP79S5Ti4JM5850jNlXyrzrZy1Gt5u7-ozVloNjk2sIxAqU7TPmwem0GbrnMHGFlOfTDa0esLpfyt1lHnE7YGCI-t_tkHiz2MDwtII80mGiQYXMm9uV4hUD&attredirects=1
- Tinholt, D., Carrara, W., Chan, W.S., Fischer, S., van Steenberg, E. (2015): "Creating Value through Open Data" SMART 2014/1072, Brussels: Capgemini, https://data.europa.eu/sites/default/files/edp_creating_value_through_open_data_0.pdf
- Manyika, J., Chui, M., Farrell, D., Van Kuiken, S., Groves, P., Almasi Doshi, E. (2013): "Open Data: Unlocking innovation and performance with liquid information", McKinsey Global Institute, https://www.mckinsey.com/business-functions/mckinsey-digital/our-insights/open-data-unlocking-innovation-and-performance-with-liquid-information

Type of regulation

Institutional regulation aimed at promoting innovation.

The Directive can be considered a type of institutional regulation as it structures the overall institutional environment in which companies and other innovators (e.g. independent technologists, researchers) act.

It can be considered a regulation targeting the promotion of innovation as its main objective is to make data held by the public sector more available to innovators and citizens, with a view to promoting the development of new products and services.

Sectors addressed

The Directive addresses public sector organisations (PSOs). The Scope of which PSOs are included in the Directive has steadily expanded since 2003. As per Art. 1 DRPSI, it applies to:

- Public sector bodies, i.e.,
  - State, regional or local authorities
  - Other bodies governed by public law, in particular
    - Museums, archives and libraries, including university libraries
    - Research performing and research funding organisations (RPOs/RFOs), universities, research institutes, research councils and other funders that receive public funding

- Public undertakings in the energy, transport, water or postal sectors, i.e., companies active in these sectors over which public authorities exercise a dominant influence by virtue of majority ownership or regulatory requirements.

These different types of PSO face different requirements under the Directive. For instance, RPOs are not obliged to make all data that their scientists collect publicly available; rather, the Directive applies only to data that has already been made publicly available in repositories (Art. 10 DRPSI). Similarly, public undertakings are not obliged to apply the Directive to data ("documents") "related to activities directly exposed to competition" (Art. 1(2)(b)(ii) DRPSI) (i.e., commercially sensitive information). There are also exceptions (for instance for cultural institutions) relating to the application of the principle of marginal-cost charging.

The number of sectors addressed by the Directive has gradually increased. In the original 2003 version, the Directive did not yet apply to cultural data (i.e., museums, archives, and libraries) nor to research data or public undertakings. Application to cultural data was first included in the 2013 revision, to research data (i.e., RPOs/RFOs) and to public undertakings in the 2019 amendment.

Scope of regulation

The Directive addresses all public sector bodies and public undertakings in the Member States and obliges them to make all their existing "documents" (i.e., data) reusable, unless the bodies and undertakings or their documents are excluded by the Directive itself or national rules, for instance for reasons of privacy/data protection, protection of critical infrastructure, or of competition (Recital 23 DRPSI). For example, as noted above, public undertakings and RPOs/RFOs are not obliged to allow re-use of all their documents (data).

Objectives

The following objectives for the Directive can be deduced from the legislative text and the Recitals, and are also enumerated in the Support Study:

- Stimulating "digital innovation, especially with regard to artificial intelligence" and the development of new products and services, especially cross-border products, and services and those that promise significant broader benefits for society, environment, and economy (Recitals 3, 8, 9, 10, 24, Articles 1(1), 2(10) DRPSI)
- Enabling citizens to gain new ways of accessing and acquiring knowledge, and promoting transparency and accountability (Recitals 11, 14)
- Fostering the growth of the digital economy and the creation of digital-economy jobs (Recital 10, 12, Article 2(10)
- Ensuring undistorted competition and development of the digital economy within the Internal Market (Recitals 15, 17 DRPSI).

Curiously, the Support Study does not explicitly list "innovation" as key objective (cf. pp. 16f., 101) and does not try to systematically assess the Directive's innovation-related effects in its Evaluation.[91] Policy officers from DG CNECT emphasised that stimulating

[91] Rather, the Support Study describes the objectives of the Directive as to "ensure that competition in the internal market is not distorted, to enable citizens to gain new ways of accessing and acquiring knowledge and to enable the creation of jobs related to the digital economy and concerning digital contents." (pp. 16f; cf. p. 101). It does refer to the "development of *Community wide* services" as an objective (p. 101, emphasis added) and analyses the Directive's impact on the creation of "new PSI based services" – but it tends to treat these more as an aspect of the goals of job creation and preventing market distortions than as major goals in their own right.

innovation by making more data available was a central, overarching objective of the Directive and its revisions.[92]

14.2 Overview of the impact assessment and support study

Role and focus of the support study

The Support Study formed a key input for the legislative process that ultimately led to the revision of the Directive in 2019.

Overview of the support study implementation

The Support Study utilised a variety of data and methods: a stakeholder consultation survey and workshops, interviews, review of the existing literature and studies, various statistical data points. It also performed a cost-benefit analysis (CBA) of different policy options for revising the Directive (see further below).

14.3 The use of Tool 21

Explicit use of the tool

Tool 21 is *not* used explicitly in the Support Study.

Extensive reference is made to the **Better Regulation agenda**, and **tool 63** on multi-criteria analysis is explicitly used.

Interviewed Policy Officers from DG CNECT had some awareness of tool 21. They noted that they mostly tended to use the various tools of the Better Regulation toolbox in an implicit manner. According to them, when preparing an impact assessment/evaluation, the focus was mainly on using the key underlying ideas, rather than explicitly following a specific tool to the letter.[93] The impression from the interview is that the tools of the Better Regulation guidelines (or at least tool 21) form part of policy officers' general conceptual "armour", but mostly do not function as structured, formal processes to be "blindly" followed.

Implicit use of tool

Step 1 Broaden consultation to capture the research and innovation angle

Extensive stakeholder consultation was performed as part of the Evaluation and Impact Assessment. Replies to an Inception Impact Assessment were solicited online, a public online consultation (273 replies) and three further online surveys[94] and three workshops were conducted, as well as a public hearing, a high-level roundtable, and two meetings with Member State representatives and National Points of Reference on scientific information.[95] Finally, as part of the Evaluation and Impact Assessment, 96 interviews were performed.

Tool 21 notes that consultations risk collecting predominantly the views of established, incumbent actors, and recommends giving particular attention to collecting the views of

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[92] Interview, 02/07/2021

[93] Interview, 02/07/2021

[94] The surveys were aimed at the culture sector, „universities and research centres", and the „re-user community", respectively. No "N" are given for the surveys in the Support Study, though the response numbers from the "re-user community" are described as "disappointing" (Support Study, p. 37)

[95] Synopsis Report for the Consultation, p. 2

start-ups and other non-incumbent or non-traditional actors. Tool 21 suggests that "research and innovation ecosystem actors" may partly serve as proxies for these. In the case of the Directive, relevant 'non-incumbent' actors aside from start-ups could include independent technologists, foundations and organisations pursuing social innovations and independent or more junior researchers (as opposed to the leaders and representatives of major RPOs). It should be noted that collecting views of non-established actors is difficult by definition, as they are hard to find and there may be no "official" definition of these actors. For instance, there is no official EU definition of what a "start-up" (as opposed to e.g., an "ordinary" SME) is.[96]

It is unclear how systematically the views of "start-ups" (however defined) and other "non-incumbent" actors were solicited during the consultations. The survey of the "re-user community" presumably also targeted start-ups (and possibly other "non-incumbents") but as the Support Study notes, the response number to this was "disappointing" (p. 37). The Synopsis Report for the Public Consultation implies that, at most, ~12% (34) of the respondents were individual SMEs[97], which could presumably include start-ups. It is unclear whether other "non-incumbents" responded.

Start-ups (or at any rate SMEs),and other "non-incumbent"-type actors participated in several of the consultative workshops and roundtable e.g., social innovation-focused foundations (Wikimedia, Open Knowledge Foundation), independent technologists and their associations (e.g. the Open Energy System Modelling Community) and researchers speaking in their capacity as independent experts. For the Support Study, the Contractor also interviewed the EuDECo Project (an H2020 project on the European Data Economy) and Kennisland, a "think/do tank" for social innovation.

The public online consultation survey instrument asked respondents for their views on the effectiveness, efficiency, relevance and coherence of the Directive, as well as EU value-added. It further asked about their views and experience of access and search for PSI, charging rules, preferred levels of openness and terms of access for data held by RPOs and public undertakings. It also inquired into actual data sharing practices of PSOs (as experienced by respondents) and barriers to PSI access and reuse, among other points.

Overall, the online consultation and the various in-person consultations[98] appear *not* to have tried to assess possible *positive* impacts of the Directive on research, innovation, emerging technologies and scale-up in detail. It was asked in general terms whether PSI was increasingly providing a basis for innovative services and products and whether the Directive was helping to make access to PSI easier/cheaper, especially for SMEs and start-ups both of which were assented to by large majorities of respondents.[99] Beyond such general questions, however, the focus of the online consultation and workshops was instead on how access, supply, usefulness and re-use of PSI might be further eased/increased (e.g., standardisation of data and metadata, charging rules, funding,

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[96] A common definition of "start-ups", used for instance by the EU Startup Monitor, is companies younger than 10 years with "innovative" products or business models and/or aiming to scale up rapidly (employee, user or revenue numbers). http://www.startupmonitor.eu/

[97] Own calculation on the basis of available data. There were 273 respondents in total, of whom 29% were "public organisations", 25% "associations", 25% "citizens"; there were also "business respondents", of whom 50% were large concerns and 40% "SMEs" (the missing 10% were not specified). Subtracting the 29% "public organisation" respondents, the 25% "association" and the 25% "citizen" respondents from 100% (all respondents) leaves 31% of respondents which presumably were the "business respondents" (100% – 29% – 25% – 25% = 31%). 31% of 273 (the total number of respondents) is ~85, suggesting that some 85 businesses responded. As just noted, 40% of the business respondents were said to be SMEs, which implies ~34 SME respondents, or ~12% of the total respondent population (273 * .31 * .4 = ~12%).

[98] As far as can be judged from the available summaries of these events.

[99] Example questions include "Based on your experience, do you consider that the objectives of the PSI Directive are being met? In particular: 'PSI is increasingly becoming a source of innovative services and products', 'PSI has become more affordable, including for Start-ups and SMEs'" (Agree strongly / slightly; Disagree strongly / slightly; Don't know)

APIs, etc.), and where barriers to access existed. Reasonably enough, given that it is rather self-evident, the underlying premise of the Directive (that greater and easier availability of PSI would enable more innovation) appears not to have been seriously tested by neither the Contractor nor the respondents and workshop participants.

Possible *negative* impacts, that the envisioned changes to the Directive might have had, were addressed in the survey and the workshops; however, it seems that these tended *not* to be discussed in terms of impacts specifically on *innovation, research or technology development*. Rather, the focus – including of the respondents/workshop participants – seems to have been on additional compliance and administrative burdens, potential negative budgetary effects on PSOs and RPOs if charging was further restricted, potential distortions of competition, and security risks. Possible adverse incentives for data collection/data provision (e.g., underinvestment in data collection and preparation) that might flow from some of the revisions of the Directive under consideration seem to have been raised only in one Workshop, and then by a participant.

Step 2 Assess potential impacts on research and innovation

The Contractor and the interviewed, surveyed and otherwise consulted stakeholders seem to have largely taken it as given and obvious that, if changes to the Directive made more data available more easily and cheaply, this would positively affect corporate and social innovation, as well as the production of underlying scientific research. In particular, it was assumed that making more data currently held by public undertakings in energy and transport, and more research data, publicly available, would strongly speed up innovation and research outputs related to these sectors. Accordingly, the following guiding questions from Step 2 of Tool 21 were implicitly addressed and answered affirmatively:

- Does the intervention impact the generation of new ideas, their adaptation and application (e.g., from the knowledge base to industry)?
- Could the measure affect the innovation dynamics of specific markets?
- Will the proposed initiative lead to societal innovation?
- Is the intervention in an area with a relatively fast pace of innovation?

The proposition "more data --> more innovation" is broadly reasonable and it makes sense that the Support Study did not seek to test or prove this in any depth, beyond providing some casual evidence of a steady growth in the number of PSI-based products and services as part of its Evaluation of the Directive.

However, several of the possible changes to the Directive proposed and analysed in the Support Study would have had the potential to affect research and innovation in more negative ways. For instance, certain possible changes to the treatment of research data and data held by public undertakings that the Support Study considered as options (ultimately rejected) for amending the Directive could have potentially raised the costs (in time and labour) and reduced incentives to invest in data collection in the first place, or for private companies to collaborate with RPOs.[100] On the other hand, these (considered but rejected) changes *also* held out the potential to make much more data openly available, with strong positive effects on innovation and research. In other words, their effects were unclear. These issues were briefly discussed in the Support Study, but

[100] Specifically, Policy Sub-option 2a.1 "Extension of the scope of the Directive to research data" canvassed the possibility of "fully [removing]" existing exceptions for RPOs and thus making the Directive applicable to any research data produced in the course of publicly funded research. Similarly, Policy Sub-option 2a.2 considered the possibility of bringing public undertakings under the existing "default rules of the PSI Directive" (Support Study, pp. 278-279). As the Support Study noted, Sub-option 2a.1 could potentially have discouraged industry to collaborate with RPOs, with negative innovation effects (p. 291). However, both Sub-options 2a.1 and 2a.2 could also conceivably discourage researchers and public undertakings from collecting hard-/costly-to-obtain data, if they would have to share it – potential consequences the Support Study did not note or explore. It is important to note that Sub-Options 2a.1 and 2a.2 were ultimately rejected (albeit partly on other grounds) and never entered the final amended Directive. The point here is primarily about how these Sub-options were and were not analysed in the Support Study, not about what ultimately became law.

not systematically analysed. In this sense, the Support Study cursorily touched on but did not systematically answer the following guiding questions of Tool 21 Step 2:

- Does the intervention affect the cooperation (e.g. circulation of data, research results or researchers) between public and corporate R&D?
- Could compliance costs and time for the development of innovative technologies/solutions be affected?

The other guiding questions listed in Step 2 of Tool 21 were not addressed, implicitly or explicitly, but also do not seem obviously relevant to the changes to the Directive considered in the Support Study.

Step 3 Address legislative design considerations

With respect to possible *impacts on innovation*, the problem of **flexibility and future-proofing** possible changes to the Directive are discussed in the Support Study at various points. A basic objective of the Evaluation was to identify emerging and future (data-) needs of stakeholders, in order to derive interventions to address these. More specifically, the Support Study notes that the identification of high-value key data sets should be a "continuous discussion", as what data sets may count as high value is likely to change over time (pp. 316, 360). In discussing and deriving possible interventions to further reduce technical barriers to PSI re-use, the Support Study also sought to take account of possible "future technical problems" and the evolving and emerging needs of data re-users and data practices (towards real-time, dynamic data and massive dumps delivered by APIs; crowdsourced data; etc.) (pp. 252 – 256).

Questions of the **compliance costs** involved in possible changes to the Directive are considered throughout the Support Study. However, the possible *innovation impacts* of rising compliance costs are addressed relatively explicitly only in regard to how changing rules around research data might impact researchers and RPOs. Conversely, how rising compliance costs might affect specifically the *innovation activities* of other public sector bodies and public undertakings is not addressed. In defence of the Support Study, it should be noted that reaching definitive answers on this point would likely be impossible. Rather, the issue of compliance costs was discussed mainly in terms of keeping the general burden on public sector bodies and public undertakings proportionate.

Questions of **regulatory certainty and clarity** and of **harmonisation** between Member States across the single market and of policy interactions are considered throughout the Support Study when discussing possible changes to the Directive, though generally without relating these directly to innovation.

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

Step 4 of Tool 21 provides a non-exhaustive list of instruments and approaches that can help make legislation more innovation-friendly. The measures proposed and assessed in the Support Study can in part be considered instances of one of these instruments/approaches; namely outcome-oriented legislation. The Support Study also systematically assesses alternative policy options, as Step 4 of Tool 21 recommends.

Other aspects

The support study draws quite extensively and explicitly on the **Better Regulation** guidelines and its concepts to structure its analysis. In particular, it is used to structure the cost-benefit analysis and compare policy options (e.g. pp. 22, 55f., 164, 217, 273, 284, 416ff.). Explicit use is made of **tool 63** (multi-criteria analysis) (p. 416ff., 435).

14.4 Impact on innovation

Approach

The Support Study consists of an Evaluation of the 2013 version of the Directive, and an Impact Assessment of possible interventions to address shortcomings in the Directive identified in the Evaluation.

The Evaluation focuses on the extent to which the following three objectives were realised by the Directive (cf. p. 102):

1. Ensuring that competition in the internal market is not distorted, *operationalised as:*
    a. Enabling development of Community-wide services and the exploitation of the economic potential of public sector information;
    b. Enhancing effective cross-border use of public sector data by private companies;
    c. Ensuring fair, proportionate and non-discriminatory conditions for the re-use of public sector information;
2. Enabling citizens to gain new ways of accessing and acquiring knowledge;
3. Enabling the creation of jobs related to the digital economy and digital contents.

To assess whether these objectives were met, the Evaluation draws primarily on the following bodies of evidence:

- Estimates of the growth of the PSI market's size and value, including by sector (data from Eurostat and prior studies);
- Qualitative information on the (growing) number of cross-border PSI-based products and services, drawing on interviews and prior studies;
- Estimates of cost savings to the public sector and government revenue growth related to greater re-use of PSI across the (then) EU-28;
- Assessments of how well the PSI market functioned and where barriers remained, as expressed in the various consultations, surveys and interviews;
- Statistics on visitor numbers and data requests from public data portals in various Member States as well as stakeholder assessments regarding citizen interest in PSI;
- Estimates of the number of persons employed in PSI-related and knowledge-intensive areas (data from Eurostat and prior studies).

These economic and social benefits are then contrasted with estimates of the costs to the public sector of opening up PSI, yielding an overall positive finding. Further analysis of the Directive's continued relevance (fit with current and future or emerging stakeholder needs), its coherence with other regulations and policies, and EU value-added are then performed, based mainly on the consultations, survey and interviews conducted, and prior studies.

From this analysis – primarily the stakeholder inputs collected in the consultations, surveys and interviews – a series of emerging and future needs of stakeholders (PSI re-users) and shortcomings in the current version of the Directive are identified. Essentially, these concern the following points:

- Lack of access to research data (excluded from the 2013 version of the Directive);
- Lack of access to data from public undertakings, especially in the energy and transport sector (excluded from the 2013 version of the Directive);
- Continued and to some extent growing use of exclusive agreements on data use between PSBs and private companies, especially in the area of "smart cities", despite efforts in the 2013 version of the Directive to restrict the use of exclusive agreements;

- Continued economic barriers to PSI reuse due to exceptions contained in the Directive to the principle of charging only marginal costs for data;
- Lack of provisions in the 2013 version of the Directive for making data available dynamically and in real time, and via APIs.

In all five points, the key issue identified in the Evaluation is that these shortcomings tend to reduce the amount of data – especially of valuable, high-quality data – available to re-users, in turn hampering innovation and the development of the data economy and related jobs.

The Support Study then develops two "policy packages" to address each of these shortcomings and thereby ensure greater data availability (and, by implication, innovation); one non-regulatory (funding, awareness-raising, recommendations, etc.), one regulatory (new legal obligations to be included in a revised Directive). A cost-benefit analysis (CBA) for each policy package relative to business as usual (BAU) is performed with respect to their effectiveness, efficiency, proportionality, legal feasibility and coherence, and practical, technical and political feasibility.

The basic conclusion of the assessment was that the second policy package (regulatory option; POL 2) would more comprehensively address the re-user needs and shortcoming of the current Directive identified and make significantly more data available than the first (non-regulatory) policy package (POL 1), though both scored significantly higher than BAU. Quantitative estimates were made for their impacts, through to 2030, on the number of stakeholders (re-users) positively affected, and the PSI-related economic value, jobs, additional government revenue and public-sector cost savings created, and these compared in turn to the economic costs to the various affected "PSI-providing" stakeholders (i.e., RPOs, public undertakings, PSBs). On this basis, POL 1 was recommended as the more efficient (albeit somewhat less effective) of the two packages.

Impacts assessed

As the above description indicates, neither the Evaluation nor the Impact Assessment of the Support Study attempt a systematic assessment of specifically the *innovation* impacts of the existing Directive or the POL 1/POL 2 packages. Rather, the proposition is taken as given that, if more data is made more easily/cheaply available to more actors, this will more or less automatically lead to more innovation, especially for high-value data like research, energy and transport-sector data. Both in the Evaluation and the Impact Assessment various pieces of – usually qualitative and anecdotal – evidence for the positive innovation effects of the Directive and proposed amendments are introduced, but mostly in a casual way. Several of the quantitative measures estimated in the Evaluation and Impact Assessment imply a positive innovation effect; e.g. if growing numbers companies are using PSI and PSI-related economic value and job numbers are rising, then the PSI is presumably being used to create new products, services or processes. However, this implication is *not* in fact spelt out in the Impact Assessment. The Evaluation also devotes a short, qualitative section to the Directive's impact on the creation specifically of new *cross-border* products and services, though the larger point of this section is *not* the Directive's positive impact on *innovation* but on the development the Single Market. Possible simultaneous *negative* effects on innovation of the Directive or POL 1/POL 2 are not discussed in the Evaluation, and only in an ad-hoc, unsystematic way in the Impact Assessment, mostly *without* explicit reference to innovation.

To be clear, this is mostly reasonable. There is no obvious reason to doubt the "more data, more innovation"-proposition and as noted, several of the quantitative measures arguably provide indirect evidence of a positive innovation effect, which is supported also by stakeholder statements. However, while these data points suggest that the Directive caused (and that POL 1/POL 2 would cause) at least certain innovations, they do not address the question of whether the Directive and/or POL 1/POL 2 might *simultaneously* also have (had) negative effects on innovation, for instance by discouraging certain forms of data collection, RPO-industry collaboration or public-private partnerships (e.g. smart city projects).

This problem seems more acute to the Impact Assessment of POL 1/POL 2 than to the Evaluation of the 2013 version of the Directive, as – at least on casual inspection – the old Directive did not include provisions that could obviously negatively impact innovation. However, several of the interventions included in the POL 2 package of policy options – which did *not* ultimately become law – could have potentially discouraged investment in data collection by public undertakings and researchers / RPOs, or negatively impacted RPO-industry collaboration and public-private partnerships. While the Impact Assessment mentions the risks of reduced RPO-industry collaboration or public-private partnerships, it does not analyse the likelihood of these risks materialising, were POL 2 to become law let alone what their *net effect* on innovation might be. The possibility that some of the POL 2 options might potentially have prompted researchers or public undertakings to reduce investment in data collection is not discussed by the Support Study, despite this being raised by a stakeholder in at least one of the consultation workshops, and its obvious threat to the Directive's entire objective.[101]

Importantly, addressing these questions in a systematic manner would *not* have changed the Impact Assessment's outcome (or the ultimate content of the revised Directive), since POL 2 was rejected in any case, due to its lower efficiency compared to POL 1. Addressing these issues could only have swung the balance further against POL 2. In this sense, it would have been superfluous to the extant Support Study. However, had POL 2 found greater favour in the Impact Assessment – not implausible, given its significantly greater effectiveness score – these questions would have been more relevant. They might have implied, for instance, a need for additional flanking interventions to mitigate possible negative effects.

Model(s) and methods used

The methodology underlying the quantitative estimations used in the Evaluation and Impact Assessment are not disclosed in the Support Study.

14.5 Impact of innovation

Impacts assessed

The Support Study does not cover the impacts of PSI-based innovation in any detail, beyond the general benefits expected from increased re-use of PSI (i.e., growth of the data economy, data economy-related jobs and government revenues, cost-savings for PSBs, etc.). Various examples of useful services deriving from PSI especially in the energy and transport sector are mentioned in a casual way, such as "intermodal travel services", "more cost-effective mobility", "energy management" and "energy control and savings"(pp. 269, 310).

[101] Such discouragement/disinvestment effects are not implausible. Academic career progression remains heavily determined by publishing impact. Collecting a unique, hard-to-obtain data set can be a worthwhile investment, especially for early-career scholars. If they are no longer able to exclusively exploit this data (as some of the reform options in the POL 2 package could potentially have meant), however, their incentive to invest heavily (especially in terms of time) into the collection of such a data set decreases measurably – especially if legislative change means that *other* scholars are now releasing large amounts of data that they too can exploit. Had POL 2 become law, it could thus plausibly have led to a short-term increase and a longer-term decrease in the production of data, especially of hard-to-obtain data, with concomitant implications for overall research output.

