Study
An Innovation Check for Regulatory Impact Assessment
Making regulation innovation-friendly
Federation of German Industries (BDI)

Digitalisation, Innovation and Healthcare

Innovation Check in Regulatory Impact Assessment
Making regulation innovation-friendly

Contents

At a glance ............................................................................................................................................................................ 7

Summary .................................................................................................................................................................................. 8

1. Introduction – Why do we need an Innovation Check Tool to assess how proposed regulation impacts innovation and the ability of business to innovate? ............................................................................................ 10
   1.1 Background .................................................................................................................................................................. 10
   1.2 Current situation ........................................................................................................................................................ 11

2. Objective of the study and summary of approach ................................................................................................. 8
   2.1 Objective .................................................................................................................................................................... 12
   2.2 Summary of approach ............................................................................................................................................ 13

3. Outcome – The tool and its possible application .................................................................................................... 14
   3.1 Innovation Check Tool .............................................................................................................................................. 14
   3.2 Which actors should be involved in assessing how proposed regulation impacts innovation and the ability of business to innovate? ........................................................................... 21

4. Recommendations .......................................................................................................................................................... 24

5. Annex I: Methodological approach ............................................................................................................................ 26

6. Annex II: Definition and literature analysis ............................................................................................................ 30
   6.1 Definition and delineation of scope of study ........................................................................................................... 30
   6.2 Literature and document analysis ........................................................................................................................... 30

   7.1 Objective and selection of area of study ................................................................................................................ 39
   7.2 Finland – Best practice findings ............................................................................................................................ 40
   7.3 The United Kingdom – Best practice findings ....................................................................................................... 41
   7.4 European Union – Best practice findings ............................................................................................................ 42
   7.5 Summarised action recommendations of the international experts interviewed ............................................. 46

8. Bibliography ...................................................................................................................................................................... 48

Imprint .................................................................................................................................................................................... 50
List of Abbreviations

BDI  Federation of German Industries
BMBF  Federal Ministry of Research and Education
BMJV  Federal Ministry of Justice and Consumer Protection
BMWi  Federal Ministry for Economic Affairs and Energy
DG  Directorate-General
EU  European Union
F&E  Research and Development
ICT  Information and Communication Technology
GGO  Joint Rules of Procedure of the Federal Ministries
KIW  Kreditanstalt für Wiederaufbau (German development bank)
NESTA  National Endowment for Science, Technology and the Arts
NKR  National Regulatory Control Council
NKRG  Law on the National Regulatory Control Council
OECD  Organisation for Economic Cooperation and Development
R&D  Research and Development
R&I  Research and Innovation
RIA  Regulatory Impact Assessment
SMBA  Small and Micro Business Assessment
SME  Small and Medium Enterprises
STEM  Science, technology, engineering and mathematics
UNICE  Union of Industrial and Employers’ Confederation of Europe
UK  United Kingdom
VCI  German Chemical Industry Association
List of figures

Figure 1: Project phases ...........................................................................................................13
Figure 2: Legislative drafting process ..................................................................................22
Figure 3: Targeted users of the Innovation Check Tool .........................................................23
Figure 4: Project phases ......................................................................................................26
Figure 5: Selecting assessment questions for the Innovation Check ....................................27

List of tables

Table 1: Overview of expert interviews ..................................................................................28
Table 2: Participating ministries – ministerial officials workshop ........................................29
Table 3: BDI Innovation Indicator .......................................................................................34
Table 4: EU Innovation Scoreboard .....................................................................................36
Table 5: Overview of countries investigated .......................................................................39
Table 6: Finnish guidelines to assess the impact of proposed regulation on innovation ..........40
Table 7: Excerpt of “Checklist for impact identification” on innovation ...............................40
Table 8: Excerpt of Better Regulation Manual – Step 4: Identify the impacts ......................41
Table 9: Excerpt of Tool #18: Selection of factors affecting innovation .............................43
Table 10: Excerpt of Tool #18: Questions to be considered on “Factors Affecting Research & Innovation” .........................................................................................44
Table 11: Excerpt of Tool #18 on how the proposed policy option/intervention affects the innovation capacity of companies, notable SMEs .....................................................................46
The German and European regulatory frameworks need to foster an innovation-friendly climate
At a glance

Background

Regulatory impact assessment in Germany currently lacks a systematic analysis of the impact of proposed regulation on the ability of business to innovate.

Outcome

In the course of this study, an Innovation Check Tool was developed for regulatory impact assessment in Germany. The tool includes a short introduction on the topic of innovation and ten questions related to the potential impact of proposed regulation on the ability of business to innovate:

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research and development (R&amp;D)</strong></td>
<td>Does the proposed regulation have any foreseeable impact on the opportunities of companies and/or research institutes to collaborate, and with it their ability to conduct R&amp;D activities?</td>
</tr>
<tr>
<td><strong>Impetus for innovation</strong></td>
<td>Does the proposed regulation spur the creation of new markets and companies and the demand for innovative products and services?</td>
</tr>
<tr>
<td><strong>Compliance costs</strong></td>
<td>Does the proposed regulation entail compliance costs for business that are directly related to R&amp;D activities and/or to the development, launch and marketing of innovations?</td>
</tr>
<tr>
<td><strong>Ex-post evaluation</strong></td>
<td>Which of these assessment questions should be analysed in an ex-post evaluation of the law?</td>
</tr>
</tbody>
</table>

| **Technological neutrality**                                             | Is the proposed regulation results-based and formulated in a technologically neutral way? Does it leave open the processes/materials/technologies that can be used to meet the regulation's requirements? |
| **Implementation timetables**                                           | Is the period set for companies to implement the proposed regulation or adapt their processes long enough (particularly if innovation-related processual changes and long-term investments are involved)? |
| **EU legislation**                                                      | Does the proposed regulation deviate from the EU legislation required to be implemented into national law? |
| **Standards and norms**                                                 | Would the proposed regulation change standards and norms in a way that is likely to impact the international competitiveness of business? |
| **Skilled staff**                                                       | Does the proposed regulation have any foreseeable impact on the availability of qualified skilled staff for companies and/or research institutes? |
| **Financing**                                                           | Does the proposed regulation have any foreseeable impact on the access of companies and/or research Financing institutes to capital and funding? |

Recommendations

- Require all ministries to use the tool
- Include the tool in the policymaking process at an early stage
- Have industry use the tool in the context of legislative hearings
- Develop consolidated guidelines for RIA (incorporating the Innovation Check Tool)
- Establish a uniform definition of other costs
- Set up a helpdesk in all ministries
- Integrate the tool as a module in the training of ministerial officials
Summary

Objective and methodological approach

The Federal Government has set itself the objective of continually promoting and improving framework conditions that stimulate innovation. Furthermore, industry has called for an official recognition of an “innovation principle” in (European) regulatory practice. But this principle requires an empirical approach to present the respective impact on the ability of business to innovate. An Innovation Check Tool should therefore become an integral part of regulatory impact assessment.

The BDI commissioned the study in hand to investigate the possibilities for developing and implementing such a tool in Germany. The objective of the study was to develop an Innovation Check Tool to enable a systematic analysis of the impact of proposed regulation on the ability of business to innovate and thus create transparency regarding the impact of the regulatory environment.

The investigation of comparable approaches taken internationally, which can also be regarded as best practices, formed a key part of this study. Interviews were also held with 16 national and international experts working in the fields of better regulation and innovation policy. An analysis of the literature relevant to the topics of regulation and innovation was also conducted.

Key findings

- Regulatory impact assessment in Germany currently lacks a systematic analysis of the impact of proposed regulation on the ability of business to innovate.

- Nor is there a tool with which to assess the regulatory impact on the ability of business to innovate even though all relevant impacts are required to be analysed in the regulatory impact assessment with an explicit presentation of the other costs.

- In the course of this study, an Innovation Check Tool was developed for regulatory impact assessment in Germany. The tool is designed to give political decision-makers the opportunity to identify potential impact on the ability of business to innovate as a basis for transparent and sound decision-making.

- The tool includes a short introduction on the topic of innovation and ten questions related to the potential impact of proposed regulation on the ability of business to innovate.
Recommendations

The following action recommendations have been derived from the findings of this study. They serve as guidance on how to take greater consideration of the ability of business to innovate and to implement the innovation principle in the drafting of proposed regulation:

- The tool should be used by all ministries for the implementation of a systematic analysis and presentation of the impact of proposed regulation on the ability of business to innovate.

- In general, consolidated guidelines should be used that cover all aspects of regulatory impact assessment. We recommend integrating the assessment questions that probe how proposed regulation will impact the ability of business to innovate into already existing guidelines.

- A comprehensive, uniform definition of other costs is needed to make it possible to present and review these costs in the first place. Indirect costs should, for example, form an aspect of this definition.

- The Innovation Check Tool is designed for use not just by the federal ministries and the National Regulatory Control Council, but also by associations in the context of hearings. The aim is that the statements produced on how proposed regulation impacts the ability of business to innovate have a uniform structure and are prepared systematically.

- As a general rule, the potential impact of proposed regulation on the ability of business to innovate should be considered early in the political debate, in advance of the drafting of the bill and the regulatory impact assessment. The interaction of numerous different legal rules within one field of regulation often presents a substantial barrier to innovation. It is therefore recommended to incorporate possible impacts as early in the political debate as possible.

- A helpdesk should be set up as a central point of contact in each ministry to provide support in the review and presentation of the possible impact of proposed regulation on the ability of business to innovate.

- The assessment and presentation of the impact of proposed regulation on the ability of business to innovate should form a part of the training of ministerial officials so that they are better able to identify the complex and often indirect correlations between proposed regulation and innovation.
1. Introduction – Why do we need an Innovation Check Tool to assess how proposed regulation impacts innovation and the ability of business to innovate?

1.1 Background

"The New High-Tech Strategy – Innovations for Germany" of the Federal Government identifies innovations as the “key to growth, employment, prosperity and quality of life". Innovations can only be created in an environment of creativity, excellence and entrepreneurship. The Federal Government has set itself the objective of continually promoting and improving framework conditions that stimulate innovation as the necessary basis for developing a high level of innovative capacity and momentum in Germany. Innovation policy should thus “focus on providing good conditions for creative minds, on promising topics, on ensuring that all players are closely networked and on providing an innovation-friendly framework, so that knowledge leads to value creation”.

A central aim here is creating a suitable regulatory environment.

A transparent presentation of the impact of regulation on the ability of business to innovate should therefore be the first step in making the regulatory environment conducive for innovation.

An environment that promotes innovation is a competitive advantage for Germany as a business location and a basic condition for German business to hold its own in international competition.

