



# Regulatory Sandboxes

Analytical paper for BusinessEurope

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# Aim and method of this paper\*

## Horizon Europe's mission areas as a framework to showcase the need for regulatory sandboxes

- The aim of this argumentation paper is to showcase **how regulatory sandboxes could improve framework conditions for innovative businesses in Europe**, being them start-ups or established small, medium or large businesses, and by that enhance Europe's competitiveness in future markets areas such as the data-driven economy, e-health and low carbon footprint products, to name a few examples.
- For the society, regulatory sandboxes mean faster access to European innovations that improve the quality of life and solve some of the most urgent problems in health, climate change and economic production without compromising on important European values such as consumer protection and privacy. They are a tool to provide society with innovations that otherwise would have needed much longer to hit markets or would not be developed at all, mainly because of too dense or unclear regulation.
- More specifically, the examples in this paper are focusing on the **five mission areas of Horizon Europe**, which are representing prioritized topic fields for research and innovation policy where the European Commission reinforces the development of new solutions for society.
- This paper shows that **investing into research and innovation is not enough**. In order to bring innovations successfully to markets, innovative businesses need better and more opportunities to test and experiment with new solutions prior to their full market development. Therefore **one concrete field of action (as an example) per mission area**, where regulatory sandboxes could increase the likelihood that innovation could be brought successfully and within short time to market, is explained in each mission area.

## Qualitative study done by innovation experts with strong expertise in regulatory sandboxes

Due to prior studies and field work on the topic of regulatory sandboxes, the innovation experts from winnovation have a strong expertise in regard to international sandbox models and the application of this innovation instrument across different countries, topic fields and sectors.

*\*This analytical paper has been developed by winnovation consulting for BusinessEurope and does not reflect the position of BusinessEurope or of its member federations.*

# Sources and process of data gathering

The following graph shows the process of information gathering for this specific study



## Identification of starting points

- > **Secondary data research**
- > **49 people / organizations contacted** in five countries:
  - United Kingdom
  - Germany
  - Greece
  - Netherlands
  - Austria



## Interviews with businesses and experts

- 18 qualitative interviews** in the period Jan-Mar 2020 with experts
  - Representatives of companies
  - Entrepreneurs (start-ups)
  - Researchers
  - Representatives of other relevant organizations



## Four concrete fields of action

- where regulatory sandboxes could improve Europe's innovation capacity:
  - renewable energy
  - medical devices
  - circular economy
  - feed

# What is a regulatory sandbox?

## The definition of the term

- Basically, regulatory sandboxes allow **innovative businesses to test new and highly innovative business ideas and products in a certain time frame under regulatory supervision** of the respective authority.
- Worldwide, there is no agreed definition for regulatory sandboxes, but a variety of models and applications of this new innovation instrument. However it is important to know that **they are never totally regulation-free zones** which would exempt a certain group of businesses from law. This means that even under regulatory sandbox conditions consumers, health and the environment have to be protected as required by the law.
- They provide a specific ease for those businesses admitted in a regulatory sandbox in order to support the development and testing of innovations which are subject to regulation. Therefore the term greenhouse – a space where development and experimentation happen under controlled framework conditions – would be a perfect metaphor.
- The **aim of a regulatory sandbox is to achieve within a certain period of time legal security for the innovations**. This means that regulators learn what (not) to rule in the future (regulatory learning) and businesses learn how to comply with regulation (business learning).

## Regulatory sandboxes started in the aftermath of the financial crisis 2008

Around the world, more and more regulatory sandboxes are established in a variety of topics and sectors. The first regulatory sandboxes were set up in the US 2012 in FinTech. This was an answer to increasingly stringent financial regulations after the 2008 economic crisis which provided a barrier for new digital business models in the finance sector. The term regulatory sandbox was finally established in the UK in 2015.

## Today, regulatory sandboxes are used across sectors and topics

For some time now, regulatory authorities have also been providing **regulatory sandboxes** outside of financial technologies. The trend goes towards **testing data-driven business models in regulatory sandboxes**, where regulation is not that big at the moment, but privacy and security also play an important role (e.g. e-health, robotics, artificial intelligence, energy, telecommunications, etc.). Regulatory sandboxes are also key to respond to challenges from (outdated) regulation which unnecessarily stifles innovation.

