

Analysis of Legal and Regulatory Barriers to Bioeconomy Development in Catalonia

B>O

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Table of Contents

| | |
|---|----|
| Executive Summary..... | 4 |
| Introduction..... | 5 |
| Legal analysis of policies, strategies and legislation in place at EU, national and regional level relevant to bioeconomy | 7 |
| EU legal framework..... | 7 |
| Spanish legal framework | 7 |
| Catalan legal framework..... | 8 |
| Classification and description of the legal and regulatory barriers to bioeconomy development in Catalonia | 11 |
| 1. Complex and long administrative procedures, lack of coordination between Administrations | 12 |
| 2. Lack of clarity about the applicable regulatory framework | 13 |
| 3. The land use regime does not allow the implementation of bioeconomy projects | 14 |
| 4. Insufficient maximum distance between the generation and consumption of renewable energy | 14 |
| 5. Lack of homogenisation in the connection process to the electricity distribution grid | 15 |
| 6. Lack or limited access to data for the development of bioeconomy projects | 15 |
| Legal opportunities and practical solutions for the development of bioeconomy-based projects in Catalonia | 17 |
| Declare bioeconomy projects as Strategic Business Projects | 17 |
| Establish regulatory sandboxes..... | 18 |
| Establish one-stop shops to provide advisory and guidance services..... | 21 |

Executive Summary

The main purpose of this report is to identify and analyse the legal and regulatory barriers mapped throughout the first period of Bioboost, as well as to provide recommendations to facilitate the development and growth of bioeconomy projects in Catalonia. The document is divided into three parts.

Part I presents a brief **legal analysis of the most relevant policies, strategies and legislation** in place at EU, national, regional and local level.

Part II describes the main **legal and regulatory barriers to bioeconomy development** in Catalonia identified so far during the implementation of Bioboost, without prejudice to any other barrier that may be detected in the future.

Part III identifies legal opportunities and proposes **recommendations and solutions** to overcome the identified barriers, without prejudice to any other legal options or recommendations that may be suggested if considered.

This report aims to serve as an example of the legal and regulatory barriers that a bioeconomy project may face during its setting up in Catalonia, without prejudice to other financial, technical or governance barriers that may exist and that are not considered in this report.

Introduction

Catalonia has an enormous potential to become a showcase for innovation and the deployment of the bioeconomy in Europe. The transition to a bioeconomy presents a unique opportunity for this region to move towards a more sustainable, resource-efficient and low-carbon future.

The objective of Bioboost is to catalyse 30M€ of additional investment in small and medium-sized bioeconomy projects in Catalonia by the end of 2025, trying to accelerate the growth of the bioeconomy in the region, by delivering Project Development Assistance (PDA) services. However, the development of bioeconomy projects faces a wide range of legal and regulatory barriers that need to be addressed.

This report aims to offer a first overview of these legal bottlenecks, as well as possible solutions and recommendations to overcome them in the current legal and administrative context of Catalonia. By understanding the existing legal barriers and possible practical and legal solutions to implement, it should be more feasible to address the challenges faced by bioeconomy projects and contribute to the development of the bioeconomy in Catalonia and Europe.

Legal analysis of policies, strategies and legislation in place at EU, national and regional level relevant to bioeconomy

EU legal framework

The birth of bioeconomy in the European Union has largely been the result of chance and necessity. The transition towards a new societal and economic model based on the sustainable and circular use of resources has become one of the main objectives of the European Union, being an important step towards a sustainable society and an environmental awareness.

Bioeconomy covers all sectors and systems that rely on biological resources (animals, plants, microorganisms and derived biomass, including organic waste), and their functions and principles. It includes and interlinks: land and marine ecosystems and the services they provide; all primary production, sectors that use and produce biological resources (agriculture, forestry, fisheries and aquaculture); and all economic and industrial sectors that use biological resources and processes to produce food, feed, bio-based products, energy and services.¹

In **2012**, The European Commission adopted a **Bioeconomy Strategy**² with five objectives: i) ensure food and nutrition security, ii) manage natural resources sustainably, iii) reduce dependence on non-renewable, unsustainable resources, (iv) mitigate and adapt to climate change, and (v) strengthen European competitiveness and create jobs. This Strategy is implemented by means of **Action Plan 2018**³ to (i) strengthen and scale in bio-based sectors, unlock investments and markets; (ii) deploy local bioeconomies rapidly across the whole Europe, and (iii) understand the ecological boundaries of bioeconomy.

In line with the Bioeconomy Strategy, in **2019** the European Commission adopted the **European Green Deal**⁴, a set of proposals to preserve, maintain and improve the EU's natural capital and protect the citizens' health and well-being from environment-related risks and impacts. The **European Climate Law**⁵ establishes a binding objective of climate neutrality by 2050 and the European Green Deal sets the blueprint for this transformational change.

In this context, the European Union has promoted many cross-cutting policies relevant for the bioeconomy to build a new model of sustainable society. However, it is important to promote inter-ministry cooperation, policy coherence and vertical coordination at local, national and EU level.

Spanish legal framework

In 2015 the **Spanish Bioeconomy Strategy: Horizon 2030**⁶ was adopted. This strategy aims to promote economic activity and improve the competitiveness and sustainability of productive sectors linked to the use of biologically based resources, promoting the generation of knowledge and its use for the development and application of derived technologies, through collaboration between the science and technology system and Spanish public and private entities. The integrated sectors into the Strategy are

¹ <https://research-and-innovation.ec.europa.eu/>.

