

Implementation and structure of a contact point for net-zero regulatory sandboxes – implementation-phase proposals

Report on a Government assignment

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Contents

1 Introduction	10
1.1 Government assignment.....	11
1.2 Legal requirements under the Act.....	12
1.3 Implementation	19
1.4 Report layout	22
2 Vinnova's proposal	24
2.1 Structure and implementation of the regulatory sandbox contact point.....	24
2.2 Identifying competent authorities	36
2.3 Preparatory actions for implementation of the contact point	42
2.4 Other parts of the Act that have a bearing on the implementation of the contact point	46
2.5 Questions for further inquiry	47
3 Presentation of supporting information for the proposal.....	51
3.1 Insights from interviews and reports	50
4 Impact assessment and identification of risks.....	63
4.1 Implications of Vinnova's proposal.....	62
4.2 Identified risks.....	67
5 Bibliography	71

Summary

This report contains proposals on how a contact point for net-zero regulatory sandboxes can be implemented in Sweden, during an implementation phase. This is in accordance with the Government's assignment to Vinnova on 19 September 2024¹ and within the framework of the future implementation of the EU's Net-Zero Industry Act (hereinafter referred to as the 'Net-Zero Industry Act' or 'the Act').²

About the report

Based on the existing legal framework, competent authorities and other stakeholders that will need to be involved are identified. A structure and working process for the contact point is proposed, as are certain preparatory measures for the entry into force of the Act. The proposals have been developed through an iterative design process that has considered and balanced a range of factors. These include the legal framework, insights from dialogues with relevant private and public stakeholders, an international perspective and previous national experiences of regulatory sandboxes. Finally, an impact assessment and risk analysis are presented, as well as issues for further investigation.

Regulatory sandboxes - a new opportunity with great uncertainty

Regulatory sandboxes are a relatively new tool for technological development in Sweden. The regulatory sandboxes will foster innovation in net-zero technologies, focusing on testing in a controlled, real-world environment. They will also foster regulatory learning and must particularly take into account the needs of SMEs and start-ups. Vinnova sees great potential in removing regulatory obstacles and increasing opportunities for innovative companies and clusters to test and verify new technologies. Such opportunities are needed for the EU and Sweden to attract and retain investment capital and excellence, and for new technologies with the potential to contribute to climate neutrality and the circular economy to reach the market faster.

Setting up a national contact point for regulatory sandboxes³ under the Net-Zero Industry Act requires careful planning and imposes new requirements for horizontal and vertical interaction among regulators, licensing and supervisory authorities (under the

¹ Ministry of Climate and Enterprise, Government Decision, *Commission to analyse how a contact point for regulatory sandboxes should be structured and implemented*, (ref. KN2024/01799, 19/09/2024).

² Regulation (EU) 2024/1735 of the European Parliament and of the Council on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (referred to below as the Net-Zero Industry Act (EU) 2024/1735)

³ The Act allows Member States to establish more than one contact point for regulatory sandboxes; Vinnova has, in its report, assumed that only one contact point will be established, in order to make implementation as simple as possible during an initial phase.

Act, “competent authorities”) and other stakeholders. In addition, ongoing contact and synchronisation with other EU Member States is needed.

Effective implementation of regulatory sandboxes requires good guidance for applicants and effective collaboration between public authorities and other bodies at national, regional and municipal level. The application process must not be unnecessarily administratively burdensome.

Summary of Vinnova’s proposals

The proposals emphasise the importance of considering the purpose of the Net-Zero Industry Act and regulatory sandboxes as a new policy instrument in the context of implementation. Given the timing of the assignment to Vinnova and the lack of implementing acts for the Act, many questions remain to be answered in greater detail. Collaboration among the relevant stakeholders will therefore be of great importance in the continued implementation.

The contact point needs a clear mandate and sufficient resources, with broad expertise in areas such as technology, law, communications, design and business development. The scope as well as the complexity of the applications received by the contact point can be expected to vary in terms of the applicable regulatory framework, the variety of innovative technologies and the number of public authorities potentially involved. Vinnova therefore proposes that one public authority be assigned a leading role as contact point. In addition, Vinnova proposes that a small number of competent authorities, central to the Act, be linked to the contact point by means of an office or council function. This is to ensure smooth and efficient handling of applicants from the start, with a breadth of interdisciplinary competences, while a broader anchoring among public authorities allows for suitable working methods and a so-called ‘gutter’ in the work with the sandboxes.

The responsibilities and roles of the competent authorities must also be clarified. In order for the regulatory sandbox system to function according to the spirit of the Act, Vinnova believes that competent authorities should have dedicated resources with sufficient expertise and clear responsibilities. It is proposed to achieve this by establishing innovation centres in the government agencies most affected by the Net-Zero Industry Act. An innovation centre is intended to serve as an interface between companies and the contact point. During the implementation phase, it is proposed that the contact point guides companies to the proper competent authority. The innovation centre is proposed to offer guidance in applying for regulatory sandboxes as well as providing early guiding support in relation to existing legislation.

Complex issues and conflicting objectives will need to be addressed. Processes that are flexible while remaining legally secure and consistent must be established, with clear definitions, selection and assessment criteria, roles and mandates. A clear plan is

needed regarding how stakeholders, individually as well as collectively, can ensure sufficient competences to deal with applicants and the sandboxes that will be involved, as well as how long-term funding will be resolved.

The issue of resources is a key aspect for both the contact point and the competent authorities, and needs to be addressed to provide the conditions for effective implementation. Previous research from the Agency for Economic and Regional Growth shows that the resource requirements of a regulatory sandbox are greatest early on, when work is initiated, and later decrease as learning occurs, both at companies and internally at the public authority.⁴ Insufficient resources can lead to longer processing times and counteract the regulatory sandbox's aim of rapidly promoting innovation and accelerating the release to market of innovative net-zero technologies.

The following bulleted items are a more detailed summary of the main proposals. The expanded proposals can be found in section 2.

Concerning the contact point

- The Act requires each Member State, when establishing regulatory sandboxes, to designate one or more contact points. Vinnova proposes *one* contact point initially. This contact point should be organised as an inter-agency office. This office should be convened by a public authority with main responsibility. Here, Vinnova is proposed as the main responsible authority in such an office.
- The contact point will serve as a 'gateway' for companies⁵ wishing to test innovative net-zero technologies in a controlled, real-world environment.
- Vinnova proposes that the contact point will guide companies to the proper competent authority.
- The contact point is proposed to receive applications, without deciding on them. Upon request, the contact point can support competent authorities in assessing whether applications meet formal requirements.
- The contact point will design, package and disseminate information and offers to relevant stakeholders, together with competent authorities
- The contact point will establish a structure for systematic learning from sandbox experiences.

Concerning competent authorities

- Competent authorities are those bodies at national, regional and municipal level that have regulatory, authorisation or supervisory functions within the scope of the Act.

⁴ Swedish Agency for Economic and Regional Growth, *Analys av genomförandet av förordningen om nettonollindustrin*, (ref. Å 2024-105, 27/03/2024).

⁵ As a collective term in this report, the term companies is used. Applicants can include companies, organisations or consortia developing innovative net-zero technologies that meet the eligibility and selection criteria set out in the Act. These eligibility and selection criteria, to be specified in implementing acts, are as yet unknown to Vinnova, but can be assumed to include innovative clusters, industry organisations, research institutes, incubators, innovation offices, science parks, the Acceleration Office or similar.

- The public authorities to be initially considered as relevant competent authorities are the Swedish Work Environment Authority, the Swedish Energy Markets Inspectorate, the Swedish Energy Agency, the six county administrative boards appointed by the Government as contact points to facilitate permit-granting processes⁶, the Swedish Environmental Protection Agency, the Geological Survey of Sweden, the Swedish Radiation Safety Authority, the municipalities, the Land and Environment Court and the Environmental Assessment Delegations.
- The competent authorities shall assess and decide on applications, as well as developing plans for and monitoring the regulatory sandbox to which an application relates.
- Public authorities should also consider granting exemptions or derogations from regulatory requirements applicable to testing activities.
- Vinnova proposes that innovation centres be established at the government agencies most affected by the Net-Zero Industry Act.

Work process

For a company-initiated regulatory sandbox, Vinnova proposes the following multi-step process. This process may need to be revised and adapted to future implementing acts of the European Commission:

1. Companies⁷ access information from public authorities on regulatory sandbox
2. Companies prepare the application
3. Companies submit the application to the contact point/office
 - The contact point/office provides guidance. A reference group of research institutes and others will be attached to the contact point, to provide the contact point and the competent authority with expertise in test and demonstration environments, technologies, innovative companies, sandbox concept-development support, etc.
4. The contact point and the competent authority engage in coordination. The application is handed over from the contact point to the main responsible competent authority for processing
5. Competent authorities assess the application
6. Main responsible competent authority takes decision on the application
7. Competent authorities prepare the regulatory sandbox and establish a plan for it. This plan should include considerations for deviations or exemptions from regulatory requirements as well as the supervisory authority and other conditions
8. Competent authorities establish the regulatory sandbox
9. Companies conduct tests/experiments in the regulatory sandbox, with supervision and support from the competent supervisory authority
10. Competent authorities consider additional regulatory exemptions

⁶ The county administrative boards of Västerbotten, Dalarna, Stockholm, Örebro, Västra Götaland and Skåne counties. Ministry of Climate and Enterprise, "Sex länsstyrelser får uppdrag att samordna och underlätta tillståndprocesser", <https://www.regeringen.se/pressmeddelanden/2024/12/sex-lansstyrelser-far-uppdrag-att-samordna-och-underlatta-tillstandsprocesser/>. Press release, 17/12/2024.

⁷ See footnote 5 above.

11. Competent authorities, together with implementing companies, close the regulatory sandbox
12. Collection of accumulated regulatory learning (implementing company, competent authority, contact point, Government Offices, Simplification Council)
13. Proposal to amend regulation is investigated and addressed is proposed to be done by the competent authority of the Simplification Council.
14. The Government Offices coordinate and follow up regulatory changes at national level
 - Harmonisation and coordination between Member States, coordinated by the Commission's EU Net-Zero Europe Platform.

Resources

It is emphasised in this report that the issue of resources is crucial for effective implementation. Vinnova estimates and proposes that resources equivalent to at least six annual work units (AWU) are required to operate a contact point office. Additional resources are needed by all involved stakeholders (see section 2.1.3) throughout the regulatory sandbox process as a whole. From competent authorities, reference group, investigation committee, coordination with the Net-Zero Europe Platform, etc.

Preparatory measures

This report identifies and proposes several preparatory measures, of which a selection is summarised below:

- The Government Offices are responsible for clarifying roles and mandates, ensuring resources throughout the regulatory sandbox process, and appointing an office for the contact point.
- It is proposed that the Government Offices designate a ministry to coordinate collaboration in the preparation of EU implementing acts starting in spring of 2025.
- A ministry should be designated as mainly responsible for national follow-up of net-zero sandboxes vis-à-vis the EU platform.
- A single ministry should be the gateway for the contact point and competent authorities regarding follow-up, regulatory learning and proposals for regulatory amendments.
- The administrative process must be regulated at national level, e.g., in a national regulation complementing the Net-Zero Industry Act.
- The legally secure handover and handling of information from applicants within and between the involved stakeholders must be ensured.
- Competent authorities must develop forms of collaboration and working methods in conjunction with the contact point.
- The contact point and competent authorities must plan for communications campaigns.

Key stakeholders

In addition to public authorities, it is proposed that other stakeholders are important for implementation:

- The Swedish Agency for Economic and Regional Growth, as a contact point for strategic projects.
- The Simplification Council (at the Swedish Agency for Economic and Regional Growth) and the Implementation Council, for collecting and investigating proposals for regulatory amendments.
- Industry organisations, able to represent the business perspective.
- Swedish Competition Authority, able to provide expertise on competition issues.

Systematic learning:

- Vinnova recommends that structures for systematic learning be established early on in order to permit continuous feedback of lessons learnt and development of working methods over time.
- Such learning should include support to target groups, internal working methods, collaboration, use of skills and modes of working.
- An evaluation of the process should be carried out at the end of the implementation phase before ordering any major changes to, for example, governance and responsibilities.
- Applying a design- and user-driven working method will ensure that the process is continuously adapted as needs and circumstances change.

1 Introduction

We live in an era where climate change constitutes a substantial threat to all life on Earth. This requires swift, effective and system-wide measures, involving laws, policies, technologies, business models, infrastructure, knowledge and innovation, as well as norms and behaviours, from the global to the local level. Today's technologies are developing fast, and AI and quantum technologies, among other factors, are expected to quicken the pace. Regulatory developments sometimes fail to keep up with technological developments, which risks delaying or even impeding innovation and the introduction of the technologies and business models with the potential to help solve the complex environmental and societal challenges we face.

Vinnova sees great potential in using regulatory sandboxes as a policy instrument to facilitate innovative companies and clusters in testing and verifying new technologies, and to remove regulatory barriers for the European market. Such efforts are needed so that the EU and Sweden can attract and retain investment capital and excellence, and so new technologies can reach the market faster.

Regulatory sandboxes can permit innovative companies to challenge more established players with new technologies, more efficient processes and circular business models.⁸ Regulatory sandboxes offer a legally formalised process for companies to work with governments in addressing the challenges posed by regulations to the development of new technologies.

The regulatory development enabled by regulatory sandboxes can also help to strengthen ecosystems in Sweden's strategically important technology sectors. Vinnova submitted a report to the Government in 2024, proposing strategically important technologies that could strengthen Sweden's competitiveness and business investment in research and development. Energy technologies for fossil-free electrification was one of six priority technology areas. In the report, Vinnova emphasises that a coherent technology policy and rapid policy development in the sector are urgent.⁹

One objection to regulatory sandboxes is that they risk distorting competition. Transparency, openness to participants instead of compartmentalisation, and sharing of results in implementation are highlighted as examples of measures to reduce this risk.¹⁰ One criticism that has emerged is that regulatory sandboxes risk requiring a lot

⁸ Lars Persson and Pehr-Johan Norbäck, *Hur påverkar regulatoriska sandlådor konkurrensen?*, Swedish Competition Authority 2023.

https://www.konkurrensverket.se/globalassets/dokument/informationsmaterial/rapporter-och-broschyrer/uppdraagsforskning/forskrapport_2023-4.pdf (Retrieved 05/12/2025)

⁹ Vinnova, *Strategic techniques for Sweden: A basis for national priorities*, Vinnova, 2024. https://www.vinnova.se/globalassets/publikationer/2024/rapport-ru-strategiska-teknikomraden_ver-01.0-final-1.pdf?cb=20241030174857 (Retrieved 03/01/2025).

¹⁰ Lars Persson and Pehr-Johan Norbäck, *Hur påverkar regulatoriska sandlådor konkurrensen?*, Swedish Competition Authority 2023. https://www.konkurrensverket.se/globalassets/dokument/informationsmaterial/rapporter-och-broschyrer/uppdraagsforskning/forskrapport_2023-4.pdf (Retrieved 05/12/2025)

resources, both for the applicants and the organisation receiving applications.¹¹ For that reason, Vinnova deems that long-term funding of the entire regulatory sandbox system is crucial to implementation. If they fail to open the way for new technologies through actual and timely development, amendment, interpretation or application of regulations, then regulatory sandboxes risk having a marginal effect as a policy instrument.¹²

The Swedish model of public administration is based on a democratic rule-of-law tradition, with public authorities serving as expert bodies independent of the national government and municipal autonomy ensuring grassroots support and legitimacy. It is also based on high levels of trust in the public sector and its mandate to issue regulations in the form of statutes that are predictable, fair and legitimate. When applying the Act, this model may bring about uncertainty regarding which public authority or authorities are competent to deal with regulatory sandbox issues in relation to a particular testing activity. Achieving the objectives ('a green and just transition') of the European Green Deal, of which the Net-Zero Industry Act is a part, will require societal stakeholders to find new forms of collaboration. This includes stakeholders within public administration as well as stakeholders from business, academia and civil society.

In 2010, the Riksdag decided that the civil service was to be innovative and collaborative as well as being legally secure and efficient, and that its quality, service and accessibility were to be developed in order to contribute to Sweden's development as well as effective work within the EU. To achieve this goal, the Government emphasised new values for public administration, such as being *innovative* and *collaborative*.¹³ We recognise that the Net-Zero Industry Act¹⁴, not least in the parts concerning the regulatory sandboxes, impacts many stakeholders and involves complex issues and potentially conflicting objectives. In the work on implementing the Act and regulatory sandboxes, the goal for public administration, together with the principles of the fundamental values of government¹⁵ for good administration, should be guiding principles.

1.1 Government assignment

Vinnova has been assigned by the Government to analyse how a contact point for net-zero regulatory sandboxes is to be structured and implemented in Sweden. The Act

¹¹ Informant A, civil servant, Erhvervsstyrelsen of Denmark. Interview, 20/11/2024; Swedish Energy Markets Inspectorate, "*Ei:s synpunkter på Vinnovas uppdrag att analysera hur en kontaktpunkt för regulatorisk försöksverksamhet bör struktureras och genomföras*", 20/12/2024, (ref. 2024-03522_22).

¹² SOU 2022:68 Förnya taktiken i takt med tekniken, förslag för en ansvarsfull, innovativ och samverkande förvaltning.