Industry has called for an official recognition of an “innovation principle" in (European) regulatory practice. The idea, which was developed by members of the European Risk Forum, is that if a regulation is to be initiated in accordance with the precautionary principle, its impact on the ability to innovate should be taken into consideration within the political decision-making process. This kind of innovation principle should not promote innovations per se, irrespective of their impact on health and the environment. But this principle requires an empirical approach to present the respective impact on the ability of business to innovate. An Innovation Check Tool should therefore become an integral part of regulatory impact assessment. The BDI commissioned the study in hand to investigate the possibilities for developing and implementing such a tool in Germany.

4 See http://www.riskforum.eu/innovation-principle.html
1.2 Current situation

Regulatory impact assessment does not presently include a systematic consideration of the impact of proposed regulation on the ability to innovate. Generally, an account of the regulatory impact must be given, whereby: “Regulatory impacts means the main impacts of a law. This covers its intended effects and unintended side-effects.” Furthermore, details have to be given on the “other costs to industry”, which, according to the Federal Government, also include aspects such as a company’s capacity to innovate and undertake research and development activities. There are currently, however, no detailed guidelines for the review and presentation of other costs in general and of the impact of proposed regulation on the ability of business to innovate specifically. In view of this, the presentation of the impact on the ability to innovate has not been comprehensive. The SME test introduced in late 2015 is designed, as part of regulatory impact assessment, to systematically review and present the other costs for small and medium-sized enterprises, including the impact on their ability to innovate and conduct research and development. However, there are equally no detailed guidelines on conducting such a review for business in general or for presenting the impact of proposed regulation on the ability of business to innovate. And yet transparency on the possible impact of regulation is essential for the development and consideration of different alternatives, which must be presented in the introductory summary (front sheet) of Federal Government bills (C. Alternatives).

The impact of proposed regulation on innovation can be both direct and indirect, usually with complex interdependencies. On the international level, action has been taken to specify the impact of proposed regulation on the ability of business to innovate explicitly in the impact assessment guidelines and to develop specific assessment instructions to enable a systematic review and presentation and therewith achieve transparency on the possible impact of regulation. An example is the European Union’s Better Regulation Toolbox (Tool #18: Impact on Research & Innovation). The EU is also currently conducting a pilot project on what it calls “Innovation Deals” aimed at enabling innovators and regulators to reach a joint understanding of how new technologies and innovations can be progressed in existing regulatory frameworks.

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5 Joint Rules of Procedure of the Federal Ministries (GGO), Section 44(1).
6 GGO, Section 44(5).
8 Ibid.
9 See Federal Government (2011): GGO, p. 60 and GGO, Section 42(1).
2. Objective of the study and summary of approach

2.1 Objective

The objective of the study in hand is to develop an Innovation Check Tool that enables a more systematic review and presentation of the impact of proposed regulation on the ability of business to innovate within the context of regulatory impact assessment. The aim of this tool is to create transparency on how the regulatory environment impacts the ability of business to innovate.

Alongside the concrete development of assessment questions for the Innovation Check Tool, this process also included an analysis of the legal basis for such a review and the actors that need to be involved.

The Innovation Check Tool is designed to facilitate the identification of the potential impact of proposed regulation on the ability of business to innovate and to make it possible to present the potential impact identified in a transparent and comprehensible manner. This tool thus provides the basis for a substantiated analysis of possible alternatives in the course of conducting a regulatory impact assessment (front sheet, C. Alternatives.)

Proposed regulation in all fields can have both direct and indirect effects on the ability of business to innovate. These effects can be positive, in that the proposed regulation is expected to stimulate innovation and contribute to making the climate more conducive to innovation; or they can be negative, in that the proposed regulation is likely to indirectly impair the capacity for innovation. Proposed regulation can also have both a positive and negative impact on the ability of business to innovate. The correlations between proposed regulation and innovation tend to be very complex and often only become apparent over the course of time. This tool includes a series of assessment questions to identify these correlations and to sensitise users to the possible impact of proposed regulation on the ability of business to innovate. It is not a conclusive list of assessment questions, as a complete, all-inclusive checklist of the possible impact is not possible on account of the complex correlations between proposed regulation and innovation.

The assessment questions of the Innovation Check Tool are designed to raise awareness of certain important determinants of the ability to innovate – it does not replace an extensive review of the impact of proposed regulation on business in general.
2.2 Summary of approach

The project was divided into five phases. These project phases and the methodological steps are presented in the figure below.

As Figure 1 shows, the results of this study are based largely on the analysis of literature and documents, as well as qualitative interviews with experts and workshops that were held with a large number of actors working on innovation policy and regulatory improvement. The following institutions and actors were involved in the study in the form of qualitative interview and/or workshops:


A detailed presentation of our methodological approach is included in Annex I: Methodological approach (Chapter 5).

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**Figure 1: Project phases**

<table>
<thead>
<tr>
<th>Phase 0: Project launch and stock-take</th>
<th>Phase I: Identification and definition of indicators (how)</th>
<th>Phase II: Review of integration of Innovation Check Tool in the RIA (where/ when)</th>
<th>Phase III: Selection of an independent review body (who)</th>
<th>Phase IV: Development of action recommendations and reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Kick-off meeting</td>
<td>- Literature research</td>
<td>- Analysis of where to integrate the Innovation Check Tool – in which RIA guidelines and where on the front sheet – and when this should be done</td>
<td>- Identification of possible independent review bodies</td>
<td>- Validation of assessment questions (ministerial workshop)</td>
</tr>
<tr>
<td>- Exploratory interviews</td>
<td>- Expert interviews</td>
<td></td>
<td>- Interviews with representatives of potential review bodies</td>
<td>- Identification of examples</td>
</tr>
<tr>
<td>- Desk research to analyse current situation from a process perspective</td>
<td>- International best practice analysis</td>
<td></td>
<td>- Synthesis and processing for selection</td>
<td>- Synthesis of findings and development of action recommendations</td>
</tr>
<tr>
<td></td>
<td>- Set of indicators / assessment questions</td>
<td></td>
<td></td>
<td>- Reporting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Presentation of findings</td>
</tr>
</tbody>
</table>

Source: BDI
3. Outcome – The tool and its possible application

The central outcome of the study is the Innovation Check Tool developed in the course of the study and which is presented in the following section (Chapter 3.1). A further aspect of study was to explore who would be the targeted users of the Innovation Check Tool, at what stage in the regulatory process such a review would be most useful and what legal basis there is in current legislation for such a review (Chapter 3.2).

3.1 Innovation Check Tool

The Innovation Check Tool is set out in detail on the following pages. The following aspects were given particular consideration in the development of this tool:

- A tool that can be used to present all theoretically possible effects of a proposed regulation on the ability to innovate is impossible on account of the complex correlations and the large differences between the various legal areas. Guidelines that consider all possible aspects would not aid regulators but would rather be seen as an additional burden. Given the fact that there are many different guidelines that need to be followed in the context of a regulatory impact assessment and the generally high degree of time pressure under which proposed regulation is drafted, extensive and detailed guidelines that take all possible effects into account would not be expedient.

- The Innovation Check Tool is therefore limited to a few central assessment questions pertaining to the ability of business to innovate. All selected assessment questions meet the following criteria:

  - They are within the scope of the impact assessment of a regulation and therefore within the scope of influence of the respective ministerial official.
  - They can be estimated ex-ante in the course of a regulatory impact assessment.
  - They are as of yet not systematically reviewed in relation to the ability of business to innovate.
  - The questions are formulated in a simple way and explanations on possible correlations have been included for every assessment question. The listed correlations should be regarded as examples. The explanations serve to illustrate possible interdependencies in order to distinguish between those effects on business that are conducive to innovation and those that impede innovation.
  - This tool is not intended to explore the substantive content of regulation with regard to innovation funding or similar factors, nor to evaluate whether a proposed regulation contains particularly innovative elements itself. The tool is also not intended to be used to evaluate between the ability of business to innovate and other, possibly divergent, interests. This would go beyond the scope of a tool of this nature.

In sum, the tool is designed to help establish transparency on how a proposed regulation will potentially impact the ability of business to innovate.
Tool used within RIA to review how a proposed regulation will impact the ability of business to innovate (Innovation Check Tool)

What are innovations?
An innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method.\(^\text{12}\)

The objective of the Innovation Check Tool

The Innovation Check Tool is designed to facilitate the identification of the potential impact of proposed regulation on the ability of business to innovate and to make it possible to present the potential impact identified in a transparent and comprehensible manner. This tool thus provides the basis for a substantiated analysis of possible alternatives in the course of conducting a regulatory impact assessment.

Proposed regulation in all fields can have both direct and indirect effects on the ability of business to innovate. These effects can be positive, in that the proposed regulation is expected to stimulate innovation and contribute to making the climate more conducive to innovation; or it can be negative, in that the proposed regulation is likely to indirectly impair the capacity for innovation.

Proposed regulation can also have both a positive and negative impact on the ability of business to innovate. The correlations between proposed regulation and innovation tend to be very complex and often only become apparent over the course of time.

This tool includes a series of assessment questions to identify these correlations and to sensitise users to the potential impact of proposed regulation and the ability of business to innovate. It is not a conclusive list of assessment questions, as a complete, all-inclusive checklist of the potential impact is not possible on account of the complex correlations between proposed regulation and innovation. The assessment questions of the Innovation Check Tool are designed to raise awareness of certain important factors in the ability to innovate – it does not replace an extensive review of the impact of proposed regulation on business in general.

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Why is important to assess how proposed regulation will impact innovation?

“The New High-Tech Strategy – Innovations for Germany” of the Federal Government identifies innovations as the “key to growth, employment, prosperity and quality of life”. The Federal Government has set itself the objective of continually promoting and improving framework conditions that stimulate innovation as the necessary basis for developing a high level of innovative capacity and momentum in Germany. Innovation policy should thus “focus on providing good conditions for creative minds, on promising topics, on ensuring that all players are closely networked and on providing an innovation-friendly framework, so that knowledge leads to value creation”.

In view of the current structural transformation taking place towards a knowledge society, the ability of societies to expand and exploit their knowledge base and translate this into innovations that lead to sustainable products and services is becoming of increasing importance. A central aim here is creating a suitable regulatory environment. Policymakers must at an early stage be able to identify firstly whether a new technology requires new regulation, and secondly, whether the regulation is likely to impact the ability of business to innovate.

The ability of business to innovate constitutes one of the most important factors for the international competitiveness of Germany as a business location. An environment that promotes innovation is a competitive advantage for Germany as a business location and a basic condition for German business to hold its own in international competition.

For whom are the assessment questions relevant?
The following assessment questions provide assistance in identifying possible direct and indirect effects of a proposed regulation on innovation and the ability of business to innovate. The assessment questions are targeted primarily at the following three actors:

- Ministerial officials
For ministerial officials, the assessment questions are a tool to aid them in detailing the main impacts of the regulation under review, covering its intended effects and unintended side-effects (Section 44(1) GGO), and in presenting the other costs to industry (Section 44(5) GGO). It is in this context that a regulation’s impact on the ability of business to innovate is assessed. The following assessment questions are designed to assist the identification of the potential impact and the structured presentation of this impact in the explanatory memorandum and introductory summary (front sheet) of the draft bill.