In principle, it should be borne in mind that the instrument of the regulatory sandbox could also **be used beyond digital topics** - where there is **high legal uncertainty for innovative companies** and to shape a new culture of innovation between administrative authorities and innovative companies: The exchange between formerly distanced parties – innovator and regulator – will become more and more intensive and take on a higher level. **In the future, regulatory sandboxing will play a greater role in the overall portfolio of economic and innovation policy measures of successful business locations.**

# Europe needs to balance innovation and regulation in a new way

## Europe's quest to increase innovation capacity

- European businesses and societies are challenged by the ongoing **fundamental transformation**. New digital technologies, AI, decarbonization, aging and the spread of infectious diseases in a globalized world, to name just a few current factors, are pushing change, lead to disruption and create a high demand for new solutions across the world.
- Innovations are developed faster and faster. Europe is facing increased innovation pressure from Asia and North America. **Europe is challenged to increase its capacity to develop innovations very fast within short times to market**. This is not only a matter of investing into research and innovation, but also of improving the capacity to commercialize newly developed products, services and business models and bring innovation to market: Barriers for accessing markets and scaling innovative business models need to be removed wherever possible and in a way that health, consumer protection and environment are always secured.
- The results of the World Competitiveness Ranking 2019 demonstrate very well that Europe is in danger of falling behind even further. The ranking of the Lausanne Business University IMD (Institute for Management Development) evaluates the categories Knowledge, Technology and Future Readiness. In the overall ranking, the USA is ahead of Singapore and Sweden. Although there are still many western countries in the top 10, a closer look reveals that **Asian countries have caught up strongly in recent years: China, Hong Kong, Taiwan and South Korea are continuously improving their rank. Singapore is unceasingly ranked at the top.**

## Regulation has to look at innovator's needs

- High innovation speed and disruption across sectors put pressure on **policy makers and regulators**: They need to allow innovation to happen, reduce barriers for innovative businesses **and guarantee at the same time consumer, health and environmental protection. This requires new instruments which make regulation more responsive to innovators needs** whilst respecting the requirement for safe, secure and environmental-friendly products and services.

## Running regulatory sandboxes offers new opportunities especially for Europe

- Regulatory sandboxes are used across the globe as a relatively new instrument of innovation policy to give innovative companies leeway in testing and implementing novel business models, services and products. Such new ways are ~~also~~ required in the European Union to best **support the interaction between innovation and regulation** for the business location. Regulatory sandboxing also changes the relationship between regulator and innovator in the direction of an active and open dialogue, not least to build and expand a modern, agile innovation culture.
- For the **European Union**, regulatory sandboxes – i.e. regulatory test laboratories for innovations, in which major innovations can be tested in special cooperation with the authorities – are especially relevant in innovation policy due to its **high regulatory density**. This can have an inhibiting effect on the activities of innovative start-ups and established companies. In addition, Europe's way to the **digital transformation can create new areas** in which regulatory experience can be gathered via sandboxes (e.g. dealing with artificial intelligence).
- More than that, regulatory sandboxing is also highly relevant for those sectors where innovation is hampered through a lack of regulation.

# How regulatory sandboxes create impact (1)

Regulatory sandboxes are used internationally as a young instrument of **open and transparent exchange between innovative organizations and the regulatory authority**. In former times, reading the law was sufficient to solve a regulatory inquiry. Today, the complexity and novelty of innovations like new digital business models or data usage make it difficult to find clear answers only by applying the text of the law. Regulators need to explore and fully understand the respective question by mapping it methodically in an appropriate policy tool like a regulatory sandbox. Thus, **regulatory sandboxes provide evidence**. They are an alternative to regulation that is based on speculation about what behaviors could result — and what risks and harms can emerge — from changing technologies or changing policies.

For FinTechs, there is already clear evidence for the impact of regulatory sandboxes. In 2017, the UK's Financial Conduct Authority (FCA) issued a report on what they had learned from their series of regulatory sandboxes:

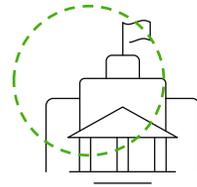
- **Regulatory sandboxes led to higher levels of innovation** with new offerings for financial consumers, including new blockchain solutions, biometric services, and custom-automated financial advice.
- **They led to more significant investment in new technology** and increase chances for innovative businesses.
- There **was little misbehavior on behalf of the participating firms**. Standard safeguards like e.g. exit plans at all stages of the sandbox minimizing the potential detriment to participating consumers worked, bespoke safeguards were added. (Jiménez et al. 2019)

Regulatory Sandboxes **are no miracle cure**; however, they can be **an important supplement** for existing innovation policy measures.

The **European Commission** has recognized the importance of a more innovation-oriented EU acquis some years ago. In 2016, so called **Innovation Deals** – voluntary cooperation agreements between the EU, innovators, and national, regional and local authorities with the **aim to gain in-depth understanding of how EU rule or regulation work in practice** – resulted from this perception. However, even though they still exist, since its introduction in 2016 only two pilots were conducted in the field of circular-economy and e-mobility. The timid implementation of Innovation Deals might be an evidence for lacking transparency for potential stakeholders. It might also be an expression of shy characteristics of Innovation Deals in terms of practical action that follow the investigation of rule or regulation that hamper innovation, i.e. mandatory amendment of respective law. Regulatory sandboxes might be a new way to reenergize the idea behind the Innovation Deals.