¹³ Govt. bill 2009/10:175 *Offentlig förvaltning för demokrati, delaktighet och tillväxt*, Ministry of Finance

¹⁴ Net-Zero Industry Act (EU) 2024/1735)

¹⁵ Swedish Agency for Public Management, *Den statliga värdegrunden, gemensamma principer för en god förvaltning*, Swedish Agency for Public Management, 2019, <https://www.statskontoret.se/siteassets/rapporter-pdf/2019/statliga-vardegrunden.pdf> (Retrieved 03/01/2025)

requires Member States to set up regulatory sandboxes for net-zero technologies at the request of any company, organisation or consortium that meets certain eligibility and selection criteria. The regulatory sandboxes will foster innovation, i.e. the innovative development and scaling-up of net-zero technologies with a focus on testing in real-world environments. They shall also foster regulatory learning and particularly take into account the special circumstances and capacities of SMEs and start-ups.

The assignment included identifying the public authorities that could be considered as competent authorities in the first instance. Furthermore, Vinnova has investigated what preparatory measures are necessary to fulfil the Act's rules on contact points for regulatory sandboxes.

Finally, the assignment has included analysing other elements of the Act that may affect the implementation of the contact point.

The assignment description states that Vinnova is to obtain views from the Swedish Energy Agency, the Swedish Energy Markets Inspectorate, the Swedish Agency for Economic and Regional Growth and other authorities and stakeholders relevant to the assignment.

The assignment was received on 19 September 2024 and has been reported on 21 February 2025.

1.2 Legal requirements under the Act

1.2.1 The Net-Zero Industry Act

The EU Net-Zero Industry Act (2024/1735), referred to here as the 'Act' or the 'Net-Zero Industry Act', has been the basis for the analysis. The Net-Zero Industry Act is part of the Green Deal Industrial Plan of the EU for 2050. The Act aims to contribute to the clean energy transition and to achieving the EU's climate target by scaling up the production capacity of key technologies. This also ensures the EU's access to secure and sustainable supplies of net-zero technologies. These key technologies are seen as crucial to reach the EU's climate target of a 55 per cent reduction in greenhouse gas emissions by 2030 compared to 1990 emission levels and climate neutrality by 2050.¹⁶

The Act regulates measures in parallel areas such as the fostering of strategic net-zero projects, streamlining permit-granting processes for critical raw materials and innovative net-zero regulatory sandboxes. The Swedish Agency for Economic and Regional Growth has been appointed to lead the assignment of recognising as net-zero strategic net-zero projects. The county administrative boards of Västerbotten, Dalarna, Stockholm, Örebro, Västra Götaland and Skåne have been appointed as national

¹⁶ European Commission, 'Net-Zero Industry Act', https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal/green-deal-industrial-plan/net-zero-industry-act_sv (Retrieved 17/01/2025);
Net-Zero Industry Act (EU) 2024/1735

contact points for streamlining permit-granting processes. The Act provides for Member States to establish, upon request, experimentation spaces in the form of net-zero regulatory sandboxes as a tool to foster innovation. In the regulatory sandboxes, exemptions and derogations from regulatory requirements may be granted for testing activities. The Act states that competent authorities shall consider whether to grant regulatory sandboxes derogations or exemptions from regulatory requirements in national law to the extent allowed by relevant Union law, while ensuring compliance with Union law and the basic requirements for net-zero technologies laid down in national law.¹⁷ Monitoring and supervision of testing should be flexible and aim at regulatory learning and reducing regulatory burdens. The regulatory sandboxes will strengthen the conditions for a faster market introduction of innovative technologies. The Act obliges Member States to also establish or designate one or more contact points for the regulatory sandboxes by 30 March 2025 at the latest.¹⁸ The main principles of this procedure are to be provided by the European Commission in implementing acts. In 2025, Sweden will start collaborating with other Member States on the content of the implementing acts. For more information on the relevance of implementing acts for Sweden's implementation, see section 2.5.1.

1.2.2 Legal basis, key concepts and provisions

The legal basis for the assignment has been the Net-Zero Industry Act, in so far as it deals with regulatory sandboxes, and other guidance from the Commission made available regarding the function and working methods of regulatory sandboxes and other similar policy instruments. As mentioned, the guidance provided in the Act is very limited, not least as regards the function and duties of the contact point.

The arrangements and conditions for the establishment and operation of the regulatory sandboxes will be communicated by the European Commission in implementing acts. The implementing acts will presumably govern to a great extent the implementation and functioning of the regulatory sandboxes. It is unclear to what extent they will include mandatory provisions from which Sweden cannot derogate. In the assignment, Vinnova has assumed that, within the given framework, Member States will be given considerable scope to find their own solutions on the national level, based on considerations of suitability and taking into account traditions of public administration and law in the Member State and other circumstances. However, it cannot be ruled out that parts of Vinnova's proposal may need to be re-examined or revised in the light of the European Commission's forthcoming implementing acts.

¹⁷ Net-Zero Industry Act (EU) 2024/1735:33

¹⁸ The Act allows Member States to establish more than one contact point for regulatory sandboxes; Vinnova has, in its report, assumed the scenario that only one contact point is established in an initial phase, in order to make implementation as simple as possible.

1.2.2.1 Basic concepts

An analysis of how regulatory sandboxes are intended to be established and to operate under the Act can be based on the Act's definitions and some other key provisions, interpreted in accordance with the Act's preamble. The Act provides the following brief definition of the term 'regulatory sandbox':

'Net-zero regulatory sandbox' means a scheme that enables undertakings to test *innovative net-zero technologies and other innovative technologies* in a controlled real-world environment, under a specific plan, developed and monitored by a competent authority (Art. 3.22).

In carrying out the assignment, Vinnova has also used the European Commission's guidance¹⁹ from 2023 on regulatory sandboxes and similar tools for technical testing and experimentation, such as test beds and 'living labs'. Among other things, the guidance provides an international overview of experiences within and outside the EU with these types of tools in a number of areas, such as energy. The guidance describes regulatory sandboxes as follows:

"Regulatory sandboxes are structured frameworks for cooperation with competent authorities that allow innovators to develop and test new ideas, products, business models and services in a controlled real-world environment under the supervision of a competent authority. Existing rules or their enforcement may be relaxed or suspended during testing under certain conditions. Competent authorities may also provide participants in the sandbox with bespoke guidance to address legal uncertainty on how legal rules and requirements apply to specific products or services developed in the sandbox. Regulatory sandboxes are always limited in terms of time and scope."

The technologies that may be subject to regulatory sandboxes are defined in the Act as follows:

'Net-zero technologies' means the technologies listed in Article 4 where they are final products, specific components or specific machinery primarily used for the production of those products (Art. 3.1).

'Innovative net-zero technologies' means net-zero technologies that comprise genuine innovations which are not currently available on the market and that are advanced enough to be tested in a controlled environment (Art. 3.12).

'Other innovative technologies' means energy-related or climate-related technologies with a proven potential to contribute to the decarbonisation of industrial or energy systems and to reduce strategic dependencies that comprise genuine innovations that are not currently

¹⁹ European Commission, *Regulatory learning in the EU, Guidance on regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy* (Commission Staff Working Document) SDW (2023) 277/2), 26/07/2023, p. 6. <https://data.consilium.europa.eu/doc/document/ST-12199-2023-INIT/en/pdf>

available on the Union market and that are advanced enough to be tested in a controlled environment (Art. 3.13).

Regarding public-sector stakeholders in connection with the establishment and implementation of regulatory sandboxes, the Act states the following:

National contact point for regulatory sandboxes

Member States shall, when setting up net-zero regulatory sandboxes, establish or designate one or more contact points. A sole contact point shall be responsible for each request to establish a net-zero regulatory sandbox. (Art. 33.1)

Competent authority

This term is not clearly defined in the Act. In a broad sense, it means national authorities with one or more of either regulatory, authorisation or supervisory functions within the scope of application of the Act. The Act gives such authorities certain key tasks in their work with regulatory sandboxes.²⁰

Competent authorities shall, inter alia:

- Select which applications will be authorised to participate in a regulatory sandbox.
- Establish and oversee a specific plan for the testing activities
- Exercise supervisory powers on the testing activities in a flexible manner to remove barriers and reduce regulatory burden and legal uncertainty.
- Consider whether to grant derogations or exemptions from regulatory requirements for the regulatory sandbox.

1.2.2.2 Key provisions of the Act

The key provisions on regulatory sandboxes are contained in Articles 33 and 34 of the Act, which include the following (Vinnova's underlining)

- Member States shall establish net-zero regulatory sandboxes at the request of any company, organisation or consortium that fulfils certain eligibility and selection criteria.
- Member States, together with local and regional authorities and other Member States where appropriate, may at their own initiative establish net-zero regulatory sandboxes.

In its guidance, the European Commission has described these two routes as follows:

"There are two approaches for setting up a sandbox: one where the request (and identification of a regulatory barrier) is initiated by innovators (the bottom-up approach); and another where the regulator identifies legislative provisions for

²⁰ Net-Zero Industry Act (EU) 2024/1735: 3.22, 33.2, 33.4, 33.5.

testing and calls for applications by interested organisations (the top-down approach).”

- Member States shall establish net-zero regulatory sandboxes, in close collaboration with industry and, where relevant, research institutes, the social partners and civil society.
- Member States shall, when setting up net-zero regulatory sandboxes, establish or designate one or more contact points. A sole contact point shall be responsible for each request to establish a net-zero regulatory sandbox.

The Act does not define the concept of a contact point, nor does it provide any further guidance on the mandate of the contact point or on the division of roles between the contact point and the competent authorities.

- The arrangements and the conditions for the establishment and operation of the net-zero regulatory sandboxes shall be adopted by means of implementing acts.
- The arrangements and the conditions shall foster innovation and regulatory learning and shall particularly take into account the special circumstances and capacities of participating SMEs and start-ups.
- The testing, development and validation shall take place under the supervision and with the support of the competent authorities. Supervisory powers shall be exercised in a flexible manner, adapting existing practices and using their discretionary powers with the objective of removing barriers, alleviating regulatory burden and reducing regulatory uncertainty, and supporting innovation in net-zero technologies or other innovative technologies.
- The competent authorities shall consider whether to grant derogations or exemptions in national law to the extent allowed by relevant Union law. The competent authorities shall ensure that the net-zero regulatory sandbox plan respects the requirements of Union law and the key objectives and essential requirements of national law.
- Regulatory sandboxes shall be designed and implemented in such a way that, where relevant, they facilitate cross-border operations between the national competent authorities. Member States that have established net-zero regulatory sandboxes shall coordinate their activities and cooperate with the objective of sharing relevant information with other Member States.
- Member States shall provide SMEs and start-ups with priority access to the net-zero regulatory sandboxes. They shall organise awareness raising activities about participation to the net-zero regulatory sandboxes by SMEs and start-ups, and, where appropriate, establish a dedicated channel for communication with SMEs and

start-ups to provide guidance and respond to queries about the implementation of regulatory sandboxes.

1.2.3 Arrangements and conditions to be provided in implementing acts

As stated, the Act provides minimal guidance on the tasks of the contact point. The Act states, in Article 33(4), that the innovators who may participate in regulatory sandboxes shall be selected by competent authorities, but does not provide any further guidance on the division of roles between these authorities and the contact point(s) to be designated. Article 33(3) refers to the adoption of implementing acts by the European Commission. The implementing acts shall specify the *arrangements and conditions for the establishment and operation* of the regulatory sandboxes.

The implementing acts shall contain common *main principles* for

- the eligibility criteria and selection procedure for participation in the net-zero regulatory sandboxes;
- the procedure for the application, participation, monitoring, exiting from and termination of the net-zero regulatory sandboxes; and
- the terms and conditions applicable to the participants.

It can be assumed that principles for the functioning and working method of the contact point, including the division of roles between the contact point and the competent authorities, will be clarified in the implementing acts.

In this context, note that the Act more clearly indicates the duties and powers of the contact points to be established for permit-granting processes for manufacturing projects, which are regulated in another part of the Act.²¹ The Act gives these contact points a role that is essentially coordinating, mediating and informative, while decisions on permit-granting and other substantive matters lie with the authorising authorities. Vinnova has refrained from drawing far-reaching conclusions from these provisions as to what will apply to regulatory sandboxes, as this would pre-empt the principles to be announced by the Commission.

In this context, it is further noted that the Swedish Agency for Economic and Regional Growth, in a previous report, has stated its view that "*the contact point* [for regulatory sandboxes] *should have the main responsibility for assessing applications, but that competent authorities should be involved and assist in the assessments.*"²² In Vinnova's opinion, this view appears contrary to Article 33(2) of the Act, which states that it is the competent authorities that are to make the selection among applications and decide who should be allowed to participate in a regulatory sandbox. According to

²¹ Net-Zero Industry Act (EU) 2024/1735) 6-12

²² Swedish Agency for Economic and Regional Growth, *Analys av genomförandet av förordningen om nettonollindustrin*, (ref. Å 2024-105, 27/03/2024).

the definition of regulatory sandbox in Article 3(22), competent authorities are also required to develop a specific plan for testing activities in the regulatory sandbox.

1.2.4 Legal conditions for derogations and exemptions

As stated above, competent authorities shall consider granting derogations and exemptions from regulatory requirements for testing activities carried out in a regulatory sandbox. To permit this, the public authority must be mandated to do so in a relevant statute.

Such a mandate may take the form of time-limited laws or regulations.²³ Another tool for derogations and exemptions are so-called experimentation or pilot clauses in law and/or regulation; that is, specific provisions relating to testing and experimental activities that authorise derogations or exemptions from the regulation of which they form part.²⁴

In 2020, the Council of the EU issued information and conclusions regarding regulatory sandboxes and the need for experimentation clauses.²⁵ Item 9 states that the Council understands 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."* The Council further states that experimentation clauses *"are often the legal basis for regulatory sandboxes, and are already used in EU legislation and in many Member States' legal frameworks."*

Within the framework of its assignment, Vinnova has not inventoried the need for additional experimentation clauses in statutes that regulate activities in the net-zero area, in order to be able to consider the deviations and exceptions prescribed by the Act. The preparation of amendments to Swedish legislation or regulations typically requires some time. To the extent that experimentation clauses are missing from the relevant legislation at the time of entry into force of the Act, the scope for derogations and exemptions is diminished, and full application of the Act's provisions on regulatory sandboxes risks being delayed or going unrealised.

²³ An example of a time-limited regulation is *Förordningen om försöksverksamhet med automatiserade fordon*, which was originally intended to apply for a five-year period from 2017. SFS 2017:309 *Förordning om försöksverksamhet med automatiserade fordon*

²⁴ In Swedish law, see, e.g., Article 6 SFS 1979:429 Swedish Forestry Act and Article 7 SFS 1993:1096 Swedish Forestry Ordinance, which authorises the Swedish Forest Agency to issue regulations on derogations to permit regulatory sandboxes.

²⁵ The European Parliament and the Council of the European Union, 2020/C 447/01, *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*

1.3 Implementation

1.3.1 Design methodology as a method in carrying out the assignment

Design methodology has been used to describe stakeholders' needs and challenges. These needs and challenges, together with the legal conditions, have been used to develop and gradually refine a proposal for how net-zero regulatory sandboxes can be structured and implemented in a first step. Design methodology is a continuous, iterative process and a structured way to address complex societal challenges involving multiple stakeholders. The method involves systematic shifts between thinking broadly and focusing. In each step, one begins by considering numerous different perspectives, and then prioritises the most relevant of these based on the needs and circumstances of the stakeholders. Finally, solutions are prototyped and tested. Given the time available for the assignment as well as the fact that implementing acts have not yet been provided, Vinnova has refrained from working out the proposals in detail, which opens up for a continued iterative and co-creative process in the future.

1.3.2 Supporting information

During the period of October to December of 2024, 22 interviews were conducted with external stakeholders. Dialogue has taken place with 12 public authorities, one industry association, five companies developing net-zero technologies, one government and one private investment company, and investigators from the Committee for Technological Innovation and Ethics (*Komet*).²⁶ In addition, discussions have been held with stakeholders in the UK (Office of Gas and Electricity Markets, OFGEM)²⁷, Denmark (*Erhvervsstyrelsen*, the Danish Business Authority)²⁸ and Finland (Ministry of Economic Affairs and Employment of Finland)²⁹ regarding their regulatory sandboxes. Vinnova has organised an informational event to which all county administrative boards have been invited. Thirty-two participants attended the meeting.

For those public authorities and stakeholders deemed to be most concerned, their views have been partly gathered through interviews. In addition, a selection of the most concerned stakeholders has been given the opportunity to respond to written questions. On 13 December 2024, Vinnova held a digital workshop with representatives from 14

²⁶The following Swedish stakeholders were contacted and given the opportunity to submit comments or suggestions: Almi Invest Green Tech, TIDIR, Technology Industries of Sweden, the programme offices of Impact Innovation programmes Net Zero Industry and Swedish Metals & Minerals, all county administrative boards, represented primarily by the county administrative boards of Norrbotten, Västerbotten, Stockholm, Västra Götaland and Skåne. Dialogue has also been conducted with the Swedish Chemicals Agency, the Swedish Competition Authority, the Swedish Environmental Protection Agency, the Swedish Agency for Marine and Water Management, the Swedish Energy Agency, the Swedish Energy Markets Inspectorate, the Swedish Agency for Economic and Regional Growth and RISE/former investigator for the Committee for Technological Innovation and Ethics (*Komet*).