- Associations
For associations, the assessment questions are a tool to assist them in structuring statements on proposed regulation that impacts innovations.

- National Regulatory Control Council (NKR)
For the National Regulatory Control Council, the assessment questions are a tool to help examine the presentation of other costs to industry pursuant to Section 1(3) of the Law on the National Regulatory Control Council (NKRG).

All parameters for innovations that are specified in the following assessment questions should therefore, ideally, also always be considered in an international comparison.

In practice, the review of all aspects of regulatory impact on an international comparison is very time-consuming. Ideally, the impact on business should always include a comparative examination by the respective addressees in order to ensure a comprehensive assessment of the relevant regulatory impact.

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15 Ibid. p. 17
16 Ibid. p. 26
17 In practice, the review of all aspects of regulatory impact on an international comparison is very time-consuming. Ideally, the impact on business should always include a comparative examination by the respective addressees in order to ensure a comprehensive assessment of the relevant regulatory impact.
### The assessment questions of the Innovation Check Tool

<table>
<thead>
<tr>
<th><strong>Is the proposed regulation likely to have direct or indirect effects on the ability of business to innovate?</strong></th>
<th>Technology neutrality</th>
<th>Implementation timetables</th>
<th>EU legislation</th>
<th>Standards and norms</th>
<th>Skilled staff</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the proposed regulation results-based and formulated in a technologically neutral way? Does it leave open the processes/materials/technologies that can be used to meet the regulation's requirements?</strong></td>
<td>Proposed regulation that is results-based and technologically neutral tends to be more conducive to innovation than regulation that stipulates the use of specific processes/materials/technologies. By specifying particular processes/materials/technologies, regulation tends to reduce the incentive to develop new, more innovative processes/materials/technologies. Proposed regulation that is formulated in a results-based and technologically neutral way leaves companies the leeway to develop innovative processes/materials/technologies to meet the targets stipulated by the regulation.</td>
<td>Brining forth innovations tends to be a costly and long-winded process, and is accompanied by high risks. Setting short periods of implementation in which companies are required to fulfill the specifications stipulated by the proposed regulation can thus obstruct long-term innovation planning. Short periods of implementation also stand in the way of combining the legally required investments with a company's own planned investments in an economically sensible manner, and this can lead to disproportionately higher conversion costs for companies. Longer periods of implementation, in contrast, enable companies to include certain investments and conversions in their longer-term innovation planning and thus reduce costs by combining the legally required changes with the company's own planned changes.</td>
<td>Proposed regulation that deviates from the EU legislation requires to be implemented into national law (e.g. by stepping up requirements to such an extent that they are out of proportion with EU legislation) can have a negative impact on the ability of companies in Germany to innovate. If, for example, an innovative product does not meet the requirements of other EU member states, this product might not be allowed to be sold in these countries. This reduces the incentive companies have to invest in innovations as it is not possible to sell the innovations in potential markets. Proposed regulation that does not, in contrast, deviate from EU legislation can have a positive impact on the ability to innovate as it contributes to further standardising the single market.</td>
<td>Proposed regulation that defines or steps up standards within the country, for example, by making certain product requirements or norms more stringent, can have a negative impact on the competitiveness and innovative capacity of domestic business. This is mainly the case when a proposed regulation defines higher standards for German business than those of international competitors, which can lead to higher costs for domestic innovations on an international comparison. Higher standards can, for example, trigger an increased relocation of production capacities and R&amp;D departments abroad. In principle, however, stepping up standards within the country can also help trigger innovations and thus contribute to the competitiveness of domestic business in the long term if, for example, the standards create the right environment for higher-quality or particularly safe products or services for which there is also demand (esp. from abroad).</td>
<td>A wide pool of domestic skilled staff (particularly in the STEM disciplines) and opportunities for the legal immigration of qualified skilled staff are important to the development of innovative capacity. Proposed regulation that narrows domestic education opportunities and impedes foreign-trained skilled staff from accessing the German labour market can have a negative impact on the ability to innovate. Proposed regulation that contributes to increasing the number of qualified skilled staff can, on the other hand, have a positive impact on the ability to innovate.</td>
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Innovation Check in Regulatory Impact Assessment  
Making regulation innovation-friendly
### Financing

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Does the proposed regulation have any foreseeable impact on the access of companies and/or research institutes to capital and funding?</td>
<td>Bringing forth innovations tends to be a costly and long-winded process, and is accompanied by high risks. Companies (esp. start-ups and SMEs) are often dependent on the availability of external financing and funding. Proposed regulation that restricts the financing of innovations or the access of companies to capital in general can therefore have a negative impact on the ability to innovate. Proposed regulation that facilitates the financing or access to (venture) capital can have a stimulating impact on innovations.</td>
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### Research and Development

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<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Does the proposed regulation have any foreseeable impact on the opportunities of companies and/or research institutes to collaborate, and with it their ability to conduct R&amp;D activities?</td>
<td>Many innovations are created in the context of collaborations, for example, between companies and (public/private or university/non-university) research institutes. Innovation networks in which these players collaborate are thus often an important precondition for innovations on account of the knowledge and infrastructure shared in this collaboration. Proposed regulation that restricts collaboration in the innovation environment and with it the access to knowledge and infrastructure can have a negative impact on the ability to innovate. Proposed regulation that, on the other hand, is favourable to or supports (also financially) collaboration and the sharing of knowledge can have a positive impact on innovation activities and contribute to improving the regulatory environment for innovations.</td>
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### Impetus for innovation

<table>
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<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Does the proposed regulation spur the creation of new markets and companies and the demand for innovative products and services?</td>
<td>Proposed regulation can impede the creation of new markets and companies and with it innovations by, for example, creating high barriers to market entry. The regulation of the demand for products and services can weaken the incentive for innovative companies both to increase their market share and to make further investments in innovations. Proposed regulation, on the other hand, that spurs the creation of new markets and companies, for example, by dismantling market entry barriers or deregulating certain areas can have a positive impact on innovations.</td>
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### Compliance costs for business and impact of these costs on ability to innovate

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<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Does the proposed regulation entail compliance costs for business that are directly related to R&amp;D activities and/or to the development, launch and marketing of innovations?</td>
<td>The compliance costs of a proposed regulation can generally have two major impacts on innovations: 1. Compliance costs related to the development of innovations or the production factors necessary to achieve these innovations (skilled staff and/or financing) or to the launch or marketing of innovations are a disincentive for innovations. For example, a proposed regulation could lead to high compliance costs for the hiring of qualified skilled staff or for the launch of a new innovative product or service. 2. Generally speaking, the higher the compliance costs, the fewer resources a company has to invest in innovation development.</td>
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### Ex-post evaluation

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>Ex-post evaluation</td>
<td>If you have calculated compliance costs of more than one million euros and therefore plan to evaluate the regulation, please note whether, on the basis of these assessment questions, you suspect that the proposed regulation will have an impact on innovations that should be analysed in an ex-post evaluation of the law.</td>
</tr>
</tbody>
</table>
Selected examples to illustrate the correlations between individual assessment components

Example 1: AMNOG

Regulation:
- The Act on the Reform of the Market for Medicinal Products (AMNOG) also introduced an early benefit assessment of innovative medicinal products.

- Section 35a of the Fifth Book of the Social Code (SGB V) stipulates that a benefit assessment needs to be conducted for all newly authorised medicinal products directly after introduction to market. The outcome is used to decide how much the German statutory health insurance funds (GKV) pay the manufacturer for the medicinal product.

- Since the entry into force of the 14th Act to Amend the Fifth Book of the Social Code over two years ago, the discounted price negotiated between the manufacturer and the GKV is required to be made public.

Barrier to innovation:
- AMNOG stifles innovation as the whole process of an early assessment of benefits does not give the participants sufficient planning certainty.

- The requirements in the authorisation procedure should be harmonised with the requirements set out in the benefit assessment and be subjected to similar criteria. Otherwise there is a risk that patients are denied access to innovative medicinal products as the health insurance funds are not just focused on day-to-day medical care and clinical practice, but also have an eye on the later reimbursement price.

- These different assessment procedures often harbour the danger that the value of medicinal products are not identified or not recognised for formal reasons.

- If this results in inadequate reimbursement prices, this has a negative impact particularly on SMEs whose main market is Germany. This can also be a real barrier to innovation for large international corporations as well.

- Amending the law with the requirement that the agreed discounted price is made public has had the result that 70 percent of the prices for new medicinal products in Germany are below those in 15 European countries taken as a comparison. Around one-third of the prices are even the lowest in the area of comparison. Germany serves as a price reference country for around 80 countries, which makes the basis for negotiations in those countries exceedingly poor. Pharmaceutical companies abroad are feeling increasing pressure from the publicly disclosed discounted prices as these prices are often regarded as the upper limit.

Classification according to the Innovation Check Tool:
- This provision of the AMNOG, and above all the amending act, fall into the category of “Standards and norms”.

- The standard introduced in the regulatory environment stifles innovation. This problem should be remedied in the near future as part of the dialogue with the pharmaceuticals industry.18

Example 2: REACH regulation

Regulation:
- The REACH regulation19 (Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force in June 2007. REACH was designed to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market. It was also designed to enhance competitiveness and innovation.


19 See Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (EC 1907/2006).

Barrier to innovation:

- Experts criticise the authorisation process mainly for being too complex and too costly and for causing a high degree of legal uncertainty.

- The authorisation of substances are decided on a case-by-case basis and only for a certain period of time set by the European Commission. An extension has to be applied for a minimum of 18 months before this period expires. This application is, again, decided on a case-by-case basis, and an extension does not necessarily have to be granted for the same substance.\(^{21}\)

- Companies can therefore not be absolutely certain that they will receive an authorisation extension, and this barrier ultimately has a negative effect on innovative capacity. This affects SMEs in particular, as the high costs and complex processes impede their development of new substances.

Classification according to the Innovation Check Tool:

- The requirements of the REACH regulation fall into the category of “Standards and norms”.

- Although this is an EU regulation, it has created a procedural standard that produces legal and planning uncertainty for companies.

Example 3: De-Mail Act

Regulation:

- The Federal Government initiated the Law on De-Mail Services in Electronic Communications (De-Mail Act)\(^{22}\) with the aim of regulating the authorisation of so-called de-mail service providers\(^{23}\) and the activities that they may conduct.

- According to the explanatory memorandum of the law,\(^{24}\) de-mail services should, among other things, enable citizens, companies and the public administration to reduce the amount of paper mail that send and receive.

Barrier to innovation:

- The assumption here is that the use of electronic messages can significantly reduce the material and process costs of paper mail and therefore lead to a substantial reduction of overall costs.

- However, the regulation is formulated with concrete specifications of processes/materials/technologies by including detailed technical guidelines in the technical section of the regulation.

- According to expert opinion, this has reduced the incentives to develop new and more innovative processes/materials/technologies.