14.6 Good practices and lessons learned

Good practice

Very extensive stakeholder input and expert opinion was solicited via some 96 interviews and several surveys and workshops. The survey instrument for the public online consultation includes extensive questions on barriers and blocks to sharing and re-use of PSI.

Replicability (resources, timing, data requirements)

The methodological approach taken in the Support Study could be replicated for the review, evaluation and impact assessment of regulatory interventions in other policy areas. The main quantitative data and sources used for the study are summarised on pp. 205–215. Replicating the economic impact and cost-benefit analysis should therefore be possible, and these data should generally also be accessible if they were needed for other studies. The qualitative analysis could likely also be replicated; whether by re-analysing the notes/transcripts from the interviews, workshops and survey/consultation inputs (if available), or by conducting new interviews, etc., with the same or comparable stakeholders. It is to be expected that replicating the methodological approach for other regulations or policy areas would require approximately the same scale of resources as were devoted to the original Support Study.

14.7 Opportunities

Scope of the analysis

As noted above, although promoting innovation was an important objective of the Directive, the Evaluation and Impact Assessment do not attempt to directly analyse its actual innovation effects. In this particular case that was probably not a problem, since policy options (POL 2) that might have also had inadvertent negative effects on innovation were ultimately advised against anyway, albeit on other grounds. However, in other circumstances a more systematic and fine-grained assessment in particular of possible negative effects on innovation (and possible ameliorating measures) may be advisable.

Data collection methods

The chosen data collection methods seem overall appropriate to the study. While the survey of the "re-user community" apparently produced very few responses despite "significant efforts" on part of Contractor (p. 37), response rates are a perennial problem that often has no good solution.

More effort could perhaps have been put into collecting data on social innovations and civic use of PSI as encouraging such use was an explicit goal of the Directive. One option for this might have been to survey or interview NGOs or data journalists working on issues of government accountability and transparency.

For *innovation impacts* – including the risk of inadvertent negative impacts, like discouraging investment in data collection – to have been made a greater focus of the study, it might have been necessary to include further questions in the survey and interview instruments. Additional quantitative estimates could possibly also have been collected, e.g. through automated analysis of the contents of App Stores. More broadly, to rigorously assess possible innovation impacts, a more theory-driven approach to data collection than was perhaps adopted in the Support Study could be advisable.

Use of data

The collected data seems to have been used appropriately and rigorously.

Case selection and design of the analysis

For some questions raised in the study – such as the use of exclusive arrangements in smart city projects and their innovation impacts – it could have been useful to conduct some more systematic case studies (e.g., paired comparisons of similar projects with and without exclusive arrangements) and pose more directly the counterfactual question of whether certain services would have come about at all, absent exclusive arrangements.

Use of indicators to monitor innovation impacts in the short, medium, and long term

On the basis of the Support Study, it is unclear to what extent innovation impacts are monitored directly and systematically.

Alternative Models

The chosen methodology was essentially appropriate. More systematic study of possible inadvertent negative innovation impacts could have been advisable, given some of the policy interventions entertained (POL 2). One possible approach to do this could have been to work in a more theory-driven manner, treating innovation as the – possibly unobserved – outcome of interest, and developing a causal model (a series of mechanisms and impact pathways) of how the proposed changes to the Directive might influence innovation positively or negatively (e.g., positively: by making more data available more cheaply; negatively: by discouraging certain data collection practices and certain collaborations). The validity of the theorised mechanisms and pathways could then have been tested through stakeholder interviews and/or rigorously selected case studies. The likely effect size of different mechanisms and the net effect overall could then have also been gauged, at least qualitatively.

It should be noted that this approach would not necessarily deliver hard quantitative estimates for innovation effects (whether measured as patents, new products/services or business processes, R&D expenditure, or publications). It could however enable policy makers to better identify regulatory design options that promise either particularly strong positive or negative innovation effects (including inadvertent ones).

It is unclear whether the EU policy-makers (i.e., Commission, Parliament and Member States) would find such an approach useful. Interviewed policy officers explained that while promoting innovation is a central concern that is always "in the back of your mind when you think about the effectiveness of some measure", currently, innovation effects are rarely assessed directly or explicitly. The fundamental reason for this, in their view, was twofold. On the one hand, innovation effects remain hard to quantify, and Impact Assessments are expected to produce quantitative evidence. Quantitative evidence may possibly also play a growing role in the political assessment of regulatory proposals by Member States and the European Parliament. On the other hand, for Member States and the European Parliament it is often the basic economic costs and benefits – in terms of GDP, jobs, company numbers, compliance/administrative expenses and revenue changes, among others – that constitute the overriding criterion by which regulatory proposals are politically assessed. Innovation in itself is more of a precursor to these outcomes of interests, than the outcome of interest itself. Since established

methodologies and data sources exist for estimating these, Impact Assessments tend to remain focused on them.[102]

[102] Interview with DG CNECT policy officers, 02/07/2021.

15. Case 4 Directive 91/271/EEC on Urban Waste-water Treatment

Title of the regulation	**Directive 91/271/EEC on Urban waste-water treatment**			
Study reference	Wood, COWI, IEEP, CHI/NTUA, HR Wallingford, CENIA (2019) Service request supporting the Evaluation of Directive 91/271/EEC concerning urban waste-water treatment – Evaluative study; doi: 10.2779/092268			
Geographic level	EU		Country	
Type of study	Impact assessment		Evaluation	

15.1 General background of the regulation

History of the legislation

The Council Directive 91/271/EEC concerning urban waste-water treatment (UWWTD) was first adopted in May 1991. The directive was amended in 1998 by Directive 98/15/EC, to clarify the requirements of the Directive in relation to discharges from urban waste-water treatment plants to sensitive areas which are subject to eutrophication.

In addition to the directive, a Commission Decision was adopted in 1993 (93/481/EEC) and replaced in 2014 (2014/413/EU). The latest decision defines the information that Member States should provide the Commission when reporting on the state of implementation of the Directive according to Article 17, and specifies the format in which the information should be provided.

While no stand-alone evaluation was conducted until 2019, the directive was included in the Fitness Check of water policies in 2012.

In 2017, the process for a second evaluation was launched, via the set-up of a joint inter-service group for both the UWWTD Evaluation and the Water Fitness Check. The evaluation was completed in November 2019, and an impact assessment is currently under way.

Responsible organisation

Directorate-General for Environment (DG ENV).

Type of regulation

This Directive in the environmental area aims to induce a shift that includes technological aspects. In that respect, it can be regarded as innovation-sensitive regulation.

Sectors addressed

Member states must ensure that agglomerations set up systems to collect urban waste-water, which covers:

- Domestic waste-water
- Mixture of waste-water (i.e. domestic and industrial)
- Waste-water from certain industrial sectors, as listed in Annex III of the directive:

- Milk-processing
- Manufacture of fruit and vegetable products
- Manufacture and bottling of soft drinks
- Potato-processing
- Meat industry
- Breweries
- Production of alcohol and alcoholic beverages
- Manufacture of animal feed from plant products
- Manufacture of gelatine and of glue from hides, skin and bones
- Malt-houses
- Fish-processing industry.

Scope of regulation

The scope of the directive was progressively extended as part of the implementation roll-out. As of now, it covers all agglomerations above 2000 inhabitants.

Objectives

The overarching objective of the directive is to protect the water environment from the adverse effects of discharges of (untreated or insufficiently treated) urban waste-water and from certain industrial discharges.

More precisely, the intervention logic of the evaluation details five objectives:

- To protect the environment from the effects of the pollution from waste-water discharged from urban treatment plants and certain industrial activities
- To improve the environmental performance of waste-water treatment plants
- To improve the environmental performance of waste-water treatment in certain industrial activities
- To enable a uniform application of the Directive in all Member States
- To deal with pathogenic organisms in sewage water.

Implementation of the regulation

Adopted in 1991, the directive entered into force in 1993. By 2005, all agglomerations within the scope of the directive had to implement the requirements, after staged transitional periods. For new Member States, deadlines to implement were adapted, and are now all expired (apart from Croatia, with a last deadline in 2023). As of 2017, implementation reports indicated that a high level of compliance was reached across the EU, although some Member States have been found to lag behind.

15.2 Overview of the impact assessment and support study

Role and focus of the support study

In 2017, a joint inter-service group was set up for the Water Fitness Check and a second (and first stand-alone) evaluation of the UWWTD, which was to be followed by an impact assessment.

The support study for the evaluation was awarded to a consortium led by Wood, in partnership with COWI, Institute for European Environment Policy, Centre for Hydrology and Informatics of the National Technical University of Athens ('CHI/NTUA'), HR Wallingford and Czech Environmental Information Agency ('CENIA').

The evaluation analysed the effectiveness, efficiency, coherence, relevance and EU-added value of the UWWTD, accounting for 30 years of research and innovation in the field of water management, as well as the evolution of the legal context.

In parallel, and feeding into the evaluation work, DG Environment collaborated with the Joint Research Centre, which provided the impact modelling. There was also collaboration with the Executive Agency for SMEs (EASME) to gather information from related projects, and the EEA which collects most data related to the implementation of the UWWTD.

Besides impact modelling, the JRC also provided a Science for Policy report answering questions provided by DG ENV, and a number of expert studies on specific topics. Notably, the collaboration with the JRC on water topics started years before the evaluation, and includes an expert group managed by the JRC, with members available for the redaction of studies, and who have access to information that would normally not be easily accessible and digestible within an evaluation.

Therefore, the support study and the overall evaluation benefited from the support of other units, which greatly widened the evidence basis.

Relevant studies:

- The effects of the Urban Waste-Water Treatment Directive – A Science for Policy Report by the Joint Research Centre
- Study supporting the Evaluation of the Urban Waste-Water Treatment Directive
- Cooperation agreement with the OECD on Estimating investment needs and financing capacities for water-related investment in EU Member States.
- The BLUE2 study on the socio-economic assessment of policies aiming to improve the quality of freshwater and the marine environment, looking notably at patents
- Other studies are mentioned on the evaluation online page.

The evaluation document also includes a report containing the key issue studies in annex.

15.3 Overview of the support study implementation

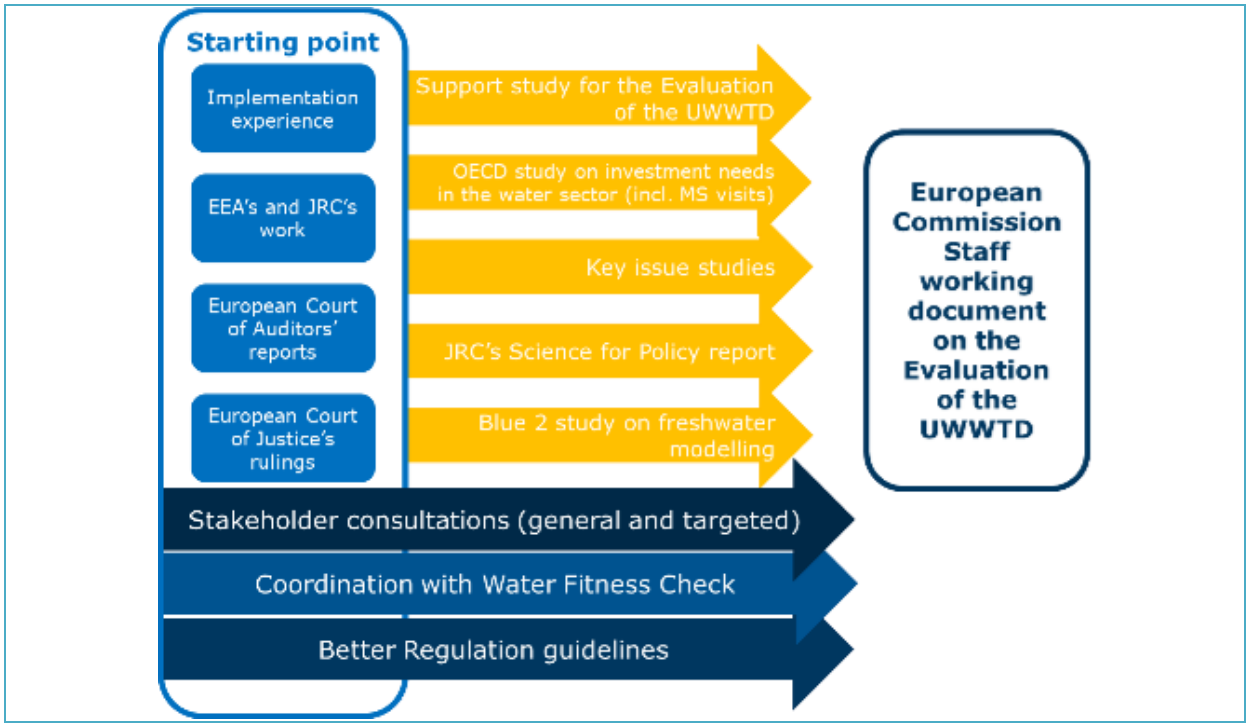
The evaluation study follows the Better Regulation guidelines and toolbox's methodology. It covers the usual criteria of effectiveness, efficiency, coherence, relevance and EU added value.

The methodology included a review of existing literature, a modelling of impacts conducted by the JRC, and stakeholder consultations. The consultations included:

- Stakeholders' feedback on the Evaluation Roadmap
- Scoping interviews (15)
- An Open Public Consultation (OPC) held via the European Commission's public consultation website
- Three thematic experts' workshops that gathered representatives from Member State Competent Authorities, Trade Associations, Non-Governmental Organisations (NGOs), European Commission services, and other organisations such as the World Bank and the Organisation for Economic Co-operation and Development (OECD)
- A stakeholder conference organised to present the preliminary findings of the analysis and gather feedback on those findings. The conference involved representatives of Member States, Trade Associations and NGOs, EU institutions, international organisations (e.g., OECD) as well as a limited number of private companies.

The assessment of the efficiency criteria included a cost and benefit analysis (CBA). As part of the CBA, innovation effects were considered by the study team. While it was not a priority, it was included from the start as an aspect to cover.

Figure 6 Evaluation process for the WWTD



Source: EC SWD

15.4 The use of Tool 21

Explicit use of the tool

The Commission's SWD includes a one-page long section on the UWWTD contribution to innovation. It concludes on the Innovation Principle, quoting Tool #21 of the Better Regulation Toolbox.

The analysis explains how the directive approaches innovation (technology neutral), and the actual effect on innovation. It concludes that the directive does not negatively impact wide-spread innovativeness and research in the sector but offers a more mixed picture as to whether it supported it. This claim is substantiated with figures on patenting, and

market share of EU based water companies. The legislation is seen as possibly having a driving effect on research and innovation. Results of the OPC on innovation are also quoted.

The Commission itself did not use the various checklist of Tool #21, due to workload issues. They did however ask the study team to investigate it. The study team used the checklists explicitly: as one evaluation question centred on innovation, they looked at the checklists to determine which questions were relevant and included them in their work.

The use of the tool was explicit, although questions were taken from the checklist in a rather implicit way (they were not always referred as "Tool #21" questions in the report).

Step 1 Broaden consultation to capture the research and innovation angle

As mentioned earlier, an extensive consultation of stakeholders took place. The evaluation roadmap received 28 stakeholders' feedback. Scoping interviews were conducted with 15 experts. The Open Public Consultation (OPC) gathered 608 answers, the expert workshops 100 participants, and the final conference 90 participants.

The OPC does includes questions on innovation effects, however respondent breakdown does not inform on specific innovation actors, as it only differentiates between higher-level stakeholder categories (NGOs, public associations, public authorities, public and private waste-water treatment plants). When analysing the answers, the team could identify technology providers or academics, but there was no deliberate attempt to distinguish them, as this level of detail was not needed for the purpose of the analysis. Overall, there was no lack of involvement of specific actors across the urban waste water life cycle. They received contributions from technology providers, plant operators, and so on. Generally speaking, technology-oriented companies such as start-ups are well mobilised by industry associations, which were consulted in the evaluation. In this sector, there is no issue of involving stakeholders, as they are generally keen on contributing, according to the study team.

Workshops covered specific themes (e.g., stormwater overflow). One workshop covered CBA aspects, which included presentations on recent research and methodological progress (in particular for costs and benefits). There was no dedicated questionnaire for the workshops, and no specific discussion on innovation. Some information was nonetheless gathered during the discussions, notably on what is now technically feasible, compared to the situation 30 years ago.

Tool #21 indicates the risk of gathering views predominantly from incumbent actors, and overshadowing information from more innovative actors. In the evaluation of the UWWTD, this risk was mitigated by the involvement of an expert group managed by the JRC, the use of key issue reports, and targeted consultation via workshops. In the case of the evaluation, this risk was also less relevant as the key focus was on what had actually happened, not what else could have been done.

The Commission points at the validation process for results during the evaluation: the expert group and the JRC provide figures on impacts, which are validated by the industry, and then by the Member States. This process is expected to minimize the risk of inaccuracy in the assessment or missing out on specific issues (notably readiness of technologies, feasibility of implementing them).

Step 2 Assess potential impacts on research and innovation

The study team made an extensive use of the checklist, selecting relevant questions early in the process. The checklists were perceived as a good reference point.

Use of Annex A checklist:

Section "Does the measure affect the research, testing or demonstration phase?": half of the questions are covered in the evaluation. The fact that the legislation is technology neutral might render some questions less pertinent or harder to assess. The evaluation addressed implementation and optimism bias on technology adoption, and the use of public funds to address the high cost of compliance.

Section "Does the measure affect incentives around investment, growth, jobs or scaling up in Europe?": 2 questions out of 5 are answered, and this aspect is overall covered in the evaluation. Some elements of quantification are included. Notably, patent activity is covered, but in general terms, there is no detailed analysis of patenting activity and its link to the UWWTD.

Inclusion in the Efficiency analysis

Answers to the questions have fed into the evaluation, notably under the efficiency criteria. Notably, the choice of technology and how it improves effectiveness of processes or mitigates the cost of implementation is covered.

Innovation was not a requirement of the legislation but was expected to happen. As such, it is addressed as a potential benefit (realised or missed opportunity). In "Other Benefits", the evaluation covers the impact on innovation. It reviews:

- Level and topic of funding allocated from the EU (desk research)
- EU share in internationally granted water technology related patents (based on existing study)
- EU share of Top 50 water services companies (reproduced from Global Water Intelligence)
- In the final cost-benefit comparison, benefit of export of technology/services is indicated as a non-quantified benefit.

Here, the evaluation clearly benefited from other studies or sources, to compensate for the lack of resources dedicated to this aspect of the legislation.

Step 3 Address legislative design considerations

Here again, the study team made an explicit use of the checklist.

Use of Annex B checklist

Section "Flexibility and future-proofing": half of the questions have been answered. Not all might be relevant. Overall, this section is well addressed.

Section "Compliance costs": this section does not appear to have been addressed. While the topic itself is covered in the evaluation, based on ex-post observation of actual innovation investment, and how innovation could help mitigate compliance cost, it does not appear that the specific questions of the checklist have been asked to stakeholders.

Section "Timing and stringency": partly addressed. Issues of harmonisation are covered.

Discussion

The main legislative design is technology neutrality. This overall renders the checklist more complicated to use, as it is likely that stakeholders will not be able to give precise answers. There is overall an assumption that since the Directive is technology neutral it does not hamper innovation in and of itself. This is later assumed to be confirmed by the increase in innovation in the domain after the adoption of the UWWTD (although there is no direct correlation analysed, due to a lack of resources).

The evaluation considered whether more could have been done to trigger innovation deployment, especially in energy efficiency (for climate change mitigation), adaptation to technological developments in treating storm water overflow, innovation in monitoring and treatment technologies (contaminants of emerging concern) ('To what extent does the Directive encourage/facilitate innovation and adaptation?'). Reuse of water sludge as part of a circular economy was also addressed. The absence of more specific/topical elements seems to have been a missed opportunity to support innovation, an aspect that is addressed in the IA carried out in 2021.

For the Directive, environmental monitoring requires a focus on the performance of treatment plants and receiving waters as well as control of sewage sludge. The required monitoring template[103] addresses innovation effects rather indirectly.

Innovation is considered as a potential way to reduce compliance costs, rather than under the angle of "how compliance cost might hamper expenses in R&D". Which technologies are used or newly developed for the purpose of effective filtering – or other means to meet the maximum concentration levels – is not monitored. Yet, examples of compliance costs are provided in the support study. Given technology neutrality, these costs may occur in research and development of new treatment technologies as much as in investment costs for the installation of established solutions. Regarding private businesses, SMEs are not particularly mentioned. This might be due to the fact that most companies are large utilities and often under public administration.

One issue for the study team in general was how to attribute impacts of the legislation itself on changes in innovation in the domain, notably regarding costs. The team looked broadly at information on budget allocation for research and innovation (notably in Horizon 2020).

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

The evaluation mostly explored how the technology-neutral legislation impacted innovation. The evaluation states: "As such, there is no evidence suggesting that the absence of legal provision in the UWWTD has hampered the development or research. Initiatives such as ENERWATER provide further support for WWTP (waste-water treatment plants) operators looking to further improve the operation of their facilities."

The Impact Assessment does explore other options further, taking inspiration from other legislation such as the Industrial Emission Directive, which follows a top-runner approach, or the use of best available technique requirements. The Impact Assessment has defined a number of areas for improvements, and within them measures that could be applied. A few of these measures are technical, and therefore have a potential for innovation. Here, the Tool #21 is used in a very targeted way. In addition, a separate study looks at the potential for introducing extended producer responsibility (EPR) schemes, and the impact assessment will have to integrate their results. Here again, the IA will benefit from separate studies.

15.5 Impact of innovation

Impacts assessed

Impacts on innovation are assessed in a qualitative way. It was not possible to quantify them, as attribution of costs or benefits could not be done in a reliable way.

Model and methods used

Regarding impact modelling, a standard and established model has been used. It is an OECD model developed by COWI, which does not cover innovation aspects.

[103] The reporting template to be used since an implementing decision in 2014 includes under "other aspects" athe question "Give details of any ongoing or planned research with regard to innovative developments in sanitation policy".

To complement the main modelling, the evaluation study drew on a BLUE2 study, which looked at patents in the water sector. This study uses a methodological approach that can be replicated.

Other aspects of innovation were covered in Key issue studies, and other existing reports prepared before or during the evaluation. The strategy by the responsible unit at DG ENV was to ask for external help using its collaboration with the JRC and EASME to widen the knowledge basis. For example, on energy efficiency, the evaluation draws on existing studies (e.g., on Green Public Procurement). Besides, the JRC modelling measured the energy use resulting from the Directive and how marginal improvement in energy use could provide savings. This can be considered as measuring how deployment of innovation could reduce the cost of the Directive. For storm water overflow, the expert workshop on storm water overflows (SWO) was used to identify MS specific examples of innovative technologies. Treatment technologies including for contaminants of emerging concern were discussed as part of a Key Issues Report in annex to the evaluation. It includes an analysis of the effectiveness of treatment techniques. It addresses challenges in adopting technologies and need for new technologies.

Finally, to complement (or feed into) the studies and the usual consultation techniques, the evaluation was supported by an expert group of about 30 experts, managed by the JRC. They bring in arguments for some technologies and whether they are ready for broad market take-up or not. Their approach is qualitative. The expert group has access to much more information as they continuously follow the topic within academia, and have access to the industry for questions, and to data from operators of water treatment plants. Anything that is purely policy related is taken up by the Commission for the evaluation and IA. Elements on specific technologies are not included since the Directive is neutral, but they are acknowledged.

In the case of the impact assessment, the OECD defined an additional benefit methodology for the purpose of the IA and for another related study. The cost approach will use an update of the COWI feasibility model, as well as additional costs provided by the study team. The study team was asked to provide inputs to the JRC model as well. However, most of these are unlikely to cover innovation impacts.

15.6 Good practices and lessons learned

Good practices

In this evaluation and the subsequent impact assessment, a key good practice was the way the Commission ensured that all actors working on the topic could be involved in supporting the study (the JRC, expert groups, EASME projects, anyone conducting related studies). This allowed to pool resources way beyond the initial evaluation budget and widened the evidence basis.

DG ENV indicated that the checklists could eventually be improved, to allow for users to more easily find the questions that are relevant to them. Providing methodologies to assess innovation in the future which could be compared to other existing models, could also help.