² [COM/2012/060/final](#), Innovating for Sustainable Growth: A Bioeconomy for Europe. This strategy was updated in 2018, [COM/2018/673 final](#). A sustainable Bioeconomy for Europe: Strengthening the connection between economy, society and the environment. The EU Bioeconomy Strategy Progress Report, [COM/2022/283 final](#), was published in June 2022.

³ European Commission, Directorate-General for Research and Innovation, Bioeconomy – The European way to use our natural resources – Action plan 2018, Publications Office, 2018, <https://data.europa.eu/doi/10.2777/79401>.

⁴ COM/2019/640 final, [The European Green Deal](#).

⁵ Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('[European Climate Law](#)').

⁶ [Spanish Bioeconomy Strategy: Horizon 2030](#).

the agri-food sector, the forestry sector, industrial bioproducts, bioenergy obtained from biomass and services associated with rural environments.

In line with the 2030 Agenda for Sustainable Development, the European Green Deal and other relevant policies adopted at EU level, in 2020 the **Spanish Circular Economy Strategy**⁷ was adopted. This Strategy establishes the foundations to promote a new production and consumption model in which the value of products, materials and resources are maintained within the economy for as long as possible. It also contributes to Spain's efforts to achieve a sustainable, decarbonized economy that uses resources efficiently and is competitive. This Strategy is materialised in successive three-year action plans. The first **Action Plan (2021-2023)**⁸ is articulated around the five axes and lines of action established by the Strategy, collecting the specific measures that will allow its development. In terms of operational functioning, the Strategy establishes the creation of a **Circular Economy Council**⁹ to collaborate in the implementation, monitoring, review and preparation of annual proposals.

In 2022 the **Law 7/2022, of 8 April, on waste and contaminated soils for a circular economy**¹⁰ was adopted as a transposition of Directive (UE) 2018/851 on waste and Directive (UE) 2019/904 on the reduction of the impact of certain plastic products on the environment (the so-called Directive on single-use plastics). Its purpose is to prevent and reduce the generation of waste and the adverse impacts of its generation and management, the reduction of the overall impact of the use of resources and the improvement of the efficiency of said use with the aim of protecting the environment and human health and moving towards a circular and low-carbon economy with innovative and sustainable business models, products and materials to guarantee the efficient functioning of Spain's internal market and long-term competitiveness.

Catalan legal framework

In 2021, the Catalan Government (Generalitat de Catalunya) approved the **Bioeconomy Strategy of Catalonia 2030 (EBC2030)**,¹¹ which aims to promote the growth and sustainable development of the Catalan economy, by fostering the production of biological resources and local and renewable processes. The 7 main strategic objectives that make up the backbone of EBC2030 are the following:

- a) Improve the use of Catalonia's biomass through characterization, quantification, optimisation of management and distribution.
- b) Develop a business network based on the circular bioeconomy throughout the territory, with particular attention to the first sector.
- c) Promote the use and consumption of bioproducts, bioenergy and biomaterials in the market.
- d) Promote resilient agroforestry landscapes and the sustainable provision of ecosystem services in the context of the circular Catalan bioeconomy.
- e) Positioning knowledge as a driver of the circular bioeconomy.
- f) Strengthen the role of the Administration and adapt the regulatory and legal framework in a way that favours the circular bioeconomy in Catalonia.
- g) Prepare Catalan society for the change towards a circular bioeconomy.

⁷ [Spanish Circular Economy Strategy.](#)

⁸ [Spanish Circular Economy Strategy Action Plan 2021-2023.](#)

⁹ [Circular Economy Council.](#)

¹⁰ [Law 7/2022, of 8 April, on waste and contaminated soils for a circular economy.](#)

¹¹ [Bioeconomy Strategy of Catalonia 2021-2030.](#) Its objectives and minimum content were approved by Government Agreement GOV/23/2020, of 11 February.

In addition, it is necessary to highlight other relevant actions that the Generalitat de Catalunya has launched in the interest of the bioeconomy, such as the:

- **Promotion Strategy for the green and the circular economy**,¹² which aims to promote sustainability as a strategic area to achieve economic recovery, increase competitiveness, create jobs and reduce environmental risks.
- **Catalan eco-design strategy for a circular and eco-innovative economy**,¹³ with the main objective of creating a stable framework to promote the design of products and services that integrate environmental criteria and thus promote more sustainable consumption and production models in Catalonia.
- **General Program for the prevention and management of waste and resources in Catalonia 2013-2020 (PRECAT20)**¹⁴ and the **Sectorial Territorial Plan for Municipal waste Management Infrastructures in Catalonia 2020 (PINFRECAT20)**.¹⁵ Two strategic instruments that aim to rigorously address the challenges in the waste management.
- **Green public procurement action plan for Catalonia 2022-2025**,¹⁶ among the objectives of which is to systematise the environmentalisation of public procurement, through the definition of a common methodology.
- **Next Generation Catalonia**,¹⁷ a report which identifies the lines of action and emblematic projects that must contribute to accelerating the ecological transition and digital transformation, with the aim of making the productive network more resilient and sustainable.
- **FEDER Operational Program of Catalonia 2021-2027**,¹⁸ which promotes investments in projects that foster competitiveness and economic development, as well as resilience in the face of climate change and the quality of life for all citizens.