²⁷ Office of Gas and Electricity Markets, <https://www.ofgem.gov.uk/> (Retrieved 10/01/2025)

²⁸ *Erhvervsstyrelsen*, <https://erhvervsstyrelsen.dk/> (Retrieved 10/01/2025)

²⁹ Ministry of Economic Affairs and Employment of Finland, <https://tem.fi/en/frontpage> (Retrieved 10/01/2025)

organisations, mainly public authorities, a trade association, Impact Innovation³⁰ programme offices and a research institute. Around 40 people from public authorities and organisations were invited. The focus of the workshop was the national contact point for regulatory sandboxes. The aim of the workshop was to improve stakeholder awareness and prepare for introduction in Sweden by presenting overall insights and working material from the assignment thus far. As a group, the participants listened, discussed and completed the working material. Participants had the opportunity to make both oral and written suggestions or comments. The comments that were received have been processed at an aggregated level, and elements have been included in this report.

The data and information collected for this report should not be considered a comprehensive or representative sample. The contents of the report were developed over a very limited period of time and are to be assessed accordingly. The report's proposals have been developed taking into account several uncertain parameters (presented in greater detail below). The prototype process description is intended for an implementation phase, which can then be gradually developed further together with the concerned stakeholders.

1.3.3 Organisation

An internal steering group at Vinnova, consisting of representatives of the organisation's management, has led the assignment, and the assignment was carried out by a working group consisting of Bianca Dochtorowicz, Eleonore Stureborg, Eva Ahlner, Johanna Dahlin and Maria Kaaman. Vinnova has had external support from consultants in parts of the process. Johana Axelsson has been the process leader.

1.3.4 Delimitations

Vinnova has analysed the responsibilities of the contact point vis-à-vis applicant companies³¹ and how the examination of applications and the establishment of regulatory sandboxes can be structured, including how to involve the other authorities and stakeholders concerned. These issues are characterised by great complexity. The contact point has several interfaces: with the applicant companies, with the competent authorities and with the Government Offices. The Vinnova prototype describes a flow between these interfaces with suggestions regarding, in broad strokes, how the process should work during *an implementation phase*. The assignment does not involve

³⁰ Impact Innovation is Sweden's innovation initiative for the 2030s. Five programmes commenced in March of 2024. The programmes' transition objectives (known as missions) focus on zero emissions from industry, sustainable supply of metals and minerals, resilient management of water resources, a reformed public sector, and sustainable urban development and mobility. The Impact Innovation programmes focus on systems innovation, in which rules and policies are one of several key areas to accelerate sustainable transitions for global competitiveness and societal benefit. An invitation to the workshop was extended to the programme offices for the Net Zero Industry Programme and sustainable and resilient metal and mineral supply.

³¹ The Act also allows Member States to initiate regulatory sandboxes themselves. The process for establishing a sandbox in this way has not been analysed in the report. See Net-Zero Industry Act (EU) 2024/1735: 33.2

analysing potential financing of regulatory sandboxes, but rather creating a structured process for dealing with the issues experienced by innovative companies linked to perceived regulatory obstacles.

The focus, organisation and work processes of previous examples of regulatory sandboxes or similar regulatory experimentation considered by Vinnova has varied.

The report's analysis and prototype process description are based on:

- Legal conditions
- Needs identified in the course of the assignment
- Experience from other policy development initiatives and from Vinnova's knowledge of innovative policy development
- Knowledge of the innovation system and ecosystems around innovative companies.

The prototype proposes a working process that includes the main features of the role of the competent authorities in setting up and operating the regulatory sandboxes. More details regarding this process or proposals regarding the working methods of the competent authorities are not provided. We note that each public authority may need to investigate further, and that common, standardised working methods may need to be developed.

A more detailed analysis of, e.g., which public authority will grant permits or deviations from a particular regulatory framework, or who will supervise various forms of testing activities relating to innovative net-zero technology, etc., has not been possible within the available time-frame. Following a general survey, we conclude that current processes for permitting and supervisory activities are complex and vary for the technology areas mentioned in the Act.³²

The Act provides that a contact point must be responsible for each request to set up a regulatory sandbox. Competent authorities are required by the Act to manage certain tasks, such as selecting applications, establishing and monitoring a plan for testing activities, considering derogations and exemptions from regulatory requirements, and providing support and supervision for the operation of the regulatory sandboxes. However, no detailed distribution of work or procedure is given. Nor does it specify which bodies in the Member States should be assigned tasks related to, e.g., informational campaigns, other guidance to applicants, or follow-up and regulatory learning in the context of regulatory sandboxes. However, the Vinnova prototype does propose a division of responsibilities for these tasks.

In addition to what is stated in the Act, Vinnova has identified additional value-adding tasks based on its knowledge of system innovation and innovative policy development. Examples of these tasks include in-depth guidance to applicants in a pre-application phase, mobilisation and collaborative management, concept development and

³² Net-Zero Industry Act (EU) 2024/1735: 4.1.

coordination of applications and regulatory sandboxes. Initially, we do not deem these tasks to be *essential* for Sweden to offer net-zero regulatory sandboxes during an implementation phase. These tasks are considered relevant for inclusion at a later stage of regulatory sandbox operations, and are therefore not included in the proposal of the report.

1.4 Report layout

SECTION 2 contains Vinnova's proposal. The report is divided into section headings that correspond to the issues in the Government's terms of reference.

Section 2.1 sets out Vinnova's proposals regarding how the contact point should be structured and implemented. The basis of the proposal is briefly described, after which the proposed responsibilities of the contact point are defined. A prototype for the work process and the interaction between stakeholders is then presented along with the reasons for its design.

Section 2.2 presents the results of Vinnova's analysis regarding which public authorities to consider competent authorities in the first stage. This section provides basic insight into the varied and occasionally overlapping responsibilities of public authorities in this area. The section also provides examples of other types of stakeholders who are crucial for implementation in line with the objectives of the Act.

Section 2.3 describes the needs that have been identified for preparatory measures related to implementation of the contact point. The examples provided are in order to provide clear governance, confidence among stakeholders and a basis for collaboration that capitalises on skills and experience.

Section 2.4 addresses other parts of the Act that have a bearing on the implementation of the contact point. This section focuses on the additional areas for measures in the Act beyond regulatory sandboxes (streamlining permit-granting processes for critical raw materials and the net-zero industry, and net-zero strategic projects) and on proposals for interaction between the Act's contact points.

Section 2.5 raises issues that have not been covered by the analysis conducted, but which must be clarified before and during the implementation phase. This includes questions about the more detailed division of responsibilities between the contact point and competent authorities and the process for setting up regulatory sandboxes. This section also describes the importance of systematic learning and what such learning must include.

SECTION 3 contains the background information which, together with the legal framework, forms the basis for the proposal submitted.

Section 3.1 presents selected insights from interviews and reports conducted with stakeholders to identify needs and highlight previous national and international experiences.

SECTION 4 contains an impact analysis and identification of risks linked to Vinnova's proposal and the implementation of the Act.

Section 4.1 describes the impact of the proposal on the contact point, competent authorities and applicants.

Section 4.2 provides examples of risks associated with the implementation of regulatory sandboxes.

2 Vinnova's proposal

The assignment included proposing how a contact point for regulatory sandboxes could be structured and implemented. In addition, Vinnova was assigned to identify the public authorities that can be considered competent authorities in the initial stage and how they can be involved in the process of examining applications and establishing regulatory sandboxes. In this section, Vinnova presents a comprehensive proposal for the process to introduce regulatory sandboxes under the Net-Zero Industry Act. The proposal is of a general nature and can be used as inspiration or scaled up in other subject areas where regulatory sandboxes are in demand. This assignment is not about funding regulatory sandboxes, but rather creating a structured process to address the issues experienced by innovative companies related to perceived regulatory obstacles.

The basis of the proposals and the prototype is presented below. How the contact point and its work could be initially implemented is proposed. This is followed by an explanatory description of the work process and the collaboration among the stakeholders.

Examples are given of public authorities that may initially serve as competent authorities, and a prototype work process is shown. The section also includes recommendations on preparatory steps to be taken for implementation and areas for further exploration.

2.1 Structure and implementation of the regulatory sandbox contact point

2.1.1 Proposal basis

Vinnova's proposal is based on an overall assessment of the following:

- Legal conditions
- Needs identified in the course of the assignment
- Experience from other policy development initiatives and from Vinnova's knowledge of innovative policy development
- Knowledge of the innovation system and ecosystems around innovative companies.

Several of the stakeholders with whom Vinnova has been in contact are curious about regulatory sandboxes. Among public authorities, there is widespread concern regarding how it will be organised, implemented and financed. Companies and industry organisations approve of the initiative. At the same time, they worry that participation may be too resource-intensive and that sensitive information may be at risk. That any legislative or regulatory changes will be made quickly enough to achieve the desired effect is a prospect that all stakeholders view with scepticism. A more detailed account of stakeholders' views can be found in section 3.1.

The desire to meet the needs identified has been weighed against the need to create a simple but effective prototype and put in place the fundamental conditions for an implementation phase. The focus has been to lay a solid but minimal foundation, at the expense of the expressed needs and wishes of some stakeholders. This is partly due to uncertainties regarding resources and demand, and partly because the conditions for implementation remain largely unclear.

The European Commission will set out the principles for the establishment and operation of regulatory sandboxes in the implementing acts to the Act. The principles shall cover, among other things, eligibility and selection criteria, the procedure for applying for and participating in the regulatory sandboxes, the monitoring of the sandboxes and the conditions to be applied to participants. Vinnova's analysis has been carried out without knowledge of the content of these forthcoming implementing acts (see section 1.21.1 on legal conditions). It is therefore not unlikely that the proposed prototype and work structure may need to be reconsidered in the context of the implementing acts.

The prototype includes process steps with more detailed issues that are not addressed in this report. For example, Vinnova has not presented any proposal for a detailed process or working methods for the competent authorities. Each authority concerned may need to analyse the Act from the perspective of its own activities and collaborate in the development of common, uniform working methods. Public authorities with less experience setting up regulatory sandboxes will need more support than others. Based on its previous experience of innovative policy development, Vinnova is able to provide support to these public authorities. In addition, a number of different initiatives on regulatory sandboxes and policy development for innovation have previously been conducted in Sweden.³³ It is necessary to adapt the lessons learnt from these initiatives to the present type of regulatory sandbox and translate them into new, applied working

³³ See, among others, Swedish Energy Markets Inspectorate, *Innovationscenter och regulatoriska sandlådor. Modellförslag och implementering för energimarknaderna i Sverige*, Swedish Energy Markets Inspectorate, 2023 <https://ei.se/download/18.56edc373186a1d5a9df2b8f/1678094189173/Innovationscenter-och-regulatoriska-sandl%C3%A5dor-Ei-R2023-03.pdf>, (Retrieved 05/12/2024);

Swedish Energy Markets Inspectorate, *FI:s syn på regulatoriska sandlådor*, Swedish Energy Markets Inspectorate, 2024. <https://www.fi.se/siteassets/fis-syn-pa-regulatoriska-sandlador.pdf> (Retrieved 27/11/2024); Swedish Authority for Privacy Protection, "Regulatorisk sandlåda om dataskydd", <https://www.imy.se/verksamhet/dataskydd/innovationsportalen/delta-i-var-regulatoriska-sandlada-om-dataskydd/> (Retrieved 10/01/2025);

Ramboll Management Consulting, *En innovationsguide för utveckling av regler och andra styrmedel*, on behalf of Vinnova, (ref. 2023-03744);

Swedish Agency for Economic and Regional Growth, *One stop myndighetsshop - En myndighetsöverskridande samverkansmodell för förenkling och ökad innovation i livsmedelssektorn*, 2024. <https://tillvaxtverket.se/download/18.b55bceb1919736dc3ea90b4/1725612475127/One%20Stop%20Myndighetsshop%20-%20En%20myndighets%C3%B6verskridande%20samverkansmodell%20f%C3%B6r%20f%C3%B6renkling%20och%20%C3%B6kad%20innovation%20i%20livsmedelssektorn.pdf> (Retrieved 06/12/2024);

Vinnova, *Regeringsuppdrag att ge stöd till offentliga aktörers arbete med regel- och policyutveckling*, Vinnova, 2023. <https://www.vinnova.se/contentassets/1f78b38101cb460fba4142f06e905876/2019-05811-slutrapport.pdf> (Retrieved 19/11/2024);

Vinnova, *Innovation för nyindustrialisering och samhällsomvandling i norra Sverige*, (ref. 2024-00753).

methods across a wide range of public authorities. Past experience from both national and international initiatives (see section 3.1) shows that it is difficult to anticipate the need for regulatory sandboxes in different areas. Therefore, a balance must be struck, whereby the authorities concerned are prepared to fulfil their responsibilities, while at the same time ensuring flexibility to deal with cases. The Government, the contact point and central competent authorities must further develop the structure and work process together, as the prerequisites, in terms of definitions, selection and assessment criteria, roles and mandates, are clarified.

Assessment of the proposal should also take account of the fact that Vinnova has not analysed which competent authority will, for example, grant permits or deviations from regulations. We note that current decision-making processes for permit-granting and supervisory activities are complex and can vary significantly across technologies. Vinnova has assumed that implementation will be adapted to the current system for permit-granting and supervision activities. This system might be complemented by a regulation in cases where a competent authority for the innovative technology in question is lacking. All applications received by the contact point must be referable to a competent authority for examination.

One final basis for the proposal has been the need to consider the changing nature and emphasis of different phases. During an initial period, building up the expertise and capacity of the contact point and developing cooperation with competent authorities will be in focus. In parallel, an intensive phase involving the design, packaging and publicising of the offer to relevant stakeholders will occur. After that, it will likely be necessary to place greater emphasis on ensuring that the applications received are managed and scrutinised appropriately, so that regulatory sandboxes can be created in formats suited to the needs of companies.

The above factors imply a high degree of uncertainty and fluidity. Establishing collaborative arrangements early on to ensure simple and powerful systemic learning measures will therefore be crucial for success, and this will require time and dedicated resources.

2.1.2 Proposed organisation and responsibilities of the contact point during the implementation phase

Initially, the contact point is proposed to support the Government Offices in the joint preparation of Commission implementing acts by Member States. The Net-Zero Industry Act allows Member States to establish more than one contact point for regulatory sandboxes. In its report, Vinnova has, in order to make implementation as simple as possible, assumed the scenario that only *one* contact point is established during an initial phase. Vinnova proposes that the contact point be organised as an inter-agency office, to be convened by a public authority with main responsibility. Here, Vinnova is proposed as the main responsible authority in such an office. A reference group of research institutes and others will be attached to the contact point, serving in a

supporting role to the contact point and competent authority with expertise in test and demonstration environments, technologies, innovative companies, sandbox concept-development support, etc. See section 2.1.3 for more information regarding this arrangement.

The Act provides for a single point of contact to be responsible for each request for the establishment of a net-zero regulatory sandbox. The meaning and scope of the responsibilities are not further defined in the Act, nor has direct guidance been drawn from similar assignments, as their purpose and conditions differ. Therefore, pending the Commission's implementing acts, limited responsibilities for the contact point are recommended. These responsibilities include:

- Design, packaging and dissemination of information and offerings to relevant stakeholders, together with competent authorities
- Receiving applications for the establishment of regulatory sandboxes. Competent authorities must assist the contact point to ensure that the right information is submitted with the application. The contact point can support the competent authority in assessing whether applications meet formal requirements.
- Transferring applications to one or more competent authorities for examination and decision
- At the request of the competent authority, participating in the formal examination of applications
- Establishing a structure for systematic learning from the process

Unless future implementing acts provide otherwise, it is up to the Member State to decide whether the contact point must take any kind of formal or substantive decision on the basis of the application. We suggest, for the reasons set out in section 2.1.4, that the contact point should not take such decisions. The contact point can support competent authorities with an assessment of formal requirements as part of a decision-making process.

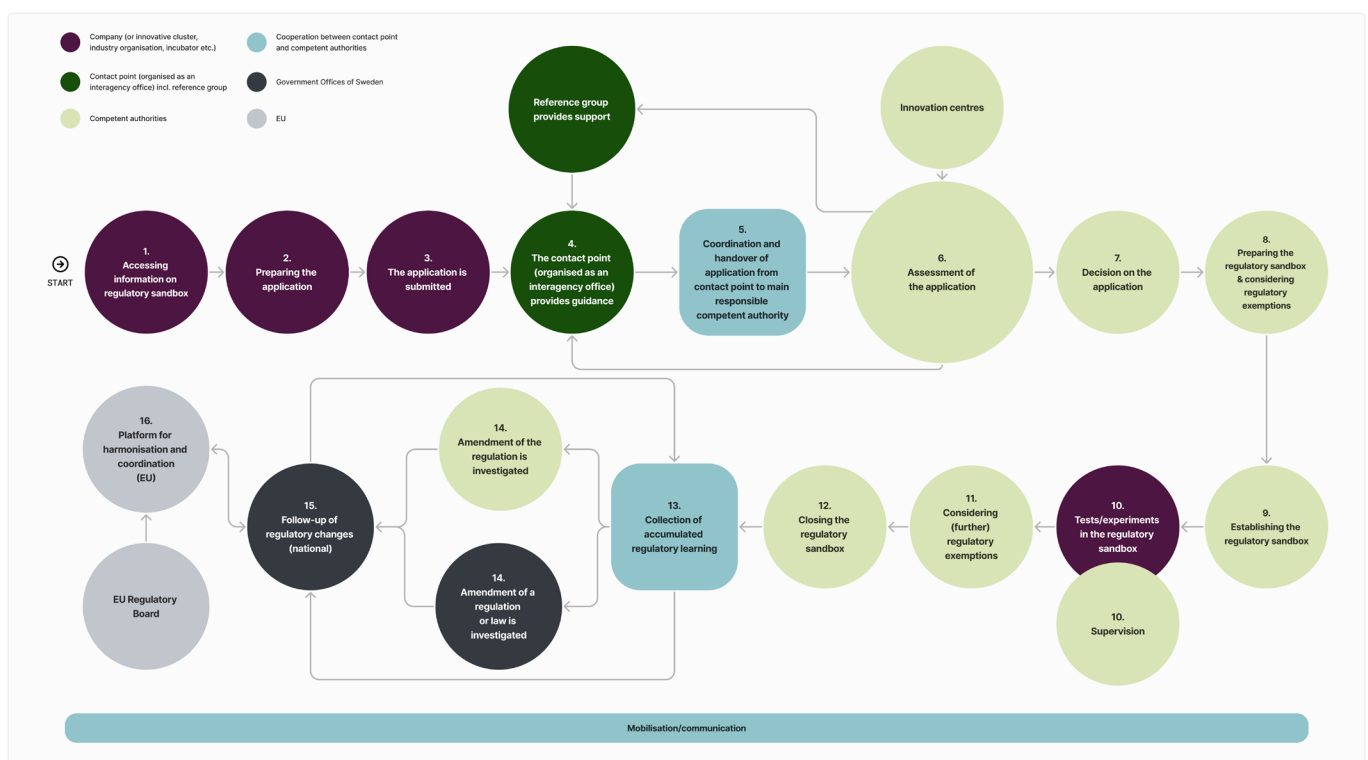
In the short term, the proposed responsibilities of the contact point are deemed to create the basic conditions necessary to commence work with such cases. Companies will have access to clearly specified offerings, and applications will be submitted to the same public authority regardless of the technology area applied for. The contact point has a general view of this area and is responsible for ensuring that cases are directed to the proper competent authority, where the mandate and technical expertise to carry out an examination exist. By providing information and serving as a gateway to regulatory sandboxes, the contact point launches the development and simplification of regulatory frameworks around innovative net-zero technologies. This, in turn, paves the way for a more rapid uptake of innovation in the field.