The study team indicated that in their case, they benefited from having access internally to engineers who could provide a reality check on claims from stakeholders, especially on technologies' readiness and capacity to quickly scale-up. Cross-disciplinarity was recommended as having a clear added value in these studies. Apart from that, they were very satisfied with the existing checklists.

Replicability of the study (resource intensity, timing, data requirements)

The study approach can certainly be repeated. The support study includes the main information on sources used. Yet, since for a replication raw data is needed, thus replication may only happen if the Client has obtained all the raw data and files with interviews and survey questions, manipulations, assumptions and the calculations made.

The support study was one major part of the overall impact assessment and other studies - including dedicated work by the JRC, may also need to be factored in the overall equation for resource intensity.

Resource intensity

According to the Commission, in the context of such a regulation (very broad, 30 years of existence with no stand-alone evaluation), time and resource constraints are a barrier to further exploration of innovation aspects. If it had not been technology-neutral, and if there had been a suspicion that it could have hindered innovation, more resources might have been spent, but since the overall assessment delivered positive answers, it never became the centre of attention and resources were spent on other aspects deemed more relevant for the analysis.

In general, the very good collaboration and synergies with the JRC and EASME has greatly helped in getting more information for the evaluation and impact assessment study. While evaluations and IA have a very limited timeline, longstanding cooperation on various themes covered by the legislation help in expanding the knowledge basis, ahead of revisions.

With more resources, the study team could have spent more time to explore data from DG RTD, especially from the CORDIS database (see below).

It was not possible for the Commission or the study team to assess the exact resource intensity to assess innovation impact, as this was bundled in the rest of the study.

Other lessons

Better regulation contains several tools, and many more things could be looked at in an evaluation or impact assessment. However, lack of time and staff do not allow to do everything thoroughly, and teams have to be very pragmatic. The easier the tool gets, the faster it can be taken up by new users, and implemented, the most likely it is to actually be used.

The study team and the Commission indicated that good practice examples could be very useful, not to simply replicate previous methodologies blindly, but as inspiration, to get an idea of what can be done with Tool #21, and how far one can go. They were however modest in thinking that this evaluation or the upcoming impact assessment could qualify as a good practice to showcase.

15.7 Opportunities

Scope of the analysis

The scope of the evaluation already included an evaluation question on innovation. The impact assessment defined a number of measures where innovation has a potential. In that sense, opportunities have been overall taken on board in both studies.

Data collection methods

In this case, the original regulation did not have an impact assessment performed, as it dates from 1991. The evaluation had to create a baseline to work with. In order to avoid this issue in the future, not only is an impact assessment now being conducted (following requirements such as the Better Regulation principles), but the Commission intends to introduce new elements in the monitoring of the upcoming legislation to facilitate the work for the next round of evaluations.

Besides, the study team indicated that it could have been interesting to dig further into the results of Horizon 2020 projects related to the UWWTD directive, to really assess to what extent research funding was introduced to drive compliance with the legislation, or not so much. This would require a closer analysis of project documents, that they indicated is not easily navigable. However, CORDIS allows to have most information

gathered in one space, which was very helpful. To explore private research or national research, such access is at the moment not really available.

Use of data

Some part of the modelling was used to contribute to the assessment. Overall, there is a lack of data. This could be further explored not only to assess the impact of innovation, but also to make the case for further innovation uptake in the sector, since the legislation will most likely not introduce new obligations in this regard, or only limited ones.

Indeed, several innovations could drive compliance cost down, or have a potential that is currently unclear. More data could drive uptake, and therefore lower the barriers to adopt innovations.

Case selection and design of the analysis

The evaluation included a selection of a few policy areas of interest, which led to key issue reports. There was no dedicated case for innovation in and of itself, but innovation aspects were somewhat addressed in several of them, when relevant.

Use of indicators to monitor innovation impacts in the short, medium, and long term

There is a very limited set of indicators in existence. For the legislation in general, there is a will to develop new indicators, which will be proposed to Member States, to improve the quality of the next evaluation round. However, it is unlikely that the EC will suggest new indicators for innovation, as they feel that the Directive already drives innovation. There is no perceived need for more detailed information, in a situation of resource constraint.

Alternative Models

The evaluation used a standard OECD/COWI model. It does not specifically cover innovation, but there is a strong preference to use this reliable and widely accepted model rather than starting to use other new models only because they add the innovation aspect.

16. Annex C: Additional information on indicators

List 1 Indicators included in the revised measurement framework for the EIS 2021

FRAMEWORK CONDITIONS (8 indicators)

- Human resources
  - * New doctorate graduates (STEM) (% share)
  - Population with tertiary education (% share)
- Attractive research systems
  - International scientific co-publications per million population
  - Top 10% most cited publications (% share)
  - Foreign doctorate students (% share)
- Digitalisation
  - Broadband penetration (% share)
  - * Individuals who have above basic overall digital skills (% share)

INNOVATION ACTIVITIES (8 indicators)

- Innovators
  - * SMEs with product innovations (% share)
  - * SMEs with business process innovations (% share)
- Linkages
  - Innovative SMEs collaborating with others (% share)
  - * Public-private co-publications per million population
  - * Job-to-job mobility of Human Resources in Science & Technology (% share)
- Intellectual assets
  - PCT patent applications per billion GDP (in PPS)
  - * Trademark applications per billion GDP (in PPS)
  - Design applications per billion GDP (in PPS)

INVESTMENTS (8 indicators)

- Finance and support
  - R&D expenditures public sector (% of GDP)
  - Venture capital expenditures (% of GDP)
  - * Direct government funding and government tax support for business R&D
- Firm investments
  - R&D expenditures business sector (% of GDP)
  - Non-R&D innovation expenditures (% of turnover)
  - * Innovation expenditure per person employed
- Use of information technologies
  - Enterprises providing training to develop or upgrade ICT skills of their personnel (96 share)
  - Employed ICT specialists (% of total employment)

IMPACTS (8 indicators)

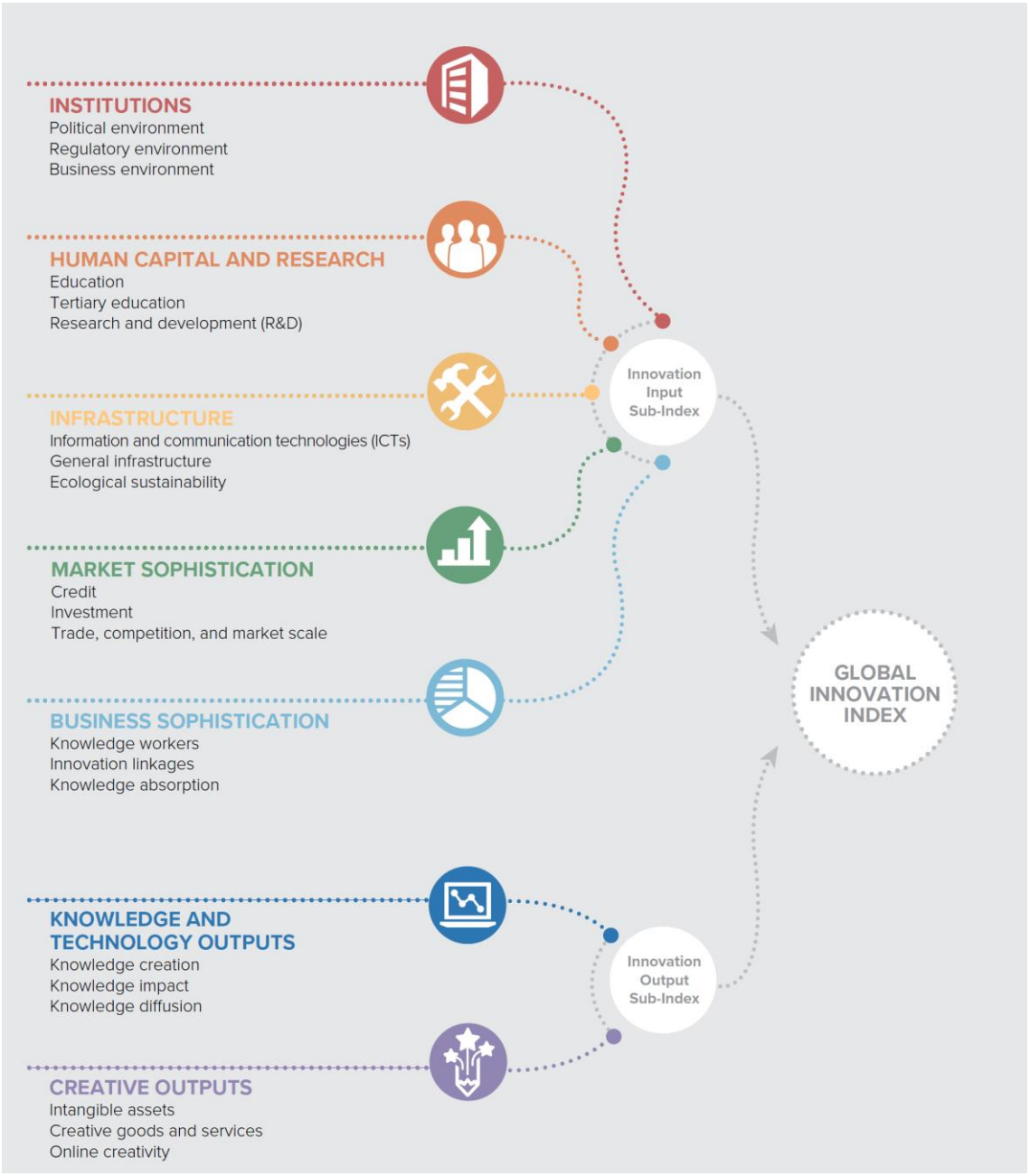
- Employment impacts
  - Employment in knowledge-intensive activities (% share)
  - * Employment in innovative enterprises (% share)
- Sales impacts
  - Medium and high-tech product exports (% share)
  - Knowledge-intensive services exports (% share)
  - Sales of new or improved products ("product innovations") (% of turnover)
- Environmental sustainability

- * Resource productivity (measured as domestic material consumption (DMC) in relation to GDP)
- * Air emissions by fine particulate matter (PM2.5) in Industry
- * Development of environment-related technologies

Source: European Commission 2021)

* New or revised indicator

Figure 7 Framework of the Global Innovation Index 2020



Source: Cornell University, INSEAD, and WIPO 2020

List 2 Framework of the Global Innovation Index 2020

1. Institution
    1.1. Political Environment
        1.1.1. Political and operational stability
        1.1.2. Government effectiveness
    1.2. Regulatory environment
        1.2.1. Regulatory quality
        1.2.2. Rule of law
        1.2.3. Cost of redundancy dismissal
    1.3. Business environment
        1.3.1. Ease of starting a business
        1.3.2. Ease of resolving insolvency
2. Human capital and research
    2.1. Education
        2.1.1. Expenditure on education
        2.1.2. Government funding per secondary student
        2.1.3. School life expectancy
        2.1.4. Assessment in reading, mathematics, and science
        2.1.5. Pupil-teacher ratio, secondary
    2.2. Tertiary education
        2.2.1. Tertiary enrolment
        2.2.2. Graduates in science and engineering
        2.2.3. Tertiary inbound mobility
    2.3. Research and development (R&D)
        2.3.1. Researchers FTE
        2.3.2. Gross expenditure on R&D (GERD)
        2.3.3. Global R&D companies, average expenditure, top 3
        2.3.4. QS university ranking score of top 3 universities
3. Infrastructure
    3.1. Information and communication technologies (ICTs)
        3.1.1. ICT access
        3.1.2. ICT use
        3.1.3. Government online service
        3.1.4. Online e-participation
    3.2. General infrastructure
        3.2.1. Electricity output
        3.2.2. Logistics performance
        3.2.3. Gross capital formation
    3.3. Ecological sustainability
        3.3.1. GDP per unit of energy use
        3.3.2. Environmental performance
        3.3.3. ISO 14001 environment certificates
4. Market Sophistication
    4.1. Credit
        4.1.1. Ease of getting credit
        4.1.2. Domestic credit to private sector
        4.1.3. Microfinance institutions gross loan portfolio
    4.2. Investment
        4.2.1. Ease of protecting minority investors
        4.2.2. Market capitalization
        4.2.3. Venture capital deals
    4.3. Trade, competition, and market scale
        4.3.1. Applied tariff rate, weighted average

        4.3.2. Intensity of local competition
        4.3.3. Domestic market scale
5. Business sophistication
    5.1. Knowledge workers
        5.1.1. Knowledge-intensive employment
        5.1.2. Firms offering formal training
        5.1.3. GERD performed by business enterprise
        5.1.4. GERD financed by business enterprise
        5.1.5. Females employed with advanced degrees
    5.2. Innovation linkages
        5.2.1. University/industry research collaboration
        5.2.2. State of cluster development
        5.2.3. GERD financed by abroad
        5.2.4. Joint venture/strategic alliance deals
        5.2.5. Patent families filed in two offices
    5.3. Knowledge absorption
        5.3.1. Intellectual property payments
        5.3.2. High-tech imports
        5.3.3. ICT services imports
        5.3.4. Foreign direct investment net inflows
        5.3.5. Research talent in business enterprise
6. Knowledge and technology outputs
    6.1. Knowledge creation
        6.1.1. Patent applications by origin
        6.1.2. PCT applications by origin
        6.1.3. Utility models by origin
        6.1.4. Scientific and technical publications
        6.1.5. Citable documents H-index
    6.2. Knowledge impact
        6.2.1. Growth rate of GDP per person engaged
        6.2.2. New business density
        6.2.3. Total computer software spending
        6.2.4. ISO 9001 quality certificates
        6.2.5. High-tech and medium-high-tech manufacturing
    6.3. Knowledge diffusion
        6.3.1. Intellectual property receipts
        6.3.2. High-tech exports
        6.3.3. ICT services exports
        6.3.4. Foreign direct investments net outflows
7. Creative outputs
    7.1. Intangible assets
        7.1.1. Trademark application class count by origin
        7.1.2. Global brand value
        7.1.3. Industrial designs by origin
        7.1.4. ICTs and organisational model creation
    7.2. Creative goods and services
        7.2.1. Cultural and creative services exports
        7.2.2. National feature films produced
        7.2.3. Entertainment and media market
        7.2.4. Printing publications and other media output
        7.2.5. Creative goods exports
    7.3. Online creativity
        7.3.1. Generic top-level domains (gTLDs)
        7.3.2. Country-code top-level domains (ccTLDs)

7.3.3. Wikipedia yearly edits
7.3.4. Mobile app creation

Source: (Cornell University, INSEAD, and WIPO 2020)

Table 11 Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
Sustainable Development Goal indicators should be disaggregated, where relevant, by income, sex, age, race, ethnicity, migratory status, disability and geographic location, or other characteristics, in accordance with the Fundamental Principles of Official Statistics.[1]	
Goals and targets (from the 2030 Agenda for Sustainable Development)	*Indicators*
Goal 1. End poverty in all its forms everywhere	
1.1 By 2030, eradicate extreme poverty for all people everywhere, currently measured as people living on less than $1.25 a day	1.1.1 Proportion of the population living below the international poverty line by sex, age, employment status and geographic location (urban/rural)
1.2 By 2030, reduce at least by half the proportion of men, women and children of all ages living in poverty in all its dimensions according to national definitions	1.2.1 Proportion of population living below the national poverty line, by sex and age
	1.2.2 Proportion of men, women and children of all ages living in poverty in all its dimensions according to national definitions
1.3 Implement nationally appropriate social protection systems and measures for all, including floors, and by 2030 achieve substantial coverage of the poor and the vulnerable	1.3.1 Proportion of population covered by social protection floors/systems, by sex, distinguishing children, unemployed persons, older persons, persons with disabilities, pregnant women, newborns, work-injury victims and the poor and the vulnerable
1.4 By 2030, ensure that all men and women, in particular the poor and the vulnerable, have equal rights to economic resources, as well as access to basic services, ownership and control over land and other forms of property, inheritance, natural resources, appropriate new technology and financial services, including microfinance	1.4.1 Proportion of population living in households with access to basic services
	1.4.2 Proportion of total adult population with secure tenure rights to land, (*a*) with legally recognized documentation, and (*b*) who perceive their rights to land as secure, by sex and type of tenure
1.5 By 2030, build the resilience of the poor and those in vulnerable situations and reduce their exposure and vulnerability to climate-related extreme events and other economic, social and environmental shocks and disasters	1.5.1 Number of deaths, missing persons and directly affected persons attributed to disasters per 100,000 population
	1.5.2 Direct economic loss attributed to disasters in relation to global gross domestic product (GDP)
	1.5.3 Number of countries that adopt and implement national disaster risk reduction strategies in line with the Sendai Framework for Disaster Risk Reduction 2015–2030
	1.5.4 Proportion of local governments that adopt and implement local disaster risk reduction strategies in line with national disaster risk reduction strategies
1.a Ensure significant mobilization of resources from a variety of sources, including through enhanced development cooperation, in order to provide adequate and predictable means for developing countries, in particular least developed countries, to implement programmes and policies to end poverty in all its dimensions	1.a.1 Total official development assistance grants from all donors that focus on poverty reduction as a share of the recipient country's gross national income
	1.a.2 Proportion of total government spending on essential services (education, health and social protection)
1.b Create sound policy frameworks at the national, regional and international levels, based on pro-poor and gender-sensitive development strategies, to support accelerated investment in poverty eradication actions	1.b.1 Pro-poor public social spending

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
Goal 2. End hunger, achieve food security and improved nutrition and promote sustainable agriculture	
2.1 By 2030, end hunger and ensure access by all people, in particular the poor and people in vulnerable situations, including infants, to safe, nutritious and sufficient food all year round	2.1.1 Prevalence of undernourishment
	2.1.2 Prevalence of moderate or severe food insecurity in the population, based on the Food Insecurity Experience Scale (FIES)
2.2 By 2030, end all forms of malnutrition, including achieving, by 2025, the internationally agreed targets on stunting and wasting in children under 5 years of age, and address the nutritional needs of adolescent girls, pregnant and lactating women and older persons	2.2.1 Prevalence of stunting (height for age <-2 standard deviation from the median of the World Health Organization (WHO) Child Growth Standards) among children under 5 years of age
	2.2.2 Prevalence of malnutrition (weight for height >+2 or <-2 standard deviation from the median of the WHO Child Growth Standards) among children under 5 years of age, by type (wasting and overweight)
	2.2.3 Prevalence of anaemia in women aged 15 to 49 years, by pregnancy status (percentage)
2.3 By 2030, double the agricultural productivity and incomes of small-scale food producers, in particular women, indigenous peoples, family farmers, pastoralists and fishers, including through secure and equal access to land, other productive resources and inputs, knowledge, financial services, markets and opportunities for value addition and non-farm employment	2.3.1 Volume of production per labour unit by classes of farming/pastoral/forestry enterprise size
	2.3.2 Average income of small-scale food producers, by sex and indigenous status
2.4 By 2030, ensure sustainable food production systems and implement resilient agricultural practices that increase productivity and production, that help maintain ecosystems, that strengthen capacity for adaptation to climate change, extreme weather, drought, flooding and other disasters and that progressively improve land and soil quality	2.4.1 Proportion of agricultural area under productive and sustainable agriculture
2.5 By 2020, maintain the genetic diversity of seeds, cultivated plants and farmed and domesticated animals and their related wild species, including through soundly managed and diversified seed and plant banks at the national, regional and international levels, and promote access to and fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge, as internationally agreed	2.5.1 Number of (*a*) plant and (*b*) animal genetic resources for food and agriculture secured in either medium- or long-term conservation facilities
	2.5.2 Proportion of local breeds classified as being at risk of extinction
2.a Increase investment, including through enhanced international cooperation, in rural infrastructure, agricultural research and extension services, technology development and plant and livestock gene banks in order to enhance agricultural productive capacity in developing countries, in particular least developed countries	2.a.1 The agriculture orientation index for government expenditures
	2.a.2 Total official flows (official development assistance plus other official flows) to the agriculture sector
2.b Correct and prevent trade restrictions and distortions in world agricultural markets, including through the parallel elimination of all forms of agricultural export subsidies and all export measures with equivalent effect, in accordance with the mandate of the Doha Development Round	2.b.1 Agricultural export subsidies
2.c Adopt measures to ensure the proper functioning of food commodity markets and their derivatives and facilitate timely access to market information, including on food reserves, in order to help limit extreme food price volatility	2.c.1 Indicator of food price anomalies
Goal 3. Ensure healthy lives and promote well-being for all at all ages	

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
Goal 3: Good Health and Well-being	
3.1 By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births	3.1.1 Maternal mortality ratio
	3.1.2 Proportion of births attended by skilled health personnel
3.2 By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births	3.2.1 Under-5 mortality rate
	3.2.2 Neonatal mortality rate
3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases	3.3.1 Number of new HIV infections per 1,000 uninfected population, by sex, age and key populations
	3.3.2 Tuberculosis incidence per 100,000 population
	3.3.3 Malaria incidence per 1,000 population
	3.3.4 Hepatitis B incidence per 100,000 population
	3.3.5 Number of people requiring interventions against neglected tropical diseases
3.4 By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being	3.4.1 Mortality rate attributed to cardiovascular disease, cancer, diabetes or chronic respiratory disease
	3.4.2 Suicide mortality rate
3.5 Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol	3.5.1 Coverage of treatment interventions (pharmacological, psychosocial and rehabilitation and aftercare services) for substance use disorders
	3.5.2 Alcohol per capita consumption (aged 15 years and older) within a calendar year in litres of pure alcohol
3.6 By 2020, halve the number of global deaths and injuries from road traffic accidents	3.6.1 Death rate due to road traffic injuries
3.7 By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes	3.7.1 Proportion of women of reproductive age (aged 15–49 years) who have their need for family planning satisfied with modern methods
	3.7.2 Adolescent birth rate (aged 10–14 years; aged 15–19 years) per 1,000 women in that age group
3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all	3.8.1 Coverage of essential health services
	3.8.2 Proportion of population with large household expenditures on health as a share of total household expenditure or income
3.9 By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination	3.9.1 Mortality rate attributed to household and ambient air pollution
	3.9.2 Mortality rate attributed to unsafe water, unsafe sanitation and lack of hygiene (exposure to unsafe Water, Sanitation and Hygiene for All (WASH) services)
	3.9.3 Mortality rate attributed to unintentional poisoning
3.a Strengthen the implementation of the World Health Organization Framework Convention on Tobacco Control in all countries, as appropriate	3.a.1 Age-standardized prevalence of current tobacco use among persons aged 15 years and older

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
3.b Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all	3.b.1 Proportion of the target population covered by all vaccines included in their national programme
	3.b.2 Total net official development assistance to medical research and basic health sectors
	3.b.3 Proportion of health facilities that have a core set of relevant essential medicines available and affordable on a sustainable basis
3.c Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries, especially in least developed countries and small island developing States	3.c.1 Health worker density and distribution
3.d Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks	3.d.1 International Health Regulations (IHR) capacity and health emergency preparedness
	3.d.2 Percentage of bloodstream infections due to selected antimicrobial-resistant organisms
Goal 4. Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all	
4.1 By 2030, ensure that all girls and boys complete free, equitable and quality primary and secondary education leading to relevant and effective learning outcomes	4.1.1 Proportion of children and young people (*a*) in grades 2/3; (*b*) at the end of primary; and (*c*) at the end of lower secondary achieving at least a minimum proficiency level in (i) reading and (ii) mathematics, by sex
	4.1.2 Completion rate (primary education, lower secondary education, upper secondary education)
4.2 By 2030, ensure that all girls and boys have access to quality early childhood development, care and pre-primary education so that they are ready for primary education	4.2.1 Proportion of children aged 24–59 months who are developmentally on track in health, learning and psychosocial well-being, by sex
	4.2.2 Participation rate in organized learning (one year before the official primary entry age), by sex
4.3 By 2030, ensure equal access for all women and men to affordable and quality technical, vocational and tertiary education, including university	4.3.1 Participation rate of youth and adults in formal and non-formal education and training in the previous 12 months, by sex
4.4 By 2030, substantially increase the number of youth and adults who have relevant skills, including technical and vocational skills, for employment, decent jobs and entrepreneurship	4.4.1 Proportion of youth and adults with information and communications technology (ICT) skills, by type of skill
4.5 By 2030, eliminate gender disparities in education and ensure equal access to all levels of education and vocational training for the vulnerable, including persons with disabilities, indigenous peoples and children in vulnerable situations	4.5.1 Parity indices (female/male, rural/urban, bottom/top wealth quintile and others such as disability status, indigenous peoples and conflict-affected, as data become available) for all education indicators on this list that can be disaggregated
4.6 By 2030, ensure that all youth and a substantial proportion of adults, both men and women, achieve literacy and numeracy	4.6.1 Proportion of population in a given age group achieving at least a fixed level of proficiency in functional (*a*) literacy and (*b*) numeracy skills, by sex
4.7 By 2030, ensure that all learners acquire the knowledge and skills needed to promote sustainable development, including, among others, through education for sustainable development and sustainable lifestyles, human rights, gender equality, promotion of a culture of peace and non-violence, global citizenship and appreciation of cultural diversity and of culture's contribution to sustainable development	4.7.1 Extent to which (i) global citizenship education and (ii) education for sustainable development are mainstreamed in (*a*) national education policies; (*b*) curricula; (*c*) teacher education; and (*d*) student assessment

