Federal Ministry
for Economic Affairs
and Energy

Reallabore
Testräume für Innovation
und Regulierung

New flexibility for innovation

Guide for formulating experimentation clauses

bmwi.de

Imprint

Publisher
Federal Ministry for Economic Affairs and Energy (BMWi)
Public Relations
11019 Berlin
www.bmwi.de

Status
December 2020

This publication is available for download only.

Design
PRpetuum GmbH, 80801 Munich

Picture credits
Getty Images
Aitor Diago / p. 2
PM Images / p. 4
Ralf Hiemisch / title

iStock
AndrewLilley / p. 7
Thomas Demarczyk / p. 10

Central ordering service for publications of the Federal Government:
Email: publikationen@bundesregierung.de
Tel.: +49 30 182722721
Fax: +49 30 18102722721

Contents

I. Introduction

Whether it's automated driving or flying, e-government, telemedicine or many other innovative, often AI-based applications, modern technologies need to be accompanied by modern and flexible regulation that enables innovation but also upholds high standards of protection. In this context, experimentation clauses are a useful legal instrument that create the necessary space in order to test innovations in the controlled environment of regulatory sandboxes. And they also allow the legal framework to be updated in a responsible and targeted manner.

Against this background, a clear mandate has recently been defined at various political levels to incorporate experimentation clauses more strongly and systematically in future legislation. For example, the **Coalition Agreement** calls for experimentation clauses and similar approaches to create new opportunities for testing innovations.[1] In their resolution from the **Conference of Economic Affairs Ministers** of 30 November 2020, the German federal states welcome the objective of systematically incorporating experimentation clauses in legislation and improving the framework for regulatory sandboxes. Similarly, on 16 November 2020, the 27 EU Member States called on the European Commission to make greater use of experimentation clauses and regulatory sandboxes in their **Council conclusions**. The business and scientific communities are also increasingly expressing a desire for more freedom to test new ideas.

The Federal Ministry for Economic Affairs and Energy (BMWi) helps legislative bodies to create and further develop experimentation clauses through its Regulatory Sandboxes Strategy.[2] Through this guide for formulating experimentation clauses and a comprehensive legal study, the BMWi for the first time presents a **systematic and practice-oriented guide** that helps lawmakers from different legal fields to develop legally secure and pro-innovation experimentation clauses.

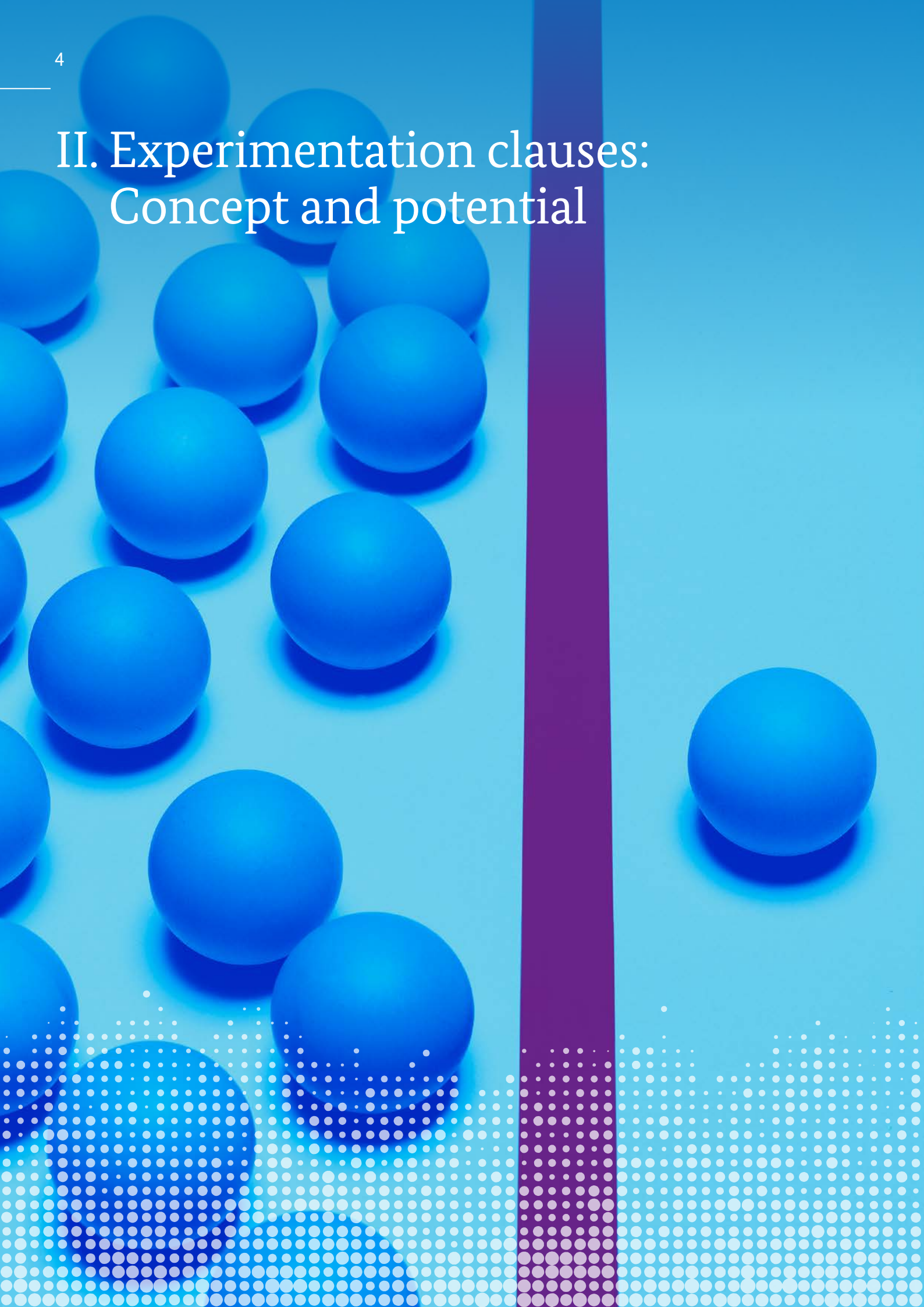
This guide starts by explaining the special features and potential of experimentation clauses, presenting specific examples and areas of application. Based on this, the main steps in developing and formulating experimentation clauses are described. A practical 'building kit' describes all of the essential and optional elements for formulating a legally secure experimentation clause and provides examples and options for wording. In order to provide a more in-depth analysis and explain the (constitutional and) legal background, reference is made in each case to the relevant passages in the detailed expert study prepared by Noerr LLP on behalf of the BMWi.[3]

1 Cf. Coalition Agreement between the CDU, CSU and SPD for the 19th legislative term, paras. 458ff., 2902ff., 1478ff., 3661ff.