2.1.3 Prototype work process

Figure 1 presents Vinnova's proposal for a comprehensive process for reviewing applications and establishing net-zero regulatory sandboxes. The prototype describes

responsibilities and visualises interfaces between the stakeholders involved. These interfaces demonstrate the need for effective forms of collaboration, coordination, consultation and structured, secure exchanges of information in case handling. The initiative is based on a business-initiated, or so-called ‘innovation-driven’, process. Under the Act³⁴, Member States themselves also have the possibility of initiating regulatory sandboxes. The process for establishing a sandbox in this way has not been analysed in the report.

Figure 1. Prototype work process for the implementation phase of net-zero regulatory sandboxes



³⁴ Net-Zero Industry Act (EU) 2024/1735) 33.2

1. Companies access information on regulatory sandbox

In the first interface between either the contact point or the competent authorities and the company, companies are informed about the possibility to apply for participation in a regulatory sandbox. In the process description, 'companies' are referred to as an umbrella term. Under the Act, applicants can include companies, organisations or consortia developing innovative net-zero technologies that fulfil the eligibility and selection criteria set out³⁵ in the Act. These eligibility and selection criteria, to be specified in implementing acts, are as yet unknown to Vinnova, but can be assumed to include innovative clusters, industry organisations, research institutes, incubators, innovation offices, science parks, the Acceleration Office³⁶ or similar.

Information can be disseminated through informational campaigns or through the dedicated channel for communication³⁷ which the Act requires of the contact point and the competent authorities. Communication and informational campaigns regarding the offerings of regulatory sandboxes are central to the process. At the bottom of the figure, in blue, note the continuous step in the process involving mobilisation and communication. Vinnova proposes that responsibility for this central task be shared between the contact point and the competent authorities. It is proposed that the contact point be granted responsibility for general communication and a shared platform, while the competent authorities are granted responsibility for communication related to the regulatory sandboxes themselves.

2. Companies prepare the application

Interested companies then enter a preparatory phase for submission of the application. This process step, we understand, can require time as well as resources for a company. In Vinnova's proposal, the company receives the help of established business facilitators in establishing the type of barriers to innovation that the application should address and whether the application complies with the Act's criteria for applicants as well as the formal application requirements. Before contacting the contact point, the company should clearly understand the challenge to be addressed in the regulatory sandbox. Thus, in this prototype, information about offerings provided by the contact point does not include any company-specific guidance in advance. The work of the contact and the competent authorities must therefore be complemented by the support of established business and innovator facilitators, including industry associations, SME developers and financiers, incubators, innovation offices, science parks or research institutes.

3. Companies submit applications to the contact point

³⁵ Net-Zero Industry Act (EU) 2024/1735) 33.2

³⁶ Acceleration Office, <https://accelerationskontoret.se/> (Retrieved 18/02/2025)

³⁷ Net-Zero Industry Act (EU) 2024/1735) 34

An application to participate in a regulatory sandbox is submitted to the contact point. The contact point needs to ensure secure information handling, as applications will typically contain business data of a sensitive nature.

4. The contact point (organised as an inter-agency office) provides guidance

Vinnova proposes that the contact point be organised in the form of an inter-agency office consisting of a small number of competent authorities of central importance to the Act. The inter-agency office is to be convened by a public authority with main responsibility. A joint office can better ensure the interdisciplinary expertise needed to guide applicants through the administrative system, while at the same time creating a broader basis for legitimacy and anchoring in public administration. The contact point is responsible for designating a main responsible competent authority to receive the handover. The contact point may, if requested by the competent authority and when appropriate, be responsible for carrying out a preliminary assessment of an application's formal requirements. Where further consultation on the submitted application is needed, the contact point can request a reference group for expert support in technology, innovative companies, concept development of the sandboxes, etc. Vinnova proposes that the contact point/office establish a reference group consisting of research institutes, incubators, etc. It is proposed to grant participants in the contact point reference group a formalised mandate to serve in the process. The contact point must establish a broad network among public authorities to understand which authority or authorities need to be called on. The company receives feedback from the contact point and is directed to the competent expert authority or authorities (hereinafter, "competent authorities").

5. Coordination and handover of application from contact point to main responsible competent authority, application forwarded for processing

This interface between the contact point and the competent authorities requires a clear prior division of responsibilities and mandates for an efficient and smooth handover of the case, where one main responsible competent authority for receiving the handover should be designated by the contact point.

6. Competent authorities assess the application

Vinnova assumes that in many cases applicants may need an assessment from more than one public authority, as the testing activities to which the application refers are covered by several existing regulations. For breakthrough technologies, any existing regulatory framework may be lacking. This will require collaboration processes that are robust, to enable competent authorities to make a joint assessment of the application. Here, too, a clear division of responsibilities must be made in advance, with the mainly responsible competent authority having a mandate to convene the other competent authorities. Assessment of the application will involve a number of steps:

- Does the application meet the eligibility criteria of the Act?
- Does the applicant technology have the potential required by the eligibility criteria in terms of level/potential of innovation?
- What environmental and/or health risks must be managed for the testing activities?

As a general rule, a consensus decision is required for an inter-agency assessment, as each public authority, region or municipality has its own assignment and mandate. A robust yet flexible decision-making process must be developed. Each application should be approved or rejected by *one* competent authority after any inter-agency assessment. The application must include, among other things, a clear description of the activity, information on risks and how they are to be managed, and other necessary documentation to enable the examining authorities to make an assessment. The competences of the competent authorities will likely need to be complemented, for example, in certain fields of technology. To meet this need, permitting the competent authorities to consult the reference group proposed to be attached to the contact point is desirable. When doing so, information security and applicable confidentiality rules must be considered.

It is proposed that the public authorities grant applicants the possibility of early dialogue and guidance from the examining authority on regulatory and application-related issues. In this way, the competent authority can quickly identify any deficiencies in the application and ensure that the correct documentation is included. Early guidance on regulatory issues will help ensure that, in some cases, establishment of a regulatory sandbox is never even necessary.

Vinnova proposes that the competent government agencies identified in section 2.2.20 establish innovation centres in order to formalise the work process of examining applications for regulatory sandboxes. The establishment of innovation centres also provides the opportunity to coordinate skills needs and unify working practices, with support from the contact point. An innovation centre can serve as the competent authority's point of contact for companies that are unsure about rules, processes or policies issued by the public authority. Such a centre can provide guidance on the application for regulatory sandboxes as well as early guidance on existing legislation, but without providing information that could be perceived as a preliminary ruling. The innovation centre can coordinate the authority's work on innovation, knowledge dissemination and regulatory development. An innovation centre also provides the contact point and other competent authorities with a clearly defined collaborator at the competent authority.

As mentioned earlier, the present assignment did not focus on financing solutions for the regulatory sandbox system. Nevertheless, it will be important to ensure conditions for the participation of the authorities concerned in the regulatory sandboxes. Vinnova has previously proposed to the Government a regulatory sandbox programme able to fund the very effort that would be required of public authorities. While the creation of

innovation centres is proposed here, further solutions are needed, especially for those public authorities that are *not* among the most central. Although the day-to-day work of an innovation centre may not be suitable for these public authorities, they may still be needed as participant authorities on a case-by-case basis, e.g., a specific municipality.

7. Main responsible competent authority takes decision on the application

The main responsible competent authority grants or rejects the application for the establishment of a regulatory sandbox (and the focus of the regulatory framework) based on the overall assessment. In Vinnova's view, the decision of the competent authority should be subject to a specific prohibition of appeal. If rejection of the application were subject to appeal under, for example, the Administrative Procedure Act (2017:1900), this risks creating significant delay and uncertainty. Protracted court proceedings cannot be considered compatible with the fundamental purpose of the Act, which is to speed up regulatory processes and grant companies access to testing and experimentation opportunities. Rejection of an application should therefore be final and not subject to appeal.

8. Competent authorities prepare the regulatory sandbox and consider regulatory exemptions

According to the Act, a specific plan for the operation of the regulatory sandbox must be drawn up by the competent authority. When developing the plan, the public authority may, if not already done and if deemed appropriate, identify regulatory requirements applicable to the testing activities and where derogations or exemptions might be considered. Competent authorities are given the possibility to grant derogations or exemptions in national law to the extent allowed by relevant Union law.³⁸ Such regulatory requirements and needs for derogations or exemptions may have already been indicated by the applicant. It should be possible to decide to grant a derogation or exemption from regulatory requirements in the plan as well as during the course of the testing activity. The plan should also indicate the supervisory authority, if different from the authority drawing up the plan. The plan should specify the time and place of the regulatory sandbox testing activity and the other conditions that will apply to the activity, such as any reporting to the supervisory authority.

9. Competent authorities establish the regulatory sandbox

The interviews reveal a clear need on the part of companies for access to testing and demonstration environments. The establishment of a regulatory sandbox may typically require access to a physical site, which, if not already existing, may require lengthy permit-granting processes. It would be desirable to review the possibility of long-term funding and to carry out an inventory of needs (need for use and responsibility for ongoing investment in upgrades) for test and demonstration environments for these technologies.

³⁸ Net-Zero Industry Act (EU) 2024/1735) 33.5

The Act states that a regulatory sandbox has a limited duration in time (given the nature and scope of the project), and, when tests and experiments are carried out, the activities are to be monitored and followed up by the competent supervisory authority. If significant risks are identified during the process, development and testing may be suspended until the risks are mitigated.

10. Companies conduct tests in regulatory sandbox

Tests/experiments are carried out by companies for a limited duration in a real, controlled environment under the supervision of the competent supervisory authority.

11. Competent authorities consider (further) regulatory exemptions

As mentioned above, the regulatory sandbox will be monitored, and, if necessary, (further) decisions will be taken on regulatory exemptions for testing activities in the regulatory sandbox.

12. Competent authorities close the regulatory sandbox

As the time of the regulatory sandbox comes to an end, closure is prepared. The competent authorities can review the testing activities with the company, draw conclusions from the results and document regulatory learning. It is proposed that competent authorities be responsible for the preparation of documentation for the dissemination of results, in cooperation with implementing companies. Based on experience³⁹, it can prove successful if the competent authority, together with the implementing company, also establishes a so-called 'exit strategy'. Such a strategy may include, for example, a plan for and analysis of any future economic, environmental or other systemic risks and consequences, management of any equipment, how the innovation will be developed further, etc. Vinnova proposes that documentation for the dissemination of results and an exit strategy should be mandatory for participating parties following decisions to establish regulatory sandboxes.

13. Collection of accumulated regulatory learning

This step is the second point of intersection between the contact point and the competent authorities. This is a very important opportunity for the Government Offices, the Swedish Simplification Council, public authorities, the contact point and the implementing companies to share regulatory learning. A dialogue with investigators and regulators at the appropriate level is prepared and implemented in several steps, based on documented learning. It is proposed that the responsibility for preparation and convening is shared between competent authorities and the contact point. Providing

³⁹ Swedish Energy Market Inspectorate, *Innovationscenter och regulatoriska sandlådor. Modellförslag och implementering för energimarknaderna i Sverige*, Energy Market Inspectorate, 2023 <https://ei.se/download/18.56edc373186a1d5a9df2b8f/1678094189173/Innovationscenter-och-regulatoriska-sandl%C3%A5dor-Ei-R2023-03.pdf>, (Retrieved 05/12/2024); Informant A, civil servant, Erhvervsstyrelsen of Denmark. Interview, 20/11/2024

information about ongoing regulatory sandboxes at an early stage to regulators, in preparation for future measures, would be advantageous.

14. Investigation and action on proposals for permanent regulatory change

If the regulatory learning shows that national rules need to be amended, Vinnova proposes that further investigation of proposals be submitted by the contact point to the Swedish Simplification Council, at the Swedish Agency for Economic and Regional Growth. It is proposed that the Simplification Council, within the terms of its assignment, urgently investigates regulatory issues related to net-zero technologies as well as future proposals from other types of regulatory sandboxes, e.g., under the EU AI Act or in the field of biotechnology.

Action for the Riksdag to amend the law or regulation in question may require governance that provides for expeditious and prioritised consideration of the proposals coming from regulatory sandboxes.

15. The Government Offices coordinate and follow up regulatory changes at national level

In the context of its responsibility for the implementation and enforcement of the Act, the Government is proposed to be responsible for liaising with the European Commission by coordinating and monitoring regulatory changes at national level, and reporting these to the European Commission. The Government Offices should identify perceived regulatory barriers linked to EU legislation, possibly with the support of the new Implementation Council⁴⁰. This requires a structured and continuous dialogue between the contact point, the competent authorities, the Simplification Council, the Implementation Council and the Government Offices.

16. Harmonisation and coordination among Member States

Regular harmonisation with other Member States' implementation and enforcement of the Act will be key. In Articles 28 and 29, the Act provides for the establishment of an EU Platform and an EU Scientific Regulatory Council. The EU Platform will act as a central hub for information exchange among Member States, companies and other stakeholders. The Scientific Regulatory Council will provide independent scientific advice and support to the Commission and Member States.

2.1.4 Requests not addressed by the proposal

In the above proposed process description, there is a discrepancy in relation to the needs and expectations of, above all, the contact point's tasks, which has been noted

⁴⁰The Implementation Council will raise a business perspective early in the EU process and work to ensure that EU legislation is not implemented above the minimum level in Sweden. The aim is to reduce the regulatory burden, administrative costs and other compliance costs for companies arising from forthcoming, new and amended EU legislation. Ministry of Climate and Enterprise, *Regeringens nya implementeringsråd ska stärka svensk konkurrenskraft*, <https://www.regeringen.se/pressmeddelanden/2024/05/regeringens-nya-implementeringsrad-ska-starka-svensk-konkurrenskraft/>. Press release 27/05/2024.

by stakeholders with whom Vinnova has had dialogues. Vinnova's proposal regarding the contact point's responsibility for assessment and support is less than what stakeholders have expressed a need for. As mentioned earlier, there is considerable uncertainty surrounding the implementation of the Act. We know very little about demand or the number of actual applicants during introduction. Further reasons for minimising the responsibility of the contact point are the following:

- *Supporting companies in a preparatory phase:*
During a preparatory phase, to offer companies the requested support to, for example, understand and define specific regulatory challenges for a regulatory sandbox, expertise in a very large number of subject areas and the capacity to potentially lead a large number of policy workshops is required. In an initial phase, it is deemed unreasonable to impose such responsibility on the contact point, when the focus should rather be on putting into place the most essential structures to handle applications and to ensure a smooth interaction between the contact point and competent authorities.
- *Responsibility of the contact point and the competent authority for assessment and decision:*
The Act states in Article 33(2) that the competent authorities are responsible for selecting applications and deciding who will be allowed to participate in a regulatory sandbox. The Act does not explicitly mention that the contact point must take decisions. Vinnova strongly favours giving the contact point the task of guiding applicants in the administrative system, without constituting a decision-making body. Further arguments in favour of this:
- Anti-competitive reasons; the listing of a limited number of types of technology⁴¹ in the Act is already perceived as restrictive.⁴² The Swedish Competition Authority believes that, given the risk of negative impact on the internal market, public authorities should take care not to further restrict competition among applicants by excluding undertakings on unreasonable grounds.⁴³ Vinnova sees a risk that this could happen with decisions at a premature stage, where applicants have not had their applications examined by the competent expert authority.
 - According to the Act, the application should not be administratively burdensome for applicants. A guiding principle of the process should be simplification and a smooth and easy process for companies. It is therefore deemed appropriate that applicants receive a decision from one body.
- Vinnova takes it for granted that the competent authorities, rather than the contact point, possess the expertise required for substantive examination⁴⁴. For the same reason, any supplements to the application should be requested by the

⁴¹ 4.2Net-Zero Industry Act (EU) 2024/1735: 4.1. The Act also addresses risks of distortion of competition and how such risks can be offset. Net-Zero Industry Act (EU) 2024/1735: 4.2.