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
4.a Build and upgrade education facilities that are child, disability and gender sensitive and provide safe, non-violent, inclusive and effective learning environments for all	4.a.1 Proportion of schools offering basic services, by type of service
4.b By 2020, substantially expand globally the number of scholarships available to developing countries, in particular least developed countries, small island developing States and African countries, for enrolment in higher education, including vocational training and information and communications technology, technical, engineering and scientific programmes, in developed countries and other developing countries	4.b.1 Volume of official development assistance flows for scholarships by sector and type of study
4.c By 2030, substantially increase the supply of qualified teachers, including through international cooperation for teacher training in developing countries, especially least developed countries and small island developing States	4.c.1 Proportion of teachers with the minimum required qualifications, by education level
Goal 5. Achieve gender equality and empower all women and girls	
5.1 End all forms of discrimination against all women and girls everywhere	5.1.1 Whether or not legal frameworks are in place to promote, enforce and monitor equality and non-discrimination on the basis of sex
5.2 Eliminate all forms of violence against all women and girls in the public and private spheres, including trafficking and sexual and other types of exploitation	5.2.1 Proportion of ever-partnered women and girls aged 15 years and older subjected to physical, sexual or psychological violence by a current or former intimate partner in the previous 12 months, by form of violence and by age
	5.2.2 Proportion of women and girls aged 15 years and older subjected to sexual violence by persons other than an intimate partner in the previous 12 months, by age and place of occurrence
5.3 Eliminate all harmful practices, such as child, early and forced marriage and female genital mutilation	5.3.1 Proportion of women aged 20–24 years who were married or in a union before age 15 and before age 18
	5.3.2 Proportion of girls and women aged 15–49 years who have undergone female genital mutilation/cutting, by age
5.4 Recognize and value unpaid care and domestic work through the provision of public services, infrastructure and social protection policies and the promotion of shared responsibility within the household and the family as nationally appropriate	5.4.1 Proportion of time spent on unpaid domestic and care work, by sex, age and location
5.5 Ensure women's full and effective participation and equal opportunities for leadership at all levels of decision-making in political, economic and public life	5.5.1 Proportion of seats held by women in (*a*) national parliaments and (*b*) local governments
	5.5.2 Proportion of women in managerial positions
5.6 Ensure universal access to sexual and reproductive health and reproductive rights as agreed in accordance with the Programme of Action of the International Conference on Population and Development and the Beijing Platform for Action and the outcome documents of their review conferences	5.6.1 Proportion of women aged 15–49 years who make their own informed decisions regarding sexual relations, contraceptive use and reproductive health care
	5.6.2 Number of countries with laws and regulations that guarantee full and equal access to women and men aged 15 years and older to sexual and reproductive health care, information and education
5.a Undertake reforms to give women equal rights to economic resources, as well as access to ownership and control over land and other forms of property, financial services, inheritance and natural resources, in accordance with national laws	5.a.1 (*a*) Proportion of total agricultural population with ownership or secure rights over agricultural land, by sex; and (*b*) share of women among owners or rights-bearers of agricultural land, by type of tenure
	5.a.2 Proportion of countries where the legal framework (including customary law) guarantees women's equal rights to land ownership and/or control

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
5.b Enhance the use of enabling technology, in particular information and communications technology, to promote the empowerment of women	5.b.1 Proportion of individuals who own a mobile telephone, by sex
5.c Adopt and strengthen sound policies and enforceable legislation for the promotion of gender equality and the empowerment of all women and girls at all levels	5.c.1 Proportion of countries with systems to track and make public allocations for gender equality and women's empowerment
Goal 6. Ensure availability and sustainable management of water and sanitation for all	
6.1 By 2030, achieve universal and equitable access to safe and affordable drinking water for all	6.1.1 Proportion of population using safely managed drinking water services
6.2 By 2030, achieve access to adequate and equitable sanitation and hygiene for all and end open defecation, paying special attention to the needs of women and girls and those in vulnerable situations	6.2.1 Proportion of population using (*a*) safely managed sanitation services and (*b*) a hand-washing facility with soap and water
6.3 By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated waste-water and substantially increasing recycling and safe reuse globally	6.3.1 Proportion of domestic and industrial waste-water flows safely treated
	6.3.2 Proportion of bodies of water with good ambient water quality
6.4 By 2030, substantially increase water-use efficiency across all sectors and ensure sustainable withdrawals and supply of freshwater to address water scarcity and substantially reduce the number of people suffering from water scarcity	6.4.1 Change in water-use efficiency over time
	6.4.2 Level of water stress: freshwater withdrawal as a proportion of available freshwater resources
6.5 By 2030, implement integrated water resources management at all levels, including through transboundary cooperation as appropriate	6.5.1 Degree of integrated water resources management
	6.5.2 Proportion of transboundary basin area with an operational arrangement for water cooperation
6.6 By 2020, protect and restore water-related ecosystems, including mountains, forests, wetlands, rivers, aquifers and lakes	6.6.1 Change in the extent of water-related ecosystems over time
6.a By 2030, expand international cooperation and capacity-building support to developing countries in water- and sanitation-related activities and programmes, including water harvesting, desalination, water efficiency, wastewater treatment, recycling and reuse technologies	6.a.1 Amount of water- and sanitation-related official development assistance that is part of a government-coordinated spending plan
6.b Support and strengthen the participation of local communities in improving water and sanitation management	6.b.1 Proportion of local administrative units with established and operational policies and procedures for participation of local communities in water and sanitation management
Goal 7. Ensure access to affordable, reliable, sustainable and modern energy for all	
7.1 By 2030, ensure universal access to affordable, reliable and modern energy services	7.1.1 Proportion of population with access to electricity
	7.1.2 Proportion of population with primary reliance on clean fuels and technology
7.2 By 2030, increase substantially the share of renewable energy in the global energy mix	7.2.1 Renewable energy share in the total final energy consumption

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
7.3 By 2030, double the global rate of improvement in energy efficiency	7.3.1 Energy intensity measured in terms of primary energy and GDP
7.a By 2030, enhance international cooperation to facilitate access to clean energy research and technology, including renewable energy, energy efficiency and advanced and cleaner fossil-fuel technology, and promote investment in energy infrastructure and clean energy technology	7.a.1 International financial flows to developing countries in support of clean energy research and development and renewable energy production, including in hybrid systems
7.b By 2030, expand infrastructure and upgrade technology for supplying modern and sustainable energy services for all in developing countries, in particular least developed countries, small island developing States and landlocked developing countries, in accordance with their respective programmes of support	7.b.1 Installed renewable energy-generating capacity in developing countries (in watts per capita)
Goal 8. Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all	
8.1 Sustain per capita economic growth in accordance with national circumstances and, in particular, at least 7 per cent gross domestic product growth per annum in the least developed countries	8.1.1 Annual growth rate of real GDP per capita
8.2 Achieve higher levels of economic productivity through diversification, technological upgrading and innovation, including through a focus on high-value added and labour-intensive sectors	8.2.1 Annual growth rate of real GDP per employed person
8.3 Promote development-oriented policies that support productive activities, decent job creation, entrepreneurship, creativity and innovation, and encourage the formalization and growth of micro-, small- and medium-sized enterprises, including through access to financial services	8.3.1 Proportion of informal employment in total employment, by sector and sex
8.4 Improve progressively, through 2030, global resource efficiency in consumption and production and endeavour to decouple economic growth from environmental degradation, in accordance with the 10-Year Framework of Programmes on Sustainable Consumption and Production, with developed countries taking the lead	8.4.1 Material footprint, material footprint per capita, and material footprint per GDP
	8.4.2 Domestic material consumption, domestic material consumption per capita, and domestic material consumption per GDP
8.5 By 2030, achieve full and productive employment and decent work for all women and men, including for young people and persons with disabilities, and equal pay for work of equal value	8.5.1 Average hourly earnings of employees, by sex, age, occupation and persons with disabilities
	8.5.2 Unemployment rate, by sex, age and persons with disabilities
8.6 By 2020, substantially reduce the proportion of youth not in employment, education or training	8.6.1 Proportion of youth (aged 15–24 years) not in education, employment or training
8.7 Take immediate and effective measures to eradicate forced labour, end modern slavery and human trafficking and secure the prohibition and elimination of the worst forms of child labour, including recruitment and use of child soldiers, and by 2025 end child labour in all its forms	8.7.1 Proportion and number of children aged 5–17 years engaged in child labour, by sex and age
8.8 Protect labour rights and promote safe and secure working environments for all workers, including migrant workers, in particular women migrants, and those in precarious employment	8.8.1 Fatal and non-fatal occupational injuries per 100,000 workers, by sex and migrant status
	8.8.2 Level of national compliance with labour rights (freedom of association and collective bargaining) based on International Labour Organization (ILO) textual sources and national legislation, by sex and migrant status

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
8.9 By 2030, devise and implement policies to promote sustainable tourism that creates jobs and promotes local culture and products	8.9.1 Tourism direct GDP as a proportion of total GDP and in growth rate
8.10 Strengthen the capacity of domestic financial institutions to encourage and expand access to banking, insurance and financial services for all	8.10.1 (*a*) Number of commercial bank branches per 100,000 adults and (*b*) number of automated teller machines (ATMs) per 100,000 adults
	8.10.2 Proportion of adults (15 years and older) with an account at a bank or other financial institution or with a mobile-money-service provider
8.a Increase Aid for Trade support for developing countries, in particular least developed countries, including through the Enhanced Integrated Framework for Trade-related Technical Assistance to Least Developed Countries	8.a.1 Aid for Trade commitments and disbursements
8.b By 2020, develop and operationalize a global strategy for youth employment and implement the Global Jobs Pact of the International Labour Organization	8.b.1 Existence of a developed and operationalized national strategy for youth employment, as a distinct strategy or as part of a national employment strategy
Goal 9. Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation	
9.1 Develop quality, reliable, sustainable and resilient infrastructure, including regional and transborder infrastructure, to support economic development and human well-being, with a focus on affordable and equitable access for all	9.1.1 Proportion of the rural population who live within 2 km of an all-season road
	9.1.2 Passenger and freight volumes, by mode of transport
9.2 Promote inclusive and sustainable industrialization and, by 2030, significantly raise industry's share of employment and gross domestic product, in line with national circumstances, and double its share in least developed countries	9.2.1 Manufacturing value added as a proportion of GDP and per capita
	9.2.2 Manufacturing employment as a proportion of total employment
9.3 Increase the access of small-scale industrial and other enterprises, in particular in developing countries, to financial services, including affordable credit, and their integration into value chains and markets	9.3.1 Proportion of small-scale industries in total industry value added
	9.3.2 Proportion of small-scale industries with a loan or line of credit
9.4 By 2030, upgrade infrastructure and retrofit industries to make them sustainable, with increased resource-use efficiency and greater adoption of clean and environmentally sound technologies and industrial processes, with all countries taking action in accordance with their respective capabilities	9.4.1 CO_2 emission per unit of value added
9.5 Enhance scientific research, upgrade the technological capabilities of industrial sectors in all countries, in particular developing countries, including, by 2030, encouraging innovation and substantially increasing the number of research and development workers per 1 million people and public and private research and development spending	9.5.1 Research and development expenditure as a proportion of GDP
	9.5.2 Researchers (in full-time equivalent) per million inhabitants
9.a Facilitate sustainable and resilient infrastructure development in developing countries through enhanced financial, technological and technical support to African countries, least developed countries, landlocked developing countries and small island developing States	9.a.1 Total official international support (official development assistance plus other official flows) to infrastructure

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
9.b Support domestic technology development, research and innovation in developing countries, including by ensuring a conducive policy environment for, inter alia, industrial diversification and value addition to commodities	9.b.1 Proportion of medium and high-tech industry value added in total value added
9.c Significantly increase access to information and communications technology and strive to provide universal and affordable access to the Internet in least developed countries by 2020	9.c.1 Proportion of population covered by a mobile network, by technology
Goal 10. Reduce inequality within and among countries	
10.1 By 2030, progressively achieve and sustain income growth of the bottom 40 per cent of the population at a rate higher than the national average	10.1.1 Growth rates of household expenditure or income per capita among the bottom 40 per cent of the population and the total population
10.2 By 2030, empower and promote the social, economic and political inclusion of all, irrespective of age, sex, disability, race, ethnicity, origin, religion or economic or other status	10.2.1 Proportion of people living below 50 per cent of median income, by sex, age and persons with disabilities
10.3 Ensure equal opportunity and reduce inequalities of outcome, including by eliminating discriminatory laws, policies and practices and promoting appropriate legislation, policies and action in this regard	10.3.1 Proportion of population reporting having personally felt discriminated against or harassed in the previous 12 months on the basis of a ground of discrimination prohibited under international human rights law
10.4 Adopt policies, especially fiscal, wage and social protection policies, and progressively achieve greater equality	10.4.1 Labour share of GDP
	10.4.2 Redistributive impact of fiscal policy[4]
10.5 Improve the regulation and monitoring of global financial markets and institutions and strengthen the implementation of such regulations	10.5.1 Financial Soundness Indicators
10.6 Ensure enhanced representation and voice for developing countries in decision-making in global international economic and financial institutions in order to deliver more effective, credible, accountable and legitimate institutions	10.6.1 Proportion of members and voting rights of developing countries in international organisations
10.7 Facilitate orderly, safe, regular and responsible migration and mobility of people, including through the implementation of planned and well-managed migration policies	10.7.1 Recruitment cost borne by employee as a proportion of monthly income earned in country of destination
	10.7.2 Number of countries with migration policies that facilitate orderly, safe, regular and responsible migration and mobility of people
	10.7.3 Number of people who died or disappeared in the process of migration towards an international destination
	10.7.4 Proportion of the population who are refugees, by country of origin
10.a Implement the principle of special and differential treatment for developing countries, in particular least developed countries, in accordance with World Trade Organization agreements	10.a.1 Proportion of tariff lines applied to imports from least developed countries and developing countries with zero-tariff
10.b Encourage official development assistance and financial flows, including foreign direct investment, to States where the need is greatest, in particular least developed countries, African countries, small island developing States and landlocked developing countries, in accordance with their national plans and programmes	10.b.1 Total resource flows for development, by recipient and donor countries and type of flow (e.g. official development assistance, foreign direct investment and other flows)

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
10.c By 2030, reduce to less than 3 per cent the transaction costs of migrant remittances and eliminate remittance corridors with costs higher than 5 per cent	10.c.1 Remittance costs as a proportion of the amount remitted
Goal 11. Make cities and human settlements inclusive, safe, resilient and sustainable	
11.1 By 2030, ensure access for all to adequate, safe and affordable housing and basic services and upgrade slums	11.1.1 Proportion of urban population living in slums, informal settlements or inadequate housing
11.2 By 2030, provide access to safe, affordable, accessible and sustainable transport systems for all, improving road safety, notably by expanding public transport, with special attention to the needs of those in vulnerable situations, women, children, persons with disabilities and older persons	11.2.1 Proportion of population that has convenient access to public transport, by sex, age and persons with disabilities
11.3 By 2030, enhance inclusive and sustainable urbanization and capacity for participatory, integrated and sustainable human settlement planning and management in all countries	11.3.1 Ratio of land consumption rate to population growth rate
	11.3.2 Proportion of cities with a direct participation structure of civil society in urban planning and management that operate regularly and democratically
11.4 Strengthen efforts to protect and safeguard the world's cultural and natural heritage	11.4.1 Total per capita expenditure on the preservation, protection and conservation of all cultural and natural heritage, by source of funding (public, private), type of heritage (cultural, natural) and level of government (national, regional, and local/municipal)
11.5 By 2030, significantly reduce the number of deaths and the number of people affected and substantially decrease the direct economic losses relative to global gross domestic product caused by disasters, including water-related disasters, with a focus on protecting the poor and people in vulnerable situations	11.5.1 Number of deaths, missing persons and directly affected persons attributed to disasters per 100,000 population
	11.5.2 Direct economic loss in relation to global GDP, damage to critical infrastructure and number of disruptions to basic services, attributed to disasters
11.6 By 2030, reduce the adverse per capita environmental impact of cities, including by paying special attention to air quality and municipal and other waste management	11.6.1 Proportion of municipal solid waste collected and managed in controlled facilities out of total municipal waste generated, by cities
	11.6.2 Annual mean levels of fine particulate matter (e.g. PM2.5 and PM10) in cities (population weighted)
11.7 By 2030, provide universal access to safe, inclusive and accessible, green and public spaces, in particular for women and children, older persons and persons with disabilities	11.7.1 Average share of the built-up area of cities that is open space for public use for all, by sex, age and persons with disabilities
	11.7.2 Proportion of persons victim of physical or sexual harassment, by sex, age, disability status and place of occurrence, in the previous 12 months
11.a Support positive economic, social and environmental links between urban, peri-urban and rural areas by strengthening national and regional development planning	11.a.1 Number of countries that have national urban policies or regional development plans that (*a*) respond to population dynamics; (*b*) ensure balanced territorial development; and (*c*) increase local fiscal space
11.b By 2020, substantially increase the number of cities and human settlements adopting and implementing integrated policies and plans towards inclusion, resource efficiency, mitigation and adaptation to climate change, resilience to disasters, and develop and implement, in line with the Sendai Framework for Disaster Risk Reduction 2015–2030, holistic disaster risk management at all levels	11.b.1 Number of countries that adopt and implement national disaster risk reduction strategies in line with the Sendai Framework for Disaster Risk Reduction 2015–2030
	11.b.2 Proportion of local governments that adopt and implement local disaster risk reduction strategies in line with national disaster risk reduction strategies
11.c Support least developed countries, including through financial and technical assistance, in building sustainable and resilient buildings utilizing local materials	*No suitable replacement indicator was proposed. The global statistical community is encouraged to work to develop an indicator that could be proposed for the 2025 comprehensive review. See E/CN.3/2020/2, paragraph 23.*

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
Goal 12. Ensure sustainable consumption and production patterns	
12.1 Implement the 10-Year Framework of Programmes on Sustainable Consumption and Production Patterns, all countries taking action, with developed countries taking the lead, taking into account the development and capabilities of developing countries	12.1.1 Number of countries developing, adopting or implementing policy instruments aimed at supporting the shift to sustainable consumption and production
12.2 By 2030, achieve the sustainable management and efficient use of natural resources	12.2.1 Material footprint, material footprint per capita, and material footprint per GDP
	12.2.2 Domestic material consumption, domestic material consumption per capita, and domestic material consumption per GDP
12.3 By 2030, halve per capita global food waste at the retail and consumer levels and reduce food losses along production and supply chains, including post-harvest losses	12.3.1 (*a*) Food loss index and (*b*) food waste index
12.4 By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment	12.4.1 Number of parties to international multilateral environmental agreements on hazardous waste, and other chemicals that meet their commitments and obligations in transmitting information as required by each relevant agreement
	12.4.2 (*a*) Hazardous waste generated per capita; and (*b*) proportion of hazardous waste treated, by type of treatment
12.5 By 2030, substantially reduce waste generation through prevention, reduction, recycling and reuse	12.5.1 National recycling rate, tons of material recycled
12.6 Encourage companies, especially large and transnational companies, to adopt sustainable practices and to integrate sustainability information into their reporting cycle	12.6.1 Number of companies publishing sustainability reports
12.7 Promote public procurement practices that are sustainable, in accordance with national policies and priorities	12.7.1 Degree of sustainable public procurement policies and action plan implementation
12.8 By 2030, ensure that people everywhere have the relevant information and awareness for sustainable development and lifestyles in harmony with nature	12.8.1 Extent to which (i) global citizenship education and (ii) education for sustainable development are mainstreamed in (*a*) national education policies; (*b*) curricula; (*c*) teacher education; and (*d*) student assessment
12.a Support developing countries to strengthen their scientific and technological capacity to move towards more sustainable patterns of consumption and production	12.a.1 Installed renewable energy-generating capacity in developing countries (in watts per capita)
12.b Develop and implement tools to monitor sustainable development impacts for sustainable tourism that creates jobs and promotes local culture and products	12.b.1 Implementation of standard accounting tools to monitor the economic and environmental aspects of tourism sustainability
12.c Rationalize inefficient fossil-fuel subsidies that encourage wasteful consumption by removing market distortions, in accordance with national circumstances, including by restructuring taxation and phasing out those harmful subsidies, where they exist, to reflect their environmental impacts, taking fully into account the specific needs and conditions of developing countries and minimizing the possible adverse impacts on their development in a manner that protects the poor and the affected communities	12.c.1 Amount of fossil-fuel subsidies (production and consumption) per unit of GDP
Goal 13. Take urgent action to combat climate change and its impacts[3]	
13.1 Strengthen resilience and adaptive capacity to climate-related hazards and natural disasters in all countries	13.1.1 Number of deaths, missing persons and directly affected persons attributed to disasters per 100,000 population

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
	13.1.2 Number of countries that adopt and implement national disaster risk reduction strategies in line with the Sendai Framework for Disaster Risk Reduction 2015–2030
	13.1.3 Proportion of local governments that adopt and implement local disaster risk reduction strategies in line with national disaster risk reduction strategies
13.2 Integrate climate change measures into national policies, strategies and planning	13.2.1 Number of countries with nationally determined contributions, long-term strategies, national adaptation plans and adaptation communications, as reported to the secretariat of the United Nations Framework Convention on Climate Change
	13.2.2 Total greenhouse gas emissions per year
13.3 Improve education, awareness-raising and human and institutional capacity on climate change mitigation, adaptation, impact reduction and early warning	13.3.1 Extent to which (i) global citizenship education and (ii) education for sustainable development are mainstreamed in (*a*) national education policies; (*b*) curricula; (*c*) teacher education; and (*d*) student assessment
13.a Implement the commitment undertaken by developed-country parties to the United Nations Framework Convention on Climate Change to a goal of mobilizing jointly $100 billion annually by 2020 from all sources to address the needs of developing countries in the context of meaningful mitigation actions and transparency on implementation and fully operationalize the Green Climate Fund through its capitalization as soon as possible	13.a.1 Amounts provided and mobilized in United States dollars per year in relation to the continued existing collective mobilization goal of the $100 billion commitment through to 2025
13.b Promote mechanisms for raising capacity for effective climate change-related planning and management in least developed countries and small island developing States, including focusing on women, youth and local and marginalized communities	13.b.1 Number of least developed countries and small island developing States with nationally determined contributions, long-term strategies, national adaptation plans and adaptation communications, as reported to the secretariat of the United Nations Framework Convention on Climate Change
Goal 14. Conserve and sustainably use the oceans, seas and marine resources for sustainable development	
14.1 By 2025, prevent and significantly reduce marine pollution of all kinds, in particular from land-based activities, including marine debris and nutrient pollution	14.1.1 (*a*) Index of coastal eutrophication; and (*b*) plastic debris density
14.2 By 2020, sustainably manage and protect marine and coastal ecosystems to avoid significant adverse impacts, including by strengthening their resilience, and take action for their restoration in order to achieve healthy and productive oceans	14.2.1 Number of countries using ecosystem-based approaches to managing marine areas
14.3 Minimize and address the impacts of ocean acidification, including through enhanced scientific cooperation at all levels	14.3.1 Average marine acidity (pH) measured at agreed suite of representative sampling stations
14.4 By 2020, effectively regulate harvesting and end overfishing, illegal, unreported and unregulated fishing and destructive fishing practices and implement science-based management plans, in order to restore fish stocks in the shortest time feasible, at least to levels that can produce maximum sustainable yield as determined by their biological characteristics	14.4.1 Proportion of fish stocks within biologically sustainable levels
14.5 By 2020, conserve at least 10 per cent of coastal and marine areas, consistent with national and international law and based on the best available scientific information	14.5.1 Coverage of protected areas in relation to marine areas