In short, all these actions and instruments are the proof that the Catalan Government is working in line with European policies, making a clear and determined commitment to fight climate change and lead the green transformation necessary to make Catalonia sustainable from an economic, social and environmental point of view.

¹² [Strategy for the promotion of the green economy and circular economy \(2015\)](#), approved by Government Agreement [GOV/73/2015](#), of 26 May.

¹³ [Catalan ecodesign strategy for a circular and eco-innovative economy](#), approved by Government Agreement [GOV/80/2015](#), of 2 June.

¹⁴ [PRECAT20](#), approved by [Royal Decree 210/2018, of 6 April](#).

¹⁵ [PINFRECAT20](#), approved by [Royal Decree 209/2018, of 6 April](#).

¹⁶ [Green public procurement action plan for Catalonia 2022-2025](#), Government Agreement [GOV/55/2020](#), of 31 March approved the objectives and minimum content of the Catalan Public Procurement Strategy.

¹⁷ [Next Generation Catalonia](#).

¹⁸ [ERDF Operational Program for Catalonia 2021-2027](#).

Classification and description of the legal and regulatory barriers to bioeconomy development in Catalonia

The transition towards a bioeconomy in Catalonia is a reality and constitutes the Government's commitment to protect the planet and develop a more sustainable economy and a society efficient in the use of resources, in accordance with the objectives set by the EU. But there are still legal barriers that create a multifaceted challenge for bioeconomy business development.

The most common barriers that bioeconomy projects face when being implemented can be divided into (i) urban planning, (ii) administrative, and (iii) sectoral barriers depending on the project and the regulatory sectors of application (waste, emissions, renewable energy, water, etc.). In this section, based on the legal analysis of policies and legislation relevant to bioeconomy and the implementation of the Bioboost project, the legal and regulatory barriers to the development of bioeconomy in Catalonia will be identified, classified and described. Recommendations and solutions will be made to facilitate the development and financing of bioeconomy projects in Catalonia.

| Barrier | Type | Description | Recommendations |
|--|-----------------------------------|--|--|
| 1. Complex and long administrative procedures and lack of coordination between Administrations in obtaining activity permits | Administrative/ Regulatory | The administrative procedure for obtaining activity permits is very complex and long. There is a lack of coordination between authorities at different levels (national, regional and local). | Unify the procedure to avoid duplication in obtaining the activity permits. Approve specific regulations to accelerate the deployment of bioeconomy projects. |
| 2. Lack of clarity about the applicable regulatory framework | Administrative/ Regulatory | The regulatory framework is outdated, complex and fragmented. | Modify and update legislation in accordance with EU, national and regional circular economy objectives and with the aim of promoting efficient use of bioresources. Establish a One-Stop Shop to provide advisory and guidance services on bioeconomy projects. |
| 3. The land use regime does not allow the implementation of bioeconomy projects | Administrative/ Urban planning | Sometimes, the urban planning of some municipalities: (i) does not foresee the activity among the land uses, (ii) the activity is incompatible with the foreseen land uses in the urban planning, or (iii) although the activity is foreseen among the land uses of urban planning, the procedure to follow to develop the activity is too long, due to the need to develop a special plan or other urban planning instrument. | Adopt urban master plans or sectoral territorial plans that establish guidelines that require the adaptation of municipal urban planning to make bioeconomy activities compatible with the land regime. |

| | | | | |
|----|--|----------------|---|---|
| 4. | Insufficient maximum distance between the generation and consumption of renewable energy | Regulatory | The maximum distance of 2,000 meters established between the generation and consumption of renewable energy is too restrictive, especially for rural areas. | Increase the maximum distance up to 20 km. |
| 5. | Lack of homogenisation in the connection process to the electricity distribution grid. | Regulatory | Energy distribution companies have their own forms and procedures to request access and connection to the electricity grid and there is no single system that indicates what capacity is released in the Spanish distribution system. | Create a single network access request model and a capacity reporting model for distributors. |
| 6. | Lack or limited access to data for the development of bioeconomy projects | Administrative | Relevant data to bioeconomy projects does not follow FAIR principles. | Create an accessible bioeconomy database. |

1. Complex and long administrative procedures, lack of coordination between Administrations

The **complex and long administrative procedures**, as well as the **lack of coordination between the Administrations at different levels** (local, regional and national) and the delay in the resolution of the permits that allow the activity to be carried out have been identified as a major obstacle and bottleneck for many bioeconomy-oriented companies.

These barriers can generate significant projects costs. For example, if a company applies for a subsidy to carry out its activity, among the requirements of the grant might figure a maximum time for the effective establishment of the activity. The delay in obtaining all necessary permits, as well as the complexity and long duration of procedures, could signify a major problem for the actual implementation of the project. One of the Bioboosters of Bioboost was in this situation and it had to request an extension –which was granted– of the period for carrying out the investments and executing the actions subsidised.

In the field of renewable energy, due to the general geopolitical context and the pressing need to accelerate energy efficiency and the deployment of renewable energy, on 22 December 2022, the Council of the EU adopted Regulation (EU) 2022/2577¹⁹ laying down a framework to accelerate the deployment of renewable energy and speed up the permitting process for renewable energy projects across the EU. With this proposal, the administrative permitting processes applicable to renewable energy projects will be further simplified and shortened, in a coordinated and harmonised manner across the EU.