⁴² Informant C, official, Technology Industries of Sweden. Interview, 10/10/2024

⁴³ Lars Persson and Pehr-Johan Norbäck, *Hur påverkar regulatoriska sandlådor konkurrensen?*, Swedish Competition Authority 2023.

[https://www.konkurrensverket.se/globalassets/dokument/informationsmaterial/rapporter-och-broschyrer/uppdraagsforskning/forskrapport_2023-4.pdf](https://www.konkurrensverket.se/globalassets/dokument/informationsmaterial/rapporter-och-broschyrer/uppdraagsforskning/forskrappport_2023-4.pdf) (Retrieved 05/12/2025)

⁴⁴ The identified competent authorities have the necessary expertise to carry out environmental and health risk assessments as well as knowledge of the regulatory framework and the potential of the technology.

deciding authority, in order to avoid any multi-stage supplements or administrative burden for applicants.

The contact point may provide pre-assessment consultations, if requested by the competent authority and if appropriate. Based on an overall assessment of the above reasons, Vinnova considers that supplementation of the application, assessment and decision is to be carried out by the competent authorities.

2.2 Identifying competent authorities

The assignment from the Government includes identifying the public authorities that are most likely to serve as competent authorities. Identifying all competent authorities that may be affected by the Act and innovative net-zero technology is a complex task. Net-zero technology can be found in everything from renewable energy and energy efficiency to carbon capture and storage. Each technology has its own specific rules and requirements. In addition, technologies can be used in a variety of sectors, such as energy, transport, industry and construction, which may require the involvement of different sectoral authorities. Some technologies may have effects that require the involvement of environmental and health authorities. Different net-zero technologies may fall under the responsibility of several public authorities, meaning that the responsibilities of the authorities concerned will overlap. The need for access to testing in physical environments will require the involvement of additional authorities and municipalities.

2.2.1 About the analysis

An overall analysis of the Act and the role it attributes to a competent authority has been carried out (see section 1.2). In addition, we have listened to the responses we received from system stakeholders (companies and public authorities) regarding contact with public authorities related to regulatory obstacles. Stakeholders were asked which public authority they had either been in contact with, or had subsequently needed to be in contact with, regarding perceived regulatory obstacles.

One factor identified by Vinnova is access to physical sites for testing and demonstration activities. In light of this, and considering insights from interviews with companies, we believe that tests of innovative net-zero technology will in many cases be subject to regulatory requirements related to the Swedish Environmental Code (1998:808). The Environmental Assessment Ordinance (2013:251), which uses activity codes to specify which activities are subject to permitting or notification under Chapter 9 of the Swedish Environmental Code, is one of several associated regulations of relevance. The Environmental Supervision Ordinance (2011:13), which regulates supervisory authorities and their tasks under the Swedish Environmental Code, is also relevant. In addition to the Swedish Environmental Code, other regulations are likely to be affected by the regulatory sandboxes.

The Environmental Permitting Inquiry has recently presented proposals for a new and coordinated environmental assessment and permitting process⁴⁵. The proposals are far-reaching and include a new environmental assessment organisation. The inquiry's proposals are proposed to be introduced at the earliest on 1 January 2028. If and when implemented, the proposals are likely to have an impact on which public authorities are competent for net-zero regulatory sandboxes. Vinnova has carried out its assignment on the basis of the current regulations.

With regard to the Swedish Environmental Code, Vinnova's survey also covered the responsibilities of public authorities (including courts), county administrative boards and municipalities with regard to permitting, supervision and standardisation. In addition, specific issues have been included based on the Net-Zero Industry Act, such as the permits for tests and experiments in real environments. Further issues have concerned which public authority is responsible for each technology listed in Article 4 of the Act.

An attempt has also been made to use artificial intelligence⁴⁶ to identify the authorities that we see as initially most affected. The Act's list of net-zero technologies has served as a starting point. The AI analysis shows that these issues are complex and difficult to understand, a conclusion reached by the Environmental Permitting Inquiry as well. Checks to ensure the quality of AI responses have revealed shortcomings. Based on this analysis, we conclude that additional public authorities are missing from among those mentioned in the compilation, and that a large number of public authorities, county administrative boards and municipalities may be affected by the Act. The public authorities have not had the opportunity to present any study of their own based on Vinnova's proposal.

2.2.2 Identification of initial competent authorities for the Net-Zero Industry Act

Based on the design of the Net-Zero Act and its description of what a competent authority must do (see section 1.2), the catalogue of nineteen different technology types, and insights from interviews, Vinnova considers that the following competent authorities may be relevant in connection with regulatory sandboxes during an *initial stage*. What the exact responsibilities will be of the authorities identified remains unclear. The role and assignment of competent authorities to decide on regulatory sandboxes must be clarified. Each public authority identified may need to carry out further investigation, but Vinnova deems those mentioned below to form a central part of implementation of the Act. It is the Government's responsibility to ensure that the authorities concerned receive assignments to permit Sweden to comply with the Act. Vinnova's proposal for responsibilities during the implementation phase is set out in section 2.

The list of the public authorities is based links to the Act. This list is not exhaustive.

⁴⁵ Swedish Government Official Reports 2024:98 *En ny samordnad miljöbedömnings- och tillståndsprövningsprocess*.

⁴⁶ Using the Microsoft Copilot tool (2025).

Swedish Work Environment Authority

Has overall responsibility for health and environmental issues in the workplace, and is responsible for supervision of risks to workers linked to the use of chemicals. Deemed to have a role in the assessment of the risks to workers and potential need for safeguards related to testing activities to be carried out under the Act.⁴⁷

Swedish Energy Markets Inspectorate

The Swedish Energy Markets Inspectorate (Ei) is an expert supervisory authority in the field of energy. Ei's is assigned to work for well-functioning energy markets. Ei supervises and develops regulation of the electricity, district heating and natural gas markets, and works to safeguard society's need for efficient energy distribution and trade. Ei's tasks and responsibilities include supervision, regulation and licence assessment under the Electricity Act (1997:857), the Natural Gas Act (2005:403) and the Act on Specified Pipelines (1978:160). Furthermore, Ei supervises a large number of EU regulations. In 2024, Ei has launched an innovation centre that provides information and guidance to stakeholders who have legal questions within the framework of the existing regulations that Ei is tasked with applying.

Swedish Energy Agency

The Swedish Energy Agency is responsible for permitting and supervision of, among other things, technologies and projects affecting carbon capture, renewable energy production or energy efficiency. The Swedish Energy Agency supports business development to enable the commercialisation of innovations and new technologies.

Municipalities

The responsibility of Sweden's municipalities for permits and supervision concerns, for example, permits and activities within the municipality, including environmental permits for activities potentially impacting the environment, such as industries and waste facilities. Municipalities oversee environmentally hazardous activities and other local environmental issues, as well as construction, solar and wind power installations, and the management of chemicals and waste.

County administrative boards

The county administrative boards assess and grant permits for major projects such as renewable energy (wind and solar power), carbon capture and bioenergy. They are also responsible for monitoring the use of technologies that have been granted permits in accordance with applicable environmental requirements and ensuring that negative environmental impacts are avoided. The county administrative boards have past experience with collaboration on horizontal as well as vertical axes within the permitting system. Vinnova proposes that the same six contact points that will coordinate and facilitate permitting processes for activities that are crucial for securing access to critical

⁴⁷ Net-Zero Industry Act (EU) 2024/1735) 33.5

raw materials and technologies needed for the climate transition⁴⁸, also represent the county administrative boards as competent authorities for regulatory sandboxes.

Land and Environment Courts

The Land and Environment Courts authorise larger and more complex testing and demonstration projects in the physical environment. This includes authorisation and supervisory decisions that may affect net-zero technology projects.

Environmental Assessment Delegations

The role of the Environmental Assessment Delegations covers the permitting, supervision and standardisation of technologies with potential environmental impacts, such as carbon capture and large-scale renewable energy projects. They monitor the compliance of permitted projects with environmental requirements and ensure that the technologies used do not bring about negative environmental impacts. They also develop standards and guidelines to ensure sustainable implementation of the technologies as well as their fulfilment of environmental requirements throughout their life cycles.

Swedish Environmental Protection Agency

The Swedish Environmental Protection Agency leads and coordinates Sweden's environmental work. The Swedish Environmental Protection Agency is the supervisory authority in the areas covered by the Swedish Environmental Code. The supervisory areas mentioned in interviews with companies that may constitute obstacles include waste legislation, but discharges to air and water, professional chemical handling, contaminated sites and energy efficiency are supervisory areas that may also be relevant for net-zero technologies. The Swedish Environmental Protection Agency has the right to litigate in Land and Environment Courts and must protect the environmental interests of the public in permitting processes.

Geological Survey of Sweden

The Geological Survey of Sweden (SGU) is the supervisory authority and expert authority on carbon sequestration. SGU has also been mandated to be the competent authority for recognising projects related to carbon sequestration as strategic net zero projects. Furthermore, SGU has been assigned by the Government to investigate regulatory development regarding carbon sequestration. SGU has a key role in the implementation of the Net-Zero Industry Act's sister regulation on critical and strategic raw materials - the European Critical Raw Materials Act, which provides an opportunity to find common synergies, e.g., regarding more efficient permitting processes.

Swedish Radiation Safety Authority

⁴⁸Ministry of Climate and Enterprise, "Sex länsstyrelser får uppdrag att samordna och underlätta tillståndprocesser", <https://www.regeringen.se/pressmeddelanden/2024/12/sex-lansstyrelser-far-uppdrag-att-samordna-och-underlatta-tillstandsprocesser/>. Press release, 17/12/2024.

The Swedish Radiation Safety Authority issues permits for activities involving radiation, such as nuclear power plants or medical applications. The Authority also has a supervisory role to ensure that these activities fulfil safety requirements.

2.2.3 Responsibilities of supervisory authorities

As this list of competent authorities is incomplete, the following three sections describe the overall responsibilities of the public authorities in relation to the Net-Zero Industry Act and regulatory sandboxes (see also section 1.2 for additional information).

The competent authorities shall be investigative, examining whether applications fulfil the selection and eligibility criteria to be set out in implementing acts. Furthermore, as stated in the Act, the competent authorities will set the conditions for the regulatory sandbox and develop an implementation plan. It is also up to the competent authorities to assess the need for and consider granting exemptions or derogations from the applicable regulatory framework. Public authorities that currently grant permits for net-zero technologies mentioned in Article 4 of the Act, as well as permits for tests and experiments in real environments, will thus become competent authorities. These include the county administrative boards and the Land and Environment Courts.

2.2.4 Responsibilities of supervisory authorities

During the period of the regulatory sandbox, the Act requires public authorities to monitor and supervise testing and experimentation activities. Authorities at central government and municipal level that currently have technical competence and supervisory responsibility for the net-zero technologies stated in Article 4 of the Act, as well as for supervision of tests and experiments in real environments, may be relevant as competent authorities. These include the Swedish Energy Agency, the Swedish Energy Markets Inspectorate, the county administrative boards, the Geological Survey of Sweden, the Swedish Radiation Safety Authority, municipalities and others.

2.2.5 Responsibilities of the Riksdag and regulatory authorities

In addition to permit-granting and supervisory authorities, other regulatory authorities and bodies may need to be involved in the work on regulatory sandboxes. Public authorities with no direct role in the establishment and operation of regulatory sandboxes, but which have issued regulations affecting the area, may also need to be involved in cases where competent authorities consider derogations or exemptions from regulations. Such public authorities and regulatory bodies will also need to be involved in the process of regulatory learning and development.⁴⁹

2.2.6 Investigating proposals for regulatory changes

In addition to amended regulations, changes to laws and/or regulations may be deemed justified as a result of the regulatory learning envisaged by the regulatory sandboxes. In

⁴⁹ It is unclear whether the concept of competent authorities under the Act also includes regulatory authorities without tasks in the permitting and supervision of the testing activities referred to.

order to fulfil the Act's objective of accelerating the development and scaling up of net-zero technologies, it is important that such changes are not delayed more than necessary. Vinnova therefore proposes a 'fast track' to investigate and prepare the legislative changes that regulatory sandboxes entail. Therefore, as mentioned in section 2.1.3, Vinnova proposes that this task be assigned to the Simplification Council at the Swedish Agency for Economic and Regional Growth. It would be advantageous for the Simplification Council to deal with proposals not only in the net-zero area, but also with future proposals emerging as a result of regulatory sandboxes in, for example, AI, biotechnology or other regulatory sandboxes.

Regarding amendments to and interpretation of EU legislation, the Net-Zero Industry Act establishes a Scientific Advisory Group on the regulatory burden on net-zero technology. The Scientific Advisory Group shall support the work of the Commission, of the European Parliament and of the Member States, by providing advisory reports on the regulatory impact and burden of Union law on industrial activities within the scope of the Act.⁵⁰ The Scientific Advisory Group should be able to provide a forum for channelling and raising questions on the needs of national regulatory sandboxes and the net-zero industry for regulatory change at EU level. Vinnova proposes that the Government and the new Implementation Council shall have responsibility for monitoring national needs vis-à-vis the EU.

2.2.7 Other stakeholders deemed important for implementation and enforcement of the Act

The following stakeholders have also been deemed important for implementation and enforcement of the Act in Sweden.

- Industry organisations - in their role of representing the business perspective at an aggregated level.
- Vinnova - able to provide expertise on the ecosystem of innovative startup and scaleup activities, innovative policy development and assessment of the innovation potential of a given technology.
- Swedish universities, incubators, innovation offices, science parks, research institutes - able to provide technical expertise, information on perceived regulatory obstacles and access to established testbeds and demonstration environments. Ongoing evaluation of the process and impact of regulatory sandboxes could help improve implementation quality.
- Acceleration Office - able to provide information on perceived regulatory obstacles and management of conflicting objectives, among other things
- Swedish Agency for Economic and Regional Growth - as contact point for strategic projects within the Act, coordination and crosstalk among potentially overlapping projects will be important. The Agency for Economic and Regional Growth plays a central role in receiving applications for net-zero manufacturing projects within the 19 net-zero technologies and energy-intensive industry

⁵⁰ Net-Zero Industry Act (EU) 2024/1735: 40.7.

decarbonisation projects covered by the Act, and in deciding whether to recognise such projects as strategic net-zero projects. The Swedish Agency for Economic and Regional Growth also operates the Simplification Council, which is proposed to serve an investigative role for necessary regulatory changes that have been identified.

- The Swedish Competition Authority - in the role of providing expertise on avoiding potential distortions of competition and market disruption as well as monitoring the long-term effects of regulatory sandboxes.

2.3 Preparatory actions for implementation of the contact point

Few public authorities in Sweden have experience with regulatory sandboxes. Even those possessing such experience are uncertain how to meet expectations regarding, among other things, available resources and the need for coordination, when implementing the Net-Zero Industry Act. Experience at national level with innovative policy development has shown the importance of clear guidance for the stakeholders involved. In order for the regulatory sandbox process to be properly established, clear guidelines and support for the work of the contact point and the competent authorities must be created at an early stage. The main principles to be communicated by the Commission in implementing acts will also likely need to be complemented by national provisions.

2.3.1 Government measures

Vinnova foresees a need for the following measures, among others:

2.3.1.1 Comprehensive measures

- A ministry should be designated as mainly responsible for national follow-up of net-zero sandboxes vis-à-vis the EU platform. A single ministry should be the gateway for the contact point and competent authorities regarding follow-up, regulatory learning and proposals for regulatory amendments. The responsibility of the Implementation Council to support the ministry in capturing proposals at national level for changes to EU regulations should be reviewed. The Implementation Council should be provided with resources and other prerequisites for this function (see section 2.2.6).
- One ministry should also be appointed to coordinate collaboration in the preparation of EU implementing acts, starting in spring of 2025. (Vinnova proposes that the Government Offices coordinate Sweden's input to the EU's implementing acts for the Net-Zero Industry Act.) It would be advantageous to have a platform that invites both private and public stakeholders to participate in

such collaboration.

- Resources should be ensured throughout the regulatory sandbox process-chain (contact point, competent authorities, contact point reference group, investigators of regulatory change proposals resulting from sandboxes, follow-up and reporting to the EU platform, involvement in the development of implementing acts).

2.3.1.2 Regulation of procedure, mandate and division of roles, etc.

- The mandate and respective roles of the contact point, the lead competent authority and the other competent authorities should be clarified in a national regulation with provisions complementing the Net-Zero Industry Act or by other appropriate means. This regulation should cover issues related to application procedure as well as the establishment, operation and termination of regulatory sandboxes and include specialised regulation of relevant issues, such as the issue of a prohibition on appeals (see section 2.1.3 item 6).
- The potential need for additional 'experimental clauses' in relevant regulations of net-zero technology, or other ways to meet public authorities' needs for authorisation to apply regulations as provided for in the Act, should be reviewed. Given the imminent entry into force of the Act and the time typically required for legislative amendments, such a review should be carried out as soon as possible.
- A review should be conducted of the potential need for amendments to the Public Access to Information and Secrecy Act to ensure the appropriate processing of sensitive information from companies in connection with the application and throughout the process.
- The current regulation of permit-granting and supervision processes may require supplementation, in the form of a solution addressing cases where the innovative technology lacks a clearly defined competent authority. All applications received by the contact point must be transmittable to a public authority with main responsibility for examining applications.

2.3.1.3 Further measures pursuant to Vinnova's proposals

Implementation and structuring in accordance with our proposal will also require the following preparatory measures:

- Designation of an office for the national contact point and the relevant competent authorities for initial implementation.
- Appointment of a multidisciplinary reference group to support the contact point during the implementation phase. More formalised responsibility for the contact

point's reference group should be considered, e.g. for involvement of research institutes via owners' directives.