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
14.6 By 2020, prohibit certain forms of fisheries subsidies which contribute to overcapacity and overfishing, eliminate subsidies that contribute to illegal, unreported and unregulated fishing and refrain from introducing new such subsidies, recognizing that appropriate and effective special and differential treatment for developing and least developed countries should be an integral part of the World Trade Organization fisheries subsidies negotiation[4]	14.6.1 Degree of implementation of international instruments aiming to combat illegal, unreported and unregulated fishing
14.7 By 2030, increase the economic benefits to small island developing States and least developed countries from the sustainable use of marine resources, including through sustainable management of fisheries, aquaculture and tourism	14.7.1 Sustainable fisheries as a proportion of GDP in small island developing States, least developed countries and all countries
14.a Increase scientific knowledge, develop research capacity and transfer marine technology, taking into account the Intergovernmental Oceanographic Commission Criteria and Guidelines on the Transfer of Marine Technology, in order to improve ocean health and to enhance the contribution of marine biodiversity to the development of developing countries, in particular small island developing States and least developed countries	14.a.1 Proportion of total research budget allocated to research in the field of marine technology
14.b Provide access for small-scale artisanal fishers to marine resources and markets	14.b.1 Degree of application of a legal/regulatory/ policy/institutional framework which recognizes and protects access rights for small-scale fisheries
14.c Enhance the conservation and sustainable use of oceans and their resources by implementing international law as reflected in the United Nations Convention on the Law of the Sea, which provides the legal framework for the conservation and sustainable use of oceans and their resources, as recalled in paragraph 158 of "The future we want"	14.c.1 Number of countries making progress in ratifying, accepting and implementing through legal, policy and institutional frameworks, ocean-related instruments that implement international law, as reflected in the United Nations Convention on the Law of the Sea, for the conservation and sustainable use of the oceans and their resources
Goal 15. Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss	
15.1 By 2020, ensure the conservation, restoration and sustainable use of terrestrial and inland freshwater ecosystems and their services, in particular forests, wetlands, mountains and drylands, in line with obligations under international agreements	15.1.1 Forest area as a proportion of total land area
	15.1.2 Proportion of important sites for terrestrial and freshwater biodiversity that are covered by protected areas, by ecosystem type
15.2 By 2020, promote the implementation of sustainable management of all types of forests, halt deforestation, restore degraded forests and substantially increase afforestation and reforestation globally	15.2.1 Progress towards sustainable forest management
15.3 By 2030, combat desertification, restore degraded land and soil, including land affected by desertification, drought and floods, and strive to achieve a land degradation-neutral world	15.3.1 Proportion of land that is degraded over total land area
15.4 By 2030, ensure the conservation of mountain ecosystems, including their biodiversity, in order to enhance their capacity to provide benefits that are essential for sustainable development	15.4.1 Coverage by protected areas of important sites for mountain biodiversity
	15.4.2 Mountain Green Cover Index
15.5 Take urgent and significant action to reduce the degradation of natural habitats, halt the loss of biodiversity and, by 2020, protect and prevent the extinction of threatened species	15.5.1 Red List Index
15.6 Promote fair and equitable sharing of the benefits arising from the utilization of genetic resources and promote appropriate access to such resources, as internationally agreed	15.6.1 Number of countries that have adopted legislative, administrative and policy frameworks to ensure fair and equitable sharing of benefits

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
15.7 Take urgent action to end poaching and trafficking of protected species of flora and fauna and address both demand and supply of illegal wildlife products	15.7.1 Proportion of traded wildlife that was poached or illicitly trafficked
15.8 By 2020, introduce measures to prevent the introduction and significantly reduce the impact of invasive alien species on land and water ecosystems and control or eradicate the priority species	15.8.1 Proportion of countries adopting relevant national legislation and adequately resourcing the prevention or control of invasive alien species
15.9 By 2020, integrate ecosystem and biodiversity values into national and local planning, development processes, poverty reduction strategies and accounts	15.9.1 (*a*) Number of countries that have established national targets in accordance with or similar to Aichi Biodiversity Target 2 of the Strategic Plan for Biodiversity 2011–2020 in their national biodiversity strategy and action plans and the progress reported towards these targets; and (*b*) integration of biodiversity into national accounting and reporting systems, defined as implementation of the System of Environmental-Economic Accounting
15.a Mobilize and significantly increase financial resources from all sources to conserve and sustainably use biodiversity and ecosystems	15.a.1 (*a*) Official development assistance on conservation and sustainable use of biodiversity; and (*b*) revenue generated and finance mobilized from biodiversity-relevant economic instruments
15.b Mobilize significant resources from all sources and at all levels to finance sustainable forest management and provide adequate incentives to developing countries to advance such management, including for conservation and reforestation	15.b.1 (*a*) Official development assistance on conservation and sustainable use of biodiversity; and (*b*) revenue generated and finance mobilized from biodiversity-relevant economic instruments
15.c Enhance global support for efforts to combat poaching and trafficking of protected species, including by increasing the capacity of local communities to pursue sustainable livelihood opportunities	15.c.1 Proportion of traded wildlife that was poached or illicitly trafficked
Goal 16. Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels	
16.1 Significantly reduce all forms of violence and related death rates everywhere	16.1.1 Number of victims of intentional homicide per 100,000 population, by sex and age
	16.1.2 Conflict-related deaths per 100,000 population, by sex, age and cause
	16.1.3 Proportion of population subjected to (*a*) physical violence, (*b*) psychological violence and (*c*) sexual violence in the previous 12 months
	16.1.4 Proportion of population that feel safe walking alone around the area they live
16.2 End abuse, exploitation, trafficking and all forms of violence against and torture of children	16.2.1 Proportion of children aged 1–17 years who experienced any physical punishment and/or psychological aggression by caregivers in the past month
	16.2.2 Number of victims of human trafficking per 100,000 population, by sex, age and form of exploitation
	16.2.3 Proportion of young women and men aged 18–29 years who experienced sexual violence by age 18
16.3 Promote the rule of law at the national and international levels and ensure equal access to justice for all	16.3.1 Proportion of victims of violence in the previous 12 months who reported their victimization to competent authorities or other officially recognized conflict resolution mechanisms
	16.3.2 Unsentenced detainees as a proportion of overall prison population

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
	16.3.3 Proportion of the population who have experienced a dispute in the past two years and who accessed a formal or informal dispute resolution mechanism, by type of mechanism
16.4 By 2030, significantly reduce illicit financial and arms flows, strengthen the recovery and return of stolen assets and combat all forms of organized crime	16.4.1 Total value of inward and outward illicit financial flows (in current United States dollars)
	16.4.2 Proportion of seized, found or surrendered arms whose illicit origin or context has been traced or established by a competent authority in line with international instruments
16.5 Substantially reduce corruption and bribery in all their forms	16.5.1 Proportion of persons who had at least one contact with a public official and who paid a bribe to a public official, or were asked for a bribe by those public officials, during the previous 12 months
	16.5.2 Proportion of businesses that had at least one contact with a public official and that paid a bribe to a public official, or were asked for a bribe by those public officials during the previous 12 months
16.6 Develop effective, accountable and transparent institutions at all levels	16.6.1 Primary government expenditures as a proportion of original approved budget, by sector (or by budget codes or similar)
	16.6.2 Proportion of population satisfied with their last experience of public services
16.7 Ensure responsive, inclusive, participatory and representative decision-making at all levels	16.7.1 Proportions of positions in national and local institutions, including (*a*) the legislatures; (*b*) the public service; and (*c*) the judiciary, compared to national distributions, by sex, age, persons with disabilities and population groups
	16.7.2 Proportion of population who believe decision-making is inclusive and responsive, by sex, age, disability and population group
16.8 Broaden and strengthen the participation of developing countries in the institutions of global governance	16.8.1 Proportion of members and voting rights of developing countries in international organisations
16.9 By 2030, provide legal identity for all, including birth registration	16.9.1 Proportion of children under 5 years of age whose births have been registered with a civil authority, by age
16.10 Ensure public access to information and protect fundamental freedoms, in accordance with national legislation and international agreements	16.10.1 Number of verified cases of killing, kidnapping, enforced disappearance, arbitrary detention and torture of journalists, associated media personnel, trade unionists and human rights advocates in the previous 12 months
	16.10.2 Number of countries that adopt and implement constitutional, statutory and/or policy guarantees for public access to information
16.a Strengthen relevant national institutions, including through international cooperation, for building capacity at all levels, in particular in developing countries, to prevent violence and combat terrorism and crime	16.a.1 Existence of independent national human rights institutions in compliance with the Paris Principles
16.b Promote and enforce non-discriminatory laws and policies for sustainable development	16.b.1 Proportion of population reporting having personally felt discriminated against or harassed in the previous 12 months on the basis of a ground of discrimination prohibited under international human rights law
Goal 17. Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development	
Finance	
	17.1.1 Total government revenue as a proportion of GDP, by source

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
17.1 Strengthen domestic resource mobilization, including through international support to developing countries, to improve domestic capacity for tax and other revenue collection	17.1.2 Proportion of domestic budget funded by domestic taxes
17.2 Developed countries to implement fully their official development assistance commitments, including the commitment by many developed countries to achieve the target of 0.7 per cent of gross national income for official development assistance (ODA/GNI) to developing countries and 0.15 to 0.20 per cent of ODA/GNI to least developed countries; ODA providers are encouraged to consider setting a target to provide at least 0.20 per cent of ODA/GNI to least developed countries	17.2.1 Net official development assistance, total and to least developed countries, as a proportion of the Organization for Economic Cooperation and Development (OECD) Development Assistance Committee donors' gross national income (GNI)
17.3 Mobilize additional financial resources for developing countries from multiple sources	17.3.1 Foreign direct investment, official development assistance and South-South cooperation as a proportion of gross national income
	17.3.2 Volume of remittances (in United States dollars) as a proportion of total GDP
17.4 Assist developing countries in attaining long-term debt sustainability through coordinated policies aimed at fostering debt financing, debt relief and debt restructuring, as appropriate, and address the external debt of highly indebted poor countries to reduce debt distress	17.4.1 Debt service as a proportion of exports of goods and services
17.5 Adopt and implement investment promotion regimes for least developed countries	17.5.1 Number of countries that adopt and implement investment promotion regimes for developing countries, including the least developed countries
Technology	
17.6 Enhance North-South, South-South and triangular regional and international cooperation on and access to science, technology and innovation and enhance knowledge-sharing on mutually agreed terms, including through improved coordination among existing mechanisms, in particular at the United Nations level, and through a global technology facilitation mechanism	17.6.1 Fixed Internet broadband subscriptions per 100 inhabitants, by speed[5]
17.7 Promote the development, transfer, dissemination and diffusion of environmentally sound technologies to developing countries on favourable terms, including on concessional and preferential terms, as mutually agreed	17.7.1 Total amount of funding for developing countries to promote the development, transfer, dissemination and diffusion of environmentally sound technologies
17.8 Fully operationalize the technology bank and science, technology and innovation capacity-building mechanism for least developed countries by 2017 and enhance the use of enabling technology, in particular information and communications technology	17.8.1 Proportion of individuals using the Internet
Capacity-building	
17.9 Enhance international support for implementing effective and targeted capacity-building in developing countries to support national plans to implement all the Sustainable Development Goals, including through North-South, South-South and triangular cooperation	17.9.1 Dollar value of financial and technical assistance (including through North-South, South-South and triangular cooperation) committed to developing countries
Trade	
17.10 Promote a universal, rules-based, open, non-discriminatory and equitable multilateral trading system under the World Trade Organization, including through the conclusion of negotiations under its Doha Development Agenda	17.10.1 Worldwide weighted tariff-average

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*	
17.11 Significantly increase the exports of developing countries, in particular with a view to doubling the least developed countries' share of global exports by 2020	17.11.1 Developing countries' and least developed countries' share of global exports
17.12 Realize timely implementation of duty-free and quota-free market access on a lasting basis for all least developed countries, consistent with World Trade Organization decisions, including by ensuring that preferential rules of origin applicable to imports from least developed countries are transparent and simple, and contribute to facilitating market access	17.12.1 Weighted average tariffs faced by developing countries, least developed countries and small island developing States
Systemic issues	
Policy and institutional coherence	
17.13 Enhance global macroeconomic stability, including through policy coordination and policy coherence	17.13.1 Macroeconomic Dashboard
17.14 Enhance policy coherence for sustainable development	17.14.1 Number of countries with mechanisms in place to enhance policy coherence of sustainable development
17.15 Respect each country's policy space and leadership to establish and implement policies for poverty eradication and sustainable development	17.15.1 Extent of use of country-owned results frameworks and planning tools by providers of development cooperation
Multi-stakeholder partnerships	
17.16 Enhance the Global Partnership for Sustainable Development, complemented by multi-stakeholder partnerships that mobilize and share knowledge, expertise, technology and financial resources, to support the achievement of the Sustainable Development Goals in all countries, in particular developing countries	17.16.1 Number of countries reporting progress in multi-stakeholder development effectiveness monitoring frameworks that support the achievement of the sustainable development goals
17.17 Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships	17.17.1 Amount in United States dollars committed to public-private partnerships for infrastructure
Data, monitoring and accountability	
17.18 By 2020, enhance capacity-building support to developing countries, including for least developed countries and small island developing States, to increase significantly the availability of high-quality, timely and reliable data disaggregated by income, gender, age, race, ethnicity, migratory status, disability, geographic location and other characteristics relevant in national contexts	17.18.1 Statistical capacity indicator for Sustainable Development Goal monitoring
	17.18.2 Number of countries that have national statistical legislation that complies with the Fundamental Principles of Official Statistics
	17.18.3 Number of countries with a national statistical plan that is fully funded and under implementation, by source of funding
17.19 By 2030, build on existing initiatives to develop measurements of progress on sustainable development that complement gross domestic product, and support statistical capacity-building in developing countries	17.19.1 Dollar value of all resources made available to strengthen statistical capacity in developing countries
	17.19.2 Proportion of countries that (*a*) have conducted at least one population and housing census in the last 10 years; and (*b*) have achieved 100 per cent birth registration and 80 per cent death registration
* As contained in the Annex of the resolution adopted by the General Assembly on 6 July 2017, Work of the Statistical Commission pertaining to the 2030 Agenda for Sustainable Development (A/RES/71/313), annual refinements contained in E/CN.3/2018/2 (Annex II), E/CN.3/2019/2 (Annex II), 2020 Comprehensive Review changes (Annex II) and annual refinements (Annex III) contained in E/CN.3/2020/2, and annual refinements contained in E/CN.3/2021/2 (Annex).	
† Indicator codes were developed by UNSD for data transfer, tracking and other statistical purposes.	

Global indicator framework for the Sustainable Development Goals and targets of the 2030 Agenda for Sustainable Development*
[1] Resolution 68/261.
[2] The Gini Coefficient will be reported as a second series in the database, as it is a component of this indicator.
[3] Acknowledging that the United Nations Framework Convention on Climate Change is the primary international, intergovernmental forum for negotiating the global response to climate change.
[4] Taking into account ongoing World Trade Organization negotiations, the Doha Development Agenda and the Hong Kong ministerial mandate.
[5] The current indicator 17.6.1 was previously listed as 17.6.2.

Source: https://unstats.un.org/sdgs/indicators/indicators-list

17. Annex D Operational guidance on assessing innovation impacts

1 Background

The Council conclusions on research and innovation friendly regulation of May 2016 stressed that, "when considering, developing or updating EU policy or regulatory measures, the 'Innovation Principle' should be applied, which entails taking into account the impact on research and innovation". Among others, the innovation principle aims to reduce the EU innovation deficit.[104] It ensures that when EU legislation is being considered, its impact on innovation is assessed.

It is therefore key to support both research and innovation at EU level. The European Commission as well as Member States recognise the importance of this principle. The European Political Strategy Centre, an in-house expert group under the previous Juncker Commission issued in 2016 a policy-note on the Innovation Principle[105] describing "*The innovation principle means ensuring that whenever policy is developed, the impact on innovation is fully assessed. The principle should provide guidance to ensure that the choice, design and regulatory tools foster innovation, rather than hamper it*."

In Impact Assessments, innovation is among the types of impacts that must be identified and assessed if they prove to be significant. Constraints on the practice, as the note further writes "*often have to do with insufficient available data, limited ability to quantify results or limited comparability of different options*". The innovation principle calls for a systematic and holistic analysis of the impacts of regulatory proposals on innovation activities. This implies an assessment of economic, environmental, and social costs, "*even if they are often hard to quantify*."

In ex-post evaluations, the Better Regulation guidelines ask explicitly for an analysis of economic, social and environmental impacts. When relevant, this also applies to innovation impacts. Unfortunately, the ex-ante as well as the ex-post analysis is hampered by the complexity of the innovation process and most of the time, a direct, explicit and quantifiable contribution of a given piece of legislation on (measurable) innovation effects remains rare. This is also because a lot of legislation is not primarily intended to foster innovation but has different objectives.

2 What is the objective of the operational guide?

The objective of this operational guide is to support the systematisation of quantification of costs and benefits of innovation in EC impact assessments and evaluations. It is aimed at practitioners and provides a hands-on step-wise approach showcased with existing practices.

Various empirical studies on the impact of different types of regulation on innovation provide a rather heterogeneous picture both regarding the type of regulation and the sectors which benefit – or not. Empirical findings show that the innovation effects of regulation vary by industry and technological area. Indeed, broken down to the sectorial level, there are marked differences. These studies also show differences between short- and long-term impacts. The short-term impacts of regulations are often negative for innovation behaviour and the costs of innovation, because of adjustments needed to comply with a new rule. In contrast, the long-term implications of forcing or encouraging

[104] Note that the innovation principle is to be understood more broadly as a principle of sustainable innovation. It can be described as follows: "EU policy and legislation should be developed, implemented and assessed in view of encouraging innovations that help realise EU's environmental, social and economic objectives, and to anticipate and harness future technological advances".

[105] EPSC (2016): Towards an Innovation principle endorsed by the Better Regulation, Issue 14, 30.06.2016

adoption, acceleration of the uptake of innovations and their spill over benefits are often positive on innovation behaviour.

Evidence from environmental regulation showed that regulation played an important role in stimulating and directing innovation when considering the type of innovation (or technical direction).[106] Depending on the context, regulation can both enable and hinder innovation activity. Regulation may have system-level effects, for example, by shifting investment opportunities to different actors and provide orientation to innovation agents contributing to system innovations (i.e. far-reaching changes that require several complementary innovations to materialise). Regulation rarely explicitly addresses innovation. In many cases regulations affect innovation indirectly and in an unintended way.

Overall, the existing body of literature suggests that the relationship between regulation and innovation is not simple or straightforward (Blind 2016). Despite some good examples and lessons, there is no established set of methods to assess the impacts of regulation on innovation and of innovation itself. The literature analysing the effects of regulation on innovative activities emphasises the need to take account of the systemic nature of innovation activities and the difficulties in attributing innovation effects to regulation. Innovation studies confirm that regulation is but one of the factors influencing innovation. Based on the innovation system approach[107], innovation evolves within a system in which many interconnected factors play a role (e.g., framework conditions, technological capabilities, culture).

Some of the challenges in measuring innovation impacts are related to the unpredictable nature of innovation, availability of data, confidentiality issues, endogeneity in studies using econometric modelling, etc. Economists in their studies tend to rely on the same sources such as patent data from Patstat, R&D and innovation related data from the Community Innovation Survey (CIS) or aggregated data from the OECD. This limits research opportunities and the narratives used in impact pathways analyses. It should also be kept in mind that innovation is only one of the many – and in most cases subordinate – policy goals for regulation. Therefore, the resources available for assessing the impacts of/on innovation are likely to be restricted.

Despite the challenges, this operational guide supports practitioners, by showcasing different degrees of quantification possible. This is done with the help of examples differentiating between cases where: 1) quantification is feasible; 2) quantification is only partially feasible and hence coupled with qualitative insights and 3) no quantification is feasible and instead an entirely qualitative approach is recommended.

3 Structure of the operational guide: a six steps approach

The operational guide for the assessment of costs and benefits of R&D and innovation effects is described in six steps. The six steps are showcased by a complete example using the Orphan Drug regulation. Reflections on challenges and prevention and mitigation recommendations are provided for practitioners of evaluations and impact assessments. The guide is further supported by a library of selected quantitative and qualitative methods.

[106] See Porter, 1990; Porter and van der Linde, 1995.

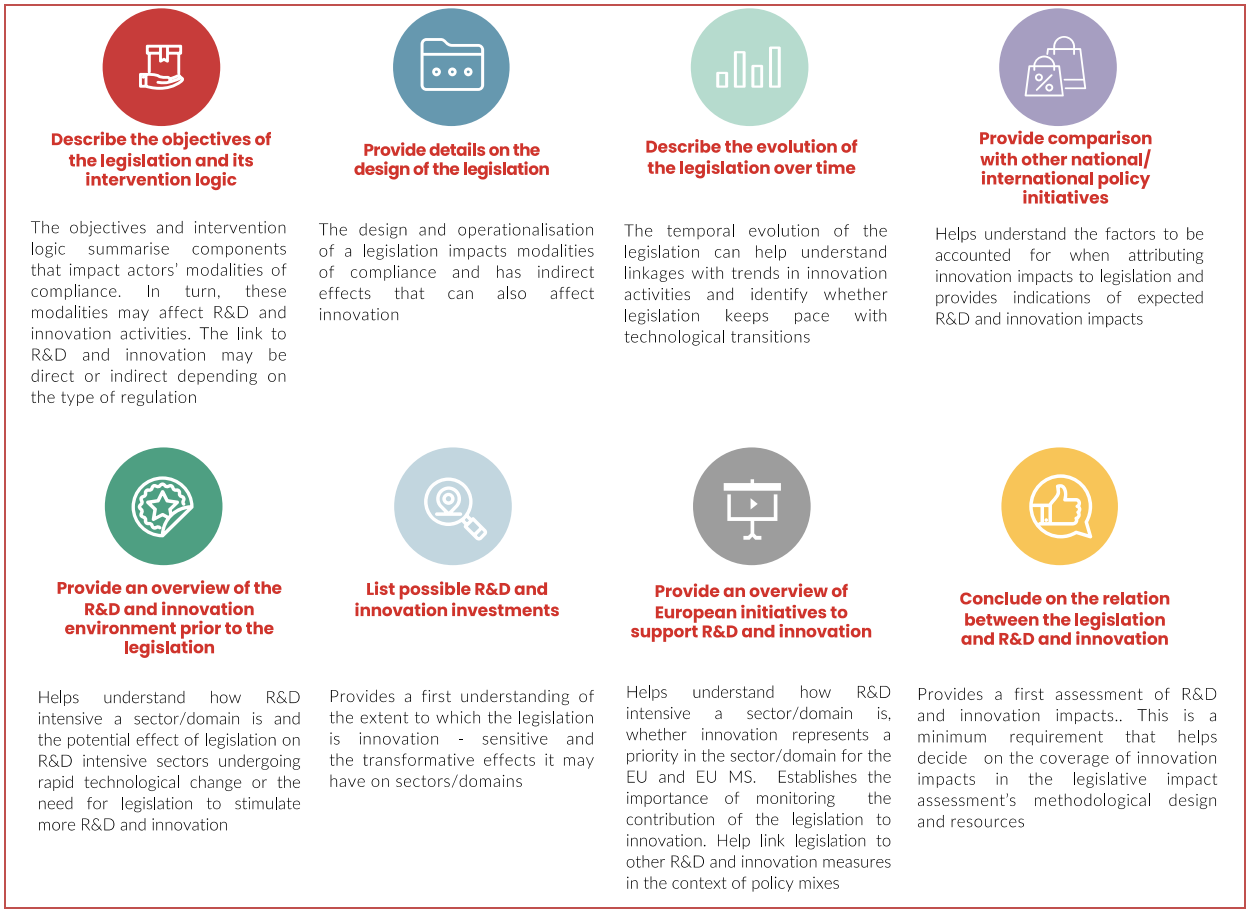
[107] For more information see section 'Methodology Overview'. Other reading suggestions on the innovation system include (non-exhaustive): 1) Lundvall, B. Å. (1992). National Systems of Innovation: Towards a Theory of Innovation and Interactive Learning; 2) Nelson, R. R. (1993). National Innovation Systems and 3) Freeman, C. (1995). The 'National System of Innovation' in historical perspective.

Figure 8 Six steps for the assessment of costs and benefits of R&D and innovation

Step 1: Identify the type of regulation and its relation to innovation

Step 1 is based on literature review and desk research. Equally, an overview of the legislation and its relation to innovation is provided. This step represents a minimum requirement which all studies should ideally fulfil given the expected information and data availability.

Figure 9 Step 1 in detail



Step 2: Map actors and their modalities of compliance

In order to **identify the key stakeholders** and a first assessment of innovation impacts of the legislation per type of stakeholder, this step uses **desk research**, **public stakeholder consultations**, **evaluation reports** or associated studies - accounting for previous/similar IAs.