2 www.bmwi.de/Redaktion/EN/Dossier/regulatory-sandboxes.html.

3 The information provided in this brochure is based on the results of the expert report *'Reallabore als Testräume für Innovation und Regulierung: Erstellung einer Arbeitshilfe zur Formulierung von Experimentierklauseln'* [Regulatory sandboxes as test spaces for innovation and regulation: Production of a guide for formulating experimentation clauses] commissioned by the Federal Ministry for Economic Affairs and Energy (Schmitz et al., 2020). This brochure offers a general overview but is not exhaustive and cannot replace specific legal analysis.

II. Experimentation clauses: Concept and potential



The use of experimentation clauses is nothing completely new. In fact, the first experimentation clauses were incorporated in German law back in the 1950s. However, it is only with the rapid advancement of digitisation in economy and society that they have gained considerable importance in Germany and worldwide in recent years.

The Council of the European Union adopted its premier conclusions on regulatory sandboxes and experimentation clauses during the 2020 German EU Council Presidency, recognising these as instruments to create an innovation-friendly and future-proof legal framework. In this context, European Member States understand experimentation clauses as:

> *"...legal provisions which enable the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis a degree of flexibility in relation to testing innovative technologies, products, services or approaches, [...] experimentation clauses are often the legal basis for regulatory sandboxes [...]."*[4]

Experimentation clauses as drivers of innovation

Experimentation clauses serve two key purposes: Firstly, where the existing legal framework does not permit certain innovations, they create the opportunity for private or public actors to test such innovations in a controlled manner in a regulatory sandbox.

Secondly, experimentation clauses allow legislators to learn at an early stage about innovations, their effects under real conditions and about the appropriate legal framework for the innovations, and to further develop the general legal framework on the basis of the information gained. Experimentation clauses are thus a building block within an innovation-friendly and evidence-based legal framework and a crucial factor in determining how attractive a country or region is for innovation.

Depending on the application, the process of testing novel technologies and business models can also entail risks or lead to other unintended effects. It is therefore always important that adequate precautions are taken regarding the specific legal interests involved and that the clauses comply with requirements under constitutional law.

Technology-neutral and widely applicable

Experimentation clauses are already incorporated across various fields of law in Germany and are often used intensively and with success. The sectors of mobility, logistics, e-government and energy have been important fields of application to date.[5]

The experimentation clause (Section 2(7)) of the Carriage of Passengers Act (PBefG), for example, is considered exemplary. It allows deviations from the regulation stipulated in passenger transport law for up to four years in order to conduct practical testing of new types or means of transport. This has made it possible in Germany to use regulatory

4 Council Conclusions on Regulatory sandboxes and experimentation clauses as tools for an innovation-friendly, future-proof and resilient regulatory framework that masters disruptive challenges in the digital age, 16 November 2020, para. 9.

5 An overview of existing experimentation clauses in German law is provided in the 'Handbook for Regulatory Sandboxes' published by the Federal Ministry for Economic Affairs and Energy, 2019, p. 67ff. Link https://www.bmwi.de/Redaktion/EN/Publikationen/Digitale-Welt/handbook-regulatory-sandboxes.pdf.

sandboxes to test new, forward-looking innovations such as ridesharing or even automated buses and shuttles. The experience gained provides an important basis for amending and updating passenger transport law.

Another example is former Section 21b(3) of the German Air Traffic Regulation, which allowed exceptions to the ban on operating drones. After this rule had been used intensively for trial projects, the experimentation clause was replaced by a uniform European regulation that allows the regular operation of such drones.

Experimentation clauses and similar legal instruments are also used in numerous other countries to test innovations, although many of the regulations have only been created fairly recently.[6]

INFORMATION BOX

Support provided by the Federal Ministry for Economic Affairs and Energy

The Regulatory Sandbox Strategy

In December 2018, the BMWi published its cross-technology and cross-sectoral Regulatory Sandbox Strategy, which is implemented by its Coordinating Office for Regulatory Sandboxes. The Strategy pursues three key goals:

Providing more scope for innovation

In order to create new regulatory space for testing innovations, additional experimentation clauses are needed in numerous different fields of law. This is why the BMWi supports the relevant bodies within the Federal Government in **creating and revising experimentation clauses**. In addition, the BMWi provides cross-cutting assistance and expert studies, such as this **Guide for formulating experimentation clauses** and an expert study on the question of whether a **general experimentation clause** and a **federal experimentation act** should be established. Exchange on these matters within the Federal Government takes place in the **interministerial Working Group on Regulatory Sandboxes**, which meets on a regular basis.

Networking and providing information

Another goal of the Regulatory Sandbox Strategy is to network and provide information for regulatory sandboxes in Germany. To do this, the **Regulatory Sandboxes Network** has been set up, in which around 530 members from companies, research and administration have now come together to engage with one another in events and workshops. The **Handbook for Regulatory Sandboxes** published by the Federal Ministry for Economic Affairs and Energy serves as a comprehensive practical aid for the implementation of regulatory sandboxes. All important information on the Regulatory Sandbox Strategy is available on the website www.reallabore-bmwi.de.

Supporting regulatory sandboxes

The BMWi runs a competition for the **'Regulatory Sandboxes Innovation Prize'**. The aim is to make outstanding regulatory sandboxes visible, recognise innovative ideas and encourage the development of new regulatory sandboxes. The Innovation Prize was presented to nine winners for the first time on 26 May 2020.

6 The expert report Reallabore – *Überblick über internationale regulatorische Ansätze und ihre Umsetzbarkeit in deutsches Recht* [Regulatory sandboxes – Overview of international regulatory approaches and their transferability into German law] (in German only), published on behalf of the Federal Ministry for Economic Affairs and Energy in November 2020, provides an overview of the various legal approaches and fields of application. Link: https://www.bmwi.de/Redaktion/DE/Publikationen/Studien/reallabore-ueberblick-ueber-internationale-regulatorische-ansaetze.html.

III. Five steps for establishing an experimentation clause

Crafting an experimentation clause is made up of five steps. The key part of this Guide focuses on formulating the experimentation clause (Step 3). However, the other steps also influence how the experimentation clause is formulated and require in-depth analysis.