In Catalonia, on 26 October 2021, Decree Law 24/2021²⁰ was approved, which accelerates the deployment of distributed and shared renewable energies. Specifically, it introduces measures in the applicable legislation to: (i) improve the social acceptance of renewable energy projects, make agricultural activity compatible with the production of renewable energy and ensure the conservation of biodiversity, territorial planning and the sustainable development of the rural environment; (ii)

¹⁹ [Council Regulation \(EU\) 2022/2577 of 22 December 2022 laying down a framework to accelerate the deployment of renewable energy.](#)

²⁰ [Decree Law 24/2021, of 26 October, accelerating the deployment of distributed and participating renewable energies.](#)

foresee the objectives in terms of renewable, distributed and shared generation in the horizon of the year 2030, and (iii) adopt administrative simplification measures in the matter of self-consumption of electrical energy.

These examples offered by recent legislation could be explored further to approve **specific regulations to accelerate the deployment of bioeconomy** projects in Catalonia.

It is also proposed as a solution to **unify the procedure for obtaining activity permits** to avoid duplication of procedures. Because currently, depending on the type of bioeconomy activity to be carried out, the procedures for obtaining the necessary permits are not unified under the same processing body. In many cases, except for those activities with a greater environmental impact, it implies that different permits must be processed, and requirements must be met in front of different Administrations and bodies. This often implies a duplication of procedures and an unnecessary expenditure of resources and time, in addition to confusion and uncertainty regarding the correct processing of permits, and lastly, whether the activity complies with all the requirements of all applicable regulations.

For example, both the urban planning and environmental legislation applicable to certain activities contain procedural requirements such as the request and issuance of reports from certain administrative bodies, as well as public information procedures. It often happens that there is an overlap between these procedures, and requests for reports are repeated to the same bodies, which end up issuing reports with the same content; or there are overlaps in public information procedures, causing an unnecessary delay in obtaining the necessary activity permits.

2. Lack of clarity about the applicable regulatory framework

Legislation applicable to bioeconomy projects can often create barriers because it is outdated or not designed for a circular (bio)economy model, because it **lacks coherence, is vague, incomplete and contains inconsistencies** that give rise to different interpretations, and above all because it is extremely technical and complex, is constantly evolving and is fragmented into multiple pieces of legislation with different scopes of application.

For example, although the installation of photovoltaic panels no longer requires a license, and a responsible declaration or responsible communication is enough, many municipalities continue to subject this installation to licensing procedures, in opposition to Law 17/2009 on free access to service activities and their exercise.²¹

In short, the legislation is complex and extremely fragmented, as different regions have their own specific laws and regulations. This situation can create significant barriers for bioeconomy projects, as compliance with the regulations can be difficult, lengthy and costly, and prevent bioeconomy projects from expanding and reaching their full potential.

As recommendations, it is proposed, in the first place, to **review the obsolete legislation** and re-align its objectives and instruments with the legislation and policies adopted at the EU, national or regional level.

In the second place, it is proposed to **establish a One-Stop Shop to provide comprehensive advisory and guidance services to bioeconomy projects** that experience difficulties in identifying and interpreting the legislation to comply and may need guidance on the administrative and regulatory procedures to follow to successfully implement the project.

²¹ [Law 17/2009, of 23 November, on free access to service activities and their exercise.](#)

3. The land use regime does not allow the implementation of bioeconomy projects

In many cases, the choice of land on which to implement the bioeconomy projects can be one of the main barriers. When developing a bioeconomy project, it is possible to encounter **urban planning barriers related to the classification** (urban, developable and non-developable) **and qualification** (parameters applicable to the land, including the determination of land uses) **of the land**, or other conditions for the development of public spaces and the construction of land.

On the one hand, the environmental authorisation or license to develop the activity is subject to urban planning compatibility and other reports from different departments of the Administration, which causes delays in obtaining it.

On the other hand, the urban planning of some municipalities sometimes (i) does not foresee the activity among the land uses, (ii) the activity is incompatible with the foreseen land uses in the urban planning, or (iii) although the activity is foreseen among the land uses of urban planning, the procedure to follow to develop the activity is too long, due to the need to develop a special plan or other urban planning instrument.²²

The development of a Special Plan needs the approval of two Administrations and, according to Legislative Decree 1/2010 approving the consolidated text of the Catalan Urban Planning Law,²³ the initial approval of the urban planning instruments implies suspension of licensing procedures until the corresponding Plan is approved. Consequently, this situation represents a legal barrier to the development of many bioeconomy projects.

The proposed solution is to **adopt urban master plans or sectoral territorial plans** that establish guidelines that require the adaptation of municipal urban planning to **make the land regime compatible with bioeconomy activities** (classification and qualification) that, with a strict interpretation of the current regulations, would not be permitted.

4. Insufficient maximum distance between the generation and consumption of renewable energy

With Royal Decree-Law 18/2022, of 18 April, the limit of 500 meters between the generation facility and the consumption point was doubled to 1,000 meters, which was established by Royal Decree 244/2019, of 5 April.

Currently, Royal Decree-Law 20/2022²⁴ establishes a **maximum distance of 2,000 meters** between the photovoltaic installation and the consumer to consider the photovoltaic installation as self-consumption. Its preamble establishes that, although it is considered important to be prudent in increasing this distance to avoid excessive losses, to continue promoting self-consumption, self-consumption through the network is boosted by increasing the distance up to 2,000 meters in the case of energy generated by photovoltaic installations.