# How regulatory sandboxes create impact (2)

## Aims and impact of regulatory sandboxes



### Regarding the involved regulatory agency

- A signal to the economy: make innovation visible on the authorities' agenda
- Regulatory learning on the part of the authority: By being close to market developments / innovations, faster and more precise reaction is possible. On the long term, reflection on regulatory standards is given. Internationally, the term "anticipatory regulation" is used. A concept in which the regulator takes a proactive role in the design of innovation framework conditions.
- Stricter alignment of regulations to the needs of end users (companies, other organizations)
- Long-term: measuring the effectiveness of regulations



### Regarding innovative businesses

- Acceleration of innovation cycles, shorter time-to-market
- Reduction of market entry barriers
- Reduction of innovation cost (as high compliance costs, e.g. for lawyers and regulatory research, can be avoided)
- Faster identification of problematic elements of a solution and faster modification loops prior to market entry
- Perception of an innovation-friendly regulatory environment to foster business investments
- Creation of trust from the side of investors

# The four types of action recommended to the European Commission

The European Commission should support regulatory sandboxes through four different types of actions:

1.



**Allowing testing of innovations by using experimenting clauses across all relevant EU legislative – in line with international practice on regulatory sandboxes type 1** (see page 10):

Currently, most regulatory frameworks in the EU and member states do not include experimenting clauses whilst these latter are foreseen in tool # 21 of Better Regulation. Experimenting clauses would allow Member States and the Commission to run regulatory sandboxes. Therefore, in order to provide highly innovative businesses (start-ups and incumbents) the opportunity to test innovative business models in real-world-environments, if EU regulation is concerned, the testing clauses should be introduced at EU level – with the support of Member State authorities to ensure a proper implementation. To make experimentation clauses that have entered into force more visible, the European Commission could launch calls for interest and properly implement regulatory sandboxes at EU level.

2.



**Enhancing regulatory learning in new areas such as AI, data and platform economy, decarbonization etc. - in line with the existing instrument for Innovation Deals of the European Commission** (see pages 7, 10):

In order to provide more innovation friendly business conditions, legislative bodies and regulators need to learn about new services and products by working directly and closely with innovative businesses. The European Commission already implemented this type of regulatory sandbox by the so-called Innovation Deals (see p. 7).

In order to increase the currently limited number of Innovation Deals, the European Commission is suggested to organize annual events on innovation topics, clarify the need for many more Topic-specific Innovation Deals and launch them accordingly. First fields of action could be data intensive business models (use of algorithm, data mining, etc.) and the scaling of digital services (Digital Services Act), but also in other new fields such as the circular economy and the decarbonization of the economy mutual learning between regulators and businesses would create high value for both sides.

# The four types of action recommended to the European Commission



**3.**

## **Providing seed funding for administrative costs of regulatory sandboxes in member states:**

The European Commission has the power to incentivize the implementation of regulatory sandboxes within the member states by providing seed money for regulatory sandboxes. This fund could cover certain costs, e.g. the administrative cost, of regulatory sandboxes. It would be a strong signal to member states and emphasize the Commission's effort in spreading regulatory sandboxes across Europe.

The administration of the fund could be overtaken by a European Network on Regulatory Sandboxes (see point 4.).

**4.**



## **Initiating a European Network on Regulatory Sandboxes (ENRESA):**

The European Commission could initiate and coordinate a network that raises the visibility of regulatory sandbox initiatives and models across Europe. The network could have different purposes, e.g.:

1. Being a source of comprehensive information on regulatory sandboxes: Providing know-how on theory and practice of regulatory sandboxes, as well as collecting international good practices to showcase possibilities and lessons learned.
2. Promoting the use of exemptions that already exist in EU directives in the member states.
3. Enabling regulatory learning on the European level and thus lead by example: Investigating regulatory matters that are lacking from exemptions but where innovators and member states have needs.
4. Raising awareness for the implementation of regulatory sandboxes in the member states, especially in matters that are beyond European competence.
5. Showcasing existing good practice of regulatory sandboxes and their outcomes in member states.
6. Coordinating high-quality and trustful knowledge exchange between different member states (and their respective agencies) for direct mutual learning.

# Two types of regulatory sandboxes

Internationally, mainly **two types of regulatory sandboxes** exist and are used. From the perspective of the European Commission, regulatory sandboxes could be promoted **both on the EU and on the member state level**.

- Sandboxes set up by the European Commission and therefore deployed on a European level would
  - pay tribute to the fact that most legislation in member states is strongly linked to EU regulation and therefore needs to be tackled also from the European angle.
  - not hamper the single market.
  - ensure companies are treated in the same way across Europe and can scale their inventions across Europe.
  - foster mutual learning of regulators in member states.
- Sandboxes on national level could be promoted by the European Commission through providing exemptions in regulations and directives. Such national regulatory sandboxes would result in great impact mentioned on page 7.