- Given our proposal to make the Simplification Council the 'fast track' for investigating proposals for regulatory changes resulting from net-zero regulatory sandboxes (in the future, possibly also in a broader sense; AI, biotechnology, etc.), the Simplification Council should receive resources and other prerequisites for this function (see section). 2.2.6

2.3.2 Contact point measures

Vinnova proposes that the contact point office take the following preparatory measures, among others:

Internal preparations

- Investigate and establish an inter-agency contact point office. Mandates, processes and responsibilities for the office must be developed. It is proposed that the responsibilities of the Government Offices include ensuring resources to this office during the implementation phase, pursuant to section 2.3.1.
- Implement forms for reporting by the contact point and competent authorities to the Government Offices.
- Detail the work process for receiving and further guiding applications for regulatory sandboxes.
- Recruit/procure any necessary expertise

Collaboration

- Together with competent authorities, develop collaborative arrangements to gather and share lessons learnt from previous efforts in policy development for innovation. Preferably, the collaboration group will receive support from experienced stakeholders such as Vinnova, the Swedish Energy Markets Inspectorate, the Swedish Authority for Privacy Protection and the Swedish Financial Supervisory Authority. International stakeholders should also be involved in this collaboration. This will allow insights regarding skills and capacity needs to be addressed and productive working methods to take root in this new context.
- Together with competent authorities, develop ways of working and collaborating, preferably using user-centred design methodology. Structures for systematic learning must be established early on for the development of working methods over time.
- Together with competent authorities, establish a secure process for handling and exchanging information that provides adequate protection for companies' sensitive information.
- Together with competent authorities, investigate the need for developed support systems for management of joint cases.

- Together with competent authorities and in accordance with the Act⁵¹, plan in-house and joint communication activities and information campaigns. A dedicated channel for communication must be established and, preferably, jointly used.⁵²
- Establish forms of crosstalk between the other contact points of the Net-Zero Industry Act for common learning and coordination of possible overlapping projects. Under the proposal, the contact point will also establish crosstalk forms with public authorities involved in the implementation of the European Critical Raw Materials Act.

2.3.3 Competent authorities measures

Vinnova proposes that the public authorities identified in section 2.2.2 take the following preparatory measures, among others:

Internal preparations

- Investigate and establish innovation centres to receive and assess applications for regulatory sandboxes. Ensure resources for such innovation centres during an introductory period to be among proposed tasks for the Government pursuant to 2.3.1.
- Implement forms of reporting by the contact point and other competent authorities to the Government Offices, the Implementation Council and the Simplification Council.
- Recruit/procure any additional expertise

Collaboration

- Together with the contact point, develop collaborative arrangements for gathering and sharing experience from previous efforts in policy development for innovation. Preferably, this work will be supported by experienced stakeholders, such as Vinnova, the Swedish Energy Markets Inspectorate, the Swedish Authority for Privacy Protection and the Swedish Financial Supervisory Authority. International stakeholders should also be involved in this collaboration. This will allow insights regarding skills and capacity needs to be addressed and take root in this new context.
- Together with the contact point, develop ways of working and collaborating, preferably using user-centred design methodology. Structures for systematic learning must be established early on for the development of working methods over time.
- Together with the contact point, establish a secure process for handling and exchanging information that provides adequate protection for companies' sensitive information.
- Together with the contact point, investigate the need for developed support systems for management of joint cases.

⁵¹ Net-Zero Industry Act (EU) 2024/1735:34

⁵² See, e.g. Swedish Companies Registration Office, Swedish Tax Agency, and Swedish Agency for Economic and Regional Growth website *verksamst.se* as potential solution, <https://verksamst.se/>.

- Together with the contact point and in accordance with the Act⁵³, plan in-house and joint communication activities and information campaigns. A dedicated channel for communication must be established and, preferably, jointly used.

2.3.4 Contact point reference group measures

The necessary formalising of the role of the contact point's reference group and development of guidelines are included among the proposed tasks of the Government, in section 2.3.1.

Vinnova proposes that the reference group take the following preparatory measures, among others:

- Establish the form of an interdisciplinary reference group with the Government-appointed representatives for the reference group's work and develop guidelines for the cooperation of this group.

2.3.5 Measures for inter-agency collaboration for regulatory learning

It is necessary to build up collaboration across common interfaces for regulatory learning. Vinnova proposes taking the following preparatory measures:

- The Government Offices, the Simplification Council, the Implementation Council, the contact point and the competent authorities shall draw up guidelines on modes of working and the division of responsibilities.
- Develop collaborative arrangements for gathering and sharing experience from previous efforts in policy development for innovation. See above proposals under 2.3.2.

2.4 Other parts of the Act that have a bearing on the implementation of the contact point

The Net-Zero Industry Act regulates measures in parallel areas, such as streamlining permit-granting processes for critical raw materials and net-zero industry, strategic net-zero projects, and net-zero regulatory sandboxes for innovative technologies.

Section 2.2.7 describes the six contact points of the county administrative boards, which will coordinate and facilitate permit-granting processes. The Swedish Agency for Economic and Regional Growth has been designated as an additional contact point for strategic projects under the Act.

Vinnova proposes the establishment of collaboration among these contact points for joint learning, consultation and coordination of any overlapping projects. Under the proposal, the contact point for regulatory sandboxes will also establish crosstalk forms

⁵³ Net-Zero Industry Act (EU) 2024/1735:34

with public authorities involved in the implementation of the European Critical Raw Materials Act.

2.5 Questions for further inquiry

2.5.1 Stakeholder analysis of Vinnova's proposal

Overall views from the stakeholders have been collected and taken into account, but the stakeholders concerned have not had the opportunity to present any study or analysis of opportunities and risks related to Vinnova's proposal. Nor has Vinnova had the opportunity to test and iterate the proposed prototype together with stakeholders in the course of the assignment, something that can be done during future collaboration. The Government Offices should reconcile and clarify the need for further investigation and analysis. Vinnova also requests that the competent authorities contribute to an overall joint analysis and the development of uniform working methods.

2.5.2 Consequences of the implementing acts

As stated in section 1.1, the European Commission will set out in implementing acts the main principles for the establishment and operation of the regulatory sandboxes, including the responsibilities and roles of the contact point and the competent authorities. The Commission can be expected to regulate the procedure in some detail in several respects, including the requirements and conditions that need to be met. It is unclear what scope will be left for Member States to adopt their own solutions to different issues. To the extent that the Commission's governance has a binding effect on Vinnova's proposals, the consequences will need to be analysed and working methods adjusted.

2.5.3 Conceptual learning structures for regulatory sandboxes

Vinnova's proposal will establish the basic conditions for implementation to be gradually developed on the basis of accumulated experience and allocated resources. Based on its knowledge of system innovation and innovative policy development, Vinnova expects that the responsibilities of the contact point and competent authorities will need to be developed in the longer term. Such tasks may include, for example:

- In-depth guidance for applicants in the pre-application phase,
- Explicit responsibility for stakeholder mobilisation
- Coordination and collaborative leadership and process management for development of the regulatory sandbox as an innovative policy instrument.

Such tasks, if they are included in the role of the contact point or another stakeholder, would represent a significant expansion of responsibility compared with the report's proposal, and, in Vinnova's view, resources should be adjusted accordingly. The expanded responsibilities should also be explored and further developed based on lessons learnt and taking into account demand. Appropriate structures for systematic

learning must be developed in 2025 so that, during implementation, they can be successfully activated and resourced and lessons learnt can be fed back on an ongoing basis.

Examples of issues that should be monitored:

- Support to regulatory sandbox target groups at different stages of the process
- Internal working methods
- Collaboration among authorities concerned and between public authorities and other organisations, nationally and internationally
- Use of skills and resources
- Modes of working to capture regulatory learning

At the end of the implementation phase, the proposal for the basic process, together with adjustments made on an ongoing basis, must be evaluated before any major changes are adopted. Such major changes may concern, for example:

- Governance
- Division of responsibilities between contact point, main responsible competent authority and other competent authorities
- National priorities regarding the focus of the regulatory sandboxes. The focus can be on technology types, challenge areas or types of support.

Vinnova proposes that design methodology continue to be used in implementing the Act. The needs and challenges of stakeholders can continue to serve as a starting point, around which this complex issue can be addressed together. Future implementing acts, experience from the initial implementation period and lessons learnt can facilitate the iteration and eventual adaptation of concepts and processes to changing circumstances.

2.5.4 Long-term funding and needs assessment of test and demonstration environments

The Act emphasises the possibility for companies to test their innovations in a real environment. Access to test and demonstration environments is also a clearly expressed need on the part of companies in order to speed up development and scale up production. A regulatory sandbox may typically require access to a physical site, which, if not already existing, may require further time-consuming bureaucracy. Taking into account a certain geographical spread, Vinnova deems it desirable to ensure long-term funding for test and demonstration environments for these technologies. An inventory of needs (for utilisation and responsibility for ongoing investment in upgrades) related to test and demonstration environments should also be made for these technologies.

2.5.5 Relationship with regulatory sandboxes in other fields

In parallel to the Net-Zero Industry Act, additional EU regulations are being introduced that also require the establishment of regulatory sandboxes, such as the EU AI Act and

the EU Biotech Act⁵⁴. Going forward, the Government and the contact point should follow the development of and relationship with other regulatory sandboxes, their processes, working methods, etc. Vinnova wishes to emphasise the importance of managing regulatory sandboxes from a holistic perspective, in which governance and coordination from the Government Offices of Sweden are central to creating the right conditions, instead of turning regulatory sandboxes into a legislative black hole.

⁵⁴ European Parliament and Council of the European Union, 2024/1689, Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act); European Commission, 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU', Document 52024DC0137, 20/03/2024, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52024DC0137>. (Retrieved 17/01/2025)

3 Presentation of supporting information for the proposal

This section presents the information supporting the views and proposals that have been collected and material from reports that, with the legal conditions, form the basis for Vinnova's proposal. This includes insights into stakeholder needs and lessons learnt from previous regulatory sandbox initiatives. The section also highlights the conditions that remain uncertain but which must be addressed.

3.1 Insights from interviews and reports

3.1.1 International environmental analysis

An environmental analysis has been carried out by identifying and contacting relevant organisations in countries involved in the establishment and implementation of net-zero regulatory sandboxes in energy. The countries identified are Denmark, Norway, Finland, the United Kingdom, the Netherlands, France, South Korea and Singapore. Interviews were conducted with Denmark, Finland and the United Kingdom. Planned interviews remain to be conducted with Norway and South Korea.

The aim of the international environmental analysis has been to learn from other countries, identify successful methods and tools that can be adapted to the Swedish context and strengthen international cooperation. Several European countries have expressed the desire for a common network to exchange expertise and experience with net-zero regulatory sandboxes related to implementation of the EU Net-Zero Industry Act.

Regulatory sandboxes have become an important tool for fostering innovation. However, the definition of a regulatory sandbox, its objectives, design and governance model differ between countries, as is clearly reflected in the project carried out by the Danish Business Authority (*Erhvervsstyrelsen*) in Denmark, where case studies on regulatory sandboxes from 24 countries have been compiled.⁵⁵

The energy-sector regulatory sandboxes listed in Denmark, France, Singapore, Lithuania and the UK have been established to enable the testing, development and launch of new products, services, methods and business models to benefit consumers, but may face obstacles in energy regulation. The green transition of the energy sector is a priority of many regulatory sandboxes, including the integration of renewable energy in Denmark, France and the UK.

⁵⁵ Erhvervsstyrelsen, *Case catalogue. Tools for agile regulation of emerging technologies. Based on qualitative data collected by the Danish Business Authority in 2021/2022 on behalf of the Agile Nations Experimental Approaches Working Group*. PowerPoint presentation, 03/09/2024.

Countries work with industry and other stakeholders in the regulatory sandboxes to exchange expertise, experiences and practices. This collaborative approach increases the efficiency of regulatory sandboxes and promotes inter-disciplinary innovation.

Regulatory sandboxes can be started by companies or by governments. Regulatory sandboxes focussing on knowledge-based support from the responsible authority based on current regulations have had the greatest impact. These sandboxes have provided a controlled environment for companies to test new ideas within the existing regulatory framework. Any regulatory derogations actually being made for regulatory sandboxes from existing legislation have been authorised for a limited period.⁵⁶ Denmark (Danish Business Authority)⁵⁷ and the United Kingdom (Office of Gas and Electricity Markets, OFGEM)⁵⁸ have both been working with regulatory sandboxes in the energy sector since 2017. Their regulatory sandboxes have been established within the framework of existing legislation. Countries have offered personalised regulatory support to help companies understand the regulatory framework and how to innovate within it. This support has involved private meetings with customised guidance for the company, as well as forwarding to relevant authorities and their networks for potential next steps. The public authorities have also used their experience with providing guidance to publish support materials on common issues that are available to the public.

In France, regulatory sandboxes have been established by amending national energy sector regulation. The Energy and Climate Act in France allows for derogations for access to and use of networks and facilities.⁵⁹ A regulatory sandbox has been established to support the development of new energy technologies and the promotion of the energy transition. Government and private business actors operate the regulatory sandbox together. The *Commission de Régulation de l'Énergie* (CRE)⁶⁰ and the *Direction générale de l'énergie et du climat* (DGE)⁶¹ both have the immediate authority to grant derogations from electricity and gas network regulations. The aim is to test how well innovations promote the energy transition and to develop the regulatory framework to effectively support the transition. CRE is responsible for the regulatory sandbox, including calls for proposals and cooperation with innovators to identify potential obstacles. CRE also makes the initial assessment of applications for regulatory sandbox experiments. If the competence of CRE does not cover a request for

⁵⁶ Erhvervsstyrelsen, *Case catalogue. Tools for agile regulation of emerging technologies. Based on qualitative data collected by the Danish Business Authority in 2021/2022 on behalf of the Agile Nations Experimental Approaches Working Group*. PowerPoint presentation, 03/09/2024.

⁵⁷ Erhvervsstyrelsen, <https://erhvervsstyrelsen.dk/> (Retrieved 10/01/2025)

⁵⁸ Office of Gas and Electricity Markets, <https://www.ofgem.gov.uk/> (Retrieved 10/01/2025)

⁵⁹ Erhvervsstyrelsen, *Case catalogue. Tools for agile regulation of emerging technologies. Based on qualitative data collected by the Danish Business Authority in 2021/2022 on behalf of the Agile Nations Experimental Approaches Working Group*. PowerPoint presentation, 03/09/2024.

⁶⁰ Commission de régulation de l'énergie, <https://www.cre.fr/> (Retrieved 10/01/2025)

⁶¹ Ministère Aménagement du territoire Transition écologique, "Direction générale de l'énergie et du climat (DGE)", <https://www.ecologie.gouv.fr/direction-generale-lenergie-et-du-climat-dgec> (Retrieved 10/01/2025)

regulatory derogation in whole or in part, the request is sent to DGEC for further assessment.⁶²

Across the various countries, common challenges related to regulatory sandboxes include the significant investment, in both time and resources, required for companies applying to and participating in regulatory sandboxes. Participation also entails a certain risk, since achieving an amended regulation, or any other concrete change, is not guaranteed after the regulatory sandbox is completed. Obstacles related to confidentiality may also make companies reluctant to share sensitive information or trade secrets in a sandbox for reasons related to competitiveness.

Experience from all countries indicates that it is of the utmost importance to establish a national contact point with a clear mandate to effectively guide companies to the right regulatory sandbox while also providing guidance to public authorities on how to set up such regulatory sandboxes. This contact point plays a crucial role in ensuring that companies receive the right support while the authorities concerned also receive the necessary guidance.

When the regulatory framework of several public authorities may be affected, collaboration among them, and coordination by the contact point, is required. The 'One-stop shop'⁶³ of the Danish Business Authority is an example of a collaboration model that coordinates among various ministries and public authorities as needed, to help companies with new technologies and business models obtain comprehensive answers and guidance. Another example is the Green Economy Regulatory Initiative (GERI) (Ministry of Trade and Industry), which is a government-wide "one-stop platform" for testing green technologies in regulatory sandboxes in Singapore. In cooperation with the relevant public authorities, GERI assesses proposals received to determine the parameters of the regulatory sandbox.⁶⁴ A clear mandate, extensive networks, relevant expertise and dedicated resources are required for the one-stop approach to be successful.

The establishment of regulatory sandboxes requires significant time, knowledge and expertise on the part of the public authorities concerned. The dialogue with Denmark indicates that an estimated two full-time employees per regulatory sandbox are required to manage the complex processes and ensure the effective functioning of the regulatory sandboxes. Regulatory sandboxes also require a critical mass of participating companies, in order to achieve sufficiently significant results that can potentially bring about a change in existing regulations.

⁶²Catharina Palm, Mikaela Almerud, Nils Karlsson and Hampus Rane, Regulatoriska sandlådor som policyinstrument, Swedish Entrepreneurship Forum, 2024. https://entreprenorsforum.se/wp-content/uploads/2024/10/Rapport_Regulatoriska_sandlador_Webb.pdf (Retrieved 04/12/2024).

⁶³Informant A, civil servant, Erhvervsstyrelsen of Denmark. Interview, 20/11/2024

⁶⁴Ministry of Trade and Industry Singapore, "Green Economy Regulatory Initiative (GERI)", <https://www.mti.gov.sg/PEP/GERI> (Retrieved 10/12/2024)

Derogations from existing regulations have thus far mainly applied to the development of specific new technologies, such as AI and drones. In interviews with the Danish Business Authority and the Office of Gas and Electricity Markets (OFGEM), the public authorities thus recommend that regulatory sandboxes with regulatory exemptions not be used as a primary option. This is because regulatory exemptions take a long time to materialise and their long-term effects have not yet been evaluated.