Although this measure empowers consumers a little more and facilitates the path towards a clean, fair, and decentralised energy transition, it would be necessary to **extend the limit for shared self-consumption in rural areas to 20 kilometres**, as neighbouring countries have done. And to include too not only energy generated by photovoltaic plants, but also the energy produced by any renewable source (e.g. biogas plants). The future regulation on **renewable energy communities**, pending approval in Spain, can help remove obstacles related to distances in the field of shared self-consumption.

²² One of our Bioboosters needed to develop a Special Plan in the area prior to the setting up of the bioeconomy project.

²³ [Legislative Decree 1/2010, of 3 August, which approves the consolidated text of the Urban Planning Law.](#)

²⁴ [Royal Decree-Law 20/2022, of 27 December, on measures to respond to the economic and social consequences of the War in Ukraine and to support the reconstruction of the island of La Palma and other situations of vulnerability.](#)

5. Lack of homogenisation in the connection process to the electricity distribution grid

In the Catalan territory there are many energy distribution companies that have their own forms and procedures to request access and connection to the electrical grid. Furthermore, there is no single system that indicates what capacity is released in the Spanish distribution system because each of the distributors has its own system.

This implies that, when deciding where to implement a bioeconomy project, it becomes very difficult to know where there is an access point and connection with capacity because distributors do not publish this information in a homogeneous way.

The **lack of homogenisation of the connection processes** to the electricity distribution grid and capacity reports make the procedures for accessing and obtaining connection permits difficult. Likewise, the difficulty in obtaining access to the grid due to lack of capacity prevents supplying the grid with renewable electricity and replacing fossil energy.

The recommendation is to create a **single application form and a capacity reporting model**.

6. Lack or limited access to data for the development of bioeconomy projects

When designing a bioeconomy project and exploring its full potential and territorial and systemic impact, it is crucial to have a complete vision and understanding of all the variables that affect its design and success.

In this sense, the **availability of data** regarding, for example, raw materials by industrial/agro-industrial activity, waste by activity, byproducts by origin activity, authorised treatment codes of each waste manager, basic data on process and combustion emissions focus, emission rates, types of controlled pollutants, emission limits, smoke temperature, waste water production m³/year by industrial or agro-industrial activity, electricity consumption kWh/year by industrial/agro-industrial activity, livestock droppings data, consumption of gas, petrol, diesel, etc. determines a realistic approximation and projection of the project costs and its viability. It is important to have individual data by activity to be able to detect the viability of bioeconomy opportunities and identify where and with whom.

The fact is that most of the necessary **data may already be in the hands of Administrations** in databases or other repositories and compilations and can be very useful for the development of the project and its business model. But sometimes **it is difficult to access** these data because they are dispersed in different public departments and are not interoperable, or access is limited to the Administration, or the data are not as complete as possible. They are sometimes published in aggregate form to preserve confidentiality, but estimates could be published disaggregated and without conflicts.

Given that the digital revolution allows the capture and analysis of massive data of all types in an automated way using sensors, communication tools, artificial intelligence, etc., it would be advisable to **create a database that integrates all data relevant to the bioeconomy**. A database with data that follows the FAIR principles (findable, accessible, interoperable and reusable), in a format that provides added value to users, and, ultimately, that contributes to implementing broader, more efficient, sustainable, and transparent bioeconomy models.

Bioboost has precisely met with different departments of the Catalan public Administration to report on this barrier, and we are working together on solutions to overcome it. The objective of the public Administration is to create a database on bioeconomy topics that companies can use and exploit to create value-added applications. Meanwhile, in the absence of discrete real data (due to lack of access to data by companies), what Bioboost is doing is estimating data from statistical correlations of grouped data (which are usually accessible).

Legal opportunities and practical solutions for the development of bioeconomy-based projects in Catalonia

The transition towards the bioeconomy is a priority through Europe. However, it is a reality that in the current legal framework there are still many legal barriers to the development of bioeconomy projects. To unlock the potential of these projects and encourage their development, this report provides possible solutions and recommendations in the context of Catalonia to try to address and overcome the administrative and regulatory barriers identified.

Declare bioeconomy projects as Strategic Business Projects

Law 18/2020 on the facilitation of economic activity²⁵ aims to establish a regulatory framework to create a more favourable framework for economic activity and facilitate competition and investment. To this end, Law 18/2020, among other mechanisms, promotes the so-called **strategic business projects** for economic growth and the guarantee of an orderly and balanced transition towards new business models, with more added value and a greater technological presence, to maintain the productive network and employment.

Article 24 of Law 18/2020 states that the Government must promote the necessary measures to designate business projects which, due to their characteristics, are strategic for the economic development in Catalonia. The following types of projects can be considered strategic:

- a) Those that provide added value in areas such as technological development and innovation, territorial development and structuring, contribution to reindustrialisation, employment generation, recovery and promotion of traditional sectors, environmental protection, promotion of diversity, social inclusion, equality, non-discrimination and reconciliation in the workplace or co-responsibility, among other economic, social and environmental criteria.
- b) Those that aim to merge small companies or incorporating emerging companies to gain dimension and increase the number of medium-sized and large companies.
- c) The investment plans in the supply distribution network necessary for the development of the economic activity carried out in Catalonia, if there is an investment plan of at least three years.