- In contrast, the European Commission adopted a regulation on electronic identification and trust services for electronic transactions in the internal market (eIDAS Regulation),\(^{25}\) the structure of which is much more positive regarding ability to innovate:

  - This regulation also regulates digital delivery services but only the fundamental issues of security and legal consequences.

  - The design of products and services is left to the providers so they are free to develop innovative processes/materials/technologies to meet the formulated targets.

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\(^{21}\) See Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (EC 1907/2006), Article 60 et seq.

\(^{22}\) See Law on De-Mail Services in Electronic Communications (De-Mail Act) of 28 April 2011 (Federal Gazette I, p. 666), as last amended by Article 3(8) of the Act of 7 August 2013 (Federal Gazette I, p. 3154).

\(^{23}\) These are defined as providers of “services on an electronic communication platform designed to be a secure, confidential and verifiable business correspondence for everyone on the internet”, see Section 1(1) De-Mail Act.


Classification according to the Innovation Check Tool:
- The regulations of the De-Mail Act fall into the category of “Technological neutrality”.
- Specific stipulations of technical details and the consequent restrictions on implementation can work against the further development of already developed technologies and there with innovation.

Example 4: The X-Ray and the Radiation Protection Ordinance

Regulation:
- An evaluation of the radiation exposure of a clinical research project with accompanying diagnostics using ionising radiation is regulated in the X-Ray and Radiation Protection Ordinance (StrlSchV).
- As part of the authorisation procedure in Germany of a clinical trial by the regulatory authority and the ethics committee (national vote), the Federal Office for Radiation Protection (BfS) must be included in the national vote and thus also legally obliged to adhere to the time periods set out in the EU Regulation on Clinical Trials (EU-CTR).

Barrier to innovation:
- This procedure is only required in this form in Germany.
- According to expert estimates, the additional authorisation required from the Federal Office for Radiation Protection has led to delays of between two and nine months for the start of a clinical study in Germany.

Classification according to the Innovation Check Tool:
- The outcome of this regulation and the raising of standards in Germany is longer and less predictable authorisation periods.
- Experts claim that this has led some companies to decide not to conduct such studies in Germany any longer.

Example 3.2 Which actors should be involved in assessing how proposed regulation impacts innovation and the ability of business to innovate?

The federal ministry with overall responsibility is generally required to present the regulatory impact of proposed regulation. According to the majority of experts surveyed, an analysis and presentation of how proposed regulation on the ability of business to innovate can have a beneficial effect on regulation if it is conducted as early as possible in the legislative process.

The review and presentation of the impact of proposed regulation on the ability of business to innovate includes, as outlined above, an analysis of complex correlations, which are often of an indirect nature. With this in mind, the various actors that are involved in the legislative process should also be incorporated in the analysis and presentation of the impact of proposed regulation on the ability of business to innovate.

The following figure shows the process of drafting a regulation and the opportunities for considering the impact of the proposed regulation on the ability of business to innovate.

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26 See Verordnung über den Schutz vor Schäden durch ionisierende Strahlen (Strahlenschutzverordnung – StrlSchV).

In the early phases of drafting a regulation, there are three actors in particular that take on a central role in relation to the review and presentation of the regulatory impact and therewith also the potential impact on the ability of business to innovate. These should also be the target recipients of the Innovation Check Tool and include:

- the respective federal ministry,
- the relevant associations, and
- the National Regulatory Control Council.

The federal ministry with overall responsibility is required to present the major impacts of a regulation (Section 44(1) GGO), and other costs to industry (Section 44(5) GGO). These other costs include the impact on the ability of business to innovate. The basic duty to review and present the impact therefore lies with the responsible federal ministry. The Innovation Check Tool developed in the course of this study should be interpreted as an aid to meet this statutory duty, one that provides guidance for the systematic identification of the major impacts of a proposed regulation on the ability of business to innovate. The tool familiarises ministerial officials with the topic of innovation while also providing them with guiding questions as an introduction to analysing and presenting the impact on the ability of business to innovate.

If their interests are affected, central and umbrella associations and the expert community at the federal level should be involved early on and provided with the draft bill as soon as possible. The Innovation Check Tool is thus also targeted at associations and expert communities. Statements that address the impacts of a proposed regulation on the ability of business to innovate should be structured according to the assessment questions and systematically present the impacts. Ideally, the presented correlations should be substantiated with quantitative data. Associations can play a key role in the provision of data and practical evidence, which is important as there is generally very little data available on the impact on the ability of business to innovate. This, in turn, makes the work of the federal ministries more difficult.

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**Figure 2: Legislative drafting process**

Phase II – Zwischenergebnisse

- Preparatory phase incl. preparatory meetings
- Preparation of ministerial draft
- Consultation on ministerial draft
- Cabinet decision on government draft
- Opinion of the Bundesrat
- Reading and vote in Bundestag
- Vote in Bundestag
- Signing and promulgation of the law

- Drafting of and consultation on positions paper
- Drafting of and consultation on positions paper
- Presentation of other costs

Source: The Potsdam eGovernment Competence Center, Vollzugsorientierte Gesetzgebung: Wie können EU, Bund, Länder und Kommunen die Folgekosten rechtlicher Vorgaben besser ermitteln? Expert opinion commissioned by the NKRF.

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28 Source: The Potsdam eGovernment Competence Center, Vollzugsorientierte Gesetzgebung: Wie können EU, Bund, Länder und Kommunen die Folgekosten rechtlicher Vorgaben besser ermitteln? Expert opinion commissioned by the NKRF.

29 “The timing, scope and selection will be left to the discretion of the lead Federal Ministry, unless specific rules stipulate otherwise.” GGO, Section 47(3).
According to Section 1(3) of the Law on National Regulatory Control Council (NKRG), the Council examines “in particular […] the description of the compliance costs of new regulations for citizens, the business sector and public administration in terms of comprehensibility and correct methodology, as well as the description of the other costs to industry and especially for small and medium-sized enterprises”. The National Regulatory Control Council thus has the duty to review the presentation of other costs to industry with regard to the impact on the ability of business to innovate. The Innovation Check Tool can also be used as a basis for the NKR to review the other costs.

The following figure illustrates the respective roles of the three actors. The impacts of a proposed regulation on the ability of business to innovate identified through the use of the Innovation Check Tool can also provide guidance to the Bundestag in the next stages of the legislative process in terms of evaluating proposals and forming political opinions.

In sum, various actors are currently involved in the presentation and review of regulatory impact. The actors specified in the GGO as responsible for the presentation and review of other areas of regulatory impact should also be responsible for presenting and reviewing the regulatory impact on the ability of business to innovate. As this is a complex issue, the tool can be useful to assist them in their impact assessment.

Figure 3: Targeted users of the Innovation Check Tool

1. Responsible lead federal ministry (GGO Sec. 44(1) and (5))
2. Associations via hearing (GGO Sec. 47(1) and (3))
3. NKR (NKRG Sec. 1 (3))
4. Recommendations

The action recommendations listed below are derived from the findings of this study. They serve as guidance on how to take greater consideration of the ability of business to innovate and to implement the innovation principle in the drafting of proposed regulation:

- A systematic review and presentation of the impact of proposed regulation on the ability of business to innovate requires action-based guidelines that assist the federal ministries in drafting regulation that takes this impact into account.

- In the interests of maintaining clarity and comprehensibility, a consolidated set of guidelines for all aspects of regulatory impact assessment are generally preferable to separate guidelines for every different aspect. We recommend integrating the assessment questions that probe how proposed regulation will impact the ability of business to innovate into already existing guidelines and/or to include them in the eGesetzgebung30 (e-legislation) project.

- The review and presentation of the impact of proposed regulation on the ability of business to innovate is not a new task in regulatory impact assessment. It is already one of the tasks of the National Regulatory Control Council. In practice, however, the presentation of these costs and their review has not been comprehensive. We make the following two recommendations to improve this situation:

  - A comprehensive, uniform definition of other costs is needed to make it possible to present and review these costs in the first place. The first steps in this direction have been taken already. A clear definition now needs to be agreed upon and used across the board. Indirect costs and the impact on the ability of business to innovate should form a part of this definition.

  - Although the presentation and review of the impact of proposed regulation on the ability of business to innovate is not a new task in regulatory impact assessment from a legal standpoint, it is, in practice, a new activity as it has not been carried out comprehensively in the past. To increase the fulfilment of these review and presentation duties in practice, sufficient personnel resources have to be made available to carry out this task. This applies in particular to the National Regulatory Control Council’s activities relating to the review of the presentation of other costs. The tasks of the National Regulatory Control Council have increased steadily, so the amount of personnel required for these tasks need to be calculated and provided for.

- The Innovation Check Tool is designed for use not just by the federal ministries and the National Regulatory Control Council, but also by associations in the context of hearings so that the statements produced on how proposed regulation impacts the ability of business to innovate have a uniform structure and are prepared systematically. A presentation of possible effects based on the assessment questions of the Innovation Check Tool would make the statements from associations more systematic and enable the presentation of concrete correlations on the basis of defined indicators – ideally supplemented with concrete figures and practical evidence. The work of the federal ministries would be made much easier if the information is provided according to a uniform standard and defined criteria.

- As a general rule, the potential impact of proposed regulation on the ability of business to innovate should be considered early in the political debate, in advance of the drafting of the bill and the regulatory impact assessment. The interaction of numerous different legal rules within one field of regulation often presents a substantial barrier to innovation. This is generally beyond the scope of influence of the respective ministerial official who is tasked with drafting regulations. This barrier was therefore outside the scope of investigation of this study. As already mentioned, first steps have been taken on the international level to address this matter. The EU is currently, for example, conducting a pilot project called “Innovation Deals”. Its aim is to improve the understanding among regulators and innovators of innovations in the context of the legislative process. It would make sense to review to what extent such approaches could be a relevant option for Germany.

- A helpdesk should be set up as a central point of contact in each ministry to provide support in the review and presentation of the potential impact of proposed regulation on the ability of business to innovate.

The review and presentation of the impact of proposed regulation on the ability of business to innovate should be incorporated in the training of ministerial officials. The complex and often indirect correlations between proposed regulation and the ability of business to innovate are easier to classify once examples of these correlations have been illustrated. In practice, in the process of drafting concrete proposed regulation there is often not the time to analyse examples that could assist in the identification of correlations. To further aid the actors involved, the Innovation Check Tool should be further developed on a continuous basis and supplemented with more concrete examples to illustrate the interdependencies of the individual components being assessed.
5. Annex I: Methodological approach

The project was divided into five phases, which are shown in the figure below:

The individual steps are described in detail in the following sections.

**Phase 0 – Project launch and stock-take**

The objective of this phase was to finalise the concrete research questions of the study, including the parameters, methodology and detailed project planning.

A kick-off meeting was held on 2 October 2015 to jointly specify the concrete research questions and to coordinate the next steps with regard to project communication and project timetable.