It should be noted that an experimentation clause must always be designed and applied in a way that focuses on the innovations to be tested and the respective subject area involved. It is not possible to establish a 'generalised' experimentation clause that stipulates rules for testing all kinds of innovative technology and business models in a regulatory sandbox as this cannot be reconciled with higher-level law. Secondly, such a clause is unlikely to be sufficiently effective to be able to be applied in a reliable manner in practice.

[→ Details: Schmitz et al. (2020), p. 11ff.]

***Step 1:** Examine and determine the factual and legal need for creating or adapting an experimentation clause.*

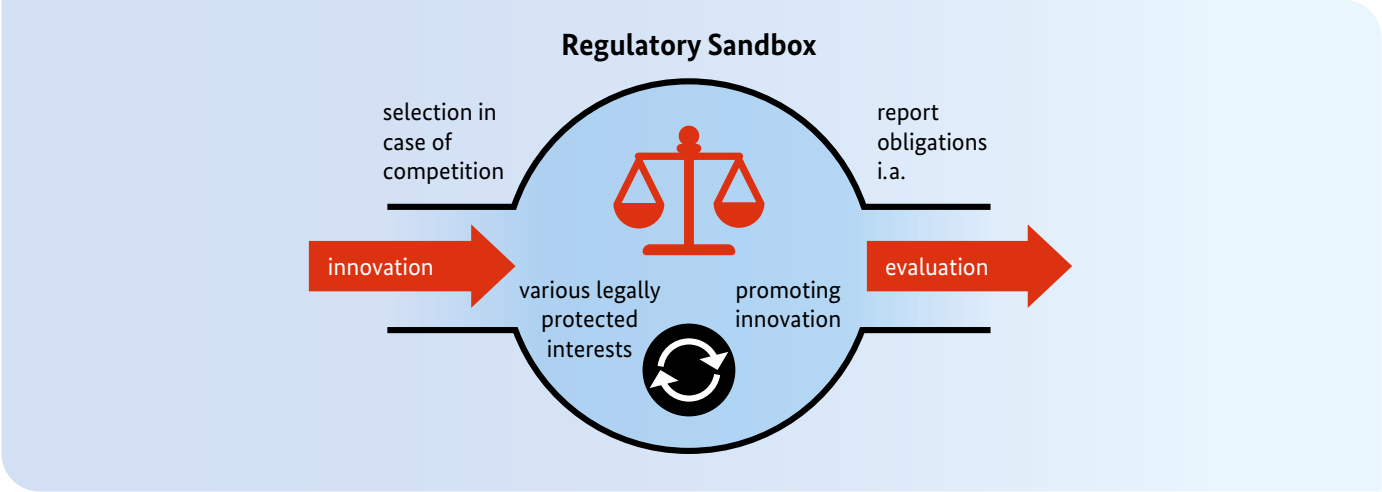
The key question in Step 1 is whether there are innovative technologies/business models offering potential benefits that have been or may be developed in the relevant regulatory area, but that cannot be tested in real-world operations due to restrictive regulations. Based upon this, it must then be determined whether an experimentation clause needs be created or an existing one modified.

***Step 2:** Examine and determine the competencies for an experimentation clause.*

In Step 2, the competencies for creating legal acts and/or ordinances have to be clarified. Although this issue is not covered by this guide, it should be pointed out that when it comes to formulating an experimentation clause, individual aspects also need to be taken into account. These might, for example, include the power to issue statutory ordinances to further substantiate (parliamentary) law.

***Step 3:** Formulate the experimentation clause around openness to innovation, responsibility for the innovation, and efficacy.*

In Step 3, the experimentation clause is formulated in a subject-specific way. This step is the primary focus in this guide. Experimentation clauses must take into account the legal context



of regulatory sandboxes based on them. They are in an area of conflict between various legally protected interests and the promotion of innovation. Experimentation clauses need to make the legal effects predictable for those affected – innovators, competitors and third parties alike – and ensure the protection of interests in an innovation-specific and risk-based manner.

The key parameters around which the experimentation clause should be formulated in order to ensure legal compliance are openness to innovation, responsibility for innovation, and efficacy.

The German Basic Law is fundamentally **open to innovation**, as can be seen from the decisions of the Federal Constitutional Court. But if an experimentation clause is to be open to innovation, it must also meet the requirements of the rule of law, in particular the requirements to be sufficiently precise. Another key parameter is the **responsibility for the innovation**, which must be observed when creating or adapting experimentation clauses and which arises from constitutional and European law, in particular the state's duties to protect its citizens. Striking a proportionate balance between openness to innovation and responsibility for the innovation is the key to formulating the experimentation clause in a way that is legally secure. Furthermore, an experimentation clause must be designed to be **effective**. This means that the standard created must be user-friendly, predictable in its prerequisites and legal consequences, and sufficiently flexible – both for the administration applying the legislation and for those wishing to test innovations, so that the experimentation clause can fulfil its purpose in practice.

[→ Details: Schmitz et al. (2020), p. 29ff.]

Particularly as the risks of the innovations to be tested vary, there can be no uniform "one size fits all" experimentation clause to cover all innovations and sectors. In addition, the bodies of standards in place in the different sectors also vary, which means that the extent to which experimentation clauses are permissible may differ.

However, by following a risk-based approach and establishing a common purpose for experimentation, it is possible to start by using a general building kit for experimentation clauses, which helps to formulate needs-based experimentation clauses for the different innovations and the various sectors subject to differing regulation. This "building kit" contains both essential and optional elements.