Preliminary/**scoping interviews with experts** in the field(s) related to the legislation are instructive in mapping costs and benefits per stakeholder type.

Depending on the complexity of the impact assessment/evaluation, **surveys** or **interviews** with the stakeholders impacted by the regulation may be needed to get additional insights on their modalities of compliance or more broadly adaptations to their RDI strategies, management, or processes.

Such modalities of compliance or strategic adaptations may involve for instance:

- **#1**: R&D skills - The intervention requires the development of new technologies for which new R&D skills are required and are sourced for in-house development
- **#2**: R&D budgets - The intervention requires the development of new technologies which is performed by increasing R&D budgets and faster prototyping
- **#3**: R&D prioritisation - The intervention requires the development of new technologies which is prioritised without impacting total R&D budgets (R&D investments in other segments slows down)
- **#4:** R&D location - Compliance leads to relocation of R&D infrastructures/centres
- **#5:** Innovation types (product) - Regulation leads to more patenting/software in the knowledge-capturing products and design characteristics
- **#6:** Innovation types (process) - Regulation leads to significantly improved production, distribution, and logistics method. This includes significant changes in techniques, equipment and/or software
- **#7:** Innovation types (organisational) - Legislation impacts the implementation of administration and management methods in business practices e.g., mobility as a service, workplace organisation or external relations
- **#8:** Innovation types (marketing) – Legislation leads to a new marketing method involving significant changes in marketing innovations, innovations in sales, after-sales services, and other customer support functions
- **#9:** R&D outsourcing - Regulation leads to purchasing new technologies
- **#10:** R&D collaboration - Regulation leads to new cooperation for R&D
- **#11:** IPR strategy - RDI changes required as a response to the regulation likely influence IPR strategies, namely with a shift to industrial secrets versus patents.

Step 3: Understand the impact of legislation on innovation and of innovation on society, environment, health, and the economy

For step 3, we recommend to consistently apply a qualitative and descriptive approach to determine innovation impact pathways. The usage of elaborated quantitative and especially econometric approaches requires access to data (which is not always available) and generally is a very labour-intensive method based on stringent assumptions, often capturing only part of innovation impacts. It can be applied in cases where the data, resources and assumptions made are deemed suitable by the research team (see steps 4 and 5 below).

As a solution for understanding and measuring the impact of 'complicated & complex' systems, we recommend using impact pathways. Mapping impact pathways requires the identification of causal mechanisms of impact, a narrative describing direct and indirect causal pathways and qualitative evidence to verify causality claims in the intervention logic.

As such, impact pathways are helpful logical tools, as they draw attention to chains of outcomes and impacts over and above the intervention logic of an initiative.

To go from the intervention logic to impact pathways we propose to use the 'Assessment Canvas Approach' (Technopolis Group, 2013).[108] This canvas indicates the mechanisms of how innovation effects may occur and diffuse from outputs to wider impacts. With the help of narratives it becomes easier to both deconstruct the logic of the intervention and to indicate where causality assumptions about impacts on wider socio-economic and environmental parameters may occur. The canvas allows for visualising impact pathways and is as such a qualitative tool. The three components of the canvas are described below and are illustrated further on.

- **Narratives**: narratives are used to describe and analyse the impact pathways of the legislation. The starting point for the development of impact pathways is the objectives of the intervention logic
- **Impact strength and directness**: the strength/direction matrix is used to document the strength or directness of the intervention on the identified outcomes or impacts
- **Measurements**: for each narrative, measurements are designed including eventual indicator(s). For each measurement, the information/data collection method(s), source(s) and analytical method(s) (e.g., topic modelling, descriptive statistics, market analysis, technology diffusion analysis, Life Cycle Analysis etc.) are equally explained. This is further explained in steps 4 and 5 below.

Impact Pathway template supporting the qualitative and quantitative narrative

Qualitative				Quantitative		
Narrative`	Impact strength and directedness`			Measurements		
Intended outcomes and impacts	Type of effect intended (direct/ indirect)	Strength of contribution (+, ++, +++)	Enablers (drivers and barriers) influenced by the intervention	Indicators / Information	Data collection methods and sources of data	Analytical methods

[108] Technopolis Group (2013): Guidebook on assessing environmental impacts of research and innovation policy. Available at: https://op.europa.eu/en/publication-detail/-/publication/00f04c38-5171-46a0-9f95-a5f36b58a04b

Step 4: Identify data/information needs

The approach for step 4 includes a sequence of logical actions needed to map information/data needs as derived from steps 1, 2, and 3. They are summarised here:

1. Identify necessary/required information for conducting the analysis on cost and benefits
2. Identify data/information needed for the different policy options
3. Review similar studies and their use of data (e.g., possibility to reuse data)
4. List available sources suitable for the analysis (primary, secondary, big data, literature)
5. Assess the data access, potential costs
6. Assess data coverage, limitations, potential
7. Provide alternative sources where needed, which can cover data needs.

A starting point for the identification of suitable data/information is the R&D and Innovation input, output indicators at micro (organisational or individual level) as provided in the following table.

Table 12 R&D and Innovation input and output indicators

	Indicators	Level of Analysis	Data Sources
RDI input	Expenditures of companies for research and development[1]	Micro	Eurostat CIS micro data; interviews
	Expenditures of companies for innovation related activities		
	Personnel working in research and development[2]		
R&D output	Scientific publications	Micro/Individual	Web of Science, Scopus
	Patent applications	Micro Organisation	European Patent Office
	Open Source software	Micro Organisation	Open Source repositories, like GitHub
Innovation outputs	**Product innovation** - Goods - Services - Goods and services include knowledge-capturing products, and combinations thereof. - Includes the design characteristics of goods and services	Micro	Eurostat CIS micro data; interviews; company websites
	Share of turnover with product innovation (new to the company, new to the market, new to the world)	Micro	Eurostat CIS micro data; interviews
	Business process innovation - Production of goods and services - Distribution and logistics - Marketing, sales and aftersales support - Information and communication systems - Administration and management - Product and business process development	Micro	Eurostat CIS micro data; interviews
	Trademark application	Micro (organisation)/individual	EUIPO[3]
	Design applications	Micro (organization)/individua)	EUIPO[4]
	ISO Certificates	Sector Micro	ISO survey[5] Organisation's website for identification and follow-up interviews
	Start ups	Sector Micro	Various sources, subject to coverage considerations: Thomson Reuters / Crunchbase[6]/ Dealroom[7]/
	Venture capital	Micro	

Step 5: Design suitable methods to collect and analyse the data

The approach for step 5 involves the design of a toolbox of methods to measure costs and benefits, which contribute to the analysis of the impact of legislation on innovation and of innovation on society, environment, health and the economy. The toolbox should be composed of different methods selected based on available information/data identified in Step 4. While the monetization/quantification of R&D and innovation costs is a requirement for evaluations and impact assessments, it is very common to only be in the position to provide a partial quantitative assessment. In most cases both quantitative and qualitative methods are required, however many existing examples include exclusively a qualitative assessment using interviews, surveys, expert panels etc. In the figures below we provide a non-exhaustive listing of methods for the assessment of costs and benefits.

Figure 10 Methods on Costs (non-exhaustive)

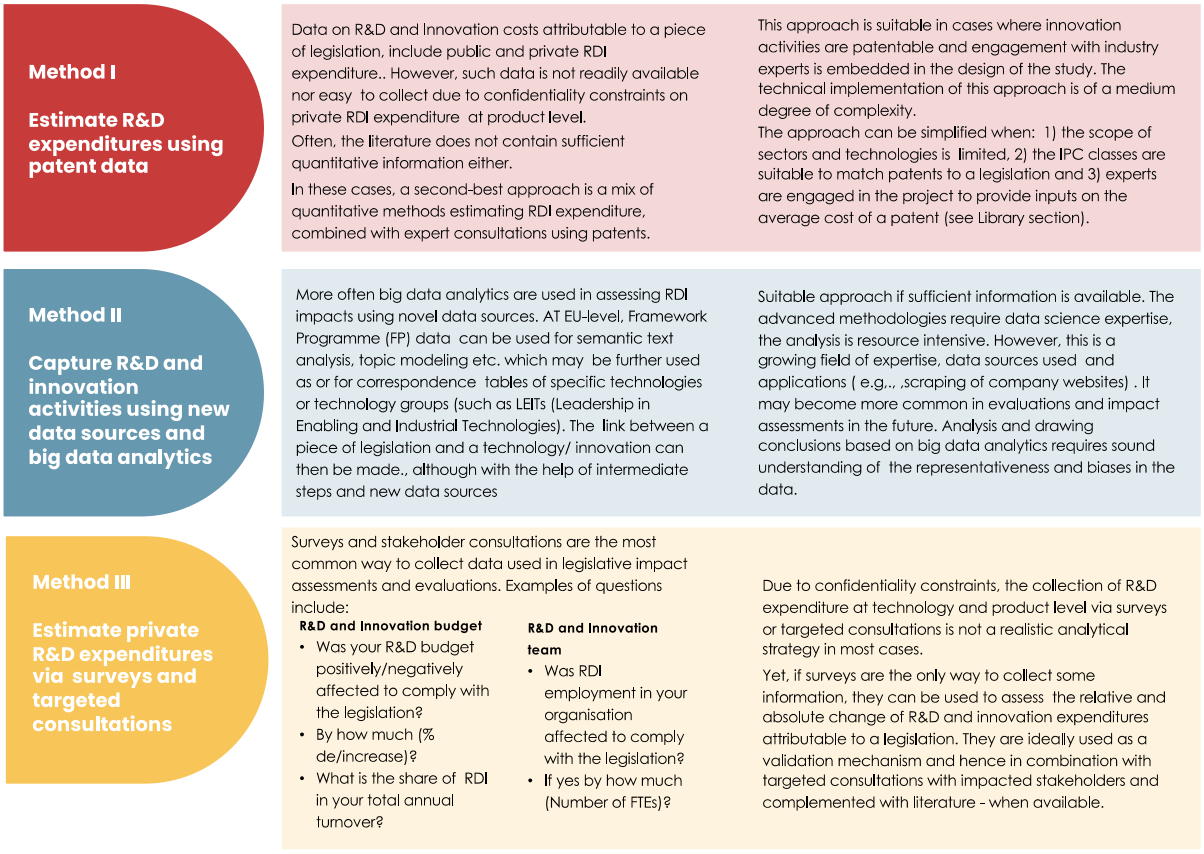
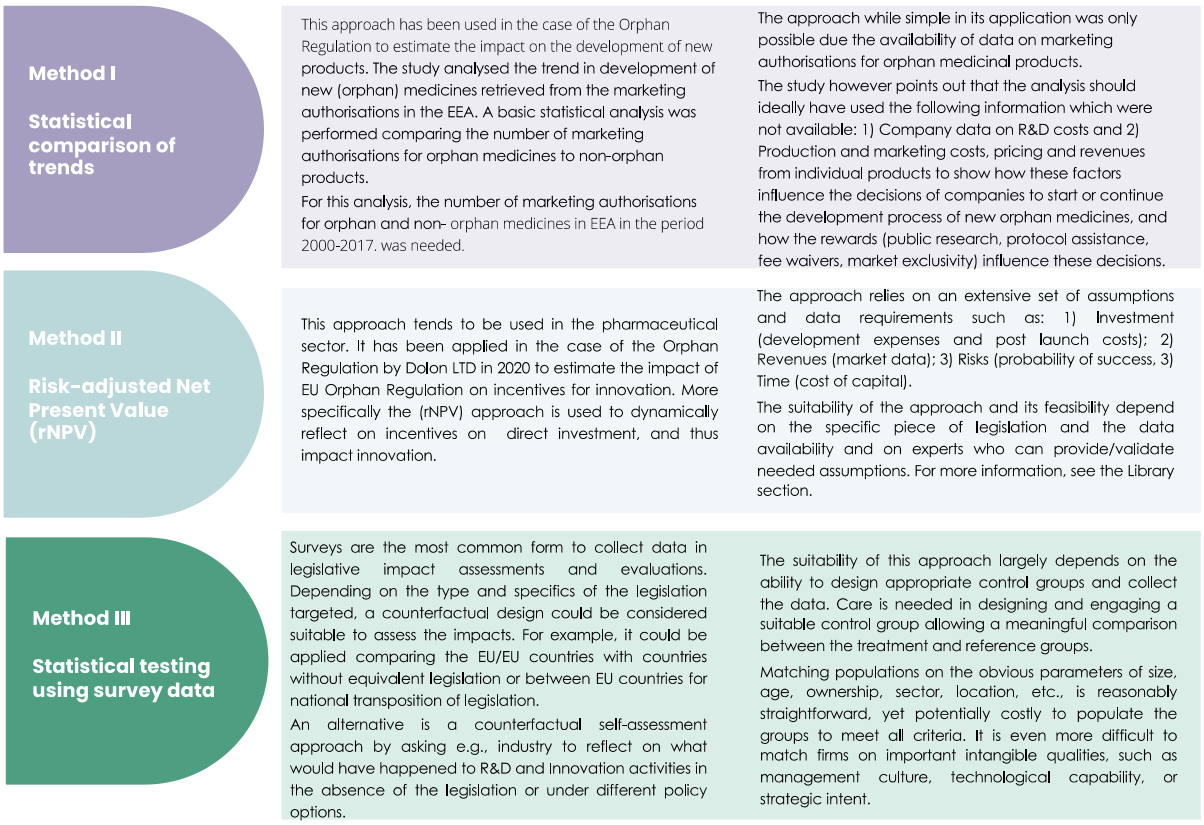


Figure 11 Methods on Benefits (non-exhaustive)



Step 6: Validate results

In step 6 results are validated. In quantitative analyses, a sensitivity analysis is typically applied (the effect of varying model parameters within known ranges), or sensitivity auditing (the effect of a number of non-quantifiable assumptions used in a model). Guidance on quantitative methods on uncertainty and sensitivity analysis are provided in Tool #65 of the Better Regulation guidelines.

In cases where a sensitivity analysis is not a suitable approach considering the mix of methods applied (see step 5), other approaches to validate results can be considered including methods of triangulating results. To validate results via triangulation three levels can be considered:

- **Data triangulation**: When multiple sources for secondary data are available, these are compared and included in the analysis. When primary data are collected for example from web scraping or other direct methods, additional data (from e.g., existing literature or Eurostat) or methods (e.g. poststratification methods) are needed to validate results and address biases in the data. When data is directly collected from trusted and validated sources (such as statistical offices) triangulation is required after application in models or constructed indicators. Both quantitative as well as qualitative sources can be used for validation, which may for instance include the use of a sounding board.
- **Methodological triangulation**: a mixed methods approach is usually applied, using both quantitative as qualitative methods for data collection. Whenever possible, a second/third method to triangulate the data collection as well as the results should be considered depending on the available resources. These may include different models, a literature review and expert interviews/reviews.
- **Investigator triangulation**: throughout the analysis usually a team with a variety of skills and expertise relevant for assessing the impact of legislation on R&D and innovation are

- engaged. Views from different internal and external experts contribute to this triangulation. In steps 4, 5 and 6 a team of individuals with complementary expertise is required. The participation of a sounding board to bring in expertise and to discuss/validate findings may equally be useful.

4 The six steps in practice

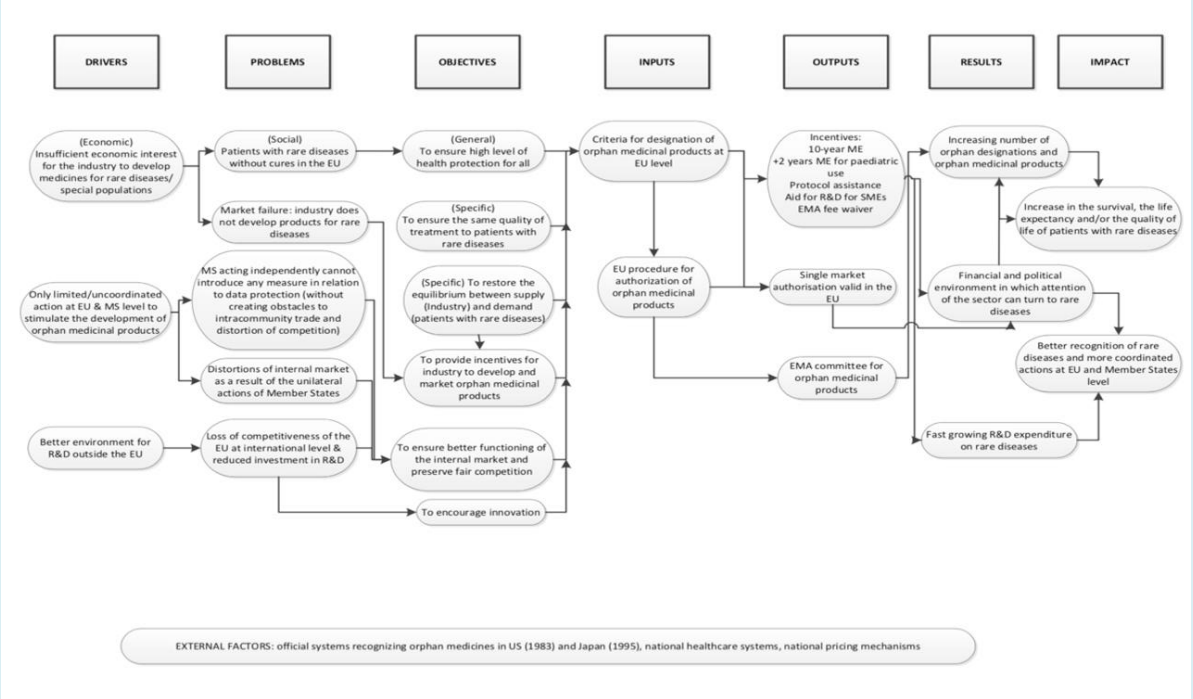
The following example is based on the Orphan Drug study to support the evaluation of the EU Orphan Regulation, which reviewed the objectives and design of the regulation and assessed to what extent it has proven effective, efficient, and relevant (2000-2017).

Step 1: Identify the type of regulation and its relation to innovation

(1) Objectives and intervention logic

This intervention logic elaborates the connection between the identified problems and the chosen policy intervention (the regulation), the connections between the inputs, outputs and outcomes. The regulation was intended to respond to the fact that patients with rare diseases did not have the same access to treatments as patients with other diseases, and that related product development had been largely ignored by the pharmaceutical industry. Therefore, a regulation was adopted that aimed to stimulate such development by providing a set of incentives. The EU Orphan Drug regulation shares not only its overarching objectives with the US Orphan Drug Act, but also substantial parts of its design. It offers a set of incentives aimed at (potential) developers of orphan medicines to encourage them to invest in the development of these products to a greater extent than they would do under normal market conditions.

Intervention logic



Source: Technopolis Group/Ecorys (2019): Study to support the evaluation of the EU Orphan Regulation

(2) Design of the regulation: Analysing the basic design and operational arrangements of the regulation helps understand modalities of compliance of impacted actors and the involvement of R&D and innovation activities. In this case, the criteria for orphan designation state that a product is eligible for designation if a sponsor can establish:

1a) that it is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition affecting not more than five in 10.000 persons in the EU when the application is made, or

1b) that it is intended for the diagnosis, prevention or treatment of a life threatening, seriously debilitating or serious and chronic condition in the Community and that without incentives it is unlikely that the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment.

2) that there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorised in the Community or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition.

(3) Evolution over time: regulation 141/2000 laid down the Community procedure for the designation of orphan medicines, for providing incentives for R&D and for placing on the market of designated orphan medicines. The original regulation identified several follow-up actions needed to effectively implement the regulation. In response to these identified follow-up actions, the implementing regulation No 847/2000, laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and the definitions of the concepts 'similar medicinal product' and 'clinical superiority' was adopted in April 2000. Since then, the EU Orphan Regulation has undergone several, relatively minor evolutions, the majority of which are clarifications as to the exact meaning of the terminology and procedures defined in the original regulation.

(4) Comparison with other regulations: The EU Orphan Regulation has been based to a significant extent on the US Orphan Drug Act. This Act also served as the inspiration for frameworks in other jurisdictions, such as Japan. The study reviewed some of the key elements of the frameworks in the US, Japan and Australia and provided details how these compare to the EU framework.

(5) Environment for R&D and innovation prior to the regulation: In the EU there were several programmes (e.g., the fourth Framework Programme 1994-1998) that aimed to improve the knowledge on rare diseases prior to the introduction of the EU Orphan Drug regulation. In France, the French National Institute of Health and Medical Research (INSERM) provided training, information and advocacy for R&D on rare diseases. Also, the Nordic Council proposed the development of a programme to collect information on rare diseases in Scandinavia, whilst in Denmark a research centre and a dedicated diagnosis and treatment facility was founded with a focus on rare diseases. However, prior to 2000 the R&D activity on Orphans was low, while there was a large unmet medical need for treatments and limited interest from the pharmaceutical industry to invest in Orphans. The Orphan Regulation addresses a market failure and it does so at EU level.

(6) List possible R&D and Innovation investments/modalities of compliance to the regulation: The development of pharmaceutical products requires significant ex-ante R&D investments. These investment decisions are influenced by the expected ability to recoup them later on (Return on Investment) by commercializing the developed drugs. The patent system was designed to allow inventors time to recover their

investments and make a fair profit, by protecting their market from competitors for a limited amount of time. In the preparation of the EU Orphan Drug regulation, policy-makers and industry recognised that the existing intellectual property rights system was insufficient to stimulate the development and marketing of orphan medicines and that additional incentives were needed. In addition, a 10-year period of market exclusivity (instead of the usually applicable 8-year period) was introduced, in line with a similar incentive in the US.

The EU Orphan Drug regulation does not explicitly determine when the compensation for R&D investments (i.e. the economic value of the exclusivity reward) is 'fair' or 'proportional', but it does indicate, in Article 8, that developers should have the "*prospect of obtaining a market exclusivity for a certain number of years during which part of the investment might be recovered*". There are several publications that determine, at a more aggregate level, to what extent differences (i.e., 'overcompensation') can be observed in the financial performance of orphan medicine developers and non-orphan developers.

(7) Complementary Initiatives to support R&D and Innovation: At the EU level, the EU has shown a strong commitment to rare disease research. It has done so, for instance, via the EU Framework Programmes for Research and Innovation, the ERA-Net for Research Programmes on Rare Diseases ERare and via its support for the International Rare Disease Research Consortium (IRDiRC). Similarly, collective resources such as the European Platform for Rare Disease Registries (EPIRARE) and RD-Connect are helpful to achieve greater standardisation and standardisation in data sharing across Europe and thus add significant value. This effect is enhanced by the creation of the European Reference Networks (ERNs). Another important initiative to highlight is also the recently (2019) launched European Platform on Rare Disease Registration (EU RD Platform).

At the national level, survey respondents were asked what main national initiatives exist in their respective countries to fund or otherwise stimulate R&D relating to orphan medicines. Researchers most frequently mentioned networking initiatives, the launch of large research programmes in the area of rare diseases and government research grants.

(8) Conclude on the relation between the regulation and R&D and innovation: The study points out that the relation of the regulation with innovation is derived from the broader policy context in which the EU Orphan Drug regulation was introduced. The objective of promoting innovation is addressed in the regulation through inputs coordinated by the EMA and the Commission which include the criteria and processes for orphan designation, and the centralised authorisation procedure for orphan medicinal products (OMPs). By linking the criteria to incentives, the regulation is expected to deliver an increase in business expenditure on R&D for orphan medicines and contribute to an increase in the number of successfully developed orphan medicines. The regulation also aims to improve the financial and political environment to support rare disease research and the development of orphan medicines. Besides the impact of the regulation *on* R&D and innovation, R&D and innovation impacts *of* the regulation on society, health systems and patients, like increase of life expectancy, are also identified as relevant and are investigated to the extent possible.

The EU Orphan Drug regulation represents an innovation sensitive regulation. The investigation of the link between the regulation and R&D and innovation is therefore central in the analysis.

Step 2: Map actors and their modalities of compliance

A **targeted consultation**, using surveys and interviews, was performed under five distinct groups of stakeholders: 1) representatives of national public authorities in EU Member States, 2) sponsors of orphan medicinal products, 3) developers of generic medicines, 4) patient and consumer organisations, and 5) academic researchers and experts. Performing interviews is a preferred option that facilitates greater understanding of the modalities of compliance.