For an initial stock-take of the current situation on considering innovations within the RIA process in Germany, a total of three exploratory interviews were held, supported by web-based desk research.

**Phase I – Identification and definition of indicators (how)**

The aim of Phase 1 was to identify an adequate set of indicators/questions that could be used within RIA to assess the impact of proposed regulation on innovation.

Literature was analysed, including studies, essays and working papers, on topics ranging from innovation, legislative procedures and regulatory impact assessment to the impact of regulation on innovative capacity and international RIA guidelines of other countries and the EU. The analysis also included looking at the extent to which indicators of existing sets of innovation indicators, such as those of the BDI Innovation Indicator and the EU Innovation Scoreboard, could be used in an ex-ante assessment within RIA.

To validate the results of the literature analysis and to identify adequate indicators/assessment questions for the ex-ante review of the impact of proposed regulation on innovations, qualitative interviews were held with innovation experts working on the national and international level.

31 See Table 1 for a detailed overview of all expert interviews held.

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**Figure 4: Project phases**

<table>
<thead>
<tr>
<th>Phase 0</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project launch and stock-take</td>
<td>Identification and definition of indicators (how)</td>
<td>Review of integration of Innovation Check Tool in the RIA (where/when)</td>
<td>Selection of an independent review body (who)</td>
<td>Development of action recommendations and reporting</td>
</tr>
</tbody>
</table>

- Kick-off meeting
- Exploratory interviews
- Desk research to analyse current situation from a process perspective
- Literature research
- Expert interviews
- International best practice analysis
- Set of indicators / assessment questions
- Analysis of where to integrate the Innovation Check Tool – in which RIA guidelines and where on the front sheet – and when this should be done
- Identification of possible independent review bodies
- Interviews with representatives of potential review bodies
- Synthesis and processing for selection
- Validation of assessment questions (ministerial workshop)
- Identification of examples
- Synthesis of findings and development of action recommendations
- Reporting
- Presentation of findings

Source: BDI
The analysis of international best practices included examining the guidelines for regulatory impact assessment of the following countries: Denmark, Estonia, Finland, the United Kingdom, the Netherlands, Austria, Poland, Sweden and the United States. The relevant guidelines of the European Commission (especially the Better Regulation Toolbox and Regulatory Screening) were also analysed. Based on the analysis of these international guidelines and the recommendations given in the exploratory interviews, the United Kingdom and Finland and the European Union were selected as areas of investigation in the analysis of international best practices. The objective of this analysis was to learn from the experiences of other countries that already incorporate an assessment of innovation effects in their respective RIA guidelines.

- How can the impact of proposed regulation on innovation be reviewed within RIA? What information is necessary for this?
- Where do the results have to be presented, and when does the review have to take place?
- Who conducts the review?

Alongside the analysis of the guidelines available from the respective lawmakers, four expert interviews were held with each institution.
The following table provides an overview of all the semi-structured expert interviews conducted as part of the study.

<table>
<thead>
<tr>
<th>Institution</th>
<th>Department / division / organisational unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Regulatory Control Council</td>
<td>Secretariat</td>
</tr>
<tr>
<td>National Regulatory Control Council</td>
<td>Secretariat Head / Deputies</td>
</tr>
<tr>
<td>Federal Chancellery</td>
<td>Bureaucracy Reduction Office</td>
</tr>
<tr>
<td>Federal Ministry for Economic Affairs and Energy</td>
<td>Future of the EU, Justice and Home Affairs, Better Regulation</td>
</tr>
<tr>
<td>Federal Ministry for Economic Affairs and Energy</td>
<td>Special Bureaucracy Reduction Projects, deregulation</td>
</tr>
<tr>
<td>Federal Ministry for Economic Affairs and Energy</td>
<td>Innovation and Technology Policy</td>
</tr>
<tr>
<td>Federal Ministry of Education and Research</td>
<td>Innovation Strategies</td>
</tr>
<tr>
<td>Federal Ministry of the Interior</td>
<td>Better Regulation, Bureaucracy Reduction, Act on E-Government, Local Authorities</td>
</tr>
<tr>
<td>Office of Technology Assessment</td>
<td>Deputy Directors</td>
</tr>
<tr>
<td>Centre for European Economic Research</td>
<td>Economics of Innovation and Industrial Dynamism</td>
</tr>
<tr>
<td>German Institute for Economic Research</td>
<td>Firms and Markets</td>
</tr>
<tr>
<td>European Commission</td>
<td>DG Research &amp; Innovation - Innovation Union Policy</td>
</tr>
<tr>
<td>European Commission</td>
<td>Secretariat-General - Impact Assessment</td>
</tr>
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<td>European Commission</td>
<td>DG Research &amp; Innovation - Evaluation Unit</td>
</tr>
<tr>
<td>Ministry of Employment and Economy, Finland</td>
<td>Better Regulation</td>
</tr>
<tr>
<td>Department for Business, Innovation and Skills, United Kingdom</td>
<td>Better Regulation</td>
</tr>
</tbody>
</table>

Phase II – Review of integration of Innovation Check Tool in the RIA (where/when)

The objective of this phase was to define at what stage in the regulatory process such a review would be most useful and what legal basis there is in current legislation for such a review.

For this purpose, the relevant legal parameters were analysed, in particular the Joint Rules of Procedure of the Federal Ministries (GGO) and the Law on the National Regulatory Control Council (NKRG). Further information was gleaned from the expert interviews.

This analysis was supplemented by an analysis of the relevant guidelines, such as the “Manual for the Preparation of Legal and Administrative Regulations”32, the “Manual for Drafting Legislation”33, the “Guide to Regulatory Impact Assessment”34 and the “Guide to Determining Compliance Costs”35.

Phase III – Selection of an independent review body (who)

The objective of this phase was to analyse which institution(s) should conduct a review of the impact of proposed regulation on innovation within the RIA process.

The first step here was to identify the various tasks of a “review”: 1) Identification of potential impacts; 2) Analysis of these potential impacts; 3) Monitoring whether the review of potential impacts on innovation was carried out.

Possible organisations that could take on one or more of the tasks listed above were then identified. Three expert interviews were then held with organisations that could take on one or more of these tasks.

The results of this phase are the identification of organisations that we recommend should be involved in a review of the impact of innovations within RIA.

Phase IV – Development of action recommendations and reporting

The objective of this phase was to bring together and process all findings produced so far.

The practical application of the developed assessment questions were discussed in an ministerial workshop on 26 January 2016. Participants from a number of federal ministries were invited to participate. The following figure shows which ministry representatives took part in the workshop.

The results of the ministerial workshop were, where relevant, fed into the final revision of the assessment questions of the Innovation Check Tool.

An outcome of the ministerial workshop were examples of how regulations have impacted innovative capacity; these examples were incorporated into the Innovation Check Tool. Further possible examples were identified through an internal survey of selected BDI member companies. The examples were then analysed with regard to their relevance and comprehensibility before being integrated into the Innovation Check Tool.

<table>
<thead>
<tr>
<th>Table 2: Participating ministries – ministerial officials workshop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
</tr>
<tr>
<td>Federal Ministry for Economic Affairs and Energy</td>
</tr>
<tr>
<td>Federal Ministry for Economic Affairs and Energy</td>
</tr>
<tr>
<td>Federal Ministry of the Interior</td>
</tr>
</tbody>
</table>
6. Annex II: Definition and literature analysis

6.1 Definition and delineation of scope of study

The OECD defines innovation as the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method. The ability of innovate is the ability to implement an idea for a new or significantly improved product, service or process, and to successfully introduce the new solution (innovation) on the market.

The ability of business to innovate is thus the ability of business to create and bring to market new or significantly improved products (goods or services) or processes, or new marketing or new organisational methods.

The object of the study in hand was to examine the options for a systematic review of the impact of proposed regulation on the ability of business to innovate within the context of regulatory impact assessment. The focus of the study was thus on the identification of the aspects of proposed regulation that could impact the ability of business to innovate. The study did not focus on analysing the different kinds of innovations (such as technical, organisational, institutional or social innovations or innovations relating to specific business segments).

In Joseph Schumpeter's classical definition of innovation, he describes the essence of innovation as the "introduction of new combinations". Schumpeter's definition of innovation distinguishes innovation from the invention phase in that it pertains to introducing new business, technical or organisational solutions on the market. This definition does not include diffusion as forming an aspect of new combinations.

This definition diverges from the R&D phases, which the OECD includes under "technology innovation activities":

"Technology innovation activities are all of the scientific, technological, organizational, financial and commercial steps, including investments in new knowledge, which actually, or are intended to, lead to the implementation of technology in new or improved products and processes." 39

So, innovations do not only comprise product innovations or technical aspects but also include new organisational methods and business models/methods. The different types of innovation can be classified as follows:

- Technical innovations (new product features/characteristics, novel products and production processes, etc.).
- Organisational innovations (new structures or procedures, new management systems, etc.).
- Innovations related to specific business segments (new services and service concepts, fundamentally new procurement and sales markets, etc.).
- Institutional innovations (new organisations such as funding agencies, new systems of regulation such as certification systems, etc.).
- Social innovations (new lifestyles, etc.).

Innovations can also be further differentiated between incremental and radical, or disruptive, innovations. 40 Incremental innovations are relatively minor improvements in already existing product lines, service offerings and processes.

- Radical, or disruptive, innovations are the introduction of completely new products, processes or business models that lastingly change the “rules of the game” on the market.

6.2 Literature and document analysis

The ability of business to innovate is determined by a number of factors. The regulatory environment is one of these factors, while other factors are largely beyond the scope of legal influence.

Furthermore, proposed regulation is generally embedded in an extensive legal framework. which makes it more difficult to identify the specific causes (proposed regulation) of specific impacts (promoting or hindering

innovation). The literature on this subject usually points out this ambiguous causal relationship:

In sum, scientific literature specifies three aspects of this causal relationship:

- Relations between regulation and innovation are seldom linear. These two variables are embedded in existing systems in which interdependencies and complex chains of cause and effect are the norm.41

- The regulatory environment can be either positive and promote innovation, or negative and hinder innovation. It can also be a mixture of the two, having both a positive and a negative impact at the same time.42

- The majority of innovation processes develop gradually over time (incremental innovation), making them very difficult to quantify/measure. There is consequently rarely clear empirical data available to substantiate statements on negative or positive correlations.

There are a number of studies on the casual relationship between regulation and innovation. Studies done by the Union of Industrial and Employers’ Confederation of Europe (UNICE), the European Commission and the German Chemical Industry Association all identify factors that determine the level of innovation.

Many of these factors are outlined in the following.

UNICE surveyed 2,500 companies in 14 European countries on the impact of regulation on innovation.46 It identified the following six “principal determinants of successful innovations”:

- Minimisation of costs
- Low time to market
- Fulfilment of customer requirements
- Ability to gain access to new ideas
- Having a flexible organisation
- Low level of uncertainty

For each of these six factors, the companies surveyed were asked whether legal standards made meeting these conditions easier or more difficult.