## Type 1: **Regulatory sandbox based on an explicit, timewise limited experimentation clause**

### Characteristics type 1:

- Core of the innovation is an extremely high, mostly technological level of novelty (e.g. autonomous driving).
- Legal classification is unclear at the time of entry into the sandbox.
- During the sandbox participation, the innovator (i.e. company or other type of organization) gets very specific and thoroughly defined rules from certain legal matters by the responsible authority, e.g. testing options, waiving certain licenses, etc.
- Legal scope: Experimental clauses that either already exist in the law or that are created through an amendment.
- Exit: As the exemption concerns a very concrete aspect of the innovation and it is time-limited, the exit from the sandbox is possible either by incorporating the innovation into existing legal framework conditions or by creating new laws that consider innovators needs.



## Type 2: **Regulatory sandbox without exemption / waiver, but with supervision of the agency (comparable to EU Innovation Deals)**

### Characteristics type 2:

- From the beginning on, it is clear that there are no experimental clauses (exemptions / waivers) or that they will not be issued.
- This type focuses on the precise legal classification of the innovation or the interpretation of the applicable legal framework.
- During the sandbox period, there is a very close, often informal collaboration between the authority and the innovator.
- Exit: The respective innovator has certainty on the legal classification of the innovation at the time of the exit from the sandbox.

# Examples of the two types of regulatory sandboxes

Internationally, there are already several regulatory sandbox initiatives under way. At this point it should be mentioned that

- 1) not all initiatives are named as regulatory sandboxes and
- 2) not every initiative is implemented in a central regulatory sandbox but in regional authorities.

Two selected examples are listed below. Further case studies can be found on page 13-26 matched with the respective Horizon Europe mission areas.



## Type 1 & 2: **New legal solutions in UK**

The UK Solicitors Regulation Authority (SRA) is looking for innovative technology-driven legal solutions that will help individuals and small and medium-sized enterprises (SMEs) to better understand, prevent or resolve their legal problems. The aim is to support a significantly different way of delivering legal services. The SRA Innovate program is a regulatory sandbox provides dedicated guidance on existing law and waivers for special cases. [www.sra.org.uk](http://www.sra.org.uk)



## Type 1: **METI regulatory sandbox Japan**

In 2017, the Japanese Ministry of Economy, Trade and Industry (METI) set up a regulatory sandbox. The aim is to develop an environment in which companies can carry out demonstration tests and pilot projects for new technologies and business models that are not provided for under the applicable regulations. The aim is to ascertain how the technology in question fits into the current regulation and which changes may be necessary. The regulatory sandbox is open to all types of technologies and topics, with a particular focus on the areas of financial services, health care, mobility and transport. [www.meti.go.jp](http://www.meti.go.jp)

# Regulatory barriers need to be addressed in all five mission areas of **Horizon Europe and beyond**



... the Commission deliberately abstains from overly detailed, heavy-handed ex ante regulation, and will prefer **an agile approach to governance that favours experimentation (such as regulatory sandboxes), iteration, and differentiation.**

*(A European Strategy for Data, 19.02.2020)*

With Horizon Europe, the European Union has the worldwide most ambitious research and innovation funding program. The newly created mission areas enable research and innovation with even more focus on the overall impact for society and the planet. Breakthrough innovations are to be expected.

However, such breakthrough innovations could bounce on the reality of dense European regulatory frameworks, that were set decades ago. Instead, modern innovations need agile regulatory frameworks that – were necessary – allow for purpose driven flexibility.

Horizon Europe 2021-2027 is dedicated to solve some of the biggest societal challenges and is designed to strengthen the EU in the global competition. Its missions form a proper first frame to showcase how and in which cases regulatory sandboxes could be implemented on the European level in order to bring European innovations to market within a short period of time. In this paper, the mission areas serve as case studies, however, regulatory sandboxing has many more application fields than just the thematic arch of Horizon Europe.

Regulatory sandboxing is a relatively new innovation policy tool without strict definitions and tight frames. Therefore, the European Commission could use the instrument beyond already known purposes, develop it further, and therefore set new (international) standards.

**The following pages illustrate that research and innovation are not sufficient to make Europe more innovative and thus competitive.**

**For each mission area in Horizon Europe one example of a regulatory challenge for upcoming innovations is described. These challenges serve as case studies to showcase the potential of regulatory sandboxes.** (Please note that missions 1 & 4 have a strong thematic fit and therefore are discussed jointly in this paper.) **Innovative companies are already now impacted by the hurdles explained in the text.**

**For each mission area a specific suggestion is made how the European Commission could take initiative and support regulatory sandboxing** in order to remove the barriers for innovators and support them in bringing innovation successfully to markets.

Horizon Europe mission area 1 & 4:

# Adaption to climate change including societal transformation & Climate-neutral and smart cities



## THE MISSION AREAS

The **Horizon Europe mission area adaption to climate change including societal transformation** is intended to support solutions and preparedness for the impact of climate change to protect lives and assets. It will include behavioral changes and social aspects **by addressing new communities beyond usual stakeholders**, which help lead to a societal transformation.

The **Horizon Europe mission area climate-neutral and smart cities** pays attention to reaching the goals and targets set out by international policy frameworks such as the COP21 Paris Agreement or the UN's Sustainable Development Goals. It recognized cities' **great potential to contribute to global challenges**.