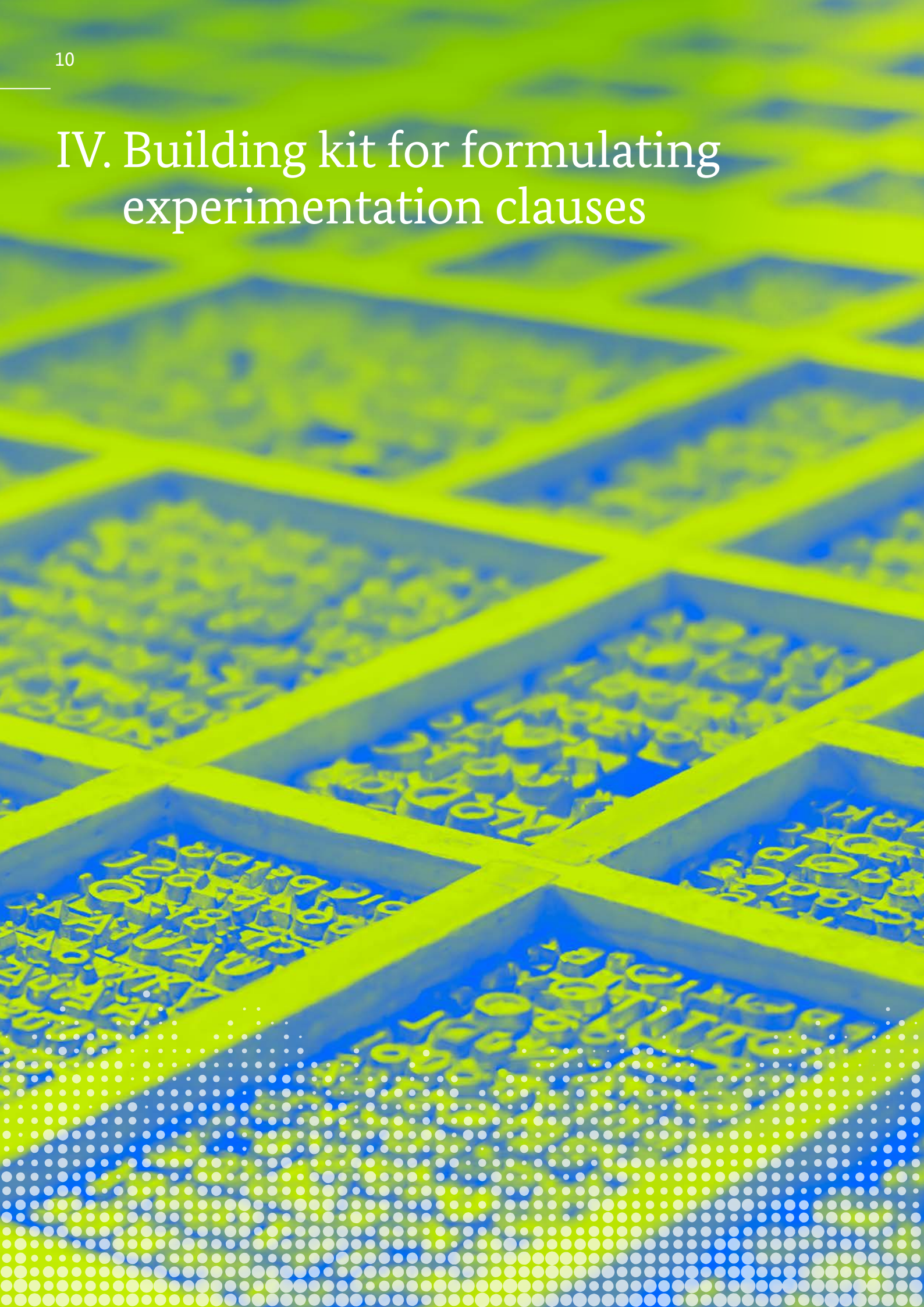
> ***Step 4:*** *Implement and apply the experimentation clause in practice.*

Once the experimentation clause is transposed into legislation by government and applied by the competent authorities and the innovators, it finally becomes a reality. While this guide does not cover either of these two aspects, they must both be considered when formulating the experimentation clause in Step 3, as the effectiveness of the clause is decisive for its application.

> ***Step 5:*** *Evaluate the experimentation clause and transfer knowledge into the legislative process.*

Due to the experimental nature of experimentation clauses, for constitutional reasons they are required to be evaluated after a reasonable amount of time and a reasonable number of trials. So Step 5 is crucial. This must already be taken into account when formulating the experimentation clause in Step 3. The knowledge about the way in which the experimental clause works and about its effectiveness provides the basis for reviewing it, improving it if necessary, and, as the case may be, transferring it into "regular operation".

IV. Building kit for formulating experimentation clauses



A "building kit" for experimentation clauses is presented below, based on which experimentation clauses can consist of a total of four sections with up to 15 elements. Some of these elements are **essential**[7], others are **optional** and do not have to be included in the regulation.

Model experimentation clause

SECTION 1: [Purpose of the testing]

SECTION 2: Constituent elements and legal consequences

General part: [Competence] [authorisation of authority] [operative part of decision], if [object of testing] and [material limitation].

Special part: [Procedural requirements for application]. [Scope (material and spatial) of the testing]. [Accompanying obligations]. [Time limit of permission/approval]. [Other ancillary provisions]. [Possibility of revocation].

SECTION 3: [Evaluation including transfer]. [Time limit for the clause].

SECTION 4: [Authorisation to issue ordinances or naming of the legal basis].

Section 1 regulates the **purpose of the testing**, which guides the competent authority in its decision-making and is an important basis for the way in which the clause is interpreted.

Section 2 forms the core of the experimentation clause, stipulating centrally whether and how the testing takes place. This paragraph includes a general part that provides the **basis for the decision by the competent authority** as well as a special part regulating the **specific design** of the testing.

Section 3 contains stipulations for the **evaluation** of the **experimentation and the respective clause** and on the **time for which it is valid**. This paragraph is crucial to regulatory learning and the transfer of knowledge into legislation.

Section 4 discusses statutory instruments (ordinances). **Ordinances** may provide a means to create **flexible rules** which can be readjusted comparatively easily if necessary.

7 Depending on the subject area, it might be the case that certain essential elements do not have to be included in the experimentation clause – for example, if there are already general regulations in place that cover these aspects.

SECTION 1

1. Purpose of testing *[optional]*

[→ Details: Schmitz et al. (2020), p. 122f.]

The formulation of an **explicit purpose of testing** serves to **clarify standards** for those applying the law, acts as an **aid to interpretation** for authorities and courts in legal practice, and guides the licensing authority as it **exercises its discretion**.

In practice, the **purpose of testing** has often been set out in **simple terms**:

***Example:* Section 2(7) Carriage of Passengers Act):** *"In order to allow for the practical testing of new modes or means of transport, [...]"*

It is, however, often advisable to formulate a **dual purpose of testing** that also emphasises **regulatory learning** as a key element **for developing permanent regulation** and thus of experimentation legislation, in addition to the practical testing of the innovation. The explicit mention of this dual purpose of testing serves to both facilitate interpretation and to provide guidance for the exercise of discretion in cases of doubt.