The following four “determinants of successful innovations” were rated by the surveyed companies as being made more difficult or much more difficult through regulation:

- Minimisation of costs (75% of companies surveyed)
- Having a flexible organisation (59% of companies surveyed)
- Low time to market (54% of companies surveyed)
- Low level of uncertainty (49% of companies surveyed)

43 These include: i) invention phases in R&D ii) phases in the implementation of innovative goods on the market. See: Pelkmans, J., Renda A. (2014a): “Does EU regulation hinder or stimulate innovation?” European Commission, p. 16.
In its report “Does EU-regulation hinder or stimulate innovation?”, the European Commission identifies the following five aspects of regulation that impact innovation:

- **Administrative burdens**
  Regulation that creates red tape or administrative burdens for companies can limit its (time) resources for innovation activities. These regulatory market entry barriers are particularly problematic for start-ups and potential new market participants.

- **Compliance burdens (stringency)**
  Compliance burdens relate to how difficult and costly it is for firms to comply with new regulatory requirements using existing ideas, technologies, processes and business models. Compliance burdens are particularly high where firms need to significantly change their behaviour or develop new technology in order to comply with the regulation.

- **Timing**
  The amount of time that a regulation gives to the targeted stakeholders for compliance with the regulatory requirements is essential to stimulate innovation. Making this period too short leads to excessive compliance costs and restricts the time available for the development and implementation of alternative processes, technologies and business models.

- **Flexibility**
  Performance- or outcome-based regulation stimulates innovation more than purely prescriptive regulation in that it sets rules and requirements for end products without specifying the means (processes/materials/technologies).

- **Uncertainty**
  Uncertainty with regard to future regulation and legal standards that lack stability/consistency can act as an inhibitor of innovation because investment in R&D generally entails long-term capital commitment.

  In a study commissioned by the German Chemical Industry Association (VCI), just under 200 VCI member companies in chemicals and pharmaceuticals were surveyed on innovation inhibitors both within and outside of the company and asked to rank these inhibitors.

  - **The external innovation inhibitors cited as having a bearing on the regulatory environment were as follows:**

    - Regulation and bureaucracy, and the comparatively unfavourable regulatory environment in Germany, were clearly identified as being the most significant obstacle to innovation. This includes notification and authorisation procedures for new products and processes and other provisions (such as documentation requirements) that tie up (time) resources. Furthermore, a changing, unstable or inconsistent legal framework can cause uncertainty that ultimately stifles innovation. Because “often, the greatest obstacle is not the regulatory requirements themselves but the inability to predict how they will evolve in the course of the innovation project. When there is a high level of uncertainty of whether the regulations in place at the start of the innovation process will remain stable over the long term, the risk to companies of investing in this project goes up.”

    - Skilled employees with specialist expertise and “innovation competence” are the cornerstones of innovative processes. This makes a broad education in STEM subjects and in research equally important as improving the immigration opportunities for foreign qualified personnel.

    - **Collaboration and innovation environment:** Innovations are often developed in collaborative projects organised in innovation networks, with (university) research institutions and R&D departments providing...
the (e.g. technological) inputs for the entrepreneurial outputs. The regulatory framework should therefore facilitate the establishment of such collaboration.

- The typically low credit ratings and minimal collateral of start-ups and SMEs makes them dependent on external financing and support. The German venture capital market is too small to close the financing gap of these target groups (above all in the start-up phase), as are the German funding schemes.

The findings produced by the literature and document analysis presented here formed the basis for developing the Innovation Check Tool’s assessment questions. These were discussed with experts in interviews. The summary of these findings is presented in Chapter 3.1.

Other sources for the identification of regulatory obstacles to the ability of business to innovate were the BDI Innovation Indicator and the EU Innovation Scoreboard. The categories and individual indicators of these two innovation indexes are outlined in the following:

**BDI Innovation Indicator:**
- The 38 individual indicators (see Table 3) are divided into five categories: education, state, enterprises, public research and society.

- The indicators were classified as either input indicators (e.g. early-stage venture capital in relation to GDP) and output indicators (e.g. public science sector patents per inhabitant).

**EU Innovation Scoreboard:**
- Has a total of 25 individual indicators (see Table 4) divided into the following three categories:

  - **Enablers**
    - e.g. Venture capital (% of GDP).

  - **Firm Activities**
    - e.g. R&D expenditure in the business sector (% of GDP).

  - **Outputs**
    - e.g. exports of medium and high-technology products as a share of total product exports.

Most of the indicators in the two indicator sets presented above are individual indicators whose assessment is only possible ex-post. These indicators are therefore not suitable for an assessment as part of the (ex-ante) regulatory impact assessment. The individual categories of the indicator sets nonetheless provided the starting point for the development of some of the assessment questions in the Innovation Check Tool.

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52 See: http://bdi.eu/themenfelder/innovation/innovationsindikator/

<table>
<thead>
<tr>
<th>Table 3: Indicators of BDI Innovation Indicator</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Foreign students as percentage of all students</td>
<td></td>
</tr>
<tr>
<td>Tertiary students per 55+ year old academic employee</td>
<td>Input</td>
</tr>
<tr>
<td>Share of employees with at least secondary (non-tertiary education)</td>
<td></td>
</tr>
<tr>
<td>Population with ISCED 6 level education in mathematics, sciences, and engineering</td>
<td>Output</td>
</tr>
<tr>
<td>Share of employees with tertiary education</td>
<td></td>
</tr>
<tr>
<td><strong>Education / State</strong></td>
<td></td>
</tr>
<tr>
<td>Annual education expenses per student (tertiary incl. R&amp;D) per student</td>
<td>Input</td>
</tr>
<tr>
<td>Quality of education system (on a scale of 1 to 7 based on expert assessments)</td>
<td>Input</td>
</tr>
<tr>
<td>Quality of the mathematical and natural science education (on a scale of 1 to 7 based on expert assessments)</td>
<td>Input</td>
</tr>
<tr>
<td>Index of PISA results in sciences, reading, mathematics (on an open scale with mean of 500 and standard deviation 100)</td>
<td>Input</td>
</tr>
<tr>
<td><strong>State</strong></td>
<td></td>
</tr>
<tr>
<td>Public demand for advanced technologies (on a scale of 1 to 7 based on expert assessments)</td>
<td>Input</td>
</tr>
<tr>
<td><strong>State / Enterprises</strong></td>
<td></td>
</tr>
<tr>
<td>B-index for tax-based funding of business R&amp;D</td>
<td>Input</td>
</tr>
<tr>
<td>Publicly funded R&amp;D in enterprises as a share of GDP</td>
<td>Input</td>
</tr>
<tr>
<td><strong>Enterprises</strong></td>
<td></td>
</tr>
<tr>
<td>Demand of companies for technological products (on a scale of 1 to 7 based on expert assessments)</td>
<td>Input</td>
</tr>
<tr>
<td>Early-stage venture capital relative to GDP</td>
<td></td>
</tr>
<tr>
<td>Importance of marketing (on a scale of 1 to 7 based on expert assessments)</td>
<td>Input</td>
</tr>
<tr>
<td>Share of international co-patents</td>
<td></td>
</tr>
<tr>
<td>Share of employees in knowledge-intensive services</td>
<td></td>
</tr>
<tr>
<td>Intensity of domestic competition (on a scale of 1 to 7 based on expert assessments)</td>
<td></td>
</tr>
<tr>
<td>Share of university R&amp;D financed by enterprises</td>
<td></td>
</tr>
<tr>
<td>Internal business R&amp;D expenditures as share of GDP</td>
<td></td>
</tr>
<tr>
<td>Public Research</td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>---</td>
</tr>
<tr>
<td>Number of researchers in FTE per 1,000 employees</td>
<td>Input</td>
</tr>
<tr>
<td>Quality of research institutions (on a scale of 1 to 7 based on expert assessments)</td>
<td></td>
</tr>
<tr>
<td>Share of international SCI co-publications</td>
<td></td>
</tr>
<tr>
<td>Country share among the top 10% of most highly cited publications</td>
<td></td>
</tr>
<tr>
<td>Number of SCI publications relative to population</td>
<td>Output</td>
</tr>
<tr>
<td>Field-specific expected impact rate of SCI publications</td>
<td></td>
</tr>
<tr>
<td>Public science sector patents per inhabitant</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Public Research / State</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>R&amp;D in public research institutions and universities as share of GDP</td>
<td>Input</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Society</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Life expectancy in years</td>
<td></td>
</tr>
<tr>
<td>Share of women in total working population</td>
<td>Input</td>
</tr>
<tr>
<td>Number of press releases on science and research per inhabitant</td>
<td></td>
</tr>
<tr>
<td>Share of post materialists (Inglehardt) in population</td>
<td></td>
</tr>
</tbody>
</table>
Table 4: Indicators of the EU Innovation Scoreboard

<table>
<thead>
<tr>
<th>Number</th>
<th>Indicator</th>
<th>Definition Numerator</th>
<th>Definition Denominator</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1.1</td>
<td>New doctorate graduates (ISCED 6) per 1000 population aged 25-34</td>
<td>Number of new doctorate graduates (ISCED 6)</td>
<td>Population aged 25-34</td>
</tr>
<tr>
<td>1.1.2</td>
<td>Percentage population aged 30-34 having completed tertiary education</td>
<td>Number of persons in age class with some form of post-secondary education (ISCED 5-8)</td>
<td>Population aged 30-34</td>
</tr>
<tr>
<td>1.1.3</td>
<td>Percentage youth aged 20-24 having attained at least upper secondary level education</td>
<td>Number of persons in age class having attained at least upper secondary level education, i.e. with ISCED level of at least 3a, 3b or 3c</td>
<td>Population aged 20-24</td>
</tr>
</tbody>
</table>

**Open, excellent and attractive research systems**

| 1.2.1  | International scientific co-publications per million population          | Number of scientific co-publications with at least one co-author based abroad (where abroad is non-EU for the EU28) | Total population  |
| 1.2.2  | Scientific publications among the top 10% most cited worldwide as % of total scientific publications of the country | Number of scientific publications among the top-10% most cited publications worldwide | Total number of scientific publications |
| 1.2.3  | Non-EU doctorate students as percentage of all doctorate students        | For EU member states: Number of doctorate students coming from a non-EU country (for non-EU countries: Number of doctorate students coming from another country) | Total number of doctorate students |