## THE FUTURE APPROACHES

Adaption to climate change means “fundamental changes in our way of living, urban and regional planning, mobility patterns, land and water use, production processes, consumption patterns, nature conservation, and energy demand” (van Nieuwaal et al. 2009: 7). Experts say, that it will no longer be enough that strategies for combating climate change only reflect the “technological, commercial and industrial dominance of our market led society” (Bergman et al.: 2010). Moreover, bottom-up innovation, namely societal innovation, needs to be offered a bigger place in the overall aspirations of climate change adaption.

One of the promising fields where consumers can already actively take part in transforming the status quo is the **energy sector**. Novel, **user-friendly technology has enabled the individuuum** in gaining its own solar energy from its own roof and for the own consumption, but also for the vicinity's requirement. The term prosumer (= a producer that is consumer at the same time) was coined and new business models will arise from these possibilities.

## THE REGULATORY PROBLEM

### LEGAL HURDLES FOR ENERGY PRODUCING BUSINESSES, MUNICIPALITIES AND CONSUMERS

The EU Renewable Energy Directive II – RED II has set the legal basis for enabling businesses, citizens, municipalities and others to become energy producers themselves and sell their own energy to neighbours. So called Renewable Energy Communities (REC) are communities that are located in the proximity of renewable energy projects that voluntarily team up for autonomous energy production and consumption.

Even though EU regulation per se opens the room for Renewable Energy Communities (REC), it **will be crucial in which way the directive will be translated into national laws by 2021:**

- > Currently, the **EU Directive defines RECs as legal entities** which makes fast **practical implementation quite complex**: Teaming up for a REC means overcoming a lot of red tape, because it is in the hand of member state legislation to require specific legal entities.
- > As RECs do not need the whole electricity network, it is considered to **reduce network charges for RECs**. Nevertheless, implementation concepts and basic questions like the amount of reduction are lacking.
- > Past experience shows, that despite EU energy market liberalization, the transformation towards renewable energy production and consumption is hampered by regulatory requirements. One example: Even though residential houses with several apartment residents are allowed to collaboratively produce renewable energy (e.g. via photovoltaic on the roof), only few house communities do that. One reason is that national implementation of EU energy liberalization puts a lot of bureaucracy and red tape into the regulation and with that hinders innovation to happen.

## THE REGULATORY SANDBOX



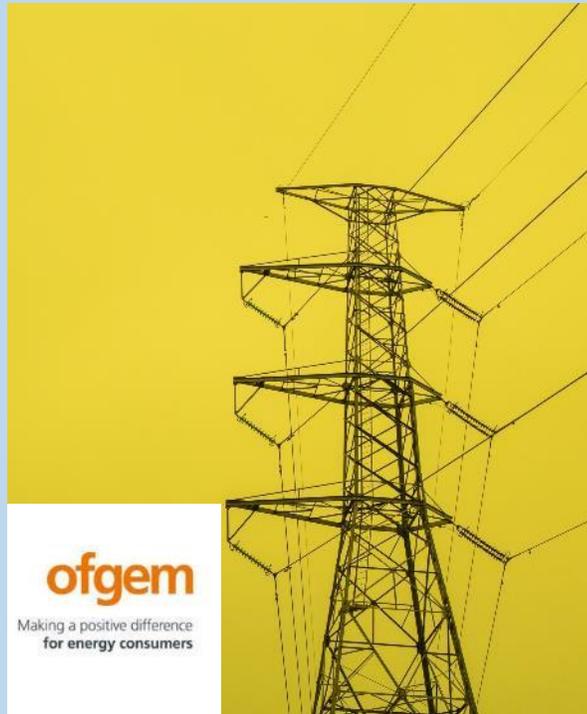
### A regulatory sandbox for spreading Renewable Energy Communities (RECs)

Basically, existing EU regulation covers the questions that currently come along with evolving consumer possibilities in the energy market. However, it is about the rules of the game that make the ultimate implementation of innovation – namely Renewable Energy Communities – and its further development difficult.

- > In order to provide interested citizens a feasible way of implementing new RECs without having a particularly deep expertise in regulatory requirements in this field – the European Commission could lead by example and call for an Innovation Deal (in other words a regulatory sandbox without exemption clause, see page 10) on that matter.
- > In that way, interested stakeholders could gather, undergo the establishment of RECs in practice and subsequently create an action plan on how to continue with Directive RED II.
- > The long-term goal of the Innovation Deal would be either to amend Directive RED II or to showcase how RECs can easily be established in member states without a high bureaucratic burden for participants such as companies and citizens.
- > Further questions that could be included are:
  1. How can network charges be reduced without discrimination of users of the traditional network? (Current reduction ideas reduce network charges for RECs at the expense of remaining customers in the network as the overall network cost do not decrease.)
  2. How could business-models look like that spread the concept of RECs and simultaneously fit into existing regulation (e.g. a power trading platforms, etc.)?
- > The result of the regulatory sandbox (Innovation Deal)
  1. would enable private households, Small and Medium Enterprises (SMEs) and municipalities in getting energy autarch.
  2. would solve the question on the reduction of network charges.
  3. would foster the establishment of novel business models in a more decentralized energy-structure.
- > In order to guarantee deep learning across member states, mutual learning (workshops, written documents, etc.) could be conducted through the European Network on Regulatory Sandboxes (ENRESA).