Possible wording: *"The purpose of this rule is to provide for the practical testing of [...] and for learning towards the potential development of permanent regulation for [...]"*

SECTION 2 – General part

2. Competence *[essential]*

[→ Details: Schmitz et al. (2020), p. 125ff.]

Competent Authority: In this section, an authority must be designated that decides whether and how the testing of an innovation can be carried out and whether it is possible to deviate from specialist legal requirements for this purpose. In general, this should be the **respective competent authority**, which has in-depth knowledge in the respective subject area. Often, the relevant authority is already defined in a **general rule** within the specialist legislation and does not need to be specified in the clause.

Involvement of authorities: Where **areas of responsibility overlap**, it should be noted that experimentation clauses will need to fit into the system by which competence is assigned. Consideration should be given to whether other authorities have to be or should be involved. Depending on the subject area and competences, this involvement can take place in simple form, e.g. through consultation, the coordination of **mutual consent** or the more intensive coordination of **consensus**.

Example: *Section 11(3) sentence 1, 1st half-sentence Trust Services Act: "Innovative identification methods which are not yet recognised by an order in the official journal can be provisionally recognised by the Federal Network Agency **in consensus** with the Federal Office for Information Security and following **hearing** of the Federal Commissioner for Data Protection and Freedom of Information for a period of up to two years [...]."*

3. Empowerment of the authority *[essential]*

[→ Details: Schmitz et al. (2020), p. 128f.]

The competent authority may be empowered in different ways:

- Binding decision ("**must**"): The authority must grant its approval as soon as the requirements of the individual case are met. No such experimentation clause has been introduced so far.

- Simple discretion ("**can**", "may", "is entitled to", "decides according to due discretion"): The authority is given room to make decisions. It does this on the basis of due discretion within an expedient scope. As a rule, it has the discretion to decide (the "whether") and to act (the "how"). Such discretionary decisions are subject to judicial review for discretionary errors (Section 40 Administrative Procedures Act).

- Intended discretion (e.g., "**should**"): The discretion of the authority "should" generally be exercised in the manner specified, unless there are circumstances involved that are atypical. Such a regulation is more innovation-friendly, and it is particularly useful if the risks associated with the testing are expected to be low.

Example: Section 2(7) Carriage of Passengers Act:
*"In order to allow for the practical testing of new modes or means of transport, **the licensing authority may**, upon request **on a case-by-case basis**, authorise exemptions […]."*

4. Content of decision *[essential]*

[→ Details: Schmitz et al. (2020), p. 129ff.]

On the legal side, it must be **specified in concrete terms what decision the authority may make**. This is based on three steps:

1. Undertake detailed analysis of the existing rules and regulations: Where are there **legal barriers to innovation**? Where are deviations and exceptions unable to be made due to **superior law** (e.g. EU law)? Does the standard contain any **exceptions that are in competition with one another** (e.g. Section 2(6) versus Section 2(7) Passenger Transport Act)?

2. Determine type of deviation to be used, options:

- **Approval/licensing (rule):** The experimentation clause contains the deviations from applicable legal provisions and provides for public space to be temporarily opened up for testing.

- **Mere option for deviation:** Derogations from certain legal provisions are granted without directly conferring any power to the innovator, e.g. empowerment of an authority to issue deviating legal ordinances *(e.g. Section 2(1) part 1 E-Government Act of Saxony).*

3. Define specific deviations, options:

- **Narrow variant:** specific designation of the provisions from which deviations can be made.

Example: *Former section 21b(3) Air Traffic Regulation: "In justified cases, the competent authority can permit exemptions from the prohibitions of operation pursuant to subsection 1 sentence 1 number 1 to 9 if the preconditions of Section 21a(3) sentence 1 are met. [...]"*

- **Broad variant:** It can also be further regulated in law that deviations from the requirements of the respective specialist legislation can be made.

Example: *Section 2(7) Carriage of Passengers Act: "[...] authorise exemptions from the provisions of this Act or from provisions adopted on the basis of this Act for a maximum period of four years, [...]."*

Within the framework of the broad variant, it can, for cases in which ordinary law is **determined by superior law**, be added if necessary that no deviations can be made for certain provisions determined by superior law **(specific exception to the exemption)** or that deviations can only be made insofar as they are compatible with superior law **(broad exception to the exemption)**.

5. Definition of what is to be tested *[essential]*

[→ Details: Schmitz et al. (2020), p. 133ff.]

The **key element** within the experimentation clause is the definition of what is to be tested. This must be formulated such that there is an appropriate **balance between specificity and flexibility**. Specificity ensures **legal certainty** (e.g. the requirement for certainty under the rule of law, general requirement for equal treatment) and **effectiveness** (transparent decision, uniform and targeted application). The authority must be put in a position whereby it is able to decide on the basis of plausible and reliable criteria which innovations are to be tested. Flexibility is needed to ensure that there is sufficient **openness for innovation**. In order to strike the right balance between specificity and flexibility, it is preferable to describe what is to be tested rather than to provide a detailed definition. This specification can be provided in the following ways:

- **Use of recognised generic terms for definable subject areas:**

Example: *Art. 19(1), 1st part E-Government Act of Bavaria: "Introduction and further development of electronic administrative infrastructures"*

- **Additional use of indefinite legal terms:** If the term itself does not encompass the innovative or novel aspect or if several innovative or novel technologies and business models are to be tested in the individual case covered by an experimentation clause, it is still possible to make use of indefinite legal terms such as "innovation", "new" or "novel". Such terms are able to cover a multiplicity of technologies and business models to be tested.

Example 1: *Section 11(3) sentence 1 first half-sentence Trust Services Act "**Innovative** identification methods."*

Example 2: *Section 2(7) Carriage of Passengers Act: "In order to allow for the practical testing of new modes or means of transport"*

It is not compulsory to specify the meaning of indefinite legal terms in more detail in the legislation. Their meaning is interpreted when the legislation is applied by authorities and courts. It can, however, be useful to specify the meaning of indef-

inite legal terms further in order to ensure that they are effective. This can be done as follows:

- **Implicit specification** through a specified **purpose of testing** (see section 1).

Example: *Section 10b(1) of the State Media Act of North Rhine-Westphalia: "Purposes of the introduction and further development of digital terrestrial transmission technologies", "Preparation of decisions on the future use of digital terrestrial transmission technologies"*

- **Specification through definition:** The indefinite legal term may be defined in the subsequent sentence or section. Due to the need for flexibility, it is preferable for the definition to be loose.