**Finances and Support**

<p>| 1.3.1  | R&amp;D expenditure in the public sector as percentage of GDP                 | All R&amp;D expenditures in the government sector (GOVERD) and the higher education sector (HERD) | Gross domestic product |
| 1.3.2  | Venture capital investment as percentage of GDP                           | Venture capital investment is defined as private equity being raised for investment in companies. Management buyouts, management buy-ins, and venture purchase of quoted shares are excluded. Data include two investment stages: Early stage (seed + start-up) and Expansion and replacement. | Gross domestic product |</p>
<table>
<thead>
<tr>
<th>FIRM ACTIVITIES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Firm Investments</strong></td>
</tr>
<tr>
<td>2.1.1</td>
</tr>
<tr>
<td>2.1.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Linkages &amp; Entrepreneurship</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2.1</td>
</tr>
<tr>
<td>2.2.2</td>
</tr>
<tr>
<td>2.2.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Intellectual Assets</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3.1</td>
</tr>
<tr>
<td>2.3.2</td>
</tr>
<tr>
<td>2.3.3</td>
</tr>
<tr>
<td>2.3.4</td>
</tr>
</tbody>
</table>
### Outputs

<table>
<thead>
<tr>
<th>Innovators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.1.1</strong> SMEs introducing product or process innovations as percentage of SMEs</td>
</tr>
<tr>
<td><strong>3.1.2</strong> SMEs introducing marketing or organisational innovations as percentage of SMEs</td>
</tr>
<tr>
<td><strong>3.1.3</strong> Employment in fast-growing enterprises (percentage of total employment)</td>
</tr>
</tbody>
</table>

### Economic Effects

<table>
<thead>
<tr>
<th>Economic Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.2.1</strong> Employment in knowledge-intensive activities (manufacturing and services) as percentage of total employment</td>
</tr>
<tr>
<td><strong>3.2.2</strong> Medium and high technology product exports as percentage of total product exports</td>
</tr>
<tr>
<td><strong>3.2.3</strong> Knowledge-intensive services exports as percentage of total service exports</td>
</tr>
<tr>
<td><strong>3.2.4</strong> Sales of new-to-market and new-to-firm innovations as percentage of turnover</td>
</tr>
<tr>
<td><strong>3.2.5</strong> License and patent revenues from abroad as percentage of GDP</td>
</tr>
</tbody>
</table>

7.1 Objective and selection of area of study

The analysis of international best practices entailed gathering information from other countries relevant to the development of the Innovation Check Tool. The guidelines of other countries (both within and outside of the EU) and of the EU itself were analysed and interviews conducted with selected experts in the field.

The aim was to investigate the respective methodological and practical approach taken in the impact assessment of proposed regulation on innovation. This information was then used to define best practices for the study objectives.

Table 5 shows which impact assessment guidelines were examined in the course of the desk research. The guidelines of the EU, Finland, the United Kingdom, Austria and Poland are the only ones that refer to innovation effects in their RIA guidelines. The most detailed documents on the investigation of how new regulation might impact innovative capacity are those published by the European Commission.

The Finnish Impact Assessment Guidelines were published as far back as 2008 so first experiences with the requirement to consider innovation have already been gathered. Finland also has a regulatory environment that is very conducive to innovation. In addition to guidelines that relate to innovation, the United Kingdom has extensive experience in “better regulation” overall. The European Commission has an extensive catalogue of guidelines and tools on the subject of innovation in regulatory impact assessment. The EU, Finland and the United Kingdom were also referred to expressly in the exploratory interviews, so these examples became the focus for the international best practice analysis. Semi-structured interviews were conducted with experts from the relevant institutions in the individual countries and of the EU.

The findings of the guidelines analysis and the expert interviews are presented below. The following results and experiences were an important basis for the development of the Innovation Check Tool.

<table>
<thead>
<tr>
<th>Country</th>
<th>Are RIA guidelines available?</th>
<th>Is impact on innovation explicitly mentioned in guidelines?</th>
<th>Is impact on competitiveness explicitly mentioned in guidelines?</th>
<th>Recommended by experts</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Finland</td>
<td>✓</td>
<td>✓</td>
<td>xxx</td>
<td>✓</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>✓</td>
<td>✓</td>
<td>↔</td>
<td>✓</td>
</tr>
<tr>
<td>Austria</td>
<td>✓</td>
<td>✓</td>
<td>↔</td>
<td>x</td>
</tr>
<tr>
<td>Poland</td>
<td>✓</td>
<td>✓</td>
<td>↔</td>
<td>x</td>
</tr>
<tr>
<td>Sweden</td>
<td>✓</td>
<td>↔</td>
<td>↔</td>
<td>✓</td>
</tr>
<tr>
<td>Denmark</td>
<td>✓</td>
<td>↔</td>
<td>↔</td>
<td>✓</td>
</tr>
<tr>
<td>Canada</td>
<td>✓</td>
<td>↔</td>
<td>↔</td>
<td>✓</td>
</tr>
<tr>
<td>US</td>
<td>✓</td>
<td>↔</td>
<td>↔</td>
<td>x</td>
</tr>
<tr>
<td>Estonia</td>
<td>✓</td>
<td>✓</td>
<td>↔</td>
<td>x</td>
</tr>
<tr>
<td>Netherlands</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

The Netherlands do not have conventional guidelines but have an online information platform on impact assessment.
7.2 Finland – Best practice findings

The impact of regulation on innovation has been included in impact assessment in Finland since 2007. RIA in Finland is based on the document “Impact Assessment in Legislative Drafting – Guidelines”, which the Finnish Ministry of Justice published in 2008.55

These guidelines stipulate the need to consider the potential impact of proposed regulation, both positive and negative, and direct and indirect.56 The section of the guidelines entitled “Impact on Businesses” includes the following assessment question on the topic of innovation: “Does the proposal have an impact on investment, research and development, or innovation?” The question is supplemented by a qualitative description of possible interdependencies (see table below).

According to the expert interviewed, it is mandatory to answer this question. So, in Finland, there is a general duty to assess the regulatory impact on innovation. The responsibility for this assessment is with the lead ministry. The explanatory text of the “Impact Assessment in Legislative Drafting – Guidelines” is available to assist ministerial officials. If they have further questions on assessing the impact on innovation, they can contact the Better Regulation Group at the Finnish Ministry of Economic Affairs and Employment. The expert interviewed said that the additional information available from the helpdesk was, however, rather sparse and that there are no additional checklists or examples on impact assessment on innovation available.

In the annex to the “Impact Assessment in Legislative Drafting – Guidelines” there is a checklist featuring more detailed and concrete questions that expand on the assessment questions in the guidelines as well as tick boxes with the options “yes”, “no” and “to be determined”. These do not, however, provide any in-depth specifications on the topic of innovation, as shown in the following table. 58

According to the expert interviewed, the checklist is generally designed to help identify relevant impact. Not all conceivable effects of regulation should be investigated, but instead focus should be given to the effects that are most relevant. Experience with the application of the official guidelines so far has shown that a detailed checklist on the topic of innovation with which to review the impact of proposed regulation in more detail is missing.

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56 Ibid. p. 10.
57 Ibid. p. 22
58 Ibid. p. 47
The information in the guidelines was generally regarded as inadequate. Furthermore, according to the expert interviewed, the impact on innovation is only assessed in rare cases.

In Finland there is currently no independent review body that monitors RIA. But the country plans to establish such a body in 2016.

The expert’s main recommendation is a simple, logically structured checklist on the topic of innovation, which is generally regarded as one of the most difficult aspects of regulatory impact assessment.

### 7.3 The United Kingdom – Best practice findings

Impact assessment in the United Kingdom is conducted according to the “Better Regulation Framework Manual”, which the Department for Business, Innovation and Skills published in March 2015. The manual sets out at what stage to carry out impact assessment and when to apply the fast track alternative. These categories also define the general scope of the required impact assessment.59

The “Better Regulation Framework Manual”, includes questions to assess the impact of proposed regulation on innovation, such as “Will proposals impact on innovation e.g. new low-carbon technologies?” It does not provide, however, any further, more specific guidelines.

<table>
<thead>
<tr>
<th>Table 8: Excerpt of Better Regulation Manual - Step 4: Identify the impacts 61</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Economic / Financial</strong></td>
</tr>
<tr>
<td>a. How will proposals impact on the market and specifically consumers and businesses? In particular, consider the impacts on small and start-up businesses (see SMBA guidance for more details).</td>
</tr>
<tr>
<td>b. Will all businesses be affected in the same way, or will there be some that benefit, while others bear costs?</td>
</tr>
<tr>
<td>c. What are the expected impacts on the wider economy (e.g. labour market)?</td>
</tr>
<tr>
<td>d. What are the impacts on competition? Will the number or range of suppliers be limited? Will their ability to compete be limited or the incentive to compete vigorously be reduced?</td>
</tr>
<tr>
<td>e. Will proposals impact on innovation e.g. new low carbon technologies?</td>
</tr>
<tr>
<td>f. What are the expected financial and resource impacts on other Departments (e.g. the Justice system)? Note that if the policy has an impact on local authorities then this must be assessed in line with guidance on new burdens.</td>
</tr>
</tbody>
</table>

The interviewed expert from the Department for Business, Innovation and Skills explained that while there is a general requirement to assess all impacts, including the impact on innovation, officials are also required to maintain a “proportionate approach” according to which only the relevant impact is assessed. The focus of impact assessment is generally on calculating the direct costs of the proposed regulation. Given that the impact on innovation is often indirect, this area of impact is often not investigated in any detail. The general rule is that a more extensive impact assessment is conducted if a significant correlation between the proposed regulation and its impact on innovation is identified at the beginning of the assessment. The lead ministry (“department”) of the proposed regulation is also responsible for conducting regulatory impact assessment. The Better Regulation Unit is available to provide the departments with assistance and advice on this procedure. The assessment is then reviewed by the Regulatory Policy Committee, which checks whether the obvious regulatory impacts have been correctly identified.

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60 Ibid p. 65.

61 Ibid p. 56.
7.4 European Union – Best practice findings

Impact assessment is required for those European Commission initiatives\textsuperscript{62} that are likely to have significant economic, social or ecological impact. For the impact assessment on European level, the Better Regulation Guideline and the Better Regulation Toolbox apply. The guidelines specify the Directorate-General responsible for the initiative as the body responsible for impact assessment.

Where an initiative is regarded as requiring impact assessment, this is carried out by an interservice steering group composed of members of all Commission offices relevant to the initiative.

One of the first tasks of the steering group is then to identify possible impacts in an initial screening. This also includes considering the impact on innovation. Cases where significant regulatory impact is to be expected are then assessed in more depth. To maintain the principle of a proportionate analysis, the steering group selects the relevant impacts and then assesses these. The procedure is based on the understanding that it is not feasible in practice to investigate every conceivable impact of the proposed regulation.

The impact assessment process includes the collection and analysis of relevant data and the consultation of stakeholders. The results of the initial screening, the Inception Impact Assessment, are published on the Commission’s internet platform. Important information is thus already made available to external parties at the beginning of the assessment, who then have the opportunity to point out possible problem areas or possible alternatives based on their own experience. Further consultations are carried out throughout the course of the assessment to collect additional information and opinions. This also includes public online participation. The findings of the consultation procedure are published on the internet to achieve as much transparency as possible.