## INTERNATIONAL EXAMPLE IN THE CONTEXT OF THE SUGGESTED REGULATORY SANDBOX

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### **Office of Gas and Electricity Markets – UK**

The British Office of Gas and Electricity Markets (Ofgem) offers regulatory sandboxes for different user-needs:

1. It guides innovators in finding the required information that are potential barriers to their ideas.
2. It provides waivers for a defined period of time in order to test innovation with special novelty degree, like, e.g. a peer-to-peer (P2P) power trading platform enabled by blockchain.

Horizon Europe mission area 2:

# Cancer



## THE MISSION AREA

The **Horizon Europe mission area cancer** is supposed to help set common goals aiming to **reverse the frightening trends in cancer**:

- > Figures from the European Commission speak of **3.5 million people newly diagnosed people with cancer** per year in Europe with **ascending trend**.
- > Currently, cancer is cause of **every fourth death** in Europe. (Eurostat 2020)

## THE FUTURE APPROACHES

### **Personalized medicine will ease cancer patient's suffering**

Personalized medicine refers to medicine that is individually tailored to a person's constitution, lifestyle and genes. It is one of the great solutions for cancer prevention, detection, and treatment. It is enabled through digital health technologies and tools, e.g. a prevention-app that scans a mole for malignancy already at a person's home. Personalized Medicine is expected to turn the wheel in cancer medicine for the benefit of the people.

## THE REGULATORY PROBLEM

### BREAKTROUGH INNOVATION IS HINDERED BY LICENCING HURDELS

Technically, there are already many possibilities for personalized medicine innovations including early detection, telemedicine solutions, apps etc. However, all these innovations, including digital solutions, are per definition medical devices and therefore fall under the **EU Medical Device Regulation (MDR)**.

- > The new **Medical Device Regulation [REGULATION (EU) 2017/745]** that comes effective in May 2020 represents even a further tightening for innovators, experts say. One of the big **innovation hurdles is the tightened-up CE marking for medical devices**. This CE marking is a prerequisite for market entry of all medical solutions including digital solutions (like apps) indicating conformity with certain standards for products sold within the EU.
- > The new MDR **classifies existing and new medical devices in higher risk classes than they have been classified in the old version of MDR** which increases the regulatory effort to get the required CE marking.
- > Furthermore, medical devices with higher risk levels need to **acquire CE marking with the participation of a so-called Notified Body**. However, the **number of notified bodies was reduced** with the result that in some European countries there are no longer any Notified Bodies, e.g. in Austria. This fact creates a **bottleneck across Europe, which massively extends the time-to-market of innovations** for innovators and it **slows down the access of seriously ill people to the required new technologies**.
- > In sharp contrast to the EU, the **USA relaxes regulation for medical devices**. The US-Food and Drug Administration (FDA) has recently brought more efficiency to regulatory oversight with the Digital Health Software Precertification (Pre -Cert) Program. The approach "aims to look first at the software developer or digital health technology developer, rather than primarily at the product, which is what we currently do for traditional medical devices". (FDA)

## THE REGULATORY SANDBOX



### A regulatory sandbox addressing certification processes for specific medical innovations

Medical devices that support the evolution of personalized medicine (diagnostic and therapeutic, analogous and digital innovations) are hindered in Europe by long bureaucratic paths which represent huge hurdles for market entry. This is also heavily hindering the approval of new solutions for cancer patients.

- > In order to facilitate live-saving medical innovations and reduce time to market, the European Commission should include an experimentation clause into the EU Medical Device Regulation [REGULATION (EU) 2017/745].
- > This experimentation clause would enable regulatory sandboxes in member states.
- > Such regulatory sandboxes would be an effective mean to introduce innovations with a particularly high patient benefit on a fast lane to markets.
- > The sandbox could provide early and time-limited testing of innovations with a **pre-CE certification**, valid as long as the innovation is under the sandbox regime. The pre-CE certification would display that it keeps consumer and health safeguards at all time during the sandbox phases.
- > Sandbox exit could be indicated by regular CE marking.

## INTERNATIONAL EXAMPLE IN THE CONTEXT OF THE SUGGESTED REGULATORY SANDBOX



### Singapore pursues its strategically important field of telemedicine in a regulatory sandbox

The Singapore Ministry of Health (MOH) has identified telemedicine amongst very important transformation fields within its health system. Telemedicine is considered “to enhance productivity and cost-effectiveness of the health system while providing most possible patient convenience” (MOH). Therefore, a Regulatory Sandbox was launched in 2018, designed for better understanding “new innovative services by partnering early with industry” (MOH).