Possible wording *"Innovations within the meaning of this experimentation clause are new or improved offerings in the area of digitisation compared to offerings that have been widespread on the market to date."*

- **Specification through enumeration:** Innovative, new or novel technologies and business models, for instance, can be listed as examples, or external criteria mentioned (e.g. belonging to an innovative industry, or ownership of a patent).

- **Specification through rules in the form of secondary legislation:** The advantage of specification though rules at sub-legislative level (e.g. an ordinance) is that the description can be adapted more quickly, which thus provides a higher openness for innovation.

6. Material limitation *[essential]*

[→ Details: Schmitz et al. (2020), p. 138f.]

Material limitation serves to balance the advantages of testing with the conflicting interests and concerns. Firstly, material limitation filters out innovations for which testing is non-justifiable due to the fact that it would involve significant risks, i.e. which are therefore not eligible for testing ("**whether**"). Secondly, this element also specifies the scope within which testing is justifiable ("**how**"). This scope is then specified by the rules in the special part of section 2.

- **General limitations** to balance conflicting interests and concerns. If these interests are manifold or indeterminate, it is advisable to use **open, negative wording** and indeterminate legal terms which can then specified in greater detail depending on the desired discretionary control. If the interests can be sufficiently determined, a **specific wording** (negative or positive) should be used.

Example of open, negative wording: *Section 2(7) Carriage of Passengers Act: "[...] approve,* ***provided that this does not conflict with public transport interests.****"*

Example using a specified undefined legal term: *Former section 21b(3) in conjunction with Section 21a(3) sentence 1 Air Traffic Regulation: "Permission shall be granted if 1. the intended operation [...] does* ***not lead to a danger to the safety of air traffic or to public safety or order, in particular to a violation of the regulations on data protection and on nature conservation, and 2. protection against aircraft noise is adequately taken into account.****"*

Example of specific, positive wording: *Section 113a sentence 1 Schools Act of Lower Saxony : "[...] permit, as far as can be expected, that* ***the economic and overall efficiency of the administration of the schools is thereby improved.****"*

- High-risk innovations often need to be made subject to **additional risk-related requirements**. Firstly, there could be **requirements relating to the innovation**, whereby the approving authority makes use of research, assessments, and certifications to confirm that the innovation is considered to be in the public interest by a recognised body. Secondly, when the testing has to be carried out by persons possessing specific knowledge and experience, **person-related requirements** are needed. Thirdly, there may be **liability-related requirements** under which liability insurance is to be concluded or declarations of exemption from liability are to be used to reduce the state's liability risk for dangers that may still be difficult to manage (but constitutional law imposes narrow limits on such exemptions from liability).

Example of object-related requirements: *Section 11(3) sentence 1 Trust Services Act: "provided that a* ***conformity assessment body*** *has confirmed* ***the equivalent security of the identification method*** *[...]."*

Example of person-related requirements: *Section 11(1) sentence 1 Regulations on Exemptions from Road Traffic Law Provisions governing Overlength Vehicles and Vehicle Combinations: "Vehicles and vehicle combinations with excess length in accordance with Section 3 sentence 1 numbers 2 to 5 may only participate in road traffic if* ***their drivers have been in continuous possession of the class CE driving licence for at least five years and have at least five years of professional experience in commercial road haulage or own-account transport.****"*

Example of liability-related requirements: *Section 43(2) Aviation Act: "The operator of an aircraft shall* ***maintain liability insurance to cover its liability for damages under this subsection*** *to an amount to be determined by ordinance."*

SECTION 2 – Special section

7. Procedural requirements *[essential]*

[→ Details: Schmitz et al. (2020), p. 152ff.]

In cases where innovators are required to file an application to make use of an experimentation clause, specifications need to be set for the application procedure at the competent authority. However, relevant provisions on these specifications do not necessarily have to be included in the experimentation clause itself if there are general rules in the applicable specialised legislation that are sufficient and can be transferred. In most cases, the individual situation for which the testing permit has been granted is likely to differ from the general case described in the specialised law. It therefore makes sense to set specific requirements on the form, content and procedure of the application, which should take into account the fact that the testing is temporary and also respond to the differing levels of risk involved with the innovations.

- **Procedure:** Individual aspects of the procedure (e.g. participation of third parties) can be stipulated, which can mostly be covered by general provisions if these correspond to the character of the testing.

- **Documents to be submitted:** Application documents must allow the authority to make an informed decision about the testing ("whether" and "how"). Depending on the individual situation, the aim should be to use **standardised documents** in order to simplify the application process. However, the use of universal application documents should not be prescribed across the board; rather, the documents selected should **provide for sufficient flexibility** based on the level of risk involved in testing of varying risk-prone innovations.

Example of standardised yet risk-based requirements:
Former section 21a(5) Air Traffic Regulation: "The competent authority shall use its discretion to determine whether additional documentation must be submitted with the application for a permit. In particular, it may further require:
1. proof that the landowner or other person entitled has consented to the ascent,
2. an expert study on the suitability of the site and the airspace concerned for the operation of unmanned aerial systems or model aircraft,
3. further technical assessments or expert studies, in particular on nature conservation and noise protection, in as far these are required in the individual case."

8. Scope of testing *[optional]*

[→ Details: Schmitz et al. (2020), p. 125ff.]

When it comes to licensing for testing, it is useful to set spatial and material limitations for each of the stages involved as appropriate. This element is optional as it is not required for all types of testing. In addition, the competent authorities will also decide what they deem the permissible scope of testing to be when they decide on approval or licensing. The wording should be dependent on the level of risk involved.

- **Open wording:** Legislation provides a broad framework for the authorities to exercise discretion. It is the competent authorities that are predominantly responsible for defining the specific parameters that will apply for an individual case of testing.

Example of open wording *Art. 19(1) E-Government Act of Bavaria: "[...] the state government can issue ordinances to provide for* ***materially and spatially limited derogations*** *from the following provisions: [...]"*

- **Specific wording:** It is often particularly useful to set different spatial and material limitations for each stage of testing as necessary. In many cases, the risks associated with testing are not fully known until some time after testing begins. It is therefore useful to initially set narrower limits, which can then be gradually relaxed if the testing proves safer in practice.

Example of gradual adjustment: *Testing of gigaliners: The approval of gigaliners for road transport for test purposes was carried out on a certain predefined route network, which was partly listed in the*

ordinance itself and partly in the annex to the ordinance. This route network was expanded, among other things, by several ordinance amendments during the test period from 2011 to 2016.