The Government must approve every four years at most, at the proposal of the Commission for the Facilitation of Economic Activity, the criteria for classifying a business project as strategic and the procedure by which a project is designated as strategic must be established by regulation. Once a business project has been designated as strategic, it is considered that there are reasons of public interest to apply the urgent procedure established by the regulations on administrative procedure, which allows deadlines to be reduced and extensions cannot be requested. Strategic business projects implicitly carry the declaration of public utility for the forced expropriation of land.

In September 2022 the Generalitat de Catalunya adopted an agreement on the criteria for classifying a business project as strategic.²⁶ According to the agreement, to be considered as strategic, projects must meet all the following criteria:

- a) Involve a minimum investment in productive fixed assets of € 20,000,000.00.
- b) Generates or maintains a minimum of 75 direct workplaces for a minimum period of 3 years, counting from the moment in which the activity that is the object of the strategic project begins.

²⁵ [Law 18/2020, of 28 December, on the facilitation of economic activity](#). It is developed by [Decree 131/2022, of 5 July, on the Regulation of the Law on Facilitation of Economic Activity](#).

²⁶ Government Agreement [GOV/177/2022](#), of 6 September.

- c) Once the investment project is materialised, the volume of purchases, services and supplies of the company from suppliers with production headquarters in Catalonia (excluding electricity, water, gas and telecommunications services) exceeds 40%, providing that this percentage is possible in Catalonia.
- d) Incorporates an action in the field of renewable energies for the self-consumption of the same productive activity, or an action in the field of the circular economy and environmental sustainability. This action must be qualified in relation to its impact on the production process.

Given the economic, social and territorial characteristics, criteria a) and b) are reduced to € 10,000,000.00 and 35 workplaces in the territorial areas of Terres de l'Ebre, Lleida, Alt Pirineu and Aran, and Penedès.

Based on these criteria and to promote bioeconomy, bioeconomy projects should be encouraged to be included in this category and be declared strategic business projects. These requirements should also be made **more flexible** to facilitate the inclusion of more projects in this category.

Establish regulatory sandboxes

Regulatory sandboxes are a relatively new legal instrument. They are part of efforts by regulators across the globe to tackle regulatory challenges generated by technological transformation, and the emergence of new products, services and business models.²⁷ They facilitate dialogue between regulators and innovators, increase innovators' knowledge of and compliance with regulatory frameworks, can accelerate the introduction of new products and services into the market and foster regulatory learning.

Although no EU commonly agreed legal definition exists, regulatory sandboxes can be broadly described as schemes that enable firms to test innovations in a controlled real-world environment, under a specific plan developed and monitored by a competent authority. They are usually organised on a case-by-case basis, include a temporary loosening or derogation of applicable rules, and feature safeguards to preserve overarching regulatory objectives, such as safety and consumer protection.²⁸ According to the Council of the European Union, experimentation clauses are often the legal basis for regulatory sandboxes and are already used in EU legislation and in Member States' legal frameworks.²⁹

The **European Commission Staff Working Document on regulatory learning in the UE**, which provides guidance on regulatory sandboxes,³⁰ states that they should:

- involve a structured approach to development and testing of innovative technologies, products, services or business models in view of possible further deployment and market release;
- be used in a controlled environment, which is often in real world;

²⁷ Other experimentation tools are testbeds and living labs. Depending on specific needs and goals, one can decide which approach (or combination of approaches) can help better policymakers and innovators.

²⁸ European Commission, '[Better regulation toolbox](#)' 2023, Tool #69.

²⁹ [Conclusions of the Council of the European Union of 16 November 2020](#) list key regulatory sandbox elements. They also describe 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 encourages the Commission to continue considering the use of experimentation clauses on a case-by-case basis when drafting and reviewing legislation, as well as to evaluate the use of experimentation clauses in ex-post evaluations and fitness checks based on an exchange of information with Member States.

³⁰ [European Commission, SWD\(2023\) 277/2 final, 29.8.23, Commission Staff Working Document, 'Regulatory learning in the EU. Guidance in regulatory sandboxes, testbeds, and living labs in the EU, with a focus section on energy'](#).

- fall under a specific plan developed with, and monitored by, a competent authority or agreed among several competent authorities;
- have safeguards to preserve overarching regulatory objectives (safety and consumer protection); and
- be aimed at regulatory learning.

At EU level, examples of existing and planned frameworks for the setting up and implementation of regulatory sandboxes in EU legislation relate to digitalisation in a broad sense, financial services, energy including net-zero technologies to achieve the EU's climate goals, health and food safety, law enforcement and transport. In particular, the **Net Zero Industry Act**³¹ introduces regulatory sandboxes to test innovative net-zero technologies in a controlled environment for a limited period. The Act provides for Member States to introduce such exceptional and temporary regulatory regimes that allow the development, testing and validation of innovative, net-zero technologies before they are placed on the market or put into service. These sandboxes can be established by the Member States at the request of any company developing innovative net-zero technologies, meeting a set of eligibility and selection criteria. When eligible, small- and medium-sized enterprises should have priority access to these sandboxes.

In several sectors, EU legislation already includes experimentation clauses that allow competent authorities to follow a new interpretation of existing rules or to exercise their margin of appreciation to implement the rules in a proportionate manner in specific cases.³² For example, the Commission **proposal to amend the Industrial Emissions Directive**³³ puts forward several measures to facilitate testing and deployment of emerging techniques with improved environmental performance: enabling the operator to derogate from BAT associated emission levels for 24 months for the purpose of testing a new technique with improved environmental performance; or allowing a longer derogation period if the investment is intended to achieve more stringent emission levels associated with the emerging technique.