One of the sandbox participants is Doctor’s World, a start-up with a mobile app for medical video-consultation on demand, medication delivery, issuing of sick leave and provision of referrals. <https://doctorworld.co/>

Horizon Europe mission area 3:

# Healthy oceans, seas, coastal and inland waters



## THE MISSION AREA

The **Horizon Europe mission area healthy oceans, seas, coastal and inland waters** raises awareness of their importance among citizens and help develop solutions on a range of issues.

- > Around 70 percent of the earth's surface is covered by water which is vital for our life (production of oxygen, regulation of climate and weather, essential transport and the economy, etc.).
- > Oceans and their ecosystems are in danger by heavy pollution. **Tons of plastic waste swim in the world seas** that causes animal deaths and harm mankind, too, as litter gets into the food chain.

## THE FUTURE APPROACHES

### **Circular economy – a growth model for nature, economy, and society**

Avoiding plastic and waste pollution in waters requires larger and more comprehensive approaches than existing linear waste management solutions. The circular economy is a promising approach comprising a regenerative system where all waste serves as a resource for other processes. However, currently only 9,1% of the global economy is circular, as the Circular Gap Report of the World Economic Forum stated in 2018. This “circularity gap” needs to be closed by innovations in order to prevent further and accelerated environmental degradation. (Circular Gap Report)

Besides the rescue of our world seas, circular economy has the potential to boost the European economy by creating thousands of green jobs: 700.000 across Europe with the effect of additional 0,5% to Europe's GDP. (Cambridge Econometrics, Trinomics, and ICF, 2018) New business models will prevail: selling a function instead of selling a product, or level of performance, allowing the company to retain ownership of the materials, and to move much quicker to provide customers with technology and product upgrades, staying ahead of the market. (University of Cambridge Institute for Sustainability Leadership – CISL, 2017)

## THE REGULATORY PROBLEM

### INNOVATORS ARE NOT ALLOWED TO USE WASTE MATERIALS

The circular economy provides an enormous potential from which the whole business location could benefit and thus the entire society. However, even smaller prerequisites for truly novel ideas to grow are sometimes lacking.

In some member states, **waste treatment** is **stricter regulated** than Art. 23 & 24 of EU Directive 2008/98/EC on waste and repealing certain Directives would suggest. That **hinders innovators**, e.g. businesses which want to reuse food waste, plastic waste or residual waste as a source for their production streams **from testing their innovations on a small scale in the member countries**.

- > For example, in Austria, **businesses with novel ideas in waste treatment cannot even get access to the waste they would need** for experiments. Although the EU Directive suggests a respective exemption, this clause was not implemented in Austria. Consequently innovative businesses with ideas how to make materials from waste circular and reuse them in new products, hardly have any chance to access waste for experimentation. They would need a waste treatment permit in order to be allowed as a waste management operator. Experts say, however, that the permit is difficult to achieve as permission procedures are very complex. A circular economy start-up, that is à priori not a traditional waste management operator, would therefore only have little realistic chance to get access to waste materials (see Waste Management Act, § 24a AWG 2002).

## THE REGULATORY SANDBOX



### A regulatory sandbox to enable novel waste management solutions

Currently, EU regulation allows testing new ideas in waste management through an exemption in Directive 2008/98/EC: Member States may exempt from the requirement of a waste treatment permit in case of disposal of their own non-hazardous waste at the place of production or recovery of waste. However, not all member states translate this innovation-friendly exemption into national law.

- > Therefore, EU regulation needs to amend its Directive 2008/98/EC on waste and repealing certain Directives in a way that member states (e.g. Austria) are obliged to translate the respective exemptions for waste innovators into national law, always in line with health, customer, and environmental protection.
- > Thus, circular economy innovators in member states could get access to waste materials otherwise being exclusively reserved to incumbents in waste treatment.
- > This would support innovative businesses from other sectors than waste management (e.g. industrial production companies, start-ups) to get access to waste in order to test circular processes and business models.
- > By making the experimental clause for waste treatment permits in the member states compulsory, innovation could be leveraged on a bigger scale through regulatory sandboxes.

## INTERNATIONAL EXAMPLE IN THE CONTEXT OF THE SUGGESTED REGULATORY SANDBOX

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### Regulatory Sandbox for testing innovative environmental services-related technologies in Singapore

The Singapore National Environment Agency (NEA) offers innovators a regulatory sandbox to trial innovative environmental services-related technologies and solutions. One of the two projects addresses a step towards zero-waste and lower carbon emissions. Therefore, national utilities provider SP Group (SP) has teamed up with Gardens by the Bay to use a system that will turn waste at the garden into thermal energy and soil conditioner. The main aim of the system is towards a zero-waste solution, one in which almost nothing will be wasted but is continuously used instead. (todayonline.com)

Horizon Europe mission area 5:

# Soil health and food



## THE MISSION AREA

The **Horizon Europe mission area soil health and food** wants to raise awareness on the importance of soils and come up with results that have a direct impact on the European Commission's Green Deal.