9. Accompanying obligations *[essential]*

[→ Details: Schmitz et al. (2020), p. 160ff.]

In order to fulfil the **government's duty to protect** third parties, especially in high-risk areas, and to evaluate the legislative rules, it may be necessary to issue accompanying obligations for the innovator or for the competent authority. These might particularly include **monitoring or reporting obligations** and the obligation to participate in **scientific studies**.

Since accompanying obligations may interfere with the fundamental rights of economic operators, they must be **justified** and **proportionate**, and their scope must be based on the duty to protect and the legitimate interest in evaluation. The more high-risk an innovation is or the earlier the stage of testing, the more extensive and detailed the monitoring and reporting obligations should be.

Example of evaluation: *Section 12(1) Regulations on Exemptions from Road Traffic Law Provisions governing Overlength Vehicles and Vehicle Combinations (old version of 1 January 2012) "[...] may only participate in road traffic if they are being **used to carry out scientific testing by the Federal Highway Research Institute**."*

Example of government monitoring: *Section 10(3) sentences 3-5 Trust Services Act: "The Federal Network Agency and the Federal Office for Information Security shall **supervise the suitability of the provisionally recognised identification methods during the entire period of the provisional recognition**. If the supervision identifies security-relevant risks [...], the supervisory body can [...] take additional measures to remedy these risks [...]."*

Example of open wording on intervals: *Section 30(2) State Media Act of North Rhine-Westphalia: "The Media Supervisory Authority should require the organisers and providers to present a progress report at **appropriate intervals** on the ongoing model and field tests [...]"*

Example of specific wording on intervals: *Item 4.6 paragraph 5 Framework for the Coordination of the Joint Federal/Länder Task for the Improvement of Regional Economic Structures: "The Länder shall submit a **written annual** report about the use of the funding to the subcommittee."*

10. Time limit for testing *[essential]*

[→ Details: Schmitz et al. (2020), p. 165ff.]

As a key element in an experimentation clause, the **time limit for testing** should be chosen in such a way that the temporary purpose of it is made clear, but sufficient time is available for testing and the associated regulatory learning process. The **duration of the time limit** can be structured in different ways:

- **No mention or open wording:** In this case, the decision on the duration of the time limit is left to the discretion of the competent authority. While this provides flexibility, it can lead to a "patchwork" of licensing practices and limit business planning capabilities.

- **Specific duration:** In this case, both the minimum and maximum amount of time for testing is set out. Where the testing of high-risk innovations is concerned, shorter testing periods (with the possibility of extension, see below) should be envisaged to start with. It is also possible to set a **flexible time frame**, e.g. by including the words "as a general rule".

***Example:* Section 2(7) Carriage of Passengers Act:** *"In order to allow for the practical testing of new modes or means of transport, the licensing authority may, upon request on a case-by-case basis, authorise exemptions [...] **for a period of no longer than four years** [...]."*

Possible wording for a flexible time frame: *"The testing shall be **limited** to an **appropriate period of time**. As a general rule, a period of **no less than two years** and no more than five years is appropriate."*

Possibility of extension: Since the testing of provisions and innovations can lead to unforeseen developments and challenges, it is generally not useful to stipulate the duration of the experimentation phase in law without being able to deviate from it in individual cases. However, the possibilities for extending the duration of testing should not be utilised without good reason; provided that testing is successful, regular operation should be the goal.

Suspensive effect of an objection and legal action: Pursuant to Section 80(1) sentences 1 and 2 Code of Administrative Court Procedure, objection and rescissory action have suspensive effect, meaning that testing permits cannot be used. This is especially problematic where rules on testing are set for a limited period of time and do not provide for the possibility of extension. Here, the following possible solutions may be used:

- **Cessation of the suspensive effect against the licensing for testing** (cf. Section 80(2) sentence 1 no. 3 Code of Administrative Court Procedure). In this variant, testing can take place despite the filing of an appeal by third parties.

Possible wording: *"The suspensive effect of an objection and a rescissory action by a third party against the licensing for testing shall cease to apply pursuant to Section 80(2) sentence 1 no. 3 Code of Administrative Court Procedure."*

- **Suspension of the testing period:** For the duration of the suspensive effect of a third-party claim or third-party action, the testing period would not elapse. In this variant, no testing can take place when an appeal is filed by a third party.

Possible wording: *The elapsing of the testing period shall be suspended by the filing of the action or appeal against the licence.*

- **Special possibility for extension:** If an appeal has a suspensive effect, an official extension of the testing period may be granted. In this variant, no testing can take place when an appeal is filed by a third party.

Possible wording: *"In the event that an action is brought or an objection filed against the licence, the duration of the time limit shall be extended accordingly."*

11. Other ancillary provisions *[optional]*

[→ Details: Schmitz et al. (2020), p. 125ff.]

As an optional element, it can also be stipulated in an experimentation clause whether and under what conditions the **decision on testing by the competent authority can be made subject to ancillary provisions**. The time limit for testing (see above) is a subset of an ancillary provision.

Example: *Former section 21b(3) sentence 2 in conjunction with Section 20(5) Air Traffic Regulation: "Permission may be granted [...] generally or for individual cases. It may be subject to ancillary provisions, in particular to conditions."*

Any special statutory provision stating that licensing can be made subject to ancillary provisions is only **of a clarifying nature**. This is because the use of ancillary provisions is already regulated in general administrative law (in Section 36 Administrative Procedures Act). In order to ensure the clarity of legislation, any special statutory provision should be used with **restraint**. In particular, it should **specify** which ancillary provisions are possible under which conditions. Ancillary provisions can be used to create solutions tailored to each individual case, giving the authority further options for action.

12. Possibility of revocation *[optional]*

[→ Details: Schmitz et al. (2020), p. 172ff.]

The experimentation clause may include a special provision for cancelling the approval or licence. However, since the Administrative Procedures Act covers revocation (Section 43(2) variant 1) by means of withdrawal (Section 48) and revocation in general (Section 49), there is usually little need for additional provisions to regulate it. It would be possible, for example, to reserve the **right to revoke** permission in accordance with Section 49(2) no. 1 if there are reasons that **correspond to the purpose of the experimentation clause** (e.g. testing is not started or falls significantly below the permitted scope), e.g.:

Possible wording: *"The licence is revocable. In addition to the grounds specified in Sections 48-49 Administrative Procedures Act, the licence may be revoked in whole or in part without compensation* ***if the testing is not carried out within two years of the licence being granted or falls significantly below the permitted scope****."*

SECTION 3

13. Evaluation und Transfer *[essential]*

[→ Details: Schmitz et al. (2020), p. 175ff.]