Through regulatory learning, public authorities have gained a better understanding of where regulatory obstacles may arise. This learning is crucial to identify and address the obstacles that companies face in their innovation process.

3.1.2 National experiences in innovative policy development and regulatory sandboxes

Regulatory sandboxes are a relatively new tool in Sweden, but experience and lessons can be drawn from several previously implemented variants of regulatory sandboxes as well as policy development. The final report of the Committee for Technological Innovation and Ethics (*Komet*) mentions several examples of different pilot projects, experiments and approaches.⁶⁵ Below is a selection of experiences gained.

The Swedish Authority for Privacy Protection was the first public authority in Sweden to introduce a national regulatory sandbox, in 2022, but with no exemption from existing legislation. The sandbox aims to provide in-depth guidance on legal grey areas related to the GDPR. Questions were selected in consultation with the companies and mainly concerned AI and information sharing⁶⁶.

The Financial Supervisory Authority (FI) has chosen not to introduce a regulatory sandbox, but instead set up an innovation centre in 2018 to act as a contact point for new activities. FI deems this centre, together with other efforts to provide clearer information and simpler permit-granting processes, to be more important than a regulatory sandbox⁶⁷.

The Swedish Energy Markets Inspectorate (Ei) has developed a proposal for a model of how regulatory sandboxes can be implemented in Sweden. Ei's proposal includes a phased implementation that begins by establishing an innovation centre, which can contribute to information, knowledge sharing and rule development. According to Ei, the supervisory or regulatory authority is responsible for the regulatory sandbox's authorisation, design and administration under the most commonly used model. Resource requirements of a regulatory sandbox are greatest early on, when work is initiated, and later decrease as learning occurs, both at companies and internally at the

⁶⁵ SOU 2022:68 *Förnya taktiken i takt med tekniken – förslag för en ansvarsfull, innovativ och samverkande förvaltning*.

⁶⁶ Carin Sundhage, Staff Analyst at the Swedish Authority for Privacy Protection (lecture notes from presentation at Vinnova on the Authority's data protection regulatory sandbox, 18/10/2024);

⁶⁷ Financial Supervisory Authority, *FI:s syn på regulatoriska sandlådor*, Financial Supervisory Authority, 2024. <https://www.fi.se/siteassets/fis-syn-pa-regulatoriska-sandlador.pdf> (Retrieved 27/11/2024).

public authority, according to Ei.⁶⁸

The Swedish Agency for Economic and Regional Growth has developed a working model for agency collaboration, One Stop Myndighetsshop, which supports innovative companies in the food-supply chain by addressing their challenges linked to regulations and permits and using, among other things, a guide service and an expert group with representatives from various public authorities to match them with solutions. The model focuses on finding solutions for companies within the framework of existing laws and regulations and on identifying the need for regulatory change. The Agency for Economic and Regional Growth emphasises the importance of daring to think outside the box and adapting regulations to support entrepreneurs in an early innovation phase, since regulations and guidelines are not adapted to them.⁶⁹ The Simplification Council is another initiative that the Agency for Economic and Regional Growth has undertaken, pursuant to a Government assignment. Its main task has been to reduce the regulatory burden and administrative costs for companies. The Council's work has included receiving and analysing proposals from the business community and others regarding how to simplify rules. The Council is also tasked with making concrete proposals to the Government regarding how to reduce the regulatory burden and administrative costs for companies.⁷⁰

Vinnova's previous initiatives in innovative policy development⁷¹ provide additional experience. The Government Offices have steered public authorities towards working in new ways via Government assignments, which is one factor that has contributed significantly to success in this work. It has been found that design-driven approaches with feedback loops are more effective than, for example, consultation rounds and commissions of inquiry.⁷² In its evaluation of Vinnova's assignments in smart policy development, the technology and spatial planning consultancy Sweco has highlighted

⁶⁸ Swedish Energy Market Inspectorate, *Innovationscenter och regulatoriska sandlådor. Modellförslag och implementering för energimarknaderna i Sverige*, 2023

<https://ei.se/download/18.56edc373186a1d5a9df2b8f/1678094189173/Innovationscenter-och-regulatoriska-sandl%C3%A5dor-Ei-R2023-03.pdf>, (Retrieved 05/12/2024)

⁶⁹ Swedish Agency for Economic and Regional Growth, *One stop myndighetsshop - En myndighetsöverskridande samverkansmodell för förenkling och ökad innovation i livsmedelssektorn*, 2024,

<https://tillvaxtverket.se/download/18.b55bceb1919736dc3ea90b4/1725612475127/One%20Stop%20Myndighetsshop%20-%20En%20myndighets%C3%B6verskridande%20samverkansmodell%20f%C3%B6r%C3%B6renkling%20och%20%C3%B6kad%20innovation%20i%20livsmedelssektorn.pdf> (Retrieved 06/12/2024)

⁷⁰ Swedish Agency for Economic and Regional Growth, "Förenklingsrådet",

<https://tillvaxtverket.se/tillvaxtverket/omtillvaxtverket/varaupdrag/allaupdrag/forenklingsradet.7518.html> (Retrieved 16/01/2025)

⁷¹ Vinnova, *Regeringsuppdrag att ge stöd till offentliga aktörers arbete med regel- och policyutveckling*,

Vinnova, 2023. <https://www.vinnova.se/contentassets/1f78b38101cb460fba4142f06e905876/2019-05811-slutrappport.pdf> (Retrieved 19/11/2024);

Vinnova, *Innovation för nyindustrialisering och samhällsomvandling i norra Sverige*, (ref 2024-00753); Ramboll Management Consulting, *En innovationsguide för utveckling av regler och andra styrmedel*, på uppdrag av Vinnova, (ref 2023-03744).

⁷² Vinnova, *Regeringsuppdrag att ge stöd till offentliga aktörers arbete med regel- och policyutveckling*, 2023.

<https://www.vinnova.se/contentassets/1f78b38101cb460fba4142f06e905876/2019-05811-slutrappport.pdf> (Retrieved 19/11/2024)

the importance of more systematic work on innovation at the public authorities⁷³ After the assignments have been completed, the innovative working methods must be introduced as part of the public authorities' regular working methods in order to achieve a longer-term effect and not end up as 'shooting stars' - spectacular but short-lived initiatives.

3.1.3 Companies

Vinnova has conducted interviews with a handful of innovation companies that develop technology in six of the 19 technology areas identified in the Act. The aim of these interviews has been to better understand the challenges faced by innovation companies in testing, validating and scaling up new technologies in a controlled real-world environment as well as their expectations regarding what needs a national contact point for establishment of regulatory sandboxes might fulfil. In addition to these companies, exploratory discussions have also been held with Technology Industries of Sweden, Almi Invest GreenTech and the investment company TIDIR to obtain insights relevant to the assignment. The programme offices for the Impact Innovation programmes Net Zero Industry and Swedish Metals & Minerals (hereinafter "the programme offices") have participated in the workshop and had the opportunity to jointly submit written comments.

The interviews revealed that it can take up to three years to find a test site and between five and seven years for full validation. This obviously entails huge costs and represents a major uncertainty for investors, negatively impacting competitiveness. Companies would wish that regulatory exemptions could influence EU legislation, even if this is not clearly stated in the Act. They are generally positive and see opportunities to facilitate the testing process, but also have concerns. Start-ups have limited resources to spend on preparing applications, and if the applications are to be designed in accordance with future EU requirements the administrative burden risks being high, and the time from application to result may be too long to create value for the companies. Companies also expressed concern about the legal definitions of the Net-Zero Industry Act as well as its delimitation to primarily cover a list of designated technology areas. This risks penalising innovative 'climate companies' which cannot be linked to the list, including companies developing innovative methods and processes to extract secondary raw materials from production waste, landfills and slag heaps. Here, according to the companies, both legislation and SNI coding are trailing behind, which limits the opportunities to utilise residual products and, ultimately, to reduce carbon emissions. Technology Industries of Sweden, together with Orgalim, has authored a document showing that, in the run up to the development of implementing acts, the

⁷³ Sweco, *Formativ utvärdering av Smart Policyutveckling*, 2023.
https://www.vinnova.se/globalassets/mikrosajter/hallbar-samhallsbyggnad/swecos_slutrapport_smart_policyutveckling_sep23.pdf (Retrieved 02/12/2024)

understanding of “net-zero technology” must be broadened to include components that are central to the identified technology areas.⁷⁴

Impact Innovation programme offices have concerns regarding a one-sided focus on start-ups. The perspective of existing industry, and their knowledge regarding the link between Swedish industry and the utilisation of new technologies, is needed.

Companies see that a well-organised national contact point has the potential to help facilitate testing in a controlled environment. The programme offices consider that the contact point's aim of facilitating access to testing is primarily through coordinating the public authorities in this respect. The companies interviewed see advantages in a ‘gateway’ and call for support in analysing and focusing on regulatory challenges related to the testing and validation of new technologies. Perceived regulatory obstacles create uncertainties, impacting the ability to attract financial capital and, consequently, delaying time to market. The companies themselves often have limited knowledge regarding the laws and regulations they must comply with. The regulations are often complex, and companies rely on consultants with legal expertise and experience in dealing with public authorities. Companies perceive that communication with the competent authorities is lacking, and they ask why and how this can be facilitated. Industry organisations provide support, but generally find it difficult to address company-specific challenges, and confidentiality is often an issue. In some cases, companies may be led to explore opportunities for scaling up and producing abroad, even if they prefer to continue operating in Sweden. This leads to frustration, not only from an economic perspective, but also because the potential to reduce carbon emissions cannot be realised. One of the Swedish companies interviewed has been approached by the EU Commission to discuss how the EU can promote their technology, which is deemed among the best in the world and of key importance for reducing negative climate impacts and strengthening EU competitiveness.

Companies expect the national contact point to offer various forms of support and guidance in the preparation of the application to establish a regulatory sandbox. During interviews, several examples emerged of needs and opportunities that a national contact point could provide, including:

- ‘Gateway’ - inter-agency pre-application guidance to identify competent authorities
- Support to gather stakeholders in establishing an overview and determining when and how various regulations affect the company in the innovation process
- Support in identifying and analysing whether perceived regulatory obstacles are related to the regulatory framework itself, or whether something else is lacking (e.g., application of the regulatory framework, communication among relevant bodies, etc.)

⁷⁴ Unofficial communication from Technology Industries of Sweden regarding a component list (European Technology Industries – *Contribution on Net-zero Technologies Components List*) currently being developed by European industry organisation Orgalim on behalf of the European Commission.

- Support and matchmaking to find optimal test, lab and demo facilities within Sweden and the EU. Several stakeholders indicated major challenges at present in finding test facilities and physical sites to validate technology, sites which must normally also be authorised to conduct tests. The European Space Range, which has removed regulatory obstacles to testing and validating innovative technology, was cited as a good example. It has sometimes been difficult to find private stakeholders willing to carry out this type of test, as it negatively affects production capacity. One company asked whether municipal/state-owned companies could provide a fast-track.

In summary, the companies interviewed mention several common needs and challenges. A well-organised contact point or ‘hub’ is deemed an effective solution for simplifying communication between companies and public authorities, as well as for offering better guidance and support for, e.g., preparation of applications and for systematic long-term regulatory learning. Coordination of public authorities in a regulatory sandbox is requested. Of course, all forms of guidance and support must consider confidentiality and competition concerns.

Technology Industries of Sweden specifically highlights the need to speed up revision of regulations that hinder the transition to a circular economy (CE). They point to regulatory sandboxes as an opportunity to accelerate the transition, by developing the use of appropriate regulatory sandboxes to analyse new regulations, update old regulations and allow testing of new and innovative solutions.⁷⁵ Technology Industries of Sweden considers that a cross-sectoral perspective on regulatory sandboxes and their application in Sweden is needed. This policy instrument appears in several new EU regulations. It is urgent to capitalise on synergies and create conditions for mutual learning in implementation, they find. Regulatory sandboxes are a relatively new policy instrument, and public authorities and companies still have a limited understanding of their function and application.

The Entrepreneurship Forum has studied twelve international regulatory sandboxes in financial technology, energy and AI as well as literature on the subject. In a report, Entrepreneurship Forum concludes that the policy instrument adds value by reducing the time and costs in going from innovative idea to market entry, increasing access to financing and reducing regulatory uncertainty. This policy instrument must be seen in the light of other policy initiatives to promote the link between innovation and the applicable regulatory framework. Establishment of a regulatory sandbox should always be preceded by a process in which one or more regulatory challenges are identified and a clear purpose and objectives are defined. This, in turn, will determine what type of regulatory sandbox is suitable to achieve the desired effect. The case studies show that the nature of regulatory sandboxes differs across technology areas. In general, AI

⁷⁵ Technology Industries of Sweden, *Cirkulär ekonomi. När affärsnytta och politiska mål går hand i hand*, 2022. https://www.teknikforetagen.se/globalassets/rapporter--publikationer/hallbar-produktion/cirkular-ekonomi--nar-affarsnytta-och-politiska-mal-gar-hand-i-hand_final.pdf?thQ1h3 (Retrieved 11/11/2024)

regulatory sandboxes are more often innovation-driven, while those in energy are often more policy-driven.

The report also touches on the risk that regulatory sandboxes may contribute to distorting competition, by providing competitive advantages to participating firms. This is countered by introducing clear and objective selection criteria, open and transparent selection processes and by requiring ongoing knowledge-sharing and dissemination of results to all market stakeholders. The report also indicates that regulatory sandboxes can promote competition by, e.g., reducing barriers to entry and thus facilitating the entry of new stakeholders into markets⁷⁶.

3.1.4 Public authorities and research institutes

Vinnova has conducted interviews with the county administrative boards of Norrbotten, Västerbotten, Stockholm, Västra Götaland and Skåne. All county administrative boards were invited to an informational event where they could submit comments and questions. Dialogues have also been held with the Swedish Energy Markets Inspectorate, the Swedish Energy Agency, the Swedish Agency for Marine and Water Management, the Swedish Chemicals Agency, the Swedish Competition Authority, the Swedish Environmental Protection Agency, RISE/former investigator for the Committee for Technological Innovation and Ethics (*Komet*) and the Swedish Agency for Economic and Regional Growth. The Swedish Association of Local Authorities and Regions (SALAR) has also been invited, but has not replied with a contact person.

3.1.4.1 Summary of opportunities and challenges

The public authorities and RISE all see regulatory sandboxes as a way of working that can bring opportunities. In their opinion, this working method can contribute to more effective legislation and improve conditions for innovation. Inter-agency collaboration in itself is seen as an added value that can contribute to more efficient processes. Overall, regulatory sandboxes are deemed to help accelerate the green transition by facilitating companies in innovative net-zero technologies. Public authorities (as well as Technology Industries of Sweden and the programme offices⁷⁷) mention the Swedish model of public administration as a challenge for establishing and managing the regulatory sandboxes, given independent public authorities and municipal autonomy. A number of public authorities express concern that they lack sufficient resources to deal with the increased workload that regulatory sandboxes can bring. The Swedish Agency for Economic and Regional Growth mentions the resource issue in its investigation of

⁷⁶Catharina Palm, Mikaela Almerud, Nils Karlsson and Hampus Rane, Regulatoriska sandlådor som policyinstrument, Swedish Entrepreneurship Forum, 2024. https://entreprenorskapsforum.se/wp-content/uploads/2024/10/Rapport_Regulatoriska_sandlador_Web.pdf (Retrieved 04/12/2024).

⁷⁷ Programme offices for the Impact Innovations programme: Net Zero Industry and Swedish Metals & Minerals

the implementation of the Net-Zero Industry Act.⁷⁸ The Danish Financial Supervisory Authority and the Danish Business Authority also indicate that the necessary resources for managing regulatory sandboxes are a challenge. The challenges mentioned in relation to resources include a compressed timetable, concerns about resource-effectiveness in supporting regulatory issues, and coordination issues among the numerous public authorities involved. In its report, the Financial Supervision Authority states that it has found it more resource-efficient to invest in an advisory innovation centre to solve companies' regulatory challenges. The Authority has chosen not to proceed with the implementation of regulatory sandboxes.⁷⁹

The public authorities wish to know how financing will be organised and whether specific funds will be set aside for this purpose. The Competition Authority emphasises the importance of ensuring that regulatory sandboxes do not distort competition, which requires, among other things, that their conditions are transparent and their results are made available to interested parties.

3.1.4.2 *Definition and responsibilities*

Stakeholders are somewhat uncertain regarding what regulatory sandboxes mean and how they differ from other methods of innovative policy development and regulatory experimentation. This indicates the need to clearly define what *must* as well as what *should be* included in net-zero regulatory sandboxes. In order to avoid ambiguity and inefficiency, the public authorities and RISE also request a clear division of responsibilities, with the roles of the contact point, the contact point's reference group of research institutes and incubators, competent authorities and the Government Offices clearly described. Guidance on this issue is expected to be clarified through Commission implementing acts. In expectation of the implementing acts, several authorities seem to be taking a wait-and-see approach to their role in the regulatory sandbox system.