The modality of compliance of the pharmaceutical industry is through product innovation. According to interviews with stakeholders, the R&D that pharmaceutical companies may engage in for orphan medicines can vary significantly considering that:

- Pharmaceutical R&D tends to have high failure rates and many products never make it to market. Discussion on the topic is present within the academic community [109]

It is not always clear at the onset, for what indication a product will be developed

- It is also possible to 'repurpose' an older already off-patent medicine as a treatment for a rare disease
- Early-stage R&D may not be done by the pharma companies themselves. Instead, it may be done by hospitals or universities receiving public funding
- Some companies may operate models whereby they in-license promising products only when they are in Phase I/II clinical trials reducing hence substantially their process and R&D costs
- Tax breaks and subsidies received by pharmaceutical companies.

Step 3: Understanding the impact of regulation on innovation and of innovation on various dimensions

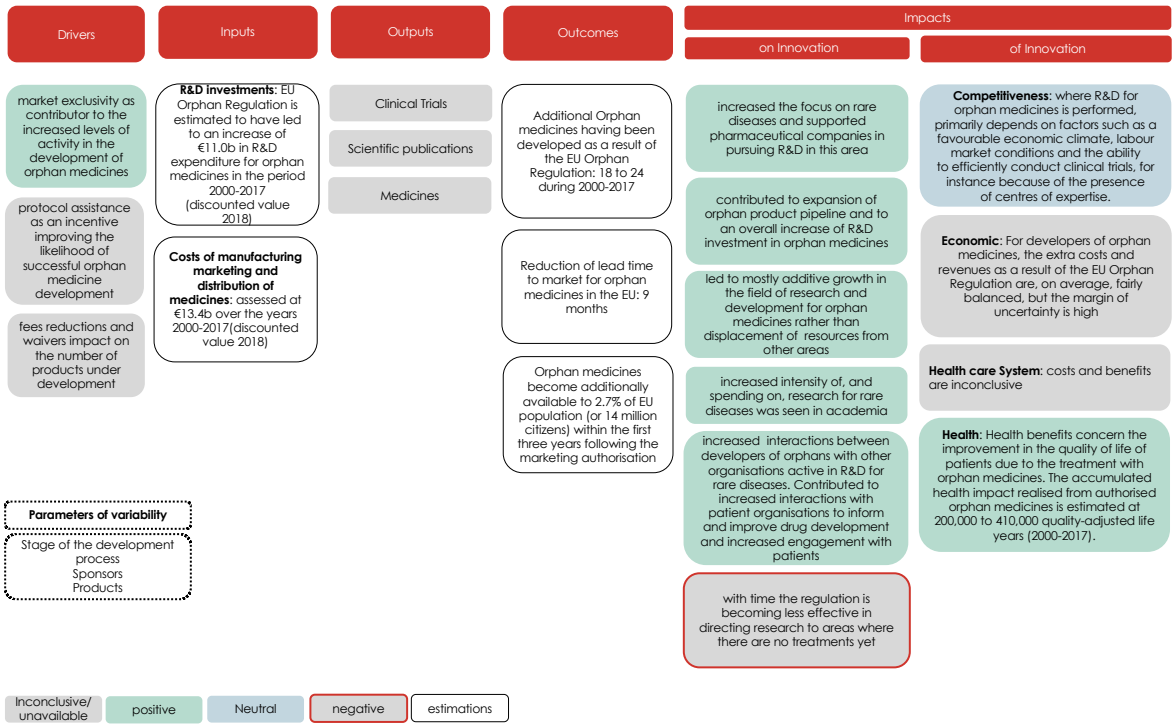
The EU Orphan Regulation aimed to provide incentives for industry to develop and market orphan medicinal products and to encourage innovation. To achieve these aims, the regulation would need to have an impact on the R&D investments focused on rare diseases in Europe.

The distinction had been made between the impact on the research environment and the impact of the realized innovation, e.g., on the competitiveness of the pharmaceutical industry in Europe. The approach is based on interviews and surveys.

In the figure below, we summarise the findings of the study structured according to the intervention logic. We indicate with the help of a colour coding scheme whether the intervention logic claims have been validated or not and to what extent by the study's toolbox and its quantitative and qualitative methods.

[109] See for instance articles on industry R&D costs such as J.A. DiMasia (2016) on 'Innovation in the pharmaceutical industry: New estimates of R&D costs', the European Commission (e.g. the Pharmaceutical Strategy for Europe) and publications analysing R&D strategies of industries e.g., McKinsey (2017) Rethinking pharma productivity.

Figure 12 Intervention logic and main findings



Source: Study team based on results published in: Technopolis Group/Ecorys (2019): Study to support the evaluation of the EU Orphan Regulation

Using the **impact pathways approach** to analyse innovation impacts, would have entailed :

- **Step 1**: starting from the objective to encourage innovation, formulate a story line. Examples could include "The Orphan Regulation encourages innovation by increasing R&D expenditures for orphan medicines" (impact on innovation) and "The increase of orphan medicines (attributable to the regulation) has led to an increase of the quality of life of patients with rare diseases" (impact of innovation) and
- **Step 2**: Orphan Regulation strength/direction matrix.

Figure 13 Strength/Direction Matrix: Impact pathway of the regulation on innovation

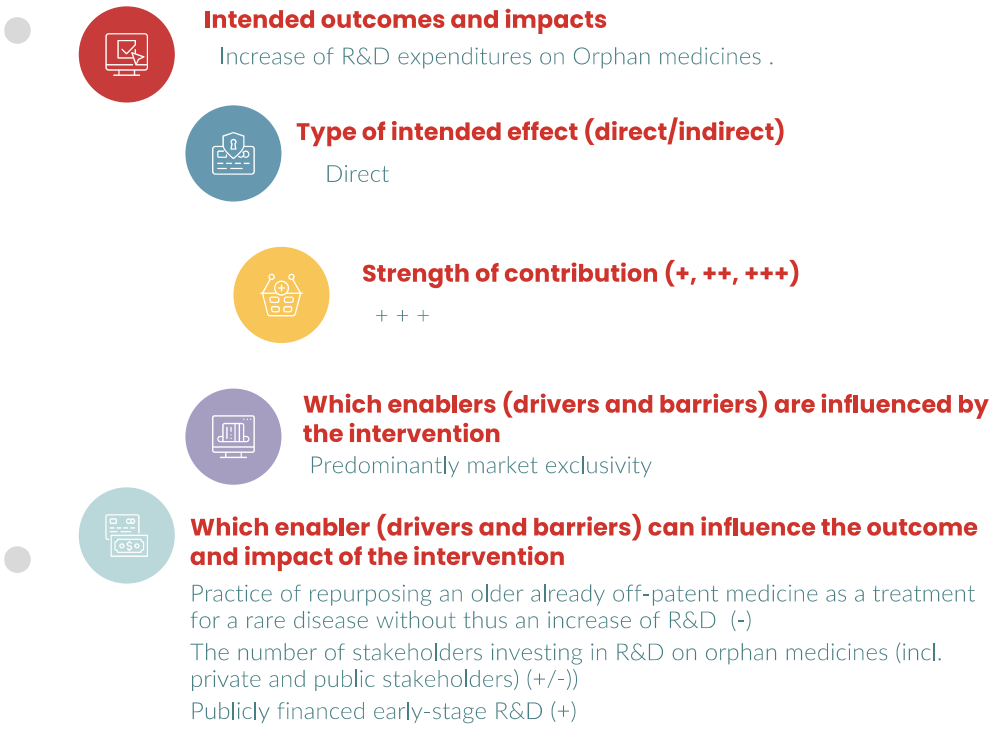
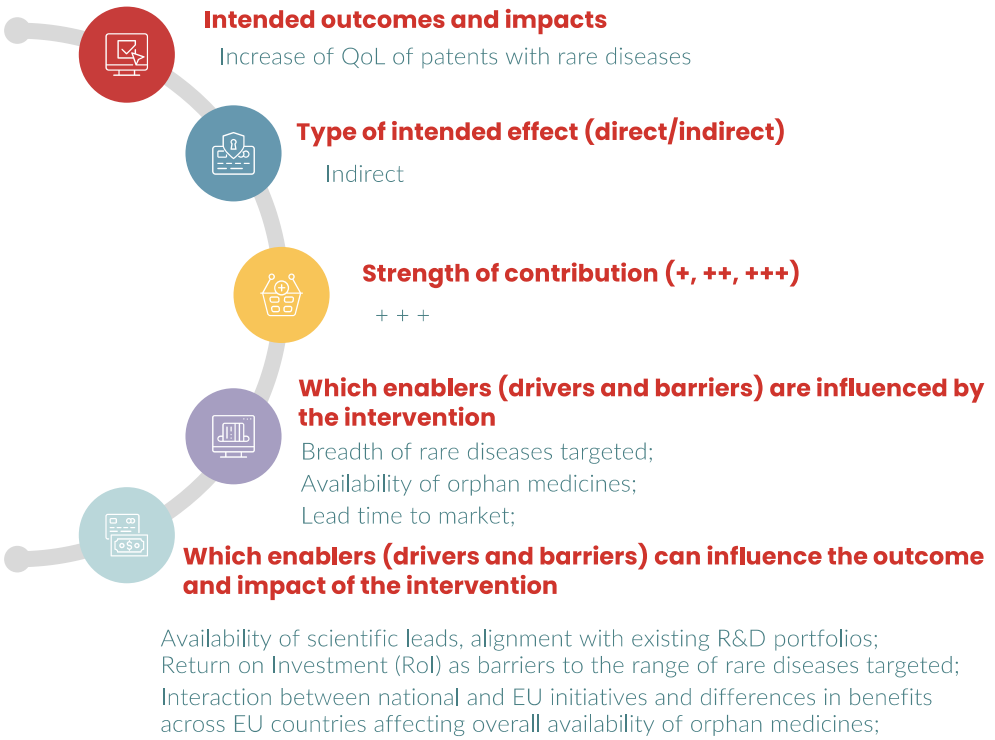


Figure 14 Strength/Direction Matrix: Impact pathway of the regulation on patients' health



Step 4: Identify data/information needs and collect the data

For the **originator company or sponsor** (the orphan designation holder), two main cost components were distinguished, with

(i) the *research and development costs* for orphan medicines
(ii) the costs of manufacturing, marketing and distribution of these orphan medicines, including a "normal" profit margin.

The revenues from sales of orphan medicines, the three rewards of the EU Orphan Regulation, (the market exclusivity, the protocol assistance (article 6), and the fee waivers (article 7 sub 2)) are regarded as benefits for the sponsors.

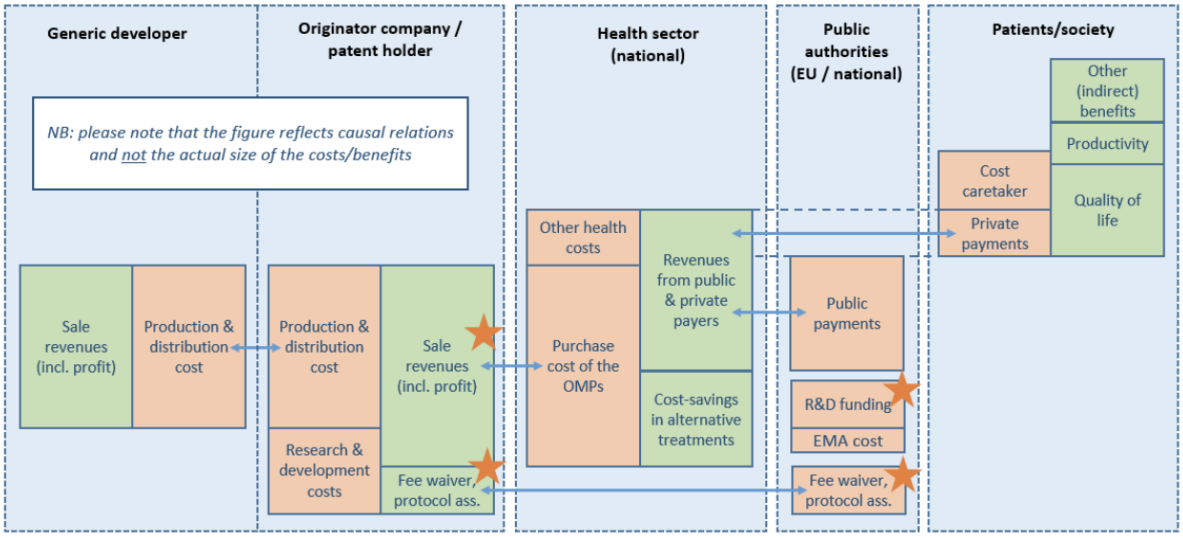
The **developers of generic medicines** have no or only limited research and development costs. Their sales revenues need to cover (only) the costs of manufacturing, marketing and distribution, including a "normal" (industry average) profit margin.

The **health sector** costs are financed from a combination of public and private sources.

Public authorities (national governments, EU) incur costs related to administrative costs (e.g., the salaries of employees involved) and costs of providing the rewards.

Patients incur costs as far as they contribute to the financing of treatment with orphan medicines. The main benefit for this group is the *health benefit derived from treatment with orphan medicines (the other angle of innovation impacts)*.

Figure 15 Overview cost (red) and benefits (green) for various stakeholders



Source: Technopolis Group/Ecorys (2019): Study to support the evaluation of the EU Orphan Regulation
Note: The orange stars refer to the four 'rewards' the EU Orphan Regulation introduced (i.e., market exclusivity, protocol assistance, fee waivers and aid for research).

The **survey approach** in combination with **interviews** was used to provide estimates of costs related to average annual R&D expenditure for originator companies or sponsor stakeholder group.

The data from Health Technology Assessment (HTA bodies) reports provided information on the Incremental Cost-Effectiveness Ratio to estimate the benefits of orphan medicine on patient/society stakeholder group.

No additional data access has been considered in the study.

The interviews and survey did not provide a sufficiently robust input for the analysis. The respondents to the survey indicated that either information regarding R&D expenditures was confidential or that such an estimate could not be provided.

Alternative sources have been used to estimate R&D costs for orphan medicines, such as scientific literature.[110]

Step 5: Design suitable methods to analyse the data

In order to quantify cost and benefits related to innovation, the methodological approach of the Orphan study was mostly based on estimates and assumption approaches.

Quantification of costs and benefits for industry

The industry has incurred higher costs due to the extra development of orphan medicines. These additional costs for industry have been calculated by using the number of newly developed orphan medicines (21 in this case) and the range of R&D costs found for orphan medicines (range €479m to €725m, see Section 8.2 of the main report; input for baseline CBA the average of this range: €602m). These cost estimates are net of subsidies received from governments and include already the cost of capital for the industry, using 11% (based on literature).

As the R&D costs can potentially be spread over worldwide sales, not all of this investment needs to be allocated to the EU market. According to the turnover data presented in the main report, the average share of EU in worldwide sales of medicines for rare diseases is estimated at 21%. As this average may not be representative for newly developed orphan medicines, a more conservative approach is taken in the Cost Utility Analysis (CUA) by allocating 60% to the EU market, based on the relative population sizes of US and EU. Given these assumptions the total additional R&D costs for industry in 2000-2017 have been estimated at 21 x € 602 m x 60% = € 7.6 billion in nominal terms.

These extra development costs have been incurred by industry in the years up to the market introduction of the additional products. In order to assess the discounted value of the extra development costs, the costs have been phased in the 10 years before the market introduction of the 21 orphan medicines. The resulting present value of this stream of costs is estimated at € 11.0 billion.

Industry Costs and Benefits, due to the Orphan Regulation, 2000-2017 (discounted value 2018, prices 2018, in € billions)

Effect	Costs	Benefits
R&D costs associated with the additional orphan medicines (EU part)	-/- €11.0b	
Sales revenues of additional orphan medicines in EU		€19.1b
Extra costs of manufacturing, marketing, distribution in EU including extra "normal profit"	-/- €13.4b	
Extra revenues due to ME reward		€4.6b
Cost saving due to protocol assistance and fee waivers		€0.2b
Total	-/- €24.4b	€23.9b
NET BENEFIT (COST)	(€ 0.6b)	
Range Net Benefits (minimum – maximum) a)	-/- €11b to +€11b	

Source: Technopolis Group/Ecorys (2019): Study to support the evaluation of the EU Orphan Regulation

Note (a) In the minimum scenario the higher R&D costs are combined with low effects on orphan medicine development and R&D compensation. In the maximum scenario opposite assumptions are used.

[110] U.S. Department of Health and Human Services (2016): The U.S. Department of Health and Human Services used the method of DiMasi (2016) to estimate the mean and median costs of development for orphan medicines. The applied method of DiMasi takes into account the cost of capital used and the costs of failures. The estimates are of US$1.0b (€725m163) and median costs of development US$0.8b (€581m).
Berdud, Drummond, & Towse, (2018): estimate the R&D costs of a new orphan medicine to be around US$521m (€479m165) for all indications and US$493m (€453m) for oncology. They conclude that the estimated R&D costs for an orphan medicine is much lower (at round 27%) than the R&D costs for a non-orphan and that this is in line with other studies, such as that by Côté et al. (Côté & Keating, 2012).

Quantification of costs and benefits for patients suffering from rare diseases:

The various cost and benefits items for this group relate to:

- Private payments for health care costs: as indicated above it has been assessed that almost all additional health care costs relating to treatment with orphan medicines are financed from public sources. The private contribution by patients is assessed at 3% of additional health care costs.
- Health benefits due to treatment with orphan medicines: these have been assessed on the basis of the extra availability (use) of orphan medicines in the EU due to the EU Orphan Regulation. The benefits have been assessed by applying the ICER (a value assessment framework for treatments for ultra-rare diseases) (€54,000 to €110,000) to the additional sales volume (€ 23.7b).
- The non-health costs of a rare disease. As explained, the impact of additional use of orphan medicines on non-health costs of rare diseases (use of social services, the costs of involvement of (professional or informal) carers outside the health system and productivity losses resulting from unplanned absences from work or early retirement by patients. Some of these costs are borne by the patients and their relatives, other costs are borne by others in society or by the government) and could not be assessed.

The additional health impact due to the regulation is estimated to be 210,000 to 440,000 Quality Adjusted Life Years (QALYs).

Costs and Benefits due to the Orphan Regulation for patients, 2000-2017 (discounted value in 2018; prices 2018, € billion)

Effect	Costs	Benefits
Private contribution to health care costs	-/- €0.7	
Change in non-health costs of disease	NDA (a)	
Health benefits		210,000-440,000 QALYs
TOTAL	-/- €0.7	

Source: Technopolis Group/Ecorys (2019): Study to support the evaluation of the EU Orphan Regulation
Note: (a): NDA: not sufficient data available to assess this effect

It is common in many studies to not be in a position to quantify or monetise all costs and benefits for all impacted stakeholder groups. Therefore, a holistic approach using qualitative information to map and assess the strength of contribution to the legislation and the magnitude of costs and benefits qualitatively for the different stakeholder groups is a necessary step. It is equally necessary to transparently report on the costs and benefits for which no conclusion has been reached. In step 3 we presented a possible way to summarise both qualitative and quantitative findings using the intervention logic as basis.

Step 6: Validate results

The calculations used for the sensitivity analysis were the most likely estimates, representing averages for the whole group of orphan medicines. There were uncertainty ranges around these averages. Applying the minimum and maximum levels would give different levels of societal costs and benefits. In addition, the sensitivity analysis also took into consideration non-quantifiable factors.

Societal cost per QALY gained as a result of the Orphan Regulation in various scenarios (in Euro)

Sensitivity analyses	Societal cost per QALY	
Baseline analysis	€58,000 – €118,000	
Baseline analysis, monopoly rent only for medicines with generic competition (44% of the total group)	€52,000 – €106,000	
Baseline analysis, extra spread as a result of Regulation 5% (instead of 2.7%)	€57,000- €116,000	
Baseline and Lower (479 m) / higher (725 m) R&D costs per orphan medicine	€53,000 -€107,000	€63,000 - -€128,000
Baseline and Lower (18) / higher (24) number of orphan medicines developed extra	€55,000- -€112,000	€61,000- €124,000
Baseline and turnover in EU market as share in worldwide turnover lower (21%) / higher (100%)	€42,000 - -€85,000	€75,000 - €152,000
Baseline and lower (1%) / higher discount rate (5%)	€56,000 - -€114,000	€60,000 - -€122,000

Source: Technopolis Group/Ecorys (2019): Study to support the evaluation of the EU Orphan Regulation

Challenges, prevention and mitigation recommendations

Measuring the costs of innovation

To **measure the costs of innovation** stemming from enterprises' compliance with a piece of legislation assumes their willingness to cooperate in the study - given the need for primary data. Before enterprises share confidential data such as costs, **Non-Disclosure Agreements** (NDAs) are typically required. This is a lengthy and potentially costly process. Prior to the NDAs, companies want to know about the complete mapping of costs, calculations, unit of measurement (absolute terms versus relative terms as share in turnover, EBITDA etc.) and final use of the data. The process takes time and it is fair to expect that only a few companies will complete the process. In the case of private R&D expenditures – and even after NDAs have been signed -, companies are unwilling to share R&D expenditures by technology or product. Alternatives, such as estimations using patent data (when deemed suitable, see Appendix 1) or desk research (literature dedicated on estimating R&D costs in a given industry), or consultations with experts on a range of technologies or Best Available Techniques (BATs) and corresponding costs can help understand the magnitude of R&D costs for different techniques.

To generalise findings of innovation cost ranges, the variability in the cost estimates

will need to account for enterprises' characteristics such as size (multinationals, large enterprises, SMEs), production tonnage, product mix, number of sites, exporting activity in terms of countries and products, and R&D profile among many others, depending on the domain of the regulation. To produce robust estimates, a sufficiently large sample of companies is required. Validation of cost ranges is typically done by interviews and surveys. The suitability and effectiveness however of a survey versus other options such as a workshop or expert consultation would need to be assessed on a case-by-case basis.

In particular, multinationals may operate on the basis of global projects allocated across different geographic locations. Ranges of figures can thus be impacted by the attribution of costs globally and it may be necessary to analyse multinationals separately from local large companies.

The **attribution of innovation costs** to a single piece of legislation may not be possible, as costs borne may be motivated by a group of legislations interacting and overlapping with one another. Also, attribution to a legislation requires a careful examination of the consistency of the baseline, the Business as Usual (BAU) option across enterprises.

R&D priorities and corporate responsibility can influence attribution of innovation costs to a piece of legislation.

Also, there is an additional complexity in distinguishing EU-originated requirements from additional national ones in the case of directives. These aspects are best carefully examined during initial scoping interviews with industry representatives or industry experts.

Note that legislations introduced in recent years lead to higher costs as investments need to be made to render a company compliant. On the other hand, in the case of newly introduced legislations, some enterprises may be going through a transition period before an exemption expires. This can explain differences between companies with the same profile but different magnitude of costs.

Accounting for **indirect innovation costs** can be an important element to bear in mind when performing the cost assessment. Examples include accounting for the delays which impact return on investment and speed to market. Opportunity costs apply in case R&D expenditures made represent a re-orientation of the budgets from one priority e.g., car safety R&D performed by OEMs to CO2 reductions.

Generalising **cost estimates** to economic sectors poses methodological challenges and requires a careful design. Different methods (e.g., using an econometric model versus using a simpler approach based on assumptions and extrapolations) may lead to different results. The different methodological approaches require discussion with experts, as often there are no resources to conduct multiple testing of different, often resource intensive methods.

Innovation costs are accounted for in the framework of compliance costs with often administrative, substantive costs, and charges representing the core of the quantitative analysis. To stimulate more explicit coverage of innovation, we propose to consistently request step 1 of this guide in evaluations and impact assessments.

Measuring the benefits of innovation

The attribution of innovation effects to a specific piece of legislation is methodologically challenging as well as strongly context dependent.

The academic work focusing on the interface of regulation and innovation is mostly descriptive since the relationship between regulation and innovation is complex, most often indirect and frequently evolving over long time periods, therefore bearing effects with long time lags.

A relevant distinction is made between *intended* and *unintended* and *direct* and *indirect* effects. This occurs since between the implementation and occurrences of a regulation's effect, several other measures may be introduced which trigger changes. Therefore, other circumstances than the regulation itself may influence innovation. Thus, a combination of quantitative and qualitative approaches is deemed more appropriate in the context of evaluations and IAs. Approaches in the wider literature include often an Impact Pathways design (see annexed Library).

Empirical evidence on the benefits of innovation-sensitive legislation is typically based on patent analysis. Patents, however, are but one output of innovation activity and are limited in capturing for example digital innovation. We propose a longer list of possible R&D and innovation outputs as annexed in Table 12.