The members of the steering group have a range of documents to help them with the impact assessment. One of the most important aids is the Better Regulation Toolbox, which the European Commission published in 2015. The Toolbox includes the key tools for better regulation as well as guidelines on carrying out impact assessment and how to assess the possible impact of legislative initiatives.

The principle of proportionate analysis also applies to the investigation of potential impact on innovation. Tool #18 (Impacts on Research & Innovation) of the toolbox has guidelines for identifying those factors that could have an impact on research and innovation.\textsuperscript{63} The application of Tool #18 is not mandatory, but is available to assist in cases where the steering group identifies significant potential impact on research and innovation.

Tool #18 can be used to help investigate the potential impact of a proposal on research and innovation activity. It presents factors that can have an impact on research and innovation and explains the possible effects. Tool #18 also has a range of questions that need to be considered in the course of impact assessment. The following table contains a selection of these factors and questions.

\textsuperscript{62} These include legislative proposals and non-legislative initiatives (white papers, action plans, spending programmes, negotiating guidelines for international agreements) as well as implementing provisions and delegated legal acts.

Table 9: Excerpt of Tool #18: Selection of factors affecting innovation

<table>
<thead>
<tr>
<th>Regulatory factors</th>
<th>Impact on innovation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process-related vs outcome-related</strong></td>
<td>Prescriptive regulations set out in detail the means by which outcomes are to be achieved, including the inputs and technologies to be used and the types of business processes, practices and models permitted. They can discourage innovation since firms have limited freedom to try out new technologies, business process, practices and models. On the other hand, performance or outcome-based regulations grant greater flexibility to businesses in how they achieve the desired outcome, stipulating only at a relatively high-level what they can and cannot do. For their success, business activities must be appropriately incentivised and enforced.</td>
</tr>
<tr>
<td><strong>Establishment of strict results</strong></td>
<td>A regulation is judged to be stringent if firms need to significantly change their behaviour or develop new technologies, processes or business models in order to comply with it. Although the evidence of the impact of stringency of regulation on innovation is ambivalent, it appears that more stringent regulations are likely to induce radical innovations, provided that the distance between regulatory requirements and the status quo is not excessive and that the outcome is specified in a technology-neutral manner.</td>
</tr>
<tr>
<td><strong>Timing</strong></td>
<td>The time given to firms to comply with a new regulation can play an important role in determining the overall impact on innovation. There is a trade-off between the benefits of innovation and the benefits of compliance. If operators are given too little time to adjust to a specific regulatory framework, this may result in an inferior technological, economic and social outcome. On the other hand, while granting firms longer (but definitive) time frames to comply may encourage them to develop more innovative technological and non-technological solutions, they may also delay the benefits of regulation.</td>
</tr>
<tr>
<td><strong>Compliance costs</strong></td>
<td>The opportunity cost of allocating limited resources to complying with regulation can imply ‘lost’ innovation. The amount of innovation which may be lost as a result of regulation depend in part on whether compliance costs are one-off or recurring, and also how quickly firms can rebuild their finances to fund further innovation activity. It may also depend on the size of firms. Lost innovation may be greater for smaller firms than larger companies because the cost of complying with regulation is disproportionately greater. An important element of compliance cost is spending on defensive R&amp;D (in order to assure safety of existing substances), which may divert R&amp;D from innovation, lock-in old technology or reduce product availability.</td>
</tr>
<tr>
<td><strong>Regulatory uncertainty</strong></td>
<td>Although there are examples where anticipation of future regulation has encouraged innovation, uncertainty about the regulatory approach, its actual shape or form is likely to hamper innovation. Developing new products and improved processes is a risky and costly process and regulatory delay and uncertainty can add to this.</td>
</tr>
<tr>
<td><strong>Interactions with other policies</strong></td>
<td>Regulatory intervention may encourage innovation if it strengthens other government policies aimed at reducing barriers to innovation (e.g. competition policy, education and skills development, procurement). On the other hand, regulatory intervention may work against other government policies by reducing the incentives to innovate or introducing distortions in the allocation of resources in the innovation system.</td>
</tr>
</tbody>
</table>

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64 Ibid p. 122 et seqq.
67 European Commission (2015): Better regulation toolbox. Box 2 Example: veterinary products – innovation stifled by the regulatory regime to such an extent that there is a lack of medicines to treat animals. p. 126.
Table 10: Excerpt of Tool #18: Questions to be considered on “Factors Affecting Research & Innovation”

How the broader context may affect research and innovation is key to designing mutually reinforcing interventions. The following questions should be considered:

- What are the main research and innovation needs in the sector? Which of those needs might be affected by the proposed intervention?
- What are the drivers and barriers to innovation in the targeted sector?
- How does the regulatory landscape in the sector impact the innovation system? How is the existing regulation or policy implemented? How does that support or hinder innovation activities?

Table 11: Excerpt of Tool #18 on how the proposed policy option/intervention affects the innovation capacity of companies, notable SMEs

How does the proposed policy option/intervention affect the innovation capacity of companies, notable SMEs?

Innovation activities are costly and long-term processes which involve high risks but they create new value and new markets. Regulation may alter incentives and choices for investment in R&I. This should be considered using the following questions:

- Would the intervention privilege or prohibit characteristics a new type of good or service could have? Could this even lead in the extreme to preventing a product group or, conversely, leading the market to a single technological solution?
- Would the proposed intervention level the market conditions between incumbent and new offers, e.g. by abolishing privileges to the former or granting incentives to purchase the latter?
- Does the implementation of the intervention put an administrative burden specifically on introducing new goods, services and production plants on a market or on their demonstration prior to market introduction?
- Does the intervention alter the rewards from innovation (e.g. the length of patent protection)?
- What is the impact on market confidence, consumer acceptance or demand for new products or technologies?
- Are there indirect effects in other sectors or policy areas such as health, employment or consumer protection?

Table 12: Excerpt of Tool #18 on how the proposed policy option/intervention affects the innovation capacity of companies, notable SMEs

Regulation can affect resources (human as well as financial means) available for innovative activities:

- Does it impinge on the price, quantity or mobility of human resources with skills appropriate to new technologies and work methods, be it vocationally trained workers or experienced managers?
- Would public or private sources (internal, credit, early stage venture capital et al.) of financing be affected? This could regard not only R&D and other innovation activities such as a first production plant, but also the first buyers of innovations or the distribution of risk and revenue in public private partnerships, for instance.
- May the intervention indirectly influence a company owners’ preference for keeping a firm size below a certain limit and hence R&D capacity, e.g., because of labour, tax or administrative rules?

Innovation is a dynamic and evolutionary process with constant interaction and feedback between the different stages, with ideas and knowledge often being developed and exchanged. Regulation can impact on the creation and diffusion of knowledge:

- Does the proposed intervention impact the generation of new ideas, their adaptation and application, including from the knowledge base to industry?
- Does it affect the co-operation (e.g. circulation of data, research results or researchers) among public researchers and between public and corporate R&D and with intermediaries that provide advice and support to R&I activities, e.g., the openness to co-operate or the distribution of benefits?
- Does the proposed intervention potentially affect the establishment of, access to and functioning of research and innovation infrastructures?
Despite the fact that there is no general requirement to apply Tool #18, one of the experts interviewed pointed out that there is a general requirement to assess the impact on competitiveness and the impact on small and medium-sized enterprises. In certain cases an assessment of the proposed regulation on innovation can therefore be required as innovation is expressly specified in these binding assessments.

Many of the tools of the Better Regulation Toolbox and other better regulation tools of the European Commission address the impact on innovation. The experts interviewed specified the following as particularly relevant:

- Better Regulation Toolbox
  - Tool #12: Risk Assessment and management
  - Tool #13: How to set objectives
  - Tool #14: How to identify policy options
  - Tool #15: The choice of policy instruments
  - Tool #16: Identification / screening of impacts
  - Tool #17: Impacts on sectoral competitiveness
  - Tool #18: Impacts on Research & Innovation
  - Tool #19: The “SME TEST”
  - Tool #23: ICT assessment, the digital economy and society
  - Operational Guidance for Assessing Impacts on Sectoral Competitiveness within the Commission Impact Assessment A Competitiveness Proofing Toolkit for use in Impact Assessments

There is also the guide “Regulatory Screening. A short guide on the innovation effects of regulation Research and Innovation”, which the Commission’s Directorate-General for Research and Innovation published in 2014. But the tools in this guide are not binding.

The resulting Impact Assessment Report is submitted to the Regulatory Scrutiny Board, which reviews the Impact Assessment Report and issues an opinion on it. The board checks that all relevant impacts have been taken into consideration. “In principle, a positive opinion is required from the Board, in order for a proposal to be tabled to the Commission along with the impact assessment.” Where the impact on innovation has not been assessed sufficiently, the Regulatory Scrutiny Board can draw attention to this at this stage.

As this procedure has only been in application for a short period of time, little experience has been gathered as yet both on the application of the Better Regulation Toolbox in general and the application of Tool #18 specifically. The experts were therefore unable to evaluate the application of these tools in practice. One of the experts surveyed informed us that additional methodological guidelines to make Tool #18 of the Better Regulation Toolbox more concrete are currently being developed.

Ex-post evaluations on the impact on innovation were also regarded as another important aspect by experts from the Commission. This is important because, on account of the complex interdependencies involved in calculating the impact on innovation, unintended negative effects can arise despite thorough prior impact assessment. Another point referred to by the experts was the importance of involving stakeholders at an early stage in order to obtain further information and data on the impact on innovation. A good culture of collaboration and communication was also seen as essential for regulatory impact assessment on the European level.

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7.5 Summarised action recommendations of the international experts interviewed

- The interviews with international experts addressed not only questions relating to the concrete impact assessment of proposed regulation in terms of innovation, but also general recommendations for the preparation of supporting and guiding material. These are summarised in the following:

- The large majority of experts interviewed agreed that one of the biggest challenges in impact assessment was estimating the impact on innovation. This is due to the fact that the term “innovation” is very abstract, the interdependencies (particularly through indirect effects) are frequently not clear to the ministerial officials and specialist expertise on innovation inhibitors is not sufficiently available. A further impediment is that impact on innovation is often ambiguous.

- Some experts expressed the opinion that it is important to take account of potential impact on the ability of business to innovate as early as possible in the legislative procedure. It was repeatedly underlined that it is practically impossible to identify all conceivable effects on innovation and that, this being so, the focus should be put on the most important aspects.

- A key success factor identified for an innovation check within the regulatory impact assessment was application-based guidelines designed for use also by persons without expertise in the field of innovation. One of the experts working in better regulation, expressly mentioned that a checklist that officials can “work through” is particularly user-friendly. In their opinion, there should also be a point of contact for officials who have queries concerning how to apply an impact assessment tool.

- Another point that was emphasised was that an independent body that reviews the regulatory impact report must be aware of the importance of innovative capacity and must therefore act in its control role to ensure this is examined in the impact assessment.
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