At the Spanish national level, there are already some regulations that foresee the regulatory sandboxes, and it could be useful to **extend this instrument to other areas, covering the bioeconomy projects**. For example, in the energy sector, the Spanish Recovery, Transformation and Resilience Plan,³⁴ an instrument for the development of the Next Generation EU recovery funds, provides for the introduction of regulatory sandboxes or regulatory test banks (see C8.R4). In this sense, Royal Decree-law 23/2020³⁵ modified the Electricity Sector Law to enable the government to establish regulatory test banks in which pilot projects are developed to facilitate research and innovation in the field of the electricity sector, and Royal Decree 568/2022³⁶ developed the general framework of the regulatory test bank. Another example is found in the field of artificial intelligence, where Royal Decree 817/2023³⁷ establishes a controlled testing environment to verify compliance with certain requirements by some artificial intelligence systems that may pose risks to people's safety, health and

³¹ [Proposal for a regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem \(Net Zero Industry Act\)](#), COM(2023) 161 final, 16.3.23. See Article 27 (Measures for small and medium enterprises) and Article 28 (Measures for small and medium enterprises). The modalities and the conditions for the establishment and operation of the net-zero regulatory sandboxes will be clarified in secondary legislation, namely, implementing acts, stemming from the proposed Regulation.

³² European Commission. SWD(2023) 277/2 final, 29.8.23.

³³ [COM/2022/156 final/3](#).

³⁴ [Resolution of 29 April 2021, publishing the Agreement of the Council of Ministers of 27 April 2021, approving the Recovery, Transformation and Resilience Plan](#), and its [addendum](#). Visit <https://planderecuperacion.gob.es/> for more information.

³⁵ [Royal Decree-Law 23/2020, of 23 June, which approves measures in energy and other areas for economic reactivation](#), see Article 4.

³⁶ [Royal Decree 568/2022, of 11 July, which establishes the general framework of the regulatory test bed for the promotion of research and innovation in the electricity sector](#).

³⁷ [Royal Decree 817/2023, of 8 November, which establishes a controlled testing environment for testing compliance with the proposed Regulation of the European Parliament and of the Council establishing harmonised standards on artificial intelligence](#).

fundamental rights, in accordance with the proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence.³⁸

Likewise, the Madrid City Council has recently approved an initial draft of the **Ordinance Mobility Sandbox**. This regulation will establish a closed controlled area to test innovative mobility projects before their commercialisation. And in December 2022 the Valladolid City Council approved the **Ordinance 'Valladolid Escenario Demostrador'**³⁹ to regulate the use of municipal assets and services of the City Council as a space to test business innovation projects.

In summary, **promoting the establishment of regulatory sandboxes could be a solution to overcome some of the administrative and regulatory barriers** identified for the bioeconomy projects.

When developing a regulatory sandbox, the following components should be considered:⁴⁰

- Design of the scheme: the design phase is of crucial importance because it determines the project's functioning and successful implementation. This design phase therefore merits **strategic thinking** in addition to all country-specific jurisdictional, institutional and market characteristics that should be considered.
- Application – selection – granting: regulatory sandbox **participation is decided on a case-by-case basis**, so the rules governing the application procedure, the eligibility and selection criteria, the possible derogations to be granted and the question of who grants these derogations (and how) need to be clear. The detailed procedure can be enshrined in legislation or, if the regulatory authority is the competent authority, can sometimes be based on the regulatory authority's own decision.

The **application procedure** can be open continuously within the boundaries of a large time window or operate with narrower windows or deadlines for the presentation of proposals. **Participation** might be open to all market participants or to a predefined group of market players. The **scope of derogation** can be narrowly set by the legislator or by the competent authority applying the scheme or left open.

The **eligibility criteria** are a key component of the sandbox scheme. The most common criteria are:

- the innovative character of the project;
- identification by the applicant of a regulatory barrier;
- contribution to policy objectives and consumer/societal benefits;
- safeguards for consumers/the wider environment;
- proof of maturity of the project;
- time limit;
- publication requirements;
- scalability; and further development potential.

The competent authority, when authorising participation in the regulatory sandbox scheme, indicates the **specific derogations granted**, their **time limit** and the reporting obligations of the participant.

³⁸ [Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence](#), COM(2021)206 final, 21.4.2021.

³⁹ [Ordinance 'Valladolid Escenario Demostrador'](#).

⁴⁰ European Commission. SWD(2023) 277/2 final, 29.8.23. This document also offers relevant information on lessons learnt and best practices in the implementation of sandboxes in the energy sector, which will be considered when proposing a regulatory sandbox to the regulatory agency or competent administration in the framework of Bioboost.

- Project execution with reporting and monitoring and final evaluation: during the execution phase, the participant has **reporting obligations**, while the competent authority has monitoring and **supervising powers**. The aim of reporting and monitoring is to ensure that the testing is carried out in compliance with the framework and conditions of the experiment. Monitoring also helps ensure that safeguard measures are respected and that there is no consumer harm or other type of harm that would require the project to be terminated or suspended.