- > Soils are the basis for food, feed, textiles, or wood. However, this important ecosystem is under pressure from an increasing population, from climate change, erosion and sea level rises.
- > Soils are highly dynamic and fragile systems - and they are a finite resource. It can take up to 1,000 years to produce 1cm of soil.

## THE FUTURE APPROACHES

### Feeding insect protein as an alternative to imported soy from South America

One of the powerful levers in supporting healthy soils lies within the field of feed-production. Currently, a big part of feed for farm animals is soy because of its protein content. Increasing meat consumption also raises the demand for feed, which results in higher demand of land and soil. Soy mainly comes from South America, where, in the end, rainforests have to give way to the need of soil.

In future, animal feed does not need to stem from soy anymore as there is already a much more sustainable alternative: Insect food (animal meal) that is produced from larvae regionally in Europe and contains high amounts of protein. Sustainability is even given in its production as the larvae could be grown on supermarket waste such as vegetables or bread. Experts say, that one kilogram of insect meal can be made from two kilograms of food waste.

## THE REGULATORY PROBLEM

### **INNOVATORS ARE NOT ALLOWED TO MARKET LIVESTOCK FEED FROM INSECTS**

Globally the demand for insect food and insect feedstuff is growing. For example in the US and Canada markets for insect-based feedstuff are growing rapidly.

However in the EU it is forbidden to feed livestock with insects. The basic ban on feeding processed animal protein ("insects", PAP) in animal feed for farm animals of Art 7 of Regulation (EC) No. 999/20012 was enforced by Regulation (EU) No. 56/2013 and most recently by Regulation (EU) 2017 / 893 relaxed with regard to "animals in aquaculture" (Annex IV, Chapter II, letter c).

This means, that it is not allowed to market insect-based feedstuff in the European Union despite for fishes in aquacultures. Ironically, it is allowed to market human insect food based on the current transitional period respective approval by the EU Novel Food Directive, but it is forbidden to feed livestock such as chicken and pigs with insect-based feedstuff. This is true despite the fact that free-range chickens and pigs would always eat insects such as larvae from soils and traditionally insects has been a natural feedstuff for these animals. Scientific research (partly funded by Horizon 2020) has proven, that insect feedstuff is safe.

Insect food would be only attractive because it avoids heavy environmental impacts such as soil degradation due to soy cultivation. The production of insect-based feedstuff in Europe has the potential to become a large market as the demand in agriculture for sustainable alternatives to imported soy is rising. The restrictive regulation hampers this market to be developed by innovative feedstuff companies.

## THE REGULATORY SANDBOX



### Testing alternative feedstuff protein from sustainable European production

Currently, feeding of insects is limited to fish in aquaculture and the selection of insects has also been limited. The enabling of first practical test in member states could provide evidence-based information of unanswered questions: What to feed the larvae? How to deal with ethical aspects? Which risks need to be considered due to allergen potential of insect protein?

- > In order to enable first practical tests in feeding insect protein (animal meal) to e.g. chicken, the European Commission would need to further relax Regulation (EU) 2017 / 893. That means including an exemption for dedicated purposes, i.e. feeding chicken and other farm animals (experimental clause).
- > Subsequently, the European Commission could start a sandbox gathering national authorities (health, agricultural, and environmental bodies) and animal feed companies, with farmers testing the usage of insects/insect-derived products. If the cost-benefit analysis in terms of economics, health, and environmental aspects is positive, legislation could be amended.
- > Regulatory sandboxes would always include safeguards regarding health, consumer and environmental protection.
- > Regulatory sandboxes would generate data about effects of alternative feed on soils, animal health, environment and human health that, in turn, could be again source for further innovation.
- > Furthermore, the proposed European Network on Regulatory Sandboxes (ENRESA) could play an important role in this field and the further development of the European agri-sector. Beyond insect protein feed, there will be many more innovative ideas in the sector (e.g. novel food like 3D printed meat, but also digitization and artificial intelligence) that will force regulatory concepts. ENRESA could provide a professional and high-quality platform for collecting ideas and concepts of future relevant innovation in the agri-sector that might need novel regulation. In this way, the EC could fall back on a unique information source that could lead to an agile system of detecting and acting for future agri-regulation.

## INTERNATIONAL EXAMPLE IN THE CONTEXT OF THE SUGGESTED REGULATORY SANDBOX

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### **Singapore Agri-Food Innovation Park**

Singapore imports more than 90% of its food. As a result, the country seeks to become itself a leader in urban agriculture and aquaculture technology. Therefore, the Ministry of Trade and Industry Singapore (MTI) has established the Agri-Food Innovation Park (AFIP), a geographical zone, which by the first half of 2021 will allow high-tech farming operators to test-bed and commercialize their new technologies. A regulatory sandbox will be part of the AFIP as the Government wants to be prepared with fitting regulation when growing new sectors.

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