Methodologies estimating the economic benefits of innovations on e.g., turnover, profitability of enterprises after the introduction of a regulation are demanding in terms of data collection and impose assumptions that may compromise the use of findings for policy purposes. There is a risk that attribution of benefits to innovation is arbitrary. Certainly, this is to be assessed on a case-by-case basis.

Innovation can be influenced by many parameters besides legislation, such as past history on innovation, R&D subsidies and other area-specific factors which need to be accounted for. As they can rarely be accounted for in quantitative terms, they are best

considered and embedded in the qualitative design as also proposed in step 1 of this guide.

The application of models is more common in IA rather than evaluation studies, where existing models developed by the EC and other institutions are typically used. According to the JRC (2019), models are most often applied in IAs to assess policy options and for the calculations of baselines. An examination of the integration of innovation in those models or the need to adapt such models accordingly is however not performed. It is therefore proposed that in IAs where cooperation with the JRC is deemed necessary, that a discussion takes place about the eventual incorporation of assumptions on innovation.

18. Library

18.1 Method I to Estimate Private R&D expenditures applied in the case Key Enabling Technologies

Estimating private R&D expenditures using patents is an applied approach suggested in R&D and innovation related research. The need for estimating R&D expenditures is grounded on the fact that statistical classification of economic activities (NACE) does not adequately display companies' R&D expenditures by technologies or specific products. Consequently, researchers and policy makers are not aware of how much business R&D is spent on certain kinds of technologies. Many policy-induced funding or support programmes all over the world, however, are geared towards financing technological developments in certain technology fields, which is why a field-specific differentiation of R&D expenditures is important. We identify two main contributions[111] and describe the approach as included in Neuhäusler et al. (2015).

What is available at the level of technologies, are patent related indicators, i.e. patent filings, which are highly correlated with R&D expenditures. The assumption behind this calculation, however, is that R&D directly leads to patents, which is not necessarily the case and is also different across sectors/fields. Yet, assuming at least an indirect relation (or a high correlation between R&D and patents with minor distortions across sectors), the shares of a company's patents in a certain field can be used to infer its R&D expenditures in the respective field. This information on firms can be aggregated at the sectoral level. On this basis, a concordance matrix between patents (in given fields) and R&D expenditures can be constructed, which includes the share of patents filed for a given technology within all patents in a given sector. These shares can then be used to assign the R&D expenditures by sectors - which are easily available - to given technology fields (see a more in-depth explanation in Neuhäusler et al. 2017).

Such an approach would for example assign 30% of business expenditure on R&D (BERD) in sector 1, 20% from Sector 2, 0% from sector 3 etc. to e.g., nano technology.

The starting point to develop such a concordance is the match of patent data to company data at the micro level, i.e., the level of patent applicant/company names. Only if this data is available, the patents of a company - for which the NACE sector is then known - per technology field can be calculated, which in aggregate results in the above-described matrix.

Second, a patent definition of the technology field of interest, e.g. nano-technology, on the basis of IPC (International Patent Classification)-classes or keywords has to exist to search for these patents by companies.

Third, a weighting scheme needs to be developed as it cannot be assumed that a patent needs the same amount of R&D investment in each sector, i.e. patent intensities in the fields need to be estimated. As a rough estimation, the classification developed in Schmoch and Gauch (2004) can be used. Yet, expert consultation should be taken into account to at least get a rough idea of the "costs" of a patent (or an invention) within a given field.

Fourth, and maybe most important, the results need to be validated by external experts, estimations by business associations or similar to make sure the approach leads to an acceptable result as it is associated with some assumptions, e.g. the patent-R&D relation. In addition, it has to be kept in mind that the conversion described can be biased by the assignment of companies to sectors, which is especially problematic for large companies that are active in several fields but are only assigned to one NACE sector.

[111] Neuhausler et al. (2015) Identifying the Technology Profiles of R&D Performing Firms: A Matching of R&D and Patent Data; Pasimeni et al. (2018) Patent-based Estimation Procedure of Private R&D: The Case of Climate Change and Mitigation Technologies in Europe.

In brief, these are the steps necessary to generate the matrix to assign R&D expenditures to technologies:

1. **Obtain the R&D expenditures by sectors**, e.g., BERD from official statistics, such as the OECD, national surveys, etc.
2. **Match patent data to company data** (e.g. PATSTAT to BvD Orbis, the EU Industrial R&D Scoreboard, ...) at the level of companies to obtain NACE sector information for companies
3. Create a **definition of the respective technology in terms of IPC classes/keywords** and search for those patents by company within the patent database
4. **Aggregate the company information to sectors** to obtain the number of patents in a given sector by technology field(s) (as the sum of patents across companies in the given sectors)
5. **Calculate the shares of patents by field in each sector**
6. Use these **shares** to assign the R&D expenditures by sectors obtained in step 1 to technology fields
7. **Estimate patent intensities** or "costs" of patents per field to weight the results accordingly. These estimates need to be developed together with experts in the field
8. **Validate the results** via consultations with industry experts.

An example of the conversion of R&D expenditures from sectors to technology fields in the case of nanotechnology for the year 2012 can be found in Table 13. The matrix of patents by NACE sectors and technology fields (here: nanotechnology) is the result of aggregating the patents in nanotechnology by the firms in the matched patent-company dataset at the level of sectors (2-digit or partly more aggregated).

On this basis, the share of nanotechnology patents in total patents in the respective sector can be calculated, i.e., the share of nanotechnology patents in sector 01-03 is 0.0%, in sectors 05-09 it is 0.9% etc. This share will then be used to assign the share of R&D in the given sector to nanotechnology research, i.e., 0 million in sectors 01-03, 4 million in sector 05-09 etc. Summing up the R&D expenditures for nanotechnology across sectors leads to the final result of 764 million Euros of R&D going into nanotechnology research in 2012. It has to be noted, however, that this is an unweighted matrix. The patent shares in nanotechnology used for the conversion could be weighted by a patent intensity within the field of nanotechnology to account for the fact that research in nanotechnology could be more/less expensive than research in other fields.

Table 13 Example of the conversion of R&D expenditures from sectors to fields in the case of nanotechnology

	Patents			BERD (year=2012)	
NACE sector	Patents in KETS Field 2 - Nanotechnology	Total patents	Share of nanotechnology patents in total patents	BERD (in m)	BERD 2012 * Share of nanotechnology patents in total patents
01_03	0	39	0.0%	609	0
05_09	65	6925	0.9%	411	4
10_12	7	5199	0.1%	2247	3
13_15	2	904	0.2%	1004	2
16_18	22	3331	0.7%	951	6
19	28	2844	1.0%	685	7
20	452	35290	1.3%	7170	92
21	139	17693	0.8%	12091	95
22	17	5596	0.3%	2815	9
23	108	7441	1.5%	1003	15
24	93	7749	1.2%	1685	20
25	1	1896	0.1%	3229	2
26	885	132092	0.7%	20192	135
27	149	36590	0.4%	5732	23
28	152	37957	0.4%	12816	51
29	65	24787	0.3%	25314	66
30	55	12474	0.4%	10665	47
31	0	414	0.0%	272	0
32	4	6244	0.1%	1752	1
33	1	163	0.6%	1376	8
35_36	2	1302	0.2%	1215	2
38_39	0	0	0.0%	187	0
41_43	10	801	1.2%	809	10
45_47	6	2258	0.3%	5509	15
49_53	1	227	0.4%	468	2
55_56	0	1	0.0%	55	0
58_60	11	4697	0.2%	1679	4
61	8	7117	0.1%	3756	4
62	72	7951	0.9%	10320	93
63	0	20	0.0%	614	0
64_66	5	3335	0.1%	2784	4
68	0	42	0.0%	71	0
69_75	21	6367	0.3%	11628	38
77_82	1	173	0.6%	812	5
84_85	0	20	0.0%	59	0
86	0	61	0.0%	283	0
87_88	0	0	0.0%	15	0
90_93	0	14	0.0%	268	0
94_98	0	12	0.0%	155	0
SUM					764

18.2 Risk-adjusted Net Present Value (rNPV) method applied for the Orphan Regulation

The risk-adjusted net present value (rNPV) approach has been applied in the case of the Orphan Regulation by Dolon LTD in 2020 to estimate the impact of EU Orphan Regulation on incentives for innovation. More specifically the rNPV approach is used to dynamically reflect how incentives direct investment, and thus impact innovation.

rNPV is a method to value risky future cash flows, given the risk of failure. The rNPV modifies the standard NPV calculation of discounted cash flow analysis by adjusting each cash flow by the estimated probability that it occurs, the estimated success rate which provides the expected cash flow. This helps estimate the amount to be invested, predicts the level and duration of the expected revenues, adjusts the expected revenues to account for the probabilities of success and accounts for the 'cost of waiting' for the revenue, that is, the discount rate. A Monte Carlo simulation was performed to account for uncertainty surrounding model inputs and the time horizon being set to the length of the patent (see also Better Regulation Guidelines, tool #57).

The approach relies on a set of assumptions and data requirements illustrated below for the case of the Orphan Regulation. The suitability of the approach and its feasibility depend on the specific piece of legislation and the data availability combined with the access to experts who can provide/validate needed assumptions.

Type	Category	Input	Data Source
Investment	Development expenses & post-launch costs	Annual preclinical costs	Wouters et al., 2020
		Annual Phase I costs	Calculation
		Annual Phase II costs	Calculation
		Cost of approval phase	Calculation
		Annual ongoing R&D costs	Berdud et al., 2020
		Cost of goods (% of revenues)	Assumption
		Selling, General and Administrative expenses (% of revenues)	Assumption
	Duration of phases	Preclinical (years)	Paul et al., 2010
		Phase I (years)	Jayasundara et al., 2019
		Phase II (years)	Jayasundara et al., 2019
		Phase III (years)	Jayasundara et al., 2019
		Approval (years)	Paul et al., 2010
		HTA (years)	EFPIA Patient W.A.I.T. Indicator 2018 survey
Revenues	Market data	Treated patient population (n)	Assumption
		Annual population growth (%)	Eurostat 2016–2019 estimates
		Peak market share, before effective market protection loss (%)	Calculation
		Ramp time to peak market share (years)	Calculation
		Market share, post effective market protection loss (%)	Assumption
		Annual price per patient (€)	Calculation based on Medic et al., 2017
		Drop in price post market protection loss (%)	Assumption
		Annual price erosion (%)	Assumption
		Revenue multiplication factor, to scale from EU5 to EU28 (%) Average number of indications per OMP	Detiček et al., 2018
		Duration of market protection, including IP/SPC/OME (years)	Technopolis Group Orphan Study
Risk	Probability of success	Preclinical (%)	Assumption
		Phase I (%)	Wong et al., 2019
		Phase II (%)	Wong et al., 2019
		Phase III (%)	Calculated using Wong et al., 2019 and Thomas et al., 2016
		Approval (%)	Thomas et al., 2016
Time	Cost of Capital	Cost of Capital	Wouters et al., 2020

Source: adapted from Dolon LTD (2020)

18.3 Statistical comparison of trends applied for the Orphan Regulation

This approach has been used in the case of the Orphan Regulation to estimate the impact on the development of new products.

The study analysed the trend in development of new (orphan) medicines retrieved from the marketing authorisations in the EEA.

A basic statistical analysis was performed comparing the number of marketing authorisations for orphan medicines as compared to those for non-orphan products.

For this analysis the required data was the number of marketing authorisations for orphan and non- orphan medicines in EEA in the period 2000-2017.

The calculations made included:

- the average number of marketing authorisation for orphan medicinal products if development of orphan medicines would have been in line with non-orphan, general ones
- the extra development, assessed as the difference between actual and expected average number measured as products per year; and
- a correction applied as some products have been withdrawn after authorization.

The study points out that the analysis should ideally have used the following information which were not available at the time of the study:

- company data on R&D costs
- production and marketing costs, pricing and revenues from individual products to show how these factors influence the decisions of companies to start or continue the development process of new orphan medicines, and how the rewards (public research, protocol assistance, fee waivers, market exclusivity) influence these decisions.

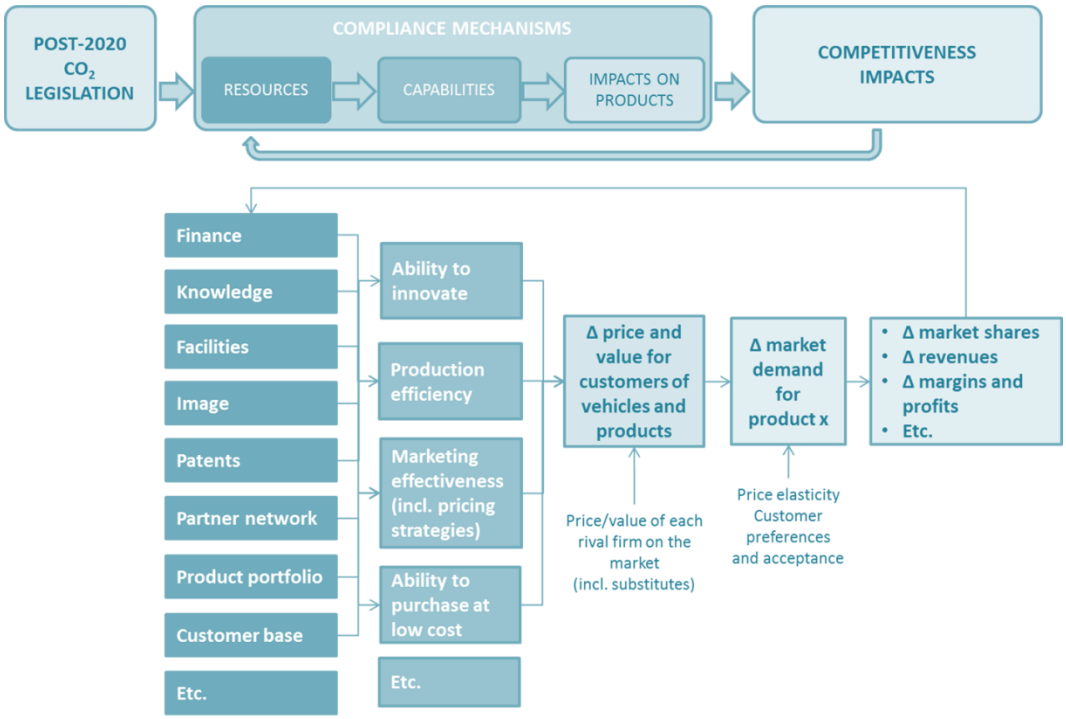
18.4 Impact pathways approach applied for the post-2020 LDV CO_2 regulation

Impact pathways are typically used by practitioners to explain and attribute impacts in complex systems. An example of such application using an impact pathway model can be found in the study "Assessment of competitiveness impacts of post-2020 LDV CO_2 regulation" prepared for the Directorate-General Climate Action of the European Commission.

The objective of this study is to assess possible impacts of post-2020 EU CO_2 legislation for light-duty vehicles (LDVs = passenger cars and light-commercial vehicles (LCVs or vans)) on the competitiveness of affected sectors in Europe. The study assesses three elements of competitiveness:

- **Cost competitiveness**: impacts from micro-economic perspective based on costs of compliance
- **Innovation competitiveness**: from a company's innovation capabilities perspective based on the need to introduce innovations to comply with regulatory requirements
- **International competitive-ness**: impacts from a macro-economic perspective, looking for example at resulting impacts on trade flows and cross-border investments.

The main conceptual model is illustrated below and has as objective to help identify possible competitiveness impact pathways of a post-2020 EU LDV CO2 legislation. This model has been used to analyse on the one hand how the legislation might affect the resources and capabilities of (companies in) affected sectors in different regions, and on the other hand how regional differences in the resources and capabilities of (companies in) affected sectors might affect their ability to deal with the consequences of the legislation.



Source: DG GROW (2015)

The **logic** applied is as follows:

- The competitiveness of companies is determined by the price and value of their products or services relative to the price and value of products or services of competing companies (selling similar products or services or alternatives that can serve as a substitute)
- Changes in the price and value of a company's product or service will change the relative attractiveness of the product or service, which will lead to changes in market shares
- The price and value of a company's products or services are determined by the company's capabilities to produce and sell attractive products or services, which in turn are determined by a range of resources
- Changes in market shares and profits resulting from changes in the competitiveness of a company's products are likely to affect the company's financial and other resources, causing a feedback loop.

The study builds on the above model to decompose for instance the relevant resources and capabilities of OEMs as basis for determining regional differences that may lead to competitiveness impacts. Detailed impact pathways are designed (see figure below) and highlights are described:

- The **financial position** of companies, which influences their ability to develop more efficient ICEVs and AFVs as well as their ability to temporarily absorb losses if competition does not allow full pass-through of the costs of compliance
  - In return, the financial position is affected by the profitability of a company's operations, which may be affected by the CO_2 legislation
- The **knowledge position of companies**, which influences their ability to develop more efficient ICEVs and AFVs vehicles
  - The **patent position** is part of the knowledge position and not only influences the ability to develop advanced ICEVs and AFVs but also to generate revenues by selling patents or licenses
- The **facilities of companies**, more specifically:
  - their efficiency of production
  - their geographical location, which influences cost of labour and possible other cost factors of production, and also determines transport costs
  - access to **suppliers** able to deliver components for the technologies of more efficient ICEVs and AFVs, and the cost at which these suppliers are able to sell the required components
- the **portfolio** of companies, which may determine:
  - why the same CO_2 reduction in vehicles with similar utility value may be more expensive for one or the other OEM
  - the extent to which OEMs can optimize the application of CO_2 reducing technologies over the entire sales portfolio and as well as to differentiate cost pass-through factors per segments (effectively allowing cross-subsidizing between segments)
- The **customer base**, which is characterised by aspects such as:
  - the brand loyalty of customers, also associated with the brand image
  - willingness to pay, or price elasticity
  - the division of sales over Europe and markets outside the EU.

18.5 Qualitative approaches

Every so often, data is not available. An example where qualitative methods complement the impact assessments to address innovation impacts is the IA on the *regulation on Minimum requirements for water reuse*. DG RTD used this as a pilot for testing the innovation principle (and thus Tool #21). Since it was not feasible to cover all aspects with monetised and quantified impacts, a qualitative assessment was performed including future projections through **expert involvement**. DG RTD invited water reuse experts from funded FP6, FP7, and Horizon 2020 projects for a dedicated workshop. The experts identified options, and reflected on innovation and market effects such as stimulating/hampering R&I, establishing/ hampering of stable product markets, fragmentation through local solutions, the stringency of the regulation, risk management etc.

Through the involvement of a group of experts, it was possible to include technological impacts.

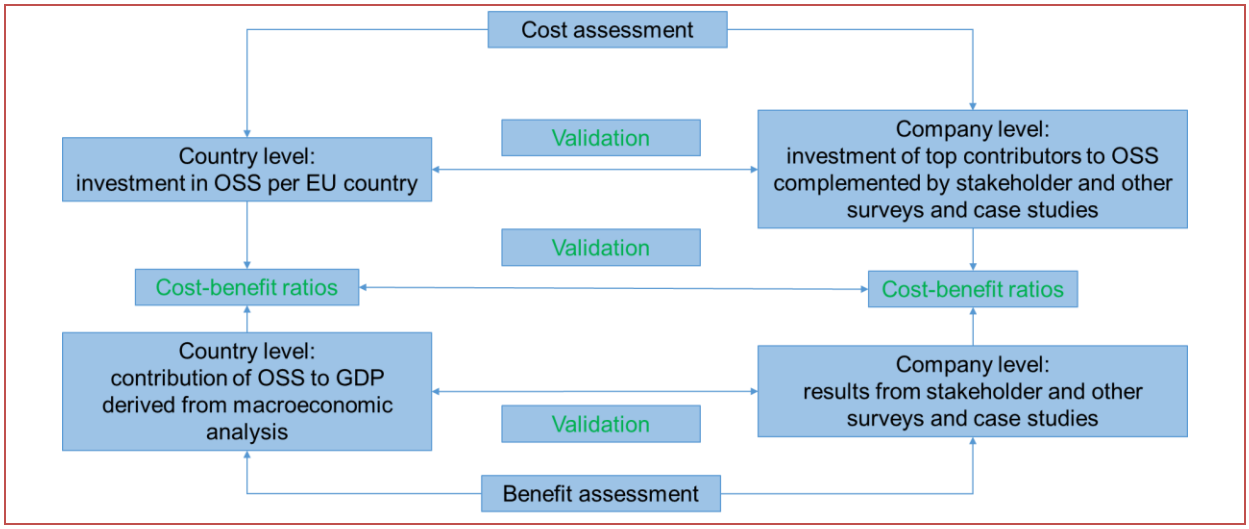
A **prospective view** was included in the *regulation on CO2 emissions standards for Heavy Duty Vehicles*. Here, the support study took into account about 80 existing technological devices but also pilots and design concepts (in total 80 devices), that all could have a (different) effect on CO_2 emission reduction of trucks. By integrating prospective technologies in the assessment, the study was able to point out anticipated technological changes beyond the current practices. Integrating a qualitative forward-looking perspective is key for future proofing.

18.6 Validation design applied for an impact assessment of Open Source

An example with a cost and benefit validation design is included in the study "the impact of Open Source software and hardware on technological independence, competitiveness and innovation in the EU economy" prepared for DG CNECT. The results of the study link to the Open Source software strategy 2020-2023.

The assessment of impacts of Open Source on the EU started with the generation of insights from econometric analyses, which focus on the assessment of the benefits at the level of the Member States. As a second step, a cost assessment was performed first at the level of the Member States and secondly on a sample of the most active companies in Open Source with a headquarter located in the EU. As a third step, the insights from the stakeholder survey and other surveys provided additional information to the cost dimension, but also to the benefit dimension mostly on a semi-qualitative level. This was complemented by mostly qualitative findings from case studies. Finally, cost-benefit ratios were determined not only at the macro level, but also at the micro level. Both were eventually matched in a last step to validate the findings from different levels and methodological approaches.

Figure 16 Validation framework of Open Source impact assessment



Source: Blind et al. 2021, p. 202

19. Auxiliary support material

Table 14 Linkages between this guide and the Better Regulation toolbox tools (2021 version)

Better Regulation Toolbox Content		Tool #	Step in guide
How to carry out an impact assessment	How to analyse problems	13	1
	How to set objectives	15	1
	How to identify policy options	16	2
Identify impacts in impact assessments, evaluations and fitness checks	Sectoral Competitiveness	21	3
	Research & innovation	22	3
Stakeholder consultation	The consultation strategy	52	4
	Conducting the consultation activities and data analysis	53	4
	Analysing data and Informing policymaking	54	5
Methodologies for analysing impacts and impact assessments, evaluation and fitness checks	Typology of costs and benefits	56	5
	Methods to assess costs and benefits	57	5
	Cost-benefit analysis	63	5
	Methods for evaluating causal effects	68	5
	Uncertainty and sensitivity analysis	65	6

Source: based on European Union, European Commission (2021). Better Regulation Toolbox.

Table 15 List of consultation questions

Questions
Impact on research and innovation
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?

Questions
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?

Source: Better Regulation Toolbox - Tool #22 (2021)

Figure 17 High level outline of a Non-disclosure Agreement (example)

1. DEFINITIONS
2. OBLIGATIONS
3. AGREEMENT NOT TO DISCLOSE OR USE CONFIDENTIAL INFORMATION
4. PERMITTED DISCLOSURES
5. EXEMPT DISCLOSURES
6. ACCURACY AND COMPLETENESS
7. DURATION
8. REPRESENTATIONS AND WARRANTIES
9. CONSEQUENCES OF BREACH
10. TERMINATION
11. NOTICES, PERMISSION OR OTHER COMMUNICATION UNDER OR IN CONNECTION WITH THIS AGREEMENT
12. NON-ASSIGNMENT or transfer any of its rights or obligations
13. SEVERANCE
14. VARIATION OF THE AGREEMENT
15. COUNTERPARTS
16. ENTIRE AGREEMENT BETWEEN THE PARTIES WITH RESPECT TO ITS SUBJECT MATTER
17. GOVERNING LAW AND JURISDICTION

ANNEX 1 – LIST OF AUTHORISED REPRESENTATIVES

ANNEX 2 – AGREED FORM CONFIDENTIALITY LETTER

ANNEX 3 – VALID SUBMISSION CONTENT

ANNEX 4 – INFORMATION DATASETS RELATING TO PERMITTED DISCLOSURES

Source: Technopolis Group

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This study provides an analysis on how innovation can be addressed in impact assessment of innovation-sensitive legislation. It does so by analysing various existing assessment studies and based on practices and expert views, provides suggestions and recommendations of how to improve quantitative analyses. The study includes a dedicated operational guide for practitioners.

Studies and reports

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