Once an experimentation clause has started to be used in practice, an evaluation needs to take place in order that the testing of innovations can lead to regulatory learning. The evaluation is intended to provide information on whether and to what extent the objectives of the provision are being achieved, how it needs to be improved, and whether and to what extent it can be transferred into standard practice. The evaluation looks at three different aspects:

1) The **evaluation of the experimentation clause** serves to determine whether its individual elements are correctly designed.

2) The **evaluation of the individual regulatory sandboxes**, which are implemented on the basis of the experimentation clause, summarises the experience gained in practice.

3) The **evaluation of the law** in which the experimentation clause is enshrined serves to determine whether the legal framework needs to be adapted.

Within the Federal Government, the evaluation of laws must also take account of the concept issued in 2013, which was further developed by the committee of state secretaries on 'Bureaucracy Reduction and Better Regulation' in a decision dated 26 November 2019.

With a view to evaluation, it makes sense for the experimentation clause to offer several components and variants:

- **Accompanying obligations** (see above), such as participation in scientific research and reporting obligations, both for the innovator to the administration, and for the administration to the legislator.

Example of cooperation obligation: *Section 12(1) Regulations on Exemptions from Road Traffic Law Provisions governing Overlength Vehicles and Vehicle Combinations (old version of 2012): "[...] only participate in road traffic if* ***they are being used to carry out scientific testing by the Federal Highway Research Institute****."*

Example of reporting obligation for the administration: *Section 1c Road Traffic Act: "The Federal Ministry of Transport and Digital Infrastructure will* ***evaluate*** *the application of the provisions [...]* ***on a scientific basis****. The Federal Government shall* ***inform the German Bundestag of the results of the evaluation****."*

- **Objectives and content:** In the experimentation clause itself or in the rationale for the regulatory project, objectives and criteria for achieving goals can be defined, on which the evaluation will subsequently be based. The methods to be used and the addressees of the results can also be mentioned.

Example: *Section 21 of the E-Government Act of Saxony: "(1) The state government shall submit a report to the Landtag in 2021 stating 1.* ***what effects*** *this act [...] has had, 2.* ***what projects have been carried out on the basis of the experimentation clause*** *in Section 20, 3. how data protection and accessibility [...] have developed, 4.* ***what costs and benefits*** *have been arisen in implementing this Act, and 5.* ***whether further development of the provisions of this Act is needed****. The evaluation must also take into account the perspective of the users of e-government services, especially citizens and businesses."*

- **Time frame:** The evaluation clause should set out when the evaluation will begin. The latter should be conducted ex-post, a reasonable time after the law enters into force. It is important that a sufficient amount of experience has already been gathered in the tests before the evaluation is carried out.

- **Responsible government agency:** It is a good idea to assign the evaluation to an institution or authority that is superior to the authority responsible for licensing the testing and that can collect information from several authorities.

Example: *Section 14 sentence 2 Freedom of Information Act: "****The German Bundestag*** *will evaluate the law on a scientific basis* ***one year before it expires****."*

- **Knowledge transfer:** It is advantageous for the experimentation clause to stipulate that the licensee designate a person to be responsible for the evaluation of the regulatory sandbox and for transmitting all of the necessary information to the competent governmental agency.

14. Time limit for the experimentation clause *[optional]*

[→ Details: Schmitz et al. (2020), p. 179f.]

As with any statutory provision, the experimentation clause can also be given a specific period of validity by including a time limit (**sunset clause**) as an optional element, which is useful if the experimentation clause is to be tried out and tested for its effectiveness and practicability itself. In this case, the **period of validity** needs to be long enough to permit a sufficient amount of testing to be conducted on the basis of the experimentation clause for meaningful findings to be achieved.

Example: *Section 13 (1) and (2) Regulations on Exemptions from Road Traffic Law Provisions governing Overlength Vehicles and Vehicle Combinations (old version): "(1) This ordinance shall enter into force on 1 January 2012. (2)* ***It shall expire at the end of 31 December 2016****."*

SECTION 4

Authorisation to issue ordinances *[optional]*

[→ Details: Schmitz et al. (2020), p. 125ff.]

Not all requirements for testing innovative technologies and business models need to be regulated in an act of parliament. Instead, there is often the optional possibility of stipulating the experimentation clause in whole or in part **by means of an ordinance**, which does not have to go through the parliamentary procedure in order to be enacted.

The use of secondary legislation, i.e. an ordinance, is particularly recommended where the elements aimed at reducing risk need to be formulated flexibly, e.g., procedural requirements such as material limitation, scope, or accompanying obligations. The **advantage** is that **ordinances can be altered more easily** if key assumptions, such as **risk assessments, change** during the course of the testing. This ensures more effective control and increased flexibility. It can also serve to provide **greater administrative guidance**, ensure **uniform practice among the authorities and accelerate procedures.**

As a rule: **The more complex the regulatory area, the more specific the administrative guidance needs to be in the form of secondary legislation.** In some cases, an experimentation clause may be stipulated entirely in an ordinance. This is particularly useful for complex and rapidly changing matters.

But there are limits to what can be regulated by ordinances. Ordinances function within the

boundaries set by the separation of powers, the requirement of parliamentary approval, the principle of democracy, and fundamental rights, and are specifically regulated by Article 80 of the Basic Law. The basis for these is always an **authorisation to issues ordinances enshrined in a parliamentary act**. In the event that the experimentation clause is placed in an act, and then further specified in an ordinance, the experimentation clause itself must contain an authorisation to issue ordinances. This authorisation to issue ordinances must satisfy the **requirement of parliamentary approval** *(essential decisions must be made by the legislator)* and the requirements of Article 80(1) sentence 2 Basic Law *(requirements for the law authorising the issuance of an ordinance)*. In addition, the statutory legal basis must be stated in the ordinance (Art. 80(1) sentence 3 Basic Law).

Example: *Section 6(1)(2)(a) Road Traffic Act: "The Federal Ministry of Transport and Digital Infrastructure shall be authorised to issue ordinances with the approval of the Bundesrat on [...]*

No. 2: the licensing of vehicles for road traffic, including exemptions from admission, the characteristics, equipment and testing of vehicles, in particular [...]

lit. a: requirements for the licensing of motor vehicles and their trailers, in particular on the construction, characteristics, inspection and approval, equipment and operation, [...]".