In the **final evaluation**, the project is usually assessed against the predefined indicators. Moreover, and as a key objective of the whole scheme from the regulatory learning perspective, competent authorities **assess whether it is necessary and appropriate to introduce new or updated elements into the regulatory framework** based on the lessons learnt.

With this overview on what a regulatory sandbox would have to consider and all the issues at stake in its development and implementation, we recommend starting a dialogue with the competent authorities in Catalonia to **consider the establishment of regulatory sandboxes in the following sectors**:

- Activity permits: the type of activity permits required to carry out an activity depends on its environmental impact. Law 20/2009 on prevention and environmental control of activities⁴¹ contains annexes that list the activities and indicate to which environmental regime they are subject, from most to least demanding: environmental authorisation, environmental license or communication. We consider it necessary to carry out an analysis of the activities related to bioeconomy projects that could potentially require a simpler activity permit, such as a communication. This 'relaxation or reduction' in the legal requirements for the exercise of the activity could be compensated by the performance of more self-controls or controls by the competent Administration. To simplify and streamline the procedures to follow in carrying out an activity, these and other aspects could be tested in a regulatory sandbox established in the field of legislation regarding the control of activities.
- Waste: some of the resources used in bioeconomy projects are considered waste by the applicable legislation (Law 7/2022), thus imposing numerous legal and administrative requirements and specific procedures to follow regarding their management, use, transportation, etc. This represents a real barrier for the development of these projects. Consideration could be given to derogating certain provisions of applicable law to permit these wastes not to be considered as wastes (nor byproducts or end-of-waste status).
- Emissions: to test and deploy emerging techniques with improved environmental performance, some emissions levels or requirements set by legislation could be relaxed or waived for a certain period.

We recommend **establishing a regulatory sandbox in the area of waste**, since we have identified that the consideration of some natural resources or materials as 'waste' is making the deployment of bioeconomy projects especially difficult.

Establish one-stop shops to provide advisory and guidance services

According to the European Commission, an important role of competent authorities is to consult and advise innovators on the limits set by existing regulatory frameworks for their activities. The **nationwide availability of one-stop shops**, where innovators can find guidance on regulatory matters specific to the respective country or territory, remains in high demand.⁴²

⁴¹ [Law 20/2009, of 4 December, on prevention and environmental control of activities.](#)

⁴² European Commission. SWD(2023) 277/2 final, 29.8.23.

As the Commission states, when innovation occurs in an already regulated area, the exact needs of the actors involved should be carefully assessed to determine and select a suitable approach to increase legal certainty. Innovators often require clarity about which rules apply to their specific case and under which circumstances. They may also need advice on how to interpret these rules or confirmation that their compliance strategy is correct. **Advisory and guidance services may be sufficient to bridge the gap between innovation and regulation** and can already indicate to what extent innovation fits within the existing framework.

As exemplified in the energy sector, the advisory-consultation services provided by the regulator or another authority or body where market participants can clarify the compliance of their project with existing regulation are needed and are often also sufficient to support innovation without requiring any regulatory exemptions or setting up a regulatory sandbox.⁴³

Advisory services that confirm that projects already fit into the current framework provide a powerful pre-selection and filtering tool to exclude proposals that should not be admitted (thus also reducing the workload for competent authorities who must assess the proposals). This service can also help innovators define their proposal and identify regulatory barriers. It can also provide individual guidance on specific rules, confirming that an activity complies with existing rules and that activity is permitted.

Advisory and consulting services can be very resource intensive (time and expertise) and regulators may lack the necessary resources to provide them.⁴⁴

In this sense, following a criterion of proximity and considering the territorial diversity of Catalonia in terms of its resources and needs, it could be established a **Bioeconomy One-Stop-Shop Office** that provides advisory and guidance services to bioeconomy projects in each region (Girona, Barcelona, Lleida and Tarragona). These offices would assume the role of evaluating projects from a technical and legal dimension and would act as a liaison with the investment community and public administration to develop innovative financing and risk-sharing solutions that, ultimately, overcome the challenges faced by bioeconomy.⁴⁵

In summary, the use of these instruments and solutions could be a way to support the development of bioeconomy projects, unlocking their potential, overcoming the administrative and regulatory barriers identified, and, ultimately, to improve the general bioeconomy legal framework.

Implementing these solutions and recommendations within the Bioboost timeframe will be truly challenging, as, for example, regulatory changes may require a lot of time for reporting, public consultation procedures, and the adoption of agreements by the Government or competent authorities. On the contrary, designing a bioeconomy database is the most feasible solution to implement within the Bioboost timeframe. In terms of establishment one-stop shops to provide advisory and guidance, Bioboost is precisely one, so at the end of the project we will better understand if and how this model is valid to be replicated. However, it is a tangible solution that competent Administrations could start testing.

⁴³ When a specific regulatory barrier is identified as hindering the entrance of the innovative solution into the market, regulatory flexibility or derogation might be needed to test that solution.

⁴⁴ The Staff Working Document explains that, in the energy sector, an interesting initiative to address this issue has been the Australian regulator's online tool to filter typical consultations before confirming the need for further direct consultation.

⁴⁵ The provision of these advisory services and guidance mentioned by the European Commission is precisely one of the objectives of Bioboost project, which brings together all key Project Development Assistance (PDA) services under one roof to deliver a one-stop shop (the 'Accelerator') for bioeconomy project development, offering a wide range of services and end-to-end project planning and mentoring.



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