3.1.4.3 *Collaboration needs within the regulatory sandbox system*

Well-functioning forms of collaboration and forums are needed to facilitate information exchange and coordinate decision-making processes. Here, for example, the county administrative boards' existing collaboration structures and experiences from permit-granting processes can be valuable to build on and learn from. However, the public authorities also emphasise that guidance from the Government Offices is very important for collaboration among public authorities to work in practice. Several public authorities emphasise the need for coordinating responsibility for collaboration; both the contact point and the main responsible competent authority are mentioned as possible options. The need for a neutral facilitator (not a public authority) in the process is also

⁷⁸ Swedish Agency for Economic and Regional Growth, *Analys av genomförandet av förordningen om nettonollindustrin*, (ref. Å 2024-105, 27/03/2024).

⁷⁹ Financial Supervisory Authority, *FI:s syn på regulatoriska sandlådor*, 2024. <https://www.fi.se/siteassets/fis-syn-pa-regulatoriska-sandlador.pdf> (Retrieved 27/11/2024); Informant A, civil servant, Erhvervsstyrelsen of Denmark. Interview, 20/11/2024

emphasised, as the public authorities mention that conflicts of interpretation can arise among them. Such a neutral party can, according to RISE, anonymise information and facilitate dialogue between companies and public authorities and, thus, contribute to coordination among authorities as well. Two county administrative boards emphasise that the contact point should have overall responsibility for managing the process and provide guidance to companies in identifying the competent authorities. The public authorities also see that a coordinating authority function, in which authorities can come together to seek viable paths, might be a way to address regulatory challenges in technology areas of strategic importance. This can overcome challenges linked to the Swedish model of public administration, in which each public authority is responsible for its own technology area, but no one is responsible for the whole.

3.1.4.4 Testing and risk assessment with establishment of regulatory sandboxes

The process for case handling and issuing decisions must be flexible and adaptable to different types of applications. The process must also be efficient and coherent, in order to avoid delays and unnecessary risks for applicants. For example, public authorities express the importance of clear criteria when assessing applications and resources allocated for public authorities to deal with enquiries received.

In order for the competent authority to carry out an efficient assessment and avoid lengthy processes requiring supplementary information, a well-designed application template is crucial. Avoiding follow-up questions is one simplification measure in the Act, which clarifies that the examining authority may not request supplementary information on matters not previously requested.

The public authorities also emphasise that risk assessment of new technologies is complex. Skills must be developed and renewed, and clear guidance on the issue is needed from central government agencies, such as the Swedish Environmental Protection Agency. Public authorities are divided on the question of who should assess potentially new technologies. In the opinion of some, this assessment must be done by expert authorities, while others state that the assessment should be done by the contact point, in consultation with competent authorities.

3.1.4.5 Comments and suggestions on the contact point and its interface

The need for a contact point for regulatory sandboxes finds broad support. It is understood that such a contact point, by acting as a single gateway to public authorities, would play an important role in facilitating companies wishing to test new net-zero technologies. Some public authorities highlight the need for the contact point, as a first instance for assessing the complex regulatory system, to sort through applicants and relieve the burden on competent authorities. At the same time, there is considerable uncertainty among public authorities as to how the contact point is to be organised and what its tasks should be. The public authorities recognise that a broad profile of skills is required for the contact point to properly guide applicants, including

legal expertise, technical understanding of different areas and good communication skills.

By building a network of competent authorities and other relevant stakeholders, the contact point can play an important role in creating the conditions for effective collaboration. The public authorities also indicate that it would be valuable for the contact point to offer methodological support to competent authorities and assume responsibility at national level for development of the capacity and processes of regulatory sandboxes.

4 Impact assessment and identification of risks

This section describes the implications of Vinnova's proposals for the contact point, competent authorities and applicant companies. The section also includes a brief account of the risks associated with the proposals and the implementation of regulatory sandboxes as policy instruments.

4.1 Implications of Vinnova's proposal

Sweden's implementation of the Net-Zero Industry Act raises expectations and places unprecedented demands on the system of public administration. Most of the processes and practices required to implement the Act are yet to be developed. According to unofficial information from the Commission, representatives from Member States will be given the opportunity to contribute to the drafting of the implementing acts starting in 2025.⁸⁰ In order to provide Swedish input, the Government Offices, the contact point and perhaps even the competent authorities will need to dedicate resources and time to this work. The contact point and competent authorities must also allocate resources to investigate and develop a common basis for work and decision-making processes, to procure system support, analyse skill needs and potentially recruit for the work on net-zero regulatory sandboxes.

4.1.1 Implications for the contact point

Under Vinnova's proposal, the contact point will initially be given very limited responsibility, which will evolve as conditions and demand become clearer. Even with a limited scope, numerous aspects of the contact point's work must be considered:

- Need for process development
- Need for IT development
- Need for competence enhancement
- Other resource needs

4.1.1.1 *Need for process development*

For a regulatory sandbox contact point to receive applications, the target groups must be aware of the opportunity. It is therefore important that the contact point itself understands the offer in depth and is able to communicate it clearly, in writing and orally, to create the right expectations. This is particularly true insofar as the contact point is tasked with organising informational campaigns aimed at SMEs, pursuant to Article 34 of the Act. This packaging and, to a certain extent, outreach must be

⁸⁰ Informant B, official at the European Commission. Call, 09/12/2024.

combined with exploration and co-creation with competent authorities, so that everyone feels confident and aware of their respective roles and responsibilities.

The contact point needs to ensure that sensitive data are handled securely, so that potential applicants feel safe participating in the offer. The contact point must also ensure that applications are processed correctly according to the provisions of the Administrative Procedure Act. Collaboration with competent authorities is key, and it is important to establish forms of information exchange and consultation that are flexible while remaining secure. Information flows and case types need to be updated at the public authority designated as the contact point to ensure that documents are handled correctly throughout the lifecycle of a case.

The opportunities for development over time are likely to be significant and will depend on factors such as resources, demand, perceived benefits and changing requirements. Therefore, work and results must be followed up to enable continuous learning. Structures for systematic learning need to be established, and a design-driven approach should be developed when setting up collaborations with relevant stakeholders, including outside the public administration, preferably based on concrete examples.

4.1.1.2 Need for IT development

The need for IT development at the contact point depends on the ambitions and priorities that are chosen as well as the starting point. In the short term, the role of any contact point should be feasible without investments in systems support, although this comes at the expense of efficiency, oversight and, to some extent, perceived security. Information exchange can be carried out via encrypted emails, with registers maintained manually.

The contact point can implement a digital solution by receiving applications via a dedicated e-service on its website. Even for public authorities currently offering e-services, this would require development of both the service itself and related underlying systems. Applications for regulatory sandboxes under the Act are a new case type and process, with elements that public authorities have not previously seen, and this will necessitate updating the archival records of public authorities.

If the contact point's support is requested in the examination of applications, system support is preferable to purely manual case handling, to ensure documentation that is legally secure and to create the necessary overview and structure. Even for public authorities whose system support for assessing certain types of applications is well developed, adaptation will be required. This is partly because the criteria are new, and assessment, as proposed by Vinnova, will not be followed by a decision by the contact point, but by another authority.

A process with significant manual elements makes it difficult to share and monitor process data. Structured data sharing, in the absence of common case-management

systems among participating authorities, requires long-term investment in closed interfaces and APIs, to which competent authorities are given keys.

To facilitate cooperation and ensure the flow of information between the contact point and competent authorities, a common digital platform would be a valuable asset. The guidelines of public authorities regarding which digital services can be used currently differ, and the technology would therefore require joint procurement of a platform that meets the needs of all involved. Such a procurement would be a significant investment for the public authorities concerned.

4.1.1.3 Need for competence enhancement

To serve as a contact point, access to a wide range of competences must be secured. These include legal, design, business development, communication and technical expertise. The need for in-house expertise will depend on how the inter-agency office is organised and what skills the other public authorities provide.

Knowledge of the permit-granting and supervision system in the environmental field and other relevant areas will be required. Furthermore, staff with insight into the innovation system around net-zero technologies and experience from the ecosystem around SMEs and policy development for innovation will be central. Experience from other national contact point assignments will also be valuable. These competences must be secured, even to a limited extent, before the contact point can address factual issues in communication and case management, make day-to-day legal decisions and create a design-driven learning process.

When designing and establishing detailed working methods and structures, expertise in process management will be crucial, especially given the number of stakeholders involved and the range of issues.

Additional competences may need to be enhanced if the contact point's assignment is expanded, for example with the content of implementing acts. This may include, for example, competences in analysis and evaluation.

Depending on the internal conditions of the public authorities, the competences needed by the contact point can be secured through internal skills development, procurement or recruitment.

4.1.1.4 Resource needs

Given previous international experience with regulatory sandboxes (see section 3.1.1), the complexity of this issue and the necessity of designing and implementing an entirely new organisation, the resource requirements for managing and running the contact point's office are estimated to be at least two annual work units (AWU). In addition, the equivalent of four AWUs will be added to secure all the competences for the office listed in the previous section.

Once the contact point has been appointed, it will initially be required to focus its resources on strengthening common knowledge, participating in the development of the implementing acts and laying the foundations for national and international collaboration.

Significant resources will subsequently be required to package and publicise the offering to relevant target groups in a way that stimulates demand and lowers thresholds. The resource requirement for the actual processing of applications is difficult to predict. This will depend on future implementing acts and the growth of demand.

With a focused launch, the core team can build competence and capacity through effective collaboration and, as needed, bring in more resources. Staffing needs are to be reviewed regularly, and a high degree of continuity is to be sought.

4.1.2 Implications for competent authorities

According to Vinnova's proposal for the initial implementation of the Act, work on the regulatory sandboxes will mainly be focused with the competent authorities. Nevertheless, in dialogue with Vinnova, several public authorities indicate that their workloads are already strained and that this new assignment will take up significant resources for them. Successful implementation will largely depend on the resources allocated to fulfil the role of the contact point and the competent authorities' tasks of assessing, deciding on and setting up the regulatory sandboxes. At the same time, the workload and resource needs of competent authorities are difficult to predict. The competent authority will vary depending on what type of applications are received by the contact point, and demand will, to some extent, be driven by supply and information about the offer.

Vinnova's proposal for implementing and structuring the assignment on regulatory sandboxes involves the inter-agency assessment of cases. As a general rule, a consensus decision is required for this assessment, as each public authority, region or municipality has its own assignment and mandate. A robust yet flexible decision-making process, ideally guided by the Government's fundamental values and the public administration objective of an innovative and collaborative civil service, must be developed.

As in the case of the contact point, the competent authorities must also be strengthened. Some competent authorities highlight the challenge posed by carrying out a risk assessment of new technologies. In consequence, the assignments of public authorities such as the Environmental Protection Agency may need to be expanded so that, for example, the county administrative boards can carry out their assignment as a competent authority in a manner that is legally secure. Competence development, to better assess the innovation potential of a new technology, is another example. These competences are deemed to currently exist to a great extent within public

administration, which is why the establishment of working methods for joint learning and competence transfer between administrative bodies will be important. It is essential that the competent authorities actively contribute their expertise to the contact point, investigations and the drafting of legislative proposals. The applications, the regulatory sandboxes and the resulting proposals may cover several different sectors and areas of law, placing high demands on both the contact point and the proposed Simplification Council's investigative capacity and access to expertise. If competent authorities are not required to actively contribute expertise to the contact point and in the development of proposals, regulatory sandboxes are unlikely to result in concrete changes to regulation.

4.1.3 Implications for investigators of legislative proposals

Both the Simplification Council and the Implementation Council are recently formed councils that are currently in an establishment phase. In its proposal, Vinnova has sought to build on established structures for regulatory simplification and investigation of proposals for regulatory changes. However, there is a risk that additional investigations will be imposed on these new councils. They, like other stakeholders in the proposed regulatory sandbox implementation process, should receive sufficient funding to avoid adversely impacting their already existing assignments. The Simplification Council has stated that both the Government and the business community has high expectations regarding what the Simplification Council will achieve, and, by loading additional tasks on the Simplification Council, prioritisation conflicts may arise with other simplification proposals. If the objective is for the Simplification Council to be able to offer a 'fast track' for proposals that come from regulatory sandboxes, then what this means from that perspective, in relation to the Government's and the business community's expectations of the Council's handling of simplification proposals in general, needs to be clarified. A gradual escalation of the Council's responsibility would be appropriate, in Vinnova's view, as the regulatory sandboxes will not result in large numbers of proposed changes to national regulation for some time.

4.1.4 Impact on applicant companies

In Vinnova's proposal, the company receives the help of established business facilitators in establishing the type of barriers to innovation that the application should address and whether the application complies with the Act's criteria for applicants as well as the formal application requirements. The proposal does not require the contact point to provide any company-specific preparatory guidance. We understand that this process step can take both time and resources for a company, entailing a risk that companies will refrain from applying for participation in the regulatory sandbox. The work of the contact point and the competent authorities therefore needs to be complemented by support from, for example, industry organisations, SME developers and financiers, incubators, innovation offices, science parks or research institutes.

Evaluation of potential further development of contact point tasks can be done after an initial pilot year. Under the current proposal, Vinnova believes that offering support in the preparatory phase would represent a significant expansion of the contact point's assignment.

One further consequence for implementation, although not based on Vinnova's proposal, is that the Commission's implementing acts are not yet in place, which means that a delay in the implementation of the Act is already a fact. Interested applicants must therefore wait for their application to be assessed, which risks delaying the market introduction of innovative net-zero technologies and depriving companies of external funding opportunities.

4.2 Identified risks

Below are examples of risks associated with the implementation of regulatory sandboxes. Some are not directly linked to the design of the Vinnova proposal.

4.2.1 Full application and impact of the Act is delayed or not realised

Vinnova believes that the EU has the right intention with regulatory sandboxes, but that it is insufficient to create favourable conditions for the development of innovative technology. Regulatory relief can be provided for testing activities, but there is a risk that regulations will remain essentially the same or that regulatory changes will take time to implement. As a result, the full application and impact of the Act's provisions on regulatory sandboxes may be delayed or not realised.

4.2.2 New requirements and expectations for public administration

The regulatory sandboxes place new demands on public administration and, with inter-agency assessment, will likely require a high degree of collaboration. There is a risk that this process will be inefficient and lengthy, with lead times, if resources are not secured throughout the process chain to the necessary extent. Several public authorities emphasise the risk that many stakeholders will be involved and that issues risk falling between the cracks even if the public authorities work together. One public authority, on the basis of its assignment, describes the process as vulnerable. If any party de-prioritises implementation, the whole process will falter. Another public authority emphasises the risk of conflicts of interest between public authorities in the assessment.

4.2.3 Resource-intensive instrument

National and international experience shows that active participation in the regulatory sandbox is required from applicants, and, based on Vinnova's analysis together with suggestions and views gathered in stakeholder dialogues, we can assume that the process for preparation of applications will be labour intensive. It is expected that this will develop and improve over time. The Government may need to consider the speed

and efficiency of the process when reviewing the governance of regulatory sandboxes. Administrative simplification and continuous improvement of the application process based on the interests of companies are important parameters for ongoing development.

For public authorities, the issue of resources is crucial for the implementation of the Act (see section 4.1.1.1 above). According to one public authority, there is a risk that this new assignment will mean that the authority's other assignments within the green transition will be neglected.

4.2.4 Distortion of competition

Regulatory sandboxes can provide competitive advantages to participating companies, and there is a risk that competition in the internal market will be impacted. Competition may also be affected by the already restrictive listing of technologies in the Act. While the Act includes the wording “other innovative technologies”, Technology Industries of Sweden is concerned that legal definitions and delimitations in the Act risk disadvantaging innovative “climate companies”. This is because, in the opinion of Technology Industries of Sweden, both legislation and SNI coding are trailing behind. In its report⁸¹, the Competition Authority has described measures to reduce the risk of distortion of competition. For those implementing regulatory sandboxes, it is recommended that the conditions of the regulatory sandbox are made transparent and that its results/data are made available beyond the circle of participants. At the same time, given transparency, there is a risk that companies will refrain from applying to participate due to the risk of having to share sensitive business information. Furthermore, the way in which the regulatory sandbox is constructed should be as open as possible - no unnecessary restrictions should be imposed. The Competition Authority has also found that the longer a regulatory sandbox lasts, the greater the benefit to those involved, particularly in terms of increased learning. Evaluating regulatory sandboxes from a competition perspective is challenging, since the effects on competition are often seen many years later. Upon establishing a regulatory sandbox, issues related to competition should also be assessed and addressed, e.g. how does the regulatory sandbox impact the market? Which stakeholders are favoured/disadvantaged?

Another risk is that certain companies may become recipients of significant state aid. In dialogue with the public authorities, they mention as an example a company potentially receiving aid from the Industrial Leap (chosen because of its focus on pilot plants) and then receiving aid to conduct experiments in a controlled environment.

⁸¹Lars Persson and Pehr-Johan Norbäck, Hur påverkar regulatoriska sandlådor konkurrensen?, Swedish Competition Authority 2023.
https://www.konkurrensverket.se/globalassets/dokument/informationmaterial/rapporter-och-broschyrer/uppdragsforskning/forskrapport_2023-4.pdf (Retrieved 05/12/2025)

Harmonisation in Member States' implementation of the Act will also be important to ensure good competition. To retain the spirit of the act, it cannot be more advantageous for a company to submit an application for participation in a regulatory sandbox to Denmark than to Sweden, for example.

4.2.5 Delayed implementation due to preparation of the implementing acts

As indicated in section 1.21.1 , the European Commission will set out in implementing acts the main principles for the establishment and operation of the regulatory sandboxes, including the responsibilities and roles of the contact point and the competent authorities. Collaboration within the EU in the preparation of the implementing acts risks delaying the implementation of the Act. It is also unclear what scope will be left for Member States to adopt their own solutions to different